STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON COMMERCIAL SCALE IN INDIA

IPC CLASSIFICATION-
[See section 146(2) and rule 131(1)] (As Amended)

In the matter of Patent No. ______________ of ______________

I/We, _____________________________________________________________
The patentee(s) or / licensee(s) under Patent No. __________ hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year 2017.

(i) The patented invention:
   {   } Worked {   } Not worked [Tick (✓) mark the relevant box].
   (a) If not worked : reasons for not working and steps being taken for working of the invention:
   (b) If worked : quantum and value (in Rupees), of the Patented Product:
      (i) manufactured in India
      (ii) imported from other countries. (give country-wise details)

(ii) The licenses and sub-licensees granted during the year; Have any license/sub-licenses been granted during year
   {   } YES {   } NO [Tick (✓) mark the relevant box].
   (a) If Yes:
      DETAILS [Tick (✓) mark the relevant box]:
      CONFIDENTIAL [   ]

      CAN BE MADE AVAILABLE UPON REQUEST U/S 146(1) [   ]

(iii) State whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

The facts and matters stated above are true to the best of my/our knowledge, information and belief.

To
The Controller of Patents,
The Patent Office,
Delhi/Mumbai/Chennai/Kolkata
Note on Section 146/ Form 27 issue and suggested approach/solution

1. Background

1.1. The petition was filed as a public interest litigation (PIL) before the Delhi High Court by Prof. Shamnad Basheer in 2015. Triggering point was dismal compliance with S.146 (r/w Rule 131) for submitting periodic working information pertaining to granted patents. Non-compliance data was released by Patent office itself in a report published on its website. Petition seeks relief in the form of directions to Patent office to take action against errant patentees and reconsideration by the government of Form 27 in its current format, among other reliefs.

1.2. The court has directed the Government to submit an affidavit outlining a plan for putting in place a standard operating procedure/enforcement mechanism.

2. Suggested approach/solution to the issue

2.1. Section 146 of the Patents Act 1970 provides as under:

146 Power of Controller to call for information from patentees. -

(1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.

(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.

(3) The Controller may publish the information received by him under sub-section (1) or sub-section (2) in such manner as may be prescribed.
Rule 131 of the Patents Rules, 2003 provides as under:

131. Form and manner in which statements required under section 146(2) to be furnished.—

(1) The statements shall be furnished by every patentee and every licensee under subsection (2) of section 146 in Form 27 which shall be duly verified by the patentee or the licensee or his authorized agent.

(2) The statements referred to in sub-rule (1) shall be furnished in respect of every calendar year within three months of the end of each year.

(3) The Controller may publish the information received by him under subsection (1) or subsection (2) of section 146.

2.2. A perusal of Section 146(3) and Rule 131(3) reveals that the words used are ‘the Controller may publish information received by him...’. The use of the word ‘may’ would indicate that the legislature intended to provide the Controller the discretion to decide whether the information received by him under Section 146(1) or (2) warrants publication or not. Thus far the Patent Office, by default, has been making available to the public all information furnished under Form 27 by a patentee. It is important to note that there is no blanket provision that mandates all information submitted to the Patent office to be made public by default. Use of the word ‘may’ requires that the Controller apply his mind in exercising the discretion vested in him, and consequently such discretion has to be backed by sound reasoning and a speaking order. Each case would have to be examined individually considering the facts and circumstances involved.

2.3. Further, the Controller has the power to intimate the patentee whether the disclosure made/information submitted by the patentee in Form 27 is sufficient disclosure for the purposes of Section 146/ Rule 131 r/w Section 83 and 84. In case it is not, the Controller may direct the patentee by virtue of powers vested under him under Section 146(1) to furnish sufficient information to satisfy requirements of Section 146. Once satisfied, the Controller may upload an order expressing his satisfaction of patentee’s compliance with requirements of Section 146/Rule 131. The discretion to
publish the information submitted by the Patentee to the Controller would still remain with the Controller.

2.4. The aforementioned analysis can be given a context when seen in light of Section 83 and 84. Under the scheme of chapter XVI titled ‘Working of patents, compulsory licenses and revocation’, the Controller needs to be satisfied regarding a patent being sufficiently worked in India. In case against a particular patent the patentee has failed to furnish working information under Form 27, or in case the patentee submits but the Controller on examination of submissions is of the opinion that requirements of Section 146/ Rule 131 are not met, he may pass an order as such. Consequently, any person interested who is otherwise entitled to apply for compulsory license under Section 84, can come to know from a perusal of online records available at the Patent office website or from physical inspection at the Patent office whether any working information pertaining to the patent has been submitted to the satisfaction of the Controller or not, which fact will be established with the presence (or absence) of the Controller’s order expressing satisfaction or the lack of it, of the patentee’s disclosure of working information under requirements of Section 146. Such person may then file a petition for compulsory license with the Controller.

3. **Conclusion:** To sum it up, the standard operating procedure (SOP) may look something like this:

   a. Patentee submits working information in Form 27 to the Controller in compliance with Section 146/ Rule 131.
   
   b. Patentee may apply for the working information not to be published by the Controller by specifying grounds / reasons for non-publication. In the absence of such application, information submitted may be made public by default.
   
   c. Controller examines submissions and decides whether he is satisfied with the information submitted by patentee for purposes of compliance with Section 146. Controller also examines the grounds for non-publication of information received from patentee.
   
   d. The Controller passes an order on the above two aspects. Order is published on the Patent office website.
e. Information submitted by patentee is accordingly either ordered to be published or withheld from public.

f. In case information is ordered to be published, a period of 4 weeks may be given to the patentee to file an appeal before IPAB, failing which the information will proceed to get published.
Centre for Internet and Society - India’s (CIS) submission to the Controller General of Patents, Designs and Trademarks (CGPDTM) pertaining to Stakeholders Meeting regarding issues related to Working of patents under the Patents Act, 1970

1. As the CGPDTM is aware, the Indian mobile device manufacturing industry is mired in issues related to licensing of standard essential patents (SEPs). Disputes have resulted in imposition of heavy interim royalty rates on Indian manufacturers, payable to foreign SEP holders. Section 146 and Rule 131 of the Patents Act, 1970 mandate patentees to provide information on working of patents, which is crucial for willing licensees to access patent working information in a timely manner. This requirement, that the details of patent working be disclosed by patentees supports several policy goals, firstly, of making the Indian population benefit from commercial use of the invention; secondly, prevents patentees from creating blocking monopolies – from obtaining and maintaining patents for the purpose of blocking others from developing technologies in the vicinity of the patented inventions; and thirdly, by showing that reasonable requirements of the public are met (or not), directly impacts the implementation of the compulsory licensing scheme of the Patents Act, 1970.

2. We note that in 2009, 2013 and 2015 the CGPDTM issued public notices calling on patent owners to comply with their obligations to file statements of working on Form 27. Further, on February 12, 2013, the Indian Patent Office (IPO) announced plans to make Form 27 submissions for the year 2012 available to the public via the IPO website. However, these measures have not yielded any significant progress, as patentees and licensees continue to not comply or defectively comply with the statutory requirements.

3. CIS’ empirical research on ICT innovations reveals that there are serious lapses as far as compliance and enforcement of statutory provisions mandating filing of Form 27 are concerned. In the past year, we studied data available from 2009-2016 for the mobile device sector, and could only identify and access 4,916 valid Forms 27, corresponding to 3,126 mobile device patents, leaving 1,186 Indian patents for which a Form 27 could have been filed, but was not found. For a surprising number of Form 27s (3%) the working status of the relevant patent was not even designated.

Even among the Form 27s that had been obtained, almost none contained useful information regarding the working of the subject patents or fully complying with the informational requirements of the Indian Patent Rules. Many patentees simply omitted required descriptive information from their forms without any explanation.

Via our research we also gathered complaints raised by patentees and industry observers regarding the structure of the Form 27 requirement itself. For example, patents covering complex, multi-component products that embody dozens of technical
standards and thousands of patents may not necessarily be amenable to the individual-level data requested by Form 27.

Thus, our findings support the arguments and findings made by the petitioners in the ongoing matter of Shamnad Basheer v. Union of India and Ors.⁸

4. Regardless, we submit that these technical difficulties should not hinder the critical statutory requirement placed on patent holders to diligently comply with Form 27 compliance. In the context of licensing of SEPs, several stakeholders recently suggested solutions as revealed from the submissions made to the TRAI Consultation on Promoting Local Telecom Manufacturing⁶:

- Two industry associations, namely Telecom Equipment Manufacturers Association of India (TEMA) and Telecom Equipment & Services Export Promotion Council (TEPC) and a telecommunication enabler Vihan Network Limited recommended that a modified and longer version of Form 27 (Form 27S) may be designed for SEP holders that should apply right at the filing stage. Section 159 of the Patent Act, 1970 empowers the central government to make such modifications to the form, as necessary.⁷

- Further, Prof. T Ramakrishna (MHRD Chair on Intellectual Property Rights) at NLSIU, specifically recommended that Form 27 may be amended to include a new column, which may require the patent holder to declare if their patent forms a part of any standard and in case of affirmative answer – the name of the Standard Setting Organisation and corresponding standard of which it is a part.

We recommend that the form may be amended to make it more comprehensive and suitable for obtaining necessary information. The same information should be made publicly accessible, in order to satisfy the Indian citizen that the patent is being properly worked.

5. Further, we would like to draw attention to our findings on deficient technical capabilities of the Indian Patent Office’s online Form 27 repository⁹:

- Some PDFs of the forms comprise scanned image files without OCR of the text. This makes them inaccessible to the visually impaired, and prevents search and discoverability of their content. This also makes them less usable by preventing copying and selection of text.

- In some cases, it was difficult to identify which one in the list of documents associated with a patent is Form 27, because of obscure filenames.
For example, for Patent Number 262228, Form 27 was named 68.262228.pdf, as found on IPAIRS.

For Patent number 260603, the filename for Form 27 was "ipindiaonline.gov.in_epatentfiling_online_frmPreview.asp.pdf" on IPAIRS.

- Inconsistency in search results found on IPAIRS. Searching for the peripheral documents of the patents, returned the results, "No PDF found" for one full week. The next week, the documents started showing. Some searches returned results for an entirely different patent number.

- Sometimes, Form 27 found on InPASS was not found on IPAIRS and vice versa.

- Runtime errors occur due to browser caching. IPAIRS returned either a 404 error or Connection Time Out ("site is taking too long to respond")

http://ipindiaonline.gov.in/patentsearch/search/index.aspx. In our opinion, it could be redirected to InPASS as it uses the same search engine as InPASS. Further, http://ipindia.nic.in/patsea.htm returned a 404 error.

6. We are thankful to the Indian Patent Office for the opportunity to make these submissions. It would be our pleasure and privilege to discuss these submissions and recommendations in details at the Stakeholders’ Meeting on 21 March, 2018.

On behalf of the Centre for Internet and Society, 16 March, 2018

Anubha Sinha
anubha@cisindia.org
Annexure

Complete Data of CIS’ Study1x

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iii Supra note (ii).
iv Refer to Appendix for a breakdown of compliance of Form 27 by patent holders in the mobile device sector.
Also, see https://spicyip.com/shamnad-basheer-v-union-of-india-ors
vii Section 159 of the Patent Act, 1970 empowers the central government to make rules. Accordingly, the Rule 131 of the Patents Rules, 2003 prescribes Form 27 as the manner in which section 146(2) of the Act is to be implemented.
An email by Rohini Lakshane (CIS) compiling these issues was sent to Dr. K.S. Kardam (Senior Joint Controller of Patents and Designs - Indian Patent Office) on 09.09.2017.

ix Supra Note (ii)
Dear Dr Dhumane,

As advised I am sending you my comments on the above mentioned subject.

1. I do believe that we should retain the requirement of "Working of Patents" as per the Indian Patents Act 1970 (as amended in 2005).

   This requirement should not be compromised under any circumstances.

2. Form 27 is totally outdated and the concept of "One Patent - One Product" has lost its relevance in the present context in Business practices and business strategies in India and the globalised world.

   We need to totally change the Form 27 in terms of the information that is asked for from the patentees. It should be appreciated that in today's world a product is often protected by a portfolio of patents. Hence the form 27 should reflect such a business reality. Further, it is no more mandatory to have the product manufactured in India even for the purposes of Section 84 of the Act. Hence details of whether the product is manufactured in India or the process is folloed in India is also irrelevant. Therefore it should be sufficient to ask for details of working in terms of whether the product and/ or process is being used to market the product in India. It should not be expected to indicate the amount in quantity and / or value of the marketed (i.e. worked ) product based on the portfolio of patents.

regards.

Professor (Dr) Prabuddha Ganguli
CEO, VISION-IPR
and
Visiting Professor, Rajiv Gandhi School of Intellectual Property Law
Indian Institute of Technology, Kharagpur, West Bengal.
Mobile: 9820352815
Dear Sir/Madam,

We are representing Epiphany IP Solutions Pvt Ltd., from Bangalore, a Company specialized in drafting and filing of patent applications.

Kindly find below our comments related to the filing of working of patents in India:

1. The applicants should be provided with an opportunity to file the working of patents even after the due date with a petition (with some prescribed fee).
2. Form 27 asks for the total value of patented product commercially worked in India. – The commercial value of a patented product is very difficult to calculate and it is highly confidential data which the companies typically won't be willing to share.
3. There are many practical difficulties in obtaining the commercial value of a patented product in India.
4. Companies with hundreds of granted patents sometimes they find it difficult to find which patent is used in which product or services. For instance, one product may involve technologies of tens of patents, so determining a value share of each patent is typically a very challenging task.
5. Companies are also averse to share the details of the licensee and sublicensee names because these details are highly confidential information, and they would not want these details to be readily available to the public.

For,
Epiphany IP Solutions Pvt Ltd.

Best regards,
Haneesh
(IP Counsel)
Dear Sirs,

Regarding the issues relating to Working of Patents, our comments are provided as follows:

1. New use of known pharmaceutical compounds shall be patentable.
2. Substantial examination shall be accelerated.
3. The supplementary data after the filing data shall be considered in argument against inventive step objection.
4. Non-patentability u/s 3 is abused by the examiner/controller.
5. Sufficiency of disclosure u/s 10 shall be relaxed to be compatible with the inventor's actual contribution.

Thank you for carefully considering the above comments.

Best regards,

David W. Cheng

DWC/Iy

GE CHENG & CO. LTD

Level 19, Tower E3, The Towers, Oriental Plaza,
No.1 East Chang An Avenue, Beijing 100738, China
Tel:+86 (10) 8518 8598, Fax: +86 (10) 8518 3600
Email: info@gechengip.com

http://www.gechengip.com
Dear Sirs,

We write with reference to the Circular dated 01 March 2018, regarding the Stakeholders Meeting regarding issues related to working of patents under the Patents Act, 1970.

We submit herewith our comments on issues relating to working of patents i.e. Section 146 of the Patents Act 1970 (as amended) read with Rule 131 of Patent Rules 2003 including Form-27, and penal provisions provided in Section 122 –

- The definition of working is not clearly defined in the Act. It is not clearly stated whether only local manufacturing amounts to working of patents or import of the patented invention is sufficient to say that the patent is worked. It is also not clear whether in cases where a patented invention is offered for sale on e-commerce sites or the e-webshops of the patentee, the patented invention is considered to be worked.

- It is also not clear about the working of the patents which claim intermediate products which are used in the manufacture of a different marketable product, or the products/processes which are intended to be used internally in the premises of the patentee for making said intermediate products.

- There is no explanation in the Act about the reasonable requirements of the public, please illustrate, with examples, as to in which cases the requirement is said to be met partly/adequately/to the fullest extent.

- In cases where the public requirement is difficult to determine due to nature of the invention, there is no guidance as to what should be written in the Form-27 regarding the public requirement.

- In cases where the quantum and/or value of the patented product is difficult to determine due to the nature of the invention, please clarify what should be submitted in the Form-27.
- The portal for the submission for Form-27 does not provide for a separate option to submit a Form-27 for licensees

- There is no guidance in the Act to determine what is a reasonable price for a patented invention

- Please provide guidance whether a POA is required to be filed while submitting the Form-27 for a licensee

- It is not clear whether a patentee is required to submit a Form-27 in case the patented invention is worked only by the licensee.

- In case the patented invention is partially manufactured in India and partially imported in India, there is no option to fill details of such situation in e-filing portal of the Indian Patent Office.

- There is a possibility that a patented product can be imported from more than one country, however, there is no option to select more than one country in e-filing portal of the Indian Patent Office.

- In case of importation of product, the field in e-filing portal reads as “Total Value of Patented product in other country”, however it should be “Total Value of Patented product imported in India from other country”.

- As per the Form-27 prescribed by the Patents Act, if invention is worked quantum and value of the patented product is required to be provided. However, in e-filing portal total value of patented Product commercially worked in rupees is asked. There is no field for quantum of the patented product.

- Please clarify whether a scanned copy of Form-27 can be submitted if the patentee has provided Form duly executed, without having power of authority on record.

*We look forward to hearing from you at the earliest.*

*Kindly acknowledge the safe receipt of this email.*

Best regards,
Ramesh C. Dhawan
OF LALL LAHIRI & SALHOTRA
To,
Shri O.P. Gupta
Controller General of Patents, Designs & Trade Marks
Bhoudhik Sampada Bhavan
Antop Hill, S.M. Road, Mumbai-400037

Re: Submission of comments on issues related to working of patents

Dear Sir:

We thank you for extending this opportunity to all stakeholders of patent system in India to provide comments and raise concerns with regard to the unique requirement of filing working statement for granted patents in India.

Based on our experience, feedbacks received from the national and foreign patentees and patent applicants in India and the concerns raised by them from time to time, LexOrbis takes this opportunity to apprise you with our comments on this issue and hope consideration of the same by the Learned Controller General and the other officials associated with this issue.

Our comments/suggestions are:

1. **Definition of “working”:**

The term “working” is not defined in the Patents Act, 1970 or the Rules made thereunder and therefore, has been subjected to several interpretations. The general principles which describe the working of the patented invention in India under Section 83(a) of the Act may not be adequate to understand the working of patents in the context of changing dynamics of industry. For many industries, local manufacturing of
patented product may not only be impractical but may be impossible to due to unavailability of capacities and skills.

The Bombay High Court in *Bayer Corporation v Union of India* has in the recent past recognized those dynamics and held the importation of a patented product in India qualifies for the “working” of the patent.

**Solution Proposed:** The term working of patent may be notified in appropriate manner to include “importation” of patented products or products made by patented process.

2. **Impracticality in collecting necessary working information by certain industry:**

The format prescribed for submitting the statement (Form 27) presumes that each granted patent results in the production of one or more product(s) and therefore the patentee can keep a track of the quantum of production and the sale of such products in India. The reality is far away from this position particularly in cases related to ICT and other hi-tech industries, where patents are used in global portfolio licensing programs or form part of pools created by technology companies. In such cases one ascertainable product may involve use of multiple patents under patent portfolios of multiple parties forming part of patent pools and/or used on the basis of cross licensing, etc. and therefore renders it impractical and in some cases almost impossible to collect relevant and correct information that need to be furnished in the working statements as provided under current format.

**Solution Proposed:** Form 27 to allow patentees to make a statement to the effect that patent is not worked in a standalone format but form part of the portfolio licensing program. The patentee may also be allowed to make a statement that it is impractical to determine whether the patented invention being part of the global portfolio program has been worked in India or not.
3. **Meeting of Public Requirement:**

As submitted above, under the changing dynamics of several industry and operations of global patent portfolio licensing, etc. it may be impossible for several industry to ascertain the working of the patent by ascertaining in which particular product the patented invention was implemented. Under those circumstances, it may further be impossible for the patentees to find out the requirements of the public related to that patented invention.

**Solution Proposed:** The patentee may be allowed to state that it is not practical to ascertain whether the requirements of the public are met or not.

4. **Confidentiality related Information:**

Voluntary licensing agreements contains many commercially sensitive and confidential information, the public disclosure of which may prove prejudicial to legitimate business and legal interests of the parties to such agreements. The Hon’ble Delhi High Court, in a public interest litigation related to the working statement requirement in India, has recognized the rights of the parties to maintain the confidentiality of commercially sensitive information. In these circumstances, providing the description of license including the names of the licensees and sub-licensees, etc. may be treated as sufficient to fulfill the requirement and rest of the contents of the license agreements may be treated as confidential.

5. **Frame work for penalizing defaulters:**

Section 122 provides a provision for penalizing the defaulters under Section 146. Section 122 talks about some threat of sanction such as imprisonment to six months or fine which may extend to 10 lakh Rupees, or both.
However, there is no specific framework or procedure mentioned in the Rules pertaining to the implementation of Section 122. Section 122 simply states about penalties and corresponding Rule 131 simply states about the submission of Form 27.

**Solution Proposed:** Rules may be amended to provide a procedure whereby any person aggrieved by not filing of working statement may file a complaint before the Patent Office and the Patent Office after giving adequate opportunity to the patentee and making necessary inquiries as it may deem fit, initiate the proceedings as prescribed under Section 122.

Yours’ sincerely,

Manisha Singh

Managing Partner, Lexorbis IP Attorneys
Dear Sir/Madam,

With reference to the above-mentioned subject regarding the provisions of working statement of Patents in the Patent Act 1970 (as amended) we hereby like to submit our comments to further streamline procedures in this regard.

The Purpose of a Working statement is to inform the public whether a patented invention is or is not being worked in India. The Working statement provides details describing the extent to which the patented invention was worked on a commercial scale in India during previous calendar year. The Working statement must be provided to the Indian Patent office using Form 27 by March 31st as per requirement U/S 146 of the Patent Act 1970. As Form 27 can be filed at IPO electronically by the Patentee, Licensee or via an agent on behalf of the Patentee or Licensee. If a Patent is worked in India, the Patentee or Licensee are requested to provide (a) the amount and value of the Patented invention (b) whether the Patented invention was or was not manufactured in India (c) whether the patented invention was imported from other countries (and if imported then the list of countries from where the Patented invention is imported from) (d) Whether or not the invention is worked or not worked in India, the patentee or licensee must provide whether any licenses or sublicenses were granted during the year and along with the public requirement has been met partly/adequately to the fullest extent possible at a reasonable price.

So looking into the holistic perspective on the Working statement U/S 146 of the Patent Act 1970, we have the following observations:

1. There are no guidelines from Patent Office for submitting FORM 27. Thus, reason for not working vary from case to case.

2. In the preview section of e-filing of Form 27 the details submitted by the Patentee is not visible as the Form is electronically generated. We are enclosing a Form 27 electronically generated for your reference.
3. In the Patent Office website in “Dynamic Patent utilities” the publication of information received from Patentees regarding working of Patented inventions on commercial scale in India U/S 146 of the Patent Act 1970 is updated up to year 2012 & 2013 so the data regarding the working statement of Patented invention regarding year 2014, 2015, 2016 is not updated by the Patent Office which creates lot of inconvenience for the Patentee or Licensee to find whether their information regarding working of their Patented invention are uploaded or not or others.

4. If there is pending of Form 27 from the Patentee or Licensee before the deadline then there should be an email alert to be sent from the Patent Office to the authorized agent or to the address for services in India to inform the Patentee or Licensee that their information regarding working of their Patented Invention U/S 146 is due to be filed.

5. The Patented invention from other sectors like technology (apart from Patentees of Pharmaceutical inventions) which involves different components it is always difficult to identify which of those Patented components require a working statement.

6. It becomes a tedious job for the patentee or licensee to determine the amount and value of their patented inventions in respect to global market.

7. There is no uniform or standard method for determining public demand e.g., for components or subcomponents incorporated into larger or composite products, it is not possible to identify the public demand for a patented subcomponent separately.

In view of these certain issues regarding the provisions of Working of Patents in the Patent Act 1970 with rule 131 of Patent Rules 2003, we request you to look into these matters so that FORM 27 shall be simplified Form for Patentees or for Licensees with defined guidelines. If you have any queries regarding our suggestions, we are always available for consultation meeting with IPO to further streamline procedures in this regard.

Yours Sincerely

Dr (Mrs) S Banerjee
IN/PA-210
L.S. Davar & Co
C Sir,
I am a former army officer, who had a stint with IIM and also a NLU after taking premature retirement from the Army. I have authored two books, of which one is under print. The first book ‘Understanding Intellectual Property’ has been well received. The second book is on patent prosecution and will be out in the market in a few months time. the publisher for both is EBC. Unfortunately it is always the poor who bear the brunt in healthcare and affordable medicines is a far cry. Though the drug pricing control order has done wonders, hospitals have found new ways of fleecing patients.
I do know that the Patent Office is overworked and this will need a separate section to deal with the information in Form 27. I do feel that form 27 needs a revision and have suggested it so the accompanying attachment. I have kept the comments/suggestions short, since you will be receiving quite a lot of comments.
Just as a point of interest I am attaching the Introduction to the second book. You may like to go through it too.

--
Regards,
Mathew

Comments on the Issues Regarding the Furnishing of Information on Working of Patents
By
LtCol (Dr) Mathew Thomas (Retd)

Section 146 of the Patent Act, 1970 mandates that the Controller of Patents can seek information on the working of patents from any of the patentees or a licencee during the life time of patent. This is to be seen in light of the grant of the patent as a quid pro quo so as to exclude others from making, copying, selling, importing the invention without permission of the inventor. The information is to be provided not less
than six months by the patentee or the licencee, within a period of three months at the end of each year.

Non-disclosure of the information and non-furnishing of the information should be treated as an offence under the Patent Act, Section 122 and is punishable with six months imprisonment or/and fine of up to ten lakhs of rupees.

The furnishing of the information mandated when seen in light of Section 83 serves several purposes; chiefly being that they are worked and that information is furnished to the government, promotes technological innovation and balances rights and obligations and social and economic welfare, safeguards public health, patent rights are not abused and the patented invention being made available to the public at reasonable and affordable prices. Health care as far from desirable and it is the poor and the marginalised who bear the brunt. Corporate hospitals charges can pull a family into poverty from which they can never be able to pull themselves up.

This requirement is critical in understanding how the patented product/process is being used as mandated by the legislature.

It would be of immense use to the public if all patent details including working as given at infra must be mandatorily placed on the company/entity website in addition to the information being furnished to the Patent Office.

A perusal of the form indicates a summary requirement of furnishing information which at best is sketchy.

So what is suggested is the Serial 3 and 4 must be modified. The modification of Form 27 Serial 3 could be under the following heads:

<p>| Sno | Nomenclature | Patent No | Date of Grant | Whether Worked in India or not | Reasons for Not working | If Imported Countries from where imported | Qty Imported in Nos/Kgs/Tonnes | Cost of Import per piece/item | Whether Licenced or not | Details of the Licencee including sublicensees | Cost of Production if Produced in |</p>
<table>
<thead>
<tr>
<th>India</th>
<th>Quantity Produced in Nos/Kgs/Tonnes</th>
<th>Stock Remaining at the end of the reporting Year</th>
<th>Stock Carried Forward</th>
<th>Market/Retail Price to Consumer</th>
<th>If Technology is Transferred for use in India Cost of Transfer</th>
<th>Remarks</th>
</tr>
</thead>
</table>

Serial 4 must also contain a statement that the information submitted is true and correct account of the details and if found incorrect at a later stage the person signing the Form is liable to be prosecuted/punished as per Section 122.
INTRODUCTION

The complexity of patent prosecution can only be gauged by the initial stages where in the application is to be prepared and prosecuted. It is challenging task getting the application in an order, drafting the claims, specifications, descriptions and then submitting it to the concerned patent office. Two things dominate the entire process, one finding the prior art relevant to the embodiment through search and framing the claims which is indirectly connected to the search and the technical examination by the patent office; and second, the critical timelines that one has to observe coupled with the responses where required. A lack of response from the patentee/applicant when due, would indicate an abandonment; and an improper or incomplete search for prior art would nullify and negate the application for a patent, due to lack of novelty. Such is the criticality of prosecuting the application, which is to say that one must be mindful of all the parts and processes. This can be understood only if one knows how to start preparing the application and drafting the claims.

Patent prosecution is the process of applying and getting a patent and relies on most parts on some of the points highlighted in the paragraph at supra. Whereas patent litigation starts when grant of a patent is being litigated upon generally due to infringement of its claims. The prosecution starts with the application and the application starts with the fundamental embodiment, preamble, description and the claims. These could be buttressed by drawings and a written description. The search and examination of the application is what sets about the grant or refusal of the patent. In between, is the office action/invitation by the patent office to correct the application or to pay the required fees etc. and the response is the reply to the invitation in which the applicant sets out to correct the observations raised by the patent office and examiner. Failure to act by the applicant may lead to refusal or abandonment of the application.

Patents granted on traditional knowledge are a case in point. Once the digitization of traditional knowledge took place, it was found that many patents were granted based on traditional knowledge, which is prohibited under the treaty. Some of them were subsequently challenged and were withdrawn by the patentees. Some others let the patent lapse due to non payment of fees. The digitization by the GoI was a step in the right direction and today many of the international patent offices refer to the digitized traditional knowledge library(TKDL) established by the GoI, before granting patents. It has about 34 million pages which could be searched.
It is found that on an average there is misappropriation of the Indian Traditional Knowledge to about 2000 patents each year.\(^1\) A study by the Ministry of Ayush in 2004 has indicated that 249 patents were taken on Yoga, in May 2005 -2300 patents, 2315 trademarks in USPTO.\(^2\)

\*Study carried out by the Ministry of Ayush\(^3\)*

<table>
<thead>
<tr>
<th>Patent Databases Studied</th>
<th>Year of Study</th>
<th>No of Patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPTO</td>
<td>2000</td>
<td>4,896</td>
</tr>
<tr>
<td>International patent offices</td>
<td>2003</td>
<td>15,000</td>
</tr>
<tr>
<td>-do-</td>
<td>2005</td>
<td>35,567</td>
</tr>
<tr>
<td>-do-</td>
<td>2008</td>
<td>85,000</td>
</tr>
</tbody>
</table>

Challenging the issue of patents for basmati and turmeric is noteworthy and they were subsequently invalidated by the USPTO. The patent on neem was also invalidated at the EPO. The traditional knowledge of this great nation and almost all the countries of the East to a large extent were freely available to the society and it is patents that have brought it a sort of profiteering. Digitization of the texts of traditional knowledge have made it easy to for patent examiners to search the ancient texts for prior art and therefore it is now difficult to patent them.

This brings us to two questions. First, can and should patent offices grant patents for frivolous inventions, which borders on being petty, and which was highlighted to some extent in the preface? Second, how do we measure quality of patents? Both the questions are tenuous and one cannot with any degree of certainty answer them outright. This leads us to the plausible answer that over a period of time, there will come a stage when the standards of patentability will become higher and as a fall out, patent offices will tend to reject applications which do not meet the higher standards of patentability. This will usher good quality patents usually found with high technology inventions and not the mundane that is highlighted in the preface.

There is also another issue critical to patent applications that of specification drafting, claims and use of highly technical words which are sometimes overemphasized by the drafter. One must be careful not give an opportunity for a potential infringer to challenge the claims on grounds of prior art or the patent examiner rejecting the claim based on prior art/lack of novelty. Both are difficult to resolve easily and could be avoided if the words/language is carefully used and drafted. There would also be a peculiar problem when applications are translated into other languages, for a word may not fully connote the desired colour of that particular word in the language translated. For example translating a Chinese application into English or a Korean application or Japanese

\(^2\) *Id.*
\(^3\) *Id.*
application or a Spanish application into English is likely to cause some degree of ambiguity. The probability is high. Though it is infrequent to see infringement cases based on interpretation regarding a particular claim in India, it is not infrequent to see them in the US. Cases have been cited in the book. For example for those interested see *Hilton Davis Chemical Co., v. Warner Jenkinson Co.*, 114 F.3d 1161 (Fed.Cir. 1997).

There has been a steady increase in patent filings world wide and particulary in technology related to smartphones. The recent report by WIPO on intangible capital global value chains makes an interesting reading. Another area where IP filings have increased is the smart phone technology, in which there has been a 20% increase in 2012 from 2002, which translates into 27% filings for smart phone patents. One interesting feature of smartphone patents is that between 1990 and 2013 the number of smartphone first patent filings worldwide grew from about 100 patents in 1990s to 2,700 patents in the narrow category in 2013 and from about 230,000 first filings in the early nineties to more than 650,000 first filings which is about 1.2 million patents overall in the broad category. That’s a mind boggling array.

The smartphones will become the standard for all financial transactions. One may find the POS machines and credit/debit cards becoming obsolete in the next few years. The card companies may have to innovate otherwise the companies are going to face a tough future. As it is with increased thrust of patenting towards making the smartphones more secure, more user friendly and adaptive with AI, it is sure going to spell the death knell of many of the companies. A smartphone packs a lot of patents and it is not far when most of the transactions will be done on the smartphone and this area will grab the attention of the patentees and researchers.

What this indicates is that the IP world is going see increased patent filings over the next few decades and probably there will be a need to monitor the quality of patent filings. This will happen and it will not be far off into the future. So the mundane patents will probably not see the light of the day unless they be classified as something else in the next two-three decades.

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(1) We would like the Indian Patent Office (IPO) to consider abolishing the working statement requirement because it imposes enormous burdens for patentees like us to check accurate and detailed information about whether or not each of our granted patents is worked in India, and if yes, about how much they are, i.e., quantum and value of patented product, manufactured in India or imported from other countries, etc.

(2) We would like the IPO to show a guideline describing reasonable input standards if it is impossible to abolish the requirement.

(3) We would like the IPO to consider introducing much more relaxed measures than ever before like the followings.
  · To abolish a requirement to confirm quantum and value of patented product.
  · To abolish a requirement to confirm quantum and value of patented product, in particular, manufactured by licensee(s) and/or sub-licensee(s) based on a cross-license agreement for example, because working of patents are not usually required in a license agreement and it is hard to provide such information.
  · To extend a deadline to submit the working statement, in particular for foreign patentees.
Comments Relating to the Working of Patents

TO:  The Controller General of Patents, Designs & Trade Marks

FROM:  Jay A. Erstling  
Of Counsel  
Patterson Thuente IP  
4800 IDS Center  
80 South 8th Street  
Minneapolis, MN 55415, USA

RE: No. CG/Circular/2018/114: Circular “Inviting comments from stakeholders regarding issues relating to work of patents”

DATE: 22nd March 2018

The Controller General of Patents, Designs and Trade Marks is to be commended and thanked wholeheartedly for inviting comments relating to the working of patents in India.

I am a US attorney with a very lengthy and deep association with India, dating back to 1989. I work closely with several Indian law firms, and I represent Indian clients in the US. I have lived in India, taught at the National Law School in Bangalore, and lectured and participated in law conferences throughout the country.

From 2002 to 2007, I served as the Director of the Office of the Patent Cooperation Treaty (PCT) at the World Intellectual Property Organization (WIPO), and Director-Advisor to the WIPO Director General. During that time, I made frequent visits to India and worked with Intellectual Property India and the Department of Industrial Property and Promotion (DIPP), as well as with FICCI, NASSCOM and other stakeholders, to ensure that matters of importance to India were properly heard in PCT and WIPO deliberations.

In view of my familiarity with Indian patent law and practice, and my decades of involvement with, and appreciation for, the country, I sincerely hope that it is not inappropriate for me to offer comments in response to the Controller General’s invitation. My comments are offered in the spirit of respect and appreciation for India and its patent system.

My substantive comments follow:

I have high regard for India’s working requirement, but I do not believe that the reporting obligation imposed on patentees by Form 27 furthers the working requirement’s objectives. I agree with many of my Indian colleagues that Form 27 is flawed. Although most countries have working requirements – and compulsory licensing is sanctioned by both the Paris Convention and the TRIPS Agreement – India is the only country, to my knowledge, that has a reporting obligation. Presumably, the purpose of the reporting obligation is to encourage patentees to
work their inventions in India, to facilitate the possibility for third parties to seek compulsory licenses if inventions are not being worked, and perhaps to discourage applicants from applying for patents if they lacked the intent to work their inventions. The problem with Form 27 is that it does not fulfill the purposes for which it was intended. Form 27 fails to further the objectives of Section 146(2) of the Patents Act, and it therefore should either be revised or eliminated altogether.

Of utmost concern with Form 27 is that two of the form’s questions are virtually impossible to answer, and yet the form imposes exceptionally heavy consequences on the failure to answer the questions accurately. Question 3(i)(b) asks patentees to furnish the “quantum and value (in Rupees) of the patented product,” including both a product manufactured in India and one imported from other countries. This question cannot be answered without exhaustive analysis when a product contains multiple patents, when a product is a component of other products, or when a product contains parts that are the result of complex licensing arrangements, as is often the case. The form makes no exception for such cases, however.

Question 3(iii) is even more problematic. It asks the patentee to state “whether the public requirement has been met partly/adequately/to the fullest extent at reasonable price.” In addition to being unreasonably vague, no patentee can possess sufficient information to answer the question correctly. A typical patentee, particularly an SME, lacks the data necessary to judge what the public requirement for a product is, no less to determine whether the patentee has met that requirement or what would constitute a reasonable price in accordance with the Government’s expectations. The only honest answer to such a question is “We don’t know.”

Form 27 thus imposes unreasonable burdens on patentees, and as long as it continues to do so, it will have little impact on encouraging compliance with the Act’s working requirement. The reality is that patentees make working decisions based on business factors, not on the threat of a reporting obligation. For potential compulsory licensees as well, Form 27 serves little purpose. Even if Form 27 were to reveal a possible compulsory licensing opportunity, a potential licensee would need to initiate a complex petition process to demonstrate that the grant of a license would be justified, and that the licensee has the means to work the invention successfully and pay a reasonable royalty. That there have been few petitions for compulsory licenses in India (or elsewhere in the world, for that matter) is no doubt due to the business reality of compulsory licensing, not to the failure of patentees to complete Form 27. Moreover, it should not be forgotten that the burden of Form 27 falls not only on patentees but also on the Patent Office, which has to collect, process and publish the forms. Form 27 may have admirable intentions, but as currently drafted, it fails to achieve them. It is an obligation without a justifiable purpose.

The simplest remedy would be to eliminate the form, but doing so is not likely, and the form does have one positive attribute: it serves as a reminder to patentees that India takes the working requirement seriously. If the Patent Office were to decide to revise the form, I would respectfully suggest the following changes:

- The most important change would be to delete questions 3(i)(b) and 3(iii). As mentioned above, the questions cannot be answered accurately and they do not serve to encourage working.
Another important change would be to eliminate the draconian penal sanctions and fines. If a patentee willfully filled out the form incorrectly, or knowingly failed to file the form, a more appropriate penalty would be to declare the patent unenforceable. A declaration of unenforceability would mean that anyone could work the invention without the need for a license or the payment of compensation. The threat of severe economic consequences, particularly for large corporations with valuable patents, would no doubt constitute sufficient motivation for patentees to comply with the reporting obligation.

When an applicant files a PCT application, the applicant can indicate that the invention is “available for licensing.” I would respectfully suggest that the Patent Office consider adding a comparable provision to Form 27. The form would ask a patentee to tick a box if the patentee wished to make the invention available for voluntary licensing, and it would invite interested third parties to contact the patentee. The ability to notify the public of licensing opportunities benefits both patentees and potential licensees, and it falls squarely within the Patent Office’s mandate to encourage the working of patented inventions in India.

Finally, Form 27 asks patentees to provide “reasons for not working and steps being taken for working of the invention” in the event that an invention is not being worked in India. In order to bring greater clarity to the working requirement, I would respectfully request that the Patent Office provide guidance as to the sorts of “reasons for not working” and “steps being taken for working” that the Patent Office deemed *prima facie* acceptable. Greater awareness on the part of patentees is likely to bring about greater efforts to ensure compliance.

I am confident that if the reporting obligation were made more rational, more patentees would comply with it. I would therefore respectfully urge the Patent Office to revise, if not eliminate, Form 27.

Again, wholehearted thanks go to the Controller General for the opportunity to submit comments. The Controller General’s invitation is an important positive step toward achieving a just and beneficial outcome.

[End of comments]
Dear Sir/Madam,

Further to my below suggestions, I would like to add that the format for reporting compliance on the below sections is not comprehensive, adequate information should be collected from the patent holders to meet the objectives of below sections, further the data is not available since 2014 in the ipnic.in website, which should be immediately uploaded and fine and penal provision should be imposed on defaulters as per the patent act and rules. Urgent action is needed to disclose to the maximum extent possible information requirement in compliance with the below sections by amending the concerned forms, so that as required compulsory licensing can be resorted to in deserving cases were the patent holder does not produce in India or elsewhere.

In this instance I would like the patent office to start a public discussion on the basis and requirement of patent life of 20 years, which is without any scientific basis, just because many countries and wipo follow it India need not follow it. The duration of patent should be linked to the investment in developing a new product or process and the duration required to realise the investment, with reasonable profits. So the duration for different patentable items should be different and cannot be fixed as 20 years it should be much less.

Do to preoccupations I would not be able to attend the public consultations, hence would require patent office to consider my views

Regards
Praveen

On Wed, Mar 21, 2018 at 8:27 PM, Praveen K <praveendoh@gmail.com> wrote:

Dear Sir/Madam,

As a citizen of India, I am of the opinion that no change is required in Section 146 of Indian patent act as amended read with rule 131 of patent rules 2003 including form 20 and penal provisions under section 122 of the Indian Patent Act. The penal provisions need to remain as it is now, to ensure parties dont make false statements and get away easily to the detriment to India and Indian citizens.

I am of the opinion no stake holder meeting is required in this regard, especially if the patent office chooses to call only select stake holders in violation of article 14 of the constitution, as the views of the selected stake holders don't represent the Indian citizens voice.

Finally I would like to place on record our patent Act as it is now is one of the best in the world especially regarding patentability requirements, and I request that the Indian Patent act should not be diluted to serve the interests of foreigners to the detriment of India and its citizens

Praveen.K
Advocate LLB, LLM, M.E,MBA.
To,

Dr. W.M. Dhumane & Dr. Usha Rao
Office of the Controller General of Patents, Designs & Trade Marks

Comments on Issues Related to Working of Patents under the Patents Act, 1970

Dear Sir/Madam,

In furtherance to the circular published by your office on 01.03.2018, we wish to submit the following comments on the issues related to working of patents under the Patents Act, 1970, and in particular the format of Form 27.

We would also like to be present at the consultation meeting scheduled on March 21, 2018 and would be grateful for an invitation for the same.

Our suggestions are already available in a writ petition\(^1\) filed by one of us before the Delhi High Court in 2015, as also in an article\(^2\) titled ‘Making Patents Work: Of IP Duties and Deficient Disclosures’ and published in the Queen Mary Journal of Intellectual Property. Nonetheless, for the sake of your convenience, we highlight as under:

**Importance of Patent Working Disclosure**

Patent working norms lie at the very heart of India’s patent system. In exchange of the grant of monopoly, the patentees are required to work their patented invention, as far as practicable, for the public benefit, by ensuring that patented products are available in adequate quantities and at reasonable prices. The failure to fulfil this mandate can trigger a penalty in the form of compulsory licensing or revocation of the patent. Besides this, courts routinely deny the grant of an equitable remedy (i.e., interim injunctions) when the patent has not been worked. The lack of access to patent working information, thus, directly impacts the possibility of such trigger/refusal of injunction and denies

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consumers and the wider public the potential to access more affordable patented inventions, a concern most starkly felt in the area of patented medicines and public health.

Therefore, it is critical to ensure that the patentees and licensees make a full and complete disclosure of the patent working information. The current format of Form 27, under which the patentees and their licensees are required to disclose the patent working information, is however insufficient to ensure this. It suffers from considerable ambiguity and omits to ask patentees for a number of important particulars that are necessary for an effective assessment of the commercial working of patented inventions. Due to these defects, it facilitates strategic non-disclosure of complete working information by patentees. A survey\(^3\) undertaken by us a few years ago revealed that between the years 2009 and 2012, a significant number of patentees who made the Form 27 filings, submitted information that was deficient in important particulars, that is, grossly incomplete, incomprehensible or inaccurate.\(^4\)

A. Reformation of Form 27

In view of the above, we recommend that the current format of Form 27 be amended. The writ petition that we filed (as mentioned above) devotes an entire section to this issue and outlines some suggestions to improve the current format of Form 27.\(^5\) We reiterate those suggestions below:

i) A critical part of Form 27 i.e. Paragraph 3 merely asks patentees and licencees to “give whatever details are available” without mandating such disclosure in stronger terms, given that it is a statutory mandate under section 146 of the Patents Act (to disclose the full extent of commercial working of the patent). Owing to this nebulous wording, patentees and licensees have strategically provided rather vague and non-specific information that makes it impossible to determine the extent of working.

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\(^3\) This survey covered close to 150 granted patents in India relating to three select categories: pharmaceutical drugs, telecommunications, and those that emanated from publicly funded research and development.

\(^4\) Shamnad Basheer v. Union of India, supra note 1, ¶¶10–16 & Annexure P-11.

\(^5\) Id., ¶¶63–64.
Paragraph 3(i)(b) of Form 27 requires patentees to state the “quantum” and “value” of the patented product manufactured in India or imported from other countries. This, however, fails to capture the actual sale of the patented invention in India. For it is not clear what is meant by “value” of the product. The term “value” and “quantum” ought to be spelt out with greater precision and specificity. It should also take into account the differential nature of the technology that patents protect. Illustratively, in the case of pharmaceutical patents, the key question is: should value be the price at which the patented drug is sold/distributed by the patentee to distributors or the final price at which the drug is sold to the patient? Ideally, the Form should call for both prices, but more so the price at which the drug is ultimately sold to the patient, as this helps determine whether the patented invention is worked to the best extent and the reasonable requirements of the public are being met. The “quantum” of product should also be indicated in clear terms. Lack of precision on this count has meant that drug patentees such as Bayer have used conflicting and confusing terminology to indicate quantum (packs vs boxes etc).

In the high technology sector, it is often the case that a single basic patent is embedded in multiple products, technologies and improvements. Since the current format of Form 27 does not call specifically for this information, patentees typically disclose only one application or product. Given the sheer importance of fostering more transparency within the high technology sector, Form 27 ought to be amended to explicitly call for this information. Specifically, the patentee must be made to disclose all technologies, applications and products (that they are aware of), where the same patent is deployed/used.

Conversely, it is often the case with telecommunications and other technology sectors, that one product contains multiple patents underlying

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it. Therefore, it is critical that all patentees who hold multiple patents covering a single product disclose other “related” patents for each such patent. A failure to disclose this information adversely impacts innovation and competitors significantly, as it unduly increases their search costs in all cases where there are potentially multiple patents covering the same product. Therefore, the present format of Form 27 ought to be amended to mandate disclosure of such information.

iii) Paragraph 3(ii) of the Form requires patentees to disclose “licenses and sub-licenses granted during the year”. However, here again, there must be more specificity. Due to the lack of emphatic specificity, a number of Form 27 submissions simply fail to disclose the details of licensees or licensing arrangements. The revised Form must begin by asking whether the patent has been licenced in the first place. If so, it must then ask for more details, such as the names of licensees and broad terms of licence that permit one to objectively ascertain if the patentee has worked the patented invention through the license to the reasonable satisfaction of the public. Not all aspects of a license can be hidden away under the guise of confidentiality. Rather, particulars such as the name of licensee/s must compulsorily be disclosed under sections 67-69 of the Patents Act. Other details can be disclosed only to the extent necessary to demonstrate that the patent has been worked. Confidential licensing terms can be redacted at the option of the Patent Office and the statutory framework does provide leeway for this.

iv) Paragraph 3(iii) of the Form requires patentees to “state whether public requirement has been met partly/adequately/to the full extent at a reasonable price”. However, this is too vague, nebulous and absurd a question, as it is difficult to imagine any patentee forthrightly declaring that they have not met the requirements of the public. Instead of requiring the patentees to merely self-attest whether or not the reasonable requirement of the invention to the public have been met, the Form ought to call for more particular information as would help the Patent Office make this assessment. In particular, the patentee ought to be asked to submit the following:
a) estimated demand of the patented invention or product;

b) extent to which the demand has been met (i.e. availability); and

c) details of any special schemes or steps undertaken by the patentee to satisfy the demand.

Further, in case of pharmaceutical patents, where the patentees claim to have met this requirement through Patient Assistance Programmes (PAPs), they must be required to clearly indicate the quantity and price (if any) in the Form. Here again, the various gaps in the Form 27 filings by Bayer in relation to the Nexavar patent are telling.7

B. Rectification of E-Filing Version of Form 27

The online version of Form 27, which can be submitted through the e-filing of patents facility (URL: https://ipindiaonline.gov.in/epatentfiling/goForLogin/doLogin), is even more problematic than the offline/physical format as it requires even less specificity in the information to be provided by patentees and licensees. Illustratively, it does not require them to submit information pertaining to the quantum of the patented product imported or manufactured. A screenshot of the online form as on 15.03.2018 is attached herewith.

This blatant dilution of an important statutory mandate enables patentees and their licensees to evade public scrutiny of the true extent to which the patent has been licensed and worked. Therefore, we recommend, as is also done in our writ petition,8 that the online version of Form 27 must be immediately rectified to enable patentees and licencees to submit full and complete working information.

C. Updating of Online Searchable Database

Currently, the patent working database on the Patent Office’s website (http://ipindiaservices.gov.in/workingofpatent/) provides access to Form 27s submitted in the calendar years 2012 and 2013 only. As a result, the Form 27 filings pertaining to the

7 Id.
8 Shamnad Basheer v. Union of India, supra note 1, ¶¶28 & 65.
years 2003 to 2011, 2014 to 2017 are not conveniently available for public viewing through a single web page/interface. Rather, one has to go through each individual patent entry to determine whether or not Form 27s have been filed and updated for that particular patent.

Further, even for the years 2012 and 2013, only the Form 27s submitted by the patentees are accessible on the database. Form 27s submitted by the patent licencees have not been uploaded. For instance, for patent number 215758, only the Form 27s submitted by Bayer (the patentee) show up on the database and not those submitted by Natco (the licensee). Furthermore, even the Patent E-Register provides copies of only Form 27s filed by the patentees in the patent working information section and not those filed by their licensees. The Form 27s submitted by patentees are also not made available for all years. For instance, for patent number 215758, the Patent E-Register reflects only Form 27s submitted by Bayer for years 2013 to 2016. The one submitted by it for 2012, which is available on the patent working database, has not been uploaded on the Patent E-Register.

In order to provide for better transparency, we recommend, as done in our writ petition,\(^9\) that the Patent Office publishes all the information relating to commercial working of all patents (as encapsulated in the various Form 27s) for all years of operation of the patent on one consolidated page on their website.

Further, may we please request that while framing the new Form 27 and implementing the patent working and disclosure requirement, the Patent Office ensure that the broad principles of patent working laid down under Section 83 of the Act are borne in mind. This will ensure that the new Form 27s and the consequent enforcement do not whittle away or dilute the patent working and disclosure mandate carefully constructed by our policy makers and enacted into law by the people’s representatives (namely, Parliamentarians).

We hope that the above comments and recommendations by us will receive serious consideration by your office.

---

\(^9\) Shamnad Basheer v. Union of India, supra note 1, at 41.
Most sincerely yours,

Prof. (Dr.) Shamnad Basheer
Honorary Research Chair Professor of IP Law, Nirma University
Visiting Professor of Law, National Law School, Bangalore
Founder and Chief Mentor, SpicyIP

Pankhuri Agarwal
Research Associate to Prof. (Dr.) Shamnad Basheer
Managing Editor, SpicyIP

N. Sai Vinod
Advocate, New Delhi
Dated: 16.03.2018

Dr. W.M. Dhumane/Dr. Usha Rao
Deputy Controller
The Patent Office
Boudhik Sampada Bhawan
Plot No. 32, Sector 14, Dwarka,
New Delhi -110072

Sub: Comments concerning working statement.

Dear Sir/Madam,

Below are some suggestions concerning Form-27/working of patents:

a. Form-27 - enable physical and eelectronic filing: currently Form-27 can only be filed electronically. It is suggested that physical filing of Form-27 be enabled even for patent agents. This would facilitate easy filing of Form-27.

b. Additional information be enabled: currently Form-27 is in a format which is tightly controlled by the manner prescribed. It is difficult to provide additional information. The rules may be amended so that entities desirous of adding any additional information may do so either in the same form or by way of a separate attachment.

c. Non-working statement be accepted by the Patent Office: Many inventions take time to get marketed and worked. Hence, many times Patentees file working statement stating clearly that the invention is not worked. The Patentee may be given liberty to explain why the invention is not being worked.

d. Failure to file working statement: It is observed in many cases that the Patentee has not filed working statement or has neglected to file working statement for one or more years. In such cases, it is suggested that if this lapse is brought to the attention of the Controller or if the Patentee realizes the same on his own, the Patentee may be given a chance to file the working statement. This is already provided for in Section 146; In case the Patentee still does not file any working statement, then penal action may be considered.

e. Simplify Form-27: The Form-27 as currently exist cause for several details such as Quantum and value in Rupees and whether the requirement of the public has been satisfy or not. Satisfaction of the requirements of the public is a subjective requirement and there is no need for such details in Form-27. Similarly, with regard to licenses, the number of licenses granted may be disclosed; however the parties and further details including royalty arrived at between the parties need not be called for as the same may often be Confidential Information.

Also at: Amsoft Business Centre, Unitech Trade Centre, Sector 43, Gurgaon - 122002, Haryana, India
f. Redacted documents: In case the Patent Office calls for any documents in support of the working statement, parties may be allowed to submit redacted documents as some of them would be uploaded on the website of the Patent Office and made public.

Your sincerely,

[Qjm]

CR jef1wari H)
Advocate
To Dr. Dhumane and Dr. Rao,

Please find the Comments below:

The patent act, although dealing explicitly with inventions and its protection with various procedures, is nevertheless bound by legal interpretation and judicial pronouncements. Subsequently, in the light of *Shamnad Basheer v/s Union of India [W.P.(C) 5590/2015]* ensuring compliance with the provision of Section 146 of the Patents Act requires careful consideration.

A review of the Para 6 and 7 of the judgment will depict that “details of licensees, licenses and sub-licensees” is only the specification with regard to number, date and particulars of the licensees and sub-licensees as also maintenance of a patent register u/s 67. However, compliance u/s 146 read with rule 131 and penal provision of S 122 of the Patent Act is subject to interpretation of statutes. The relevant wordings are highlighted in bold in text below. This, in present context, requires deliberation. It will also be pertinent to add that non-working of patents is a ground for compulsory licensing and revocation of patents.

S 146 of the Patent’s Act summarily states that:

- The Controller *may* (and not shall) during continuance of the patent (i.e. after grant), by written notice ask a patentee/licensee to furnish information to the extent to which the patented invention has been commercially worked in India.
- Not withstanding above, the patentee/licensee *shall* (and not may) furnish such information (in accordance with rule 21 in Form 27) yearly or update the IPO time to time.
- The Controller *may* (not shall) publish the information received by him in a prescribed manner.

U/s 122, the punitive measures for non-compliance with s 146 is punishable with fine which may extend to ten lakh rupees. Furnishing wrong information will be punishable with imprisonment which may extend to six months, or with fine, or with both.

*Thanks & Regards,*
Mayuree Sengupta
Mobile: 9899101875
*Advocate & Registered Patent Agent*
*Intellectual Property Manager (IPM)*
*Regional Centre for Biotechnology*
*Faridabad, India.*
Dear Both,

With regard to the above mentioned subject line we would like to raise the following points:

- For patents being worked in India the online form (Form-27) demands details on the Quantum & Value of patented product, which is very difficult to ascertain when a patent protects one or more components of the product manufactured or vice versa. Furthermore there are no definitions relating to what denotes Quantum and what denotes value as per the Act.

- Import data per country: Difficult to populate accurate details

- Form has no option for reporting a product which is both manufactured and imported

- Form demands to indicate if the public demand is met adequately / partially / to the fullest : No definitions/ scales for assessment as per the Act

- Mandate on the licensees to file form 27 becomes tedious and in cases of single licensee results in duplication of work

- Overall this exercise involves considerable resource and time for applicants

- It appears that these information are by large not used by anyone and hence appears to be an effort with no apparent value and remains merely a burden imposed by the Act.

We will happy to visit and present our inputs during the proposed meeting on 21-Mar-18.

Best Regards

S. Giriraj
S. Giriraj Kumar
Team Leader – IP,
GirirajKumar.S@saint-gobain.com
Saint-Gobain India Pvt. Ltd.
Intellectual Property Law Department
No: 1 FA, Phase-II, “C” Block, Kanagam Road, Tharamani, Chennai-600 113
Mobile: 9940200993
SUBJECT: Comments on the Issues related to Working of patents under the Patents Act, 1970. (Stakeholders Meeting)

Through this representation, we would like to bring to your notice the challenges faced regarding requirements of Working Statements U/S 146 of the Indian Patents Act, 1970.

It is understood that the prevailing Form 27 is not “aligned to changing Industry dynamics”, is “ambiguous”, and “lacks clarity” and deserves consideration for appropriate amendments by the Indian Patents Office.

We have annexed our comments of existing situation in this regard. We are highly hopeful that our submission shall be considered and will be acted upon towards bringing amendments in Form 27.

Kind Regards,

Vikrant Rana

S.S. Rana and Co.
Remarks of S.S. Rana & Co. on Form 27

BACKGROUND

Under Indian Patents law, every patentee and every licensee of a granted patent is required to file a statement as to the extent to which the patented invention has been worked on a commercial scale in India. Working statements are only required for granted patents. Working statements are required to be filed annually in respect of all granted patents in India. The time line to file the statement is March 31 every year for the preceding calendar year.

The concerns faced while complying with existing requirement for filing working statement and proposed solutions are listed below:

**Concern 1**

*Patentees find it difficult to justify the data in relation to the quantity of goods sold by them and the corresponding revenue achieved during the financial year. Various Patentee would not like to provide the desired information on Form 27 as the information is either highly confidential or not available.*

**Solution:** It is suggested that an option may be provided to mention the goods and the revenue in a range format (for example 0-1000, 1000-10000, more than 10000) as sold by the Patentee and the revenue achieved during the financial year.

**Quantum of Goods**

**Scenario 1** – If the Patentee has achieved a specific value in regard to the quantum of goods sold, the details should be furnished on the Form.

**Scenario 2** - If it is difficult for the Patentee to determine the quantum of goods sold, then a range of quantum of goods sold as applicable may be chosen.

Example: Quantum of Goods (Patentee to tick the appropriate option)

- 0-50
- 50-100
- 100-500
- above 500.

**Revenue**

**Scenario 1** – If the Patentee has obtained a specific revenue value on sale of goods, the details are to be furnished.
Scenario 2 - If the Patentee is not sure of the value of revenue obtained upon sale of goods, then a range of the revenue can be furnished on the Form under a separate section.

Example: Value of patented product- in standard currency or multiple currency (Patentee to tick the appropriate option)
- 0-500
- 500-10,000
- 10,000-50,000
- 50,000-10,000
- above 10,000

Concern 2

The Form 27 model is non-existent for inventions pertaining to ICT sectors and others, where on product is not based on one patent, but covered in portfolio of patents. The existing working statement is filed individually for each patent. The patentee faces several issues in providing separate working statement for inventions that belong to the same cluster.

Solution: There should be provision of a single statement for multiple patents worked in a cluster in one product with reasons. Related multiple patents covering the same product (which are common in mobile telecom industry and CRIs), the details should be furnished as a single statement, rather than filing separate working statements for individual patents, provided that the said inventions are not used/sold/licensed/ manufactured separately.

Concern 3

Licensee is not filing Form 27

Solution- After financial year end, the Controller may issue a list of Licensees who have not furnished the details required in a patent as per Section 146 of the Act, directing them to provide the details within a specific deadline.

The details of such Licensees may be retrieved from the Form 27 filed by the Patentee mentioning the name of licensee(s).

Statistical Data

1. In 2013, the Office of Controller General of Patents, Designs and Trademarks (CGPDTM) had issued a notification (No. CO/Public Notice/2013/77) directing all Patentees and Licensees (whether exclusive or otherwise) to furnish information and statement regarding the commercial working of patented invention in India (in
compliance with Section 146 and Rule 131 of the Patent Act). It would be interesting to see whether this has impacted the incoming foreign filings into India by analyzing is there is any correlation of in the numbers of patent filing by foreign applicants’ *vis-a-vis* the numbers of Foreign Filing License (FFL) being sought.

Presently, as can be seen in the statistics from the Annual Report of the CGPDTM, patentees are reporting the working of their patents very errantly

<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patents in Force</td>
<td>39,989</td>
<td>43,920</td>
<td>42,632</td>
<td>43,256</td>
<td>44,524</td>
</tr>
<tr>
<td>From 27 received</td>
<td>27,825</td>
<td>27,946</td>
<td>33,088</td>
<td>31,990</td>
<td>39,507</td>
</tr>
<tr>
<td>Reported as working</td>
<td>7,431</td>
<td>6,201</td>
<td>8,435</td>
<td>7,900</td>
<td>8,589</td>
</tr>
<tr>
<td>WORKING NOT REPORTED</td>
<td>12,164</td>
<td>15,974</td>
<td>9,544</td>
<td>11,266</td>
<td>5,017</td>
</tr>
<tr>
<td>Patents in Force NOT REPORTED %</td>
<td>30%</td>
<td>36%</td>
<td>22%</td>
<td>26%</td>
<td>11%</td>
</tr>
<tr>
<td>Compulsory License Issued</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Let’s analyze the number of foreign applicant filing *vis-a-vis* the numbers of Foreign Filing License (FFL) being sought over the last few years

**Conclusion**
The Form 27 declaration merely requires patentees to state whether or not the reasonable requirement of the invention to the public have been met.

Further, the Government should require the Patentee to provide information in a yes or no format for the working of patents.

The burden of proof of working should be left on the Patentee, if called upon by the Controller or application of third parties for Compulsory Licensing (CL) or on the discretion of the Controller.

Hammering the last nail, there is a need to update the Patent Rules and amend ‘Form 27’ in a manner that cater to the emerging technological fields in India and the expansion of the ambit of inventions.
To

Dr.W.M.Dhumane and Dr.Usha Rao
Office of The Controller General of Patents, Designs & Trademarks,
Boudhik Sampada Bhavan
S.M.Road, Antop Hill
Mumbai- 400037 (India)

Dear Sir/ Madam

Sub: Inviting comments from stakeholders regarding issues relating to working of patents- Reg’

Ref: Circular No.CG/Circular/2018/114 Dt. 16.03.2018

Here are some comments/ suggestions on issues related to working of patents under Section -146 of Indian Patents Act 1970 read with Rule 131 of Patents rules 2003 including Form-27

<table>
<thead>
<tr>
<th>No.</th>
<th>Suggested additional inclusion</th>
<th>Reason for the suggestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Complete particulars of the parties, licensees, sub-licensees including address, email, phone numbers etc., who practiced the subject patent in India during the year.</td>
<td>Brevity in where the patent is actually being worked</td>
</tr>
<tr>
<td>2</td>
<td>Particulars of new parties, if any, approached during the year for the subject patent license.</td>
<td>To understand the dynamic status of working of patent</td>
</tr>
<tr>
<td>3</td>
<td>Have you denied the license of the subject patent to anyone? If so state the particulars of the parties and the grounds/reasons with particulars for denial.</td>
<td>Fair working of patent in concurrence with Section.83</td>
</tr>
<tr>
<td>4</td>
<td>State whether the revenue particulars provided for the subject patent also involve any other product or process patents granted in India including cross licensing of patents.</td>
<td>To bring transparency in the disclosures as pertaining to revenue share of particular patent. This gives clarity to stakeholders at large involved in several commercial transactions pertaining to the product / process patents</td>
</tr>
<tr>
<td>5</td>
<td>Whether the patent is also commercialized outside India, If so</td>
<td>Ensure that the working of patent is on par with the similar geographies in the public interest</td>
</tr>
<tr>
<td></td>
<td>a) pricing particulars in other countries and Indian pricing</td>
<td></td>
</tr>
</tbody>
</table>
b) whether pricing in India is at equitable level, give particulars 

c) Justify in the public interest how it is reasonable pricing in India 

6 Justify whether the patentee complied the principles laid down under Sec.83 of the Patents Act, 1970. 

To put some obligatory responsibilities on the patentee to follow the General principles laid down under Sec.83 in the national interest. Not contrary to public order. 

7 State the particulars of field of invention and industry(ies) practicing the patent. 

Most of the patentees have invention being protected in a particular field, yet they are trying to monopolize on fields not relevant in guise of application. Very classic examples of many biotechnology patents are visible. 

8 In working of patents, whether the patentee is not claiming the product / process outside that the claims granted under the patent. 

This is to have clarity from the patentee that the product/process is worked upon only in the scope of claims granted and not outside. 

9 If patent is licensed, describe what was provided to the licensee to license the patent. 

In the public interest, this is asked for to have more clarity as to what is actually given to the licensee in the subject matter. 

10 Provide the particulars of infringement proceedings, if any, filed during the year against the subject patent. 

Has the patentee come across any unauthorized working of patents during the year. If so, provide the details of the parties and the action taken against them. 

I kindly request you to consider these points in the national interest. 

Thanking You 
O.K.Tara 
(IN/PA 2849) 

O.K.Tara - (IN/PA 2849) 
Manager- IP& PPV 
NSL 
Hyderabad 
Contact: 9949030701
Provisions under the Indian Patents Act and Rules

1. Section 146 of the Indian Patents Act is the substantive provision in relation to working statements. Section 146 has two aspects:

   (a) Under Section 146(1), the Controller has the power to call for information from the Patentee/Licensee to submit periodical statements as to the extent to which the patented invention has been commercially working in India.

   (b) Section 146(2) prescribes the requirement of filing working statements by every Patentee and every Licensee as to the extent to which the patented invention has been worked on a commercial scale in India.

2. The form is prescribed by Rule 131 which is Form 27. Rule 131(3) provides the Controller that the discretion NOT TO PUBLISH information received by him under Section 146 as it uses the expression “may”.

3. Section 122 of the Indian Patents Act provides penal consequences for failure to submit working statements which can extend to Rs. 10 lakhs. This amount was increased from Rs. 20,000/- w.e.f. January 1, 2005 when the product patent regime was brought into force. Furnishing of incorrect information includes the consequences such as fine and/or imprisonment.

Challenges in filing and submitting form 27

1. Onerous and time consuming: The filing and submission of Form 27 is onerous and is time consuming which only dissuades companies from filing patent applications in India and seeking patent protection. The reason for this is:

   a. It is against the philosophy of the government of encouraging investment in the country;
   b. It is against the concept of “Ease of doing Business” in India as the consequences are too harsh for non-compliance.
c. The information that is being provided is not being analyzed by the government to assess:
   i. The technologies that are being worked in India;
   ii. Identifying the reasons for technologies not being worked;

iii. Determine the time period being required to work a patent in India and delays associated with it that could be a function of policies of the government, approvals from ministries (Environment ministry / drug heath regulatory authorities; investment cost etc); absence of other enabling technologies; or no market need. The Government then needs to take steps in the larger interest of the economy to see how technology transfer can be facilitated in India.

iv. Even otherwise, if the object is for “compulsory license”, in any case, the prospective licensee can approach the patentee for negotiations for a voluntary license or can make an application to the controller under Section 146(1).

2. **Difficulty in identifying the patent in Form 27:**

   - It would be difficult in the current scenario to be able to accurately map the contribution of a single application to a product.

   - Form 27 applicable across all technologies and does not take into account the challenges associated with it.

   - A patent could be worked in several products across many field of technology such as automobiles, semiconductors, pharmaceuticals telecommunications, computers, nanotechnology etc or a cluster of patents can be covered one product

   - Missing details of products covered by a patent may, potentially, render a licensee as non-complaint with working requirement.
3. **Patented Product not defined:**
   a. The term ‘patented product’ is not defined under the Patents Act. The term ‘patented article’ is defined under Section 2(o) of the Act as an article in respect of which a patent is in force.
   
b. This term therefore needs to be removed from Form 27

4. **Confidential information**
   - There is no requirement of the law to provide quantum and value of the patented invention under Section 146 and Rule 131;
   - Further, there is a difficulty in accurately determining the value of the patented invention that is incorporated into a product i.e giving value of a product that can include several patents or one patent be included in several products is not indicative of the value of the patent;
   - Apportionment of a value to a patent incorporated into a product that is covered by multiple patents sometimes is not possible;
   - Where such detail relates to a confidentiality obligation, a provision of providing this information to the patent office, on demand and under terms of confidentiality, should be made.

5. **Details of countries from which product is imported:**
   - Irrelevant to ‘commercial scale’ and therefore can be deleted.

6. **The licenses and sub-licenses granted during the year need to be provided:**
• The disclosure of number of licensees and sub-licensees granted during the year ought to be sufficient under Section 146(2). The names of the licensee and the sales are irrelevant besides not being feasible.

• There could be situation where a patent is licensed on a lump sum royalty basis and possibly the licensee might not have sold any product; There are different licensing models.

7. Meeting the public requirements:

• This is not necessary under Section 146 of the Indian Patents Act;

• Meeting public requirements partially/ adequately or to the fullest extent is ambiguous;

• Burden on patent holder to do a market study. What is reasonable in one technology field or for one patentee may be unreasonable for another.

8. Reasonable price:

• The phrase is ambiguous besides not a requirement under Section 146

• Reasonable price will not be the same for all technologies.

• A patented product would be priced high during early years following launch. Price may fall later.

• What is a reasonable price for an innovator company that has invested time money and research in a technology might not be reasonable to a company that has made no investment in research.
9. **Unreasonable penalties:**

   - Any third party may access this information under the Right to Information Act and try to prove it is inaccurate and false.

   - Since Form 27 is ambiguous, high probability of providing incomplete information.

10. **Proposal:**

    - Make Form 27 simpler and be applicable across technologies after taking into account their challenges.
    - Include IPC classification to analyse the information provided across all technologies
    
    - Give option of one Form 27 for a cluster of patents
    
    - Patentee may submit whatever information is available along with self-declaration.
    
    - Confidential information ought to be protected and should not be published (“MAY” in Section 146(3)
    
    - Revision of Form 27 should be through a stakeholder consultative process within a time frame as has been done by the patent office in past
    
    - Under rule 146(2), the word “and” should be read as “or” in view of Section 146(1) in order to avoid inconsistency between the statements filed by the licensee/patentee.
    
    - It should not be mandatory for the Patentee to disclose the name of the licensee as it is not a requirement under Section 146.
• The Indian Courts have recognized the importance of confidentiality clubs such that confidential information may not be disclosed to 3rd parties. Reference is made to Section 69(4) that clearly mandates non-disclosure of terms and conditions of the license upon request.

• In case there is more information that might be required by the Controller, they can always exercise discretion under Section 146(1) and request for information.

• The expressions such as “whether public requirement has been met partly/adequately/to the fullest extent at reasonable price” is not required under Section 146

• Reduce penalties

• A revised format of Form 27 in marked up and clean is herewith enclosed.

End of document
Dear Shri Sushil K Satpute

Subject: Whitepaper on the Proposal for amendment of Form 27

We are writing on behalf of our membership that has brought to our attention regarding issues concerning requirements of Working Statements U/S 146 of The Indian Patents Act 1970.

Existing Form 27, is understood to be not aligned to changing Industry dynamics and adds immense undue work load besides extensive paper work that impacts “Freedom to Operate” as well as “Ease of Doing Business” in India. The filing requirements are such that impinges upon “Confidentiality” and might also be misused by some bad faithed members/willful infringers.

We have annexed out detailed analysis of existing situation in this regard and also propose some solutions to make filing requirements simpler. We are highly hopeful that our submission shall be considered and will be acted upon.

We look forward for kind consideration.

With kind regards.

Yours sincerely,

(D.S. Rawat)

Shri Sushil K Satpute
Director
Department of Industrial Policy and Promotion
Udyog Bhawan, New Delhi 110011
ANNEXURE

INDUSTRY SUBMISSION ON “WORKING OF PATENTS IN INDIA”
Draft Whitepaper on the Proposal for amendment of Form 27

A. Historical Background of the Patents Act and Rules introducing ‘Working Requirement’:

a. The underlying Patent Policy providing impetus to the Indian Patent law has been mainly oriented towards the pharmaceutical industry since independence.

After independence, Indian Patent law was not changed and given the high prices of pharmaceutical components and medicines in the country a national-level committee was commissioned in 1948 under the chairmanship of Dr. T. B. Chand, a retired High Court judge. This was the first national committee which addressed the patent law and led to the formation of a number of national pharmaceutical companies (e.g. Hindusthan Antibiotics Limited in 1954 and Indian Drugs and Pharmaceutical Limited in 1961).

With the continued high prices of medicines, another national level committee was commissioned in 1957 under the leadership of Justice N. Rajagopala Ayyangar in 1957, which later became well known as the Ayyangar Committee. The Committee emphasized on Art. 21 of the Indian Constitution (which guarantees to its citizen the right to life and good health) in light of the medicine prices and studied Patent laws of different countries.

With inputs of the Ayyangar Committee The Patents Bill 1965 included provisions for the Working requirement (also removed product patents for pharmaceuticals, shortened process patents for pharmaceuticals to seven years and introduced compulsory licenses). The Patent Bill of 1965 was passed by the Lok Sabha (lower chamber) but lapsed in the Rajya Sabha (upper chamber) of the parliament and finally it was passed and the Indian Patent Act 1970 (Act No. 39 of 1970) became effective in April 1972 with the adoption of the Patent Rules in 1971.

b. Reason for introducing mandatory working requirement;

There were 2,237 licensed drug manufacturers in India in 1969-70, of which 80-90% were foreign multinational companies and for various reasons most of the patents were not worked in India.

The government was of the opinion that the mandatory working requirement and the removal of the product patent regime in the pharmaceutical arena would make medicines available to the Indian people at large.
B. World Intellectual Property Organization (WIPO) and World Trade Organization (WTO) on the ‘Working requirement’:

a. Paris Convention;
The Paris Convention for Protection of Industrial Property, 1883 administered by the WIPO, provides for working of a patent under Article 5 A. It states, “(1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent. ...”

b. TRIPS Agreement;
The Agreement on Trade-Related aspects of Intellectual Property Rights a foundational WTO Agreement defines Patentable subject matter in Article 27 and states, “1. ... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

C. Statutory Intent and supporting Office Procedure:

a. Statutory requirement;
Section 146 of The Patent Act provides, “Power of Controller to call for information from Patentees” wherein (2) states, “Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.”

b. Office Procedure as per Patent Rule;
Rule 131 provides the Form and manner in which the statement is to be furnished and states,
“(1) The statements shall be furnished by every patentee and every licensee under sub-section (2) of section 146 in Form 27 which shall be duly verified by the patentee or the licensee or his authorized agent.
(2) The statements referred to in sub-rule (1) shall be furnished in respect of every calendar year within the three months of the end of each year.
(3) The Controller may publish the information received by him under sub-section (1) or sub-section (2) of section 146 in the Official Gazette and in such manner as he may deem fit.”
D: Provisions in the Patents Act to prevent abuse of patent right by the Patentee:

c. Pre-grant and Post-grant oppositions (Section 25): Several grounds for opposing the grant of patent as well as getting a patent revoked post grant are available to any person and interested person, respectively.

d. Revocation of Patents (Section 64): Several grounds for revocation of patents by person interested or the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court.

e. Revocation of Patent in Public interest (Section 66): Grant of patent under section 47 is subject to many conditions. Government on its own or on its behalf may make, use, and import any patented invention if it deems fit. At any point in time, the Government may intervene with the rights of the patentee and practice the patented invention. The Central Government has power to revoke the patent if the patent proves prejudicial to the public.

f. Compulsory Licenses (Section 84): The Controller may grant a compulsory license in response to an application made by any interested person provided (a) the reasonable requirements of the public have not been satisfied; (b) the patented invention is not available to public at a reasonably affordable price; and (c) the patented invention is not worked in the territory of India (emphasis added).

g. Revocation of Patents by the Controller for non-working (Section 85): Even after the expiration of 2 years from the date of order of the first compulsory license, the Controller may order revocation of a patent for which a compulsory license has been granted and that has not been worked.

h. Chapter XVII: Use of inventions for the purposes of Government and acquisition of inventions by central government (Sections 99 to 103): The title of the chapter XVII itself indicates that the inventions can be used by the Government and the Central Government can acquire the inventions based on several grounds.

E. Existing Form 27 is not attuned to changing Industry Dynamics

Basic principles of working of inventions are listed under Section 83. Thus Section 146 and Rule 131 empowers the Controller to request for information about working of patents in India strictly for the purposes mentioned under Section 83. However, nothing mentioned in Form 27 would enable the Controller in determining the considerations prescribed under Section 83. Further, existing Form 27 is archaic and is not attuned to changing industry dynamics. For example, information regarding an invention on the bearing inside an engine assembly which has no relevance in maintaining public health, safety and saving public life may have no real-world significance. Similarly,
Industry dynamics are changing continually where different models are adopted to ensure that patented inventions are worked. Models may include manufacturing, licensing, cross-licensing, contracts etc. “Licensing” is a model adopted by some sectors especially ICT as this is pro-competitive and removes any market entry barriers. Licensing enables entry of many new firms leading to availability of products at most competitive prices such as in telecommunications sector. Existing 27 is not aligned to changing Industry dynamics and deserves consideration for appropriate amendments by IPO. We are highlighting below some of the concerns faced while complying with existing requirements and propose some changes.

Concerns:

i. Portfolio Licensing:
Existing Form 27 is based on presumption that one product is equivalent to one patent. However such a model is non-existent in ICT sector where one product is not based on one patent but is actually covered in portfolio of patents and such portfolios are owned by different Patentees. For example, mobile phones, tablets, smart watches etc. which might incorporate multiple inventions covered in multiple patents. The existing working statement is required to be filed individually for each patent, which might suit in case of pharmaceutical inventions but not for ICT sector.

a. Solution Proposed: Provision should be there in Form 27 for single statement for multiple patents (e.g. Patent Nos. ..., or Patent Nos. ...) not worked singly but in a cluster with reasons substantiating the same or in the alternative;

b. Specifying that the single patent forms a part of the portfolio license.

ii. Existing requirements impinges upon Confidentiality:
Under a Licensing model, IP owner is under an obligation to keep important business data concerning licensees as confidential. Form 27 impinges upon that “Right to Confidentiality”. Each license agreement is unique and there cannot be one-size fit all model and hence licensing terms and conditions varies and are market driven. Any such disclosure in Form 27 with regard to commercial arrangements shall seriously prejudice interests of licensee as well as licensor. Such information may be misused by unwilling licensees to gain competitive advantage over willing licensees. This can also be misused by unwilling licensees to get this important data out in public domain. This will increase litigation costs substantially where IP owner will be sued by licensees for the breach of confidentiality or for not been able to secure confidential business information such as sales figures, anticipated revenue/profit. This will threaten businesses, hurt global licensing model and will potentially chill innovation cycle.
Solution proposed:
a. Given the fact that some of the information that need to be furnished are business/commercial information and not necessarily on whether the patents are worked or not (e.g. related to licenses and sub-licenses granted, etc.), they need to be deleted.

b. Further, while the requirement of notifying whether worked through manufacturing or licensing or by importation (discussed above in ii. & iii.) could be retained but the requirement for providing quantum and valuation needs to be removed.

iii. Filing requirements increases substantial work load and Paper work
Filing of Form 27 for all patents is mandated every year even for those patents for which the working statements have been filed the previous year. This unnecessarily increases paperwork and engages considerable time. As can be seen from data/table below, the rate at which ICT related filings are done at IPO are growing at substantial rate. Thus, filing working statements for each patent, so granted, until the time it is expired increases immense pressure on IP owners and also impacts Ease of Doing Business in India. Furthermore, requiring patentees to spend enormous resources to gather and provide detailed financial data every year, tips the balance as held by The Delhi High Court in the Natco Pharma v. Bayer

Table:

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Source: Annual Report 2015-16 of Indian Patent & Trade Marks Office – Appendix E. The numbers indicated in the table is cumulative of the following fields of invention – Computers/Electronics” & “Communication”
Solution Proposed:
There should be two sections of the form, one for first time filing (for patents granted within the last three years) and another section for those cases where the working statement had already been filed in the previous year and being continued. There might be a sub-section in this section for those cases in which the mode of working has changed (e.g. from Manufacturing to Licensing).

iv. Mode of Working and Filing liability:
There is need to provide clarity on Working through importation subsequent to the IPAB Order (M.P. Nos. 74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM) in Bayer Corp. USA v DIPP, Controller General of Patents and Others wherein working through importation was allowed.

Solution Proposed:
In case where Patents are worked via licenses, any one party should file the FORM 27, i.e. the Patentee (Licensor) or the Licensee. The burden should not be on both the parties.

v. Difficulty in determining whether the patented invention has been worked or not:
In view of the large portfolio of patent applications that are pending before the Indian patent office for patentees and in respect of patents granted to the patentees worldwide, and an equally large portfolio of products developed and sold in India and abroad, the patentees often find it extremely difficult to determine whether the invention of a given patent has been worked in India or not.

Further, there are thousands of inventions covered in a given products. Implementation of each invention is not centralized and are often handled by different groups in the patentees’ organization across the globe. Such factors render it extremely difficult for the patentees to conclusively ascertain whether a patented invention is worked or not worked in India.

Therefore, in case Form 27 is mandated, the Applicant should be allowed to write the following: It is not practical to determine conclusively whether the patent has been worked or not. Further, we have not received any feedback from anyone in India that the patented invention is not available in India adequately or at affordable price.

vi. Difficulty in determining whether the patented invention met public requirement partly / adequately / to the fullest extent:
For reasons explained above, it is extremely difficult to collate the data that would enable the patentees to conclusively select any one of the categories mentioned in Form 27.
Therefore, in case Form 27 is mandated, the Applicant should be allowed to write the following: It is not practical to determine conclusively whether the public requirement has been met adequately. We have not received any feedback from anyone in India that the patented invention is not available in India adequately or at affordable price.

F. Conclusion:

Laws and supporting Rules and Regulations are dynamic in nature and address the economic and social requirements of the people.

The filing of Form 27 is embedded in the Patent Rules and follows the statutory intent of the Controller obtaining information on how the Patents are worked within three years of the grant.

India’s innovation has expanded beyond pharmaceuticals and the contribution of other industries, e.g. ICT, electronics, automobiles, renewable energy among others is worth noting. The case of ICT industry is worth noting since it has not only helped India to gain global prominence as a software major but it has enabled advanced wireless technology products to be available at the most reasonable prices.

There is need to update the Patent Rules and amend ‘Form 27’ in a manner that cater to the emerging technological fields in India and the expansion of the ambit of invention beyond pharmaceuticals. This note has addressed the amendment requirement while maintaining the statutory intent of filing the ‘Working Statement’.
From:

Bosch Group of companies in India
Robert Bosch Engineering and Business Solutions Private Ltd,
123, Industrial Layout, Koramangala
Bangalore 560095

To:

Dr. W. M. Dhumane
Indian patent office

Respected Sir,

Sub: Proposal on the practice of filing working statements in view of the PIL

The legislative intent underlying the practice of working statements was to put a mechanism in place to ensure that the patent holders do not enjoy monopoly of the patented technology without contributing to the promotion of technological innovation and to the transfer of the technology to the society. Section 146 (1) and Section 146 (2) govern the implementation of working statements practice.
The Controller has been given powers under Section 146 (1) to call the patentees to provide statement of working on a periodic basis, to ensure that the patent holder disseminates the patented technology to the society.

1. Intent of form 27:

In our opinion, the requirement of submission of Form 27 is to ensure that patents granted do not impede protection of public health and nutrition and should act as an instrument to promote public interest particularly in sectors of vital importance for socio-economic and technological development of India. It is clear that Form 27 acts as an instrument for the Controller to ensure that the public health requirements needed to address the public health problems are made available to the public at a reasonable price.

2. Problems with the current practice of submission of Form 27 information:

It is our opinion that very few patents fall under the public health and nutrition domain which is a concern for the IPO. The IPO is targeting a much larger group (comprising patent holders from automobile, software, computer, IT, consumer electronics, semiconductors, telecom, power generation and distribution sectors) thereby burdening the larger group to submit statement of working which could be unreasonable.

The patent holders could submit the statement of working but the problem lies in the fact that the information sought in Form 27 is not concise, lacks clarity and there are ambiguities in understanding and interpreting the sought information. Some of the problems with providing the required information is outlined below:

a. Working of the patents

The time given by Indian patent office for working of the patented technology is 3 years. But in many cases, the patented technology may need support from other surrounding technologies/infrastructure which may not be available within the time stipulated by the Indian patent office. As we are working in various advanced technological fields like emission controls, safe and comfortable driving, connected vehicles, connected industries, Internet of things, smart living etc, these patented technologies depend heavily on external factors like cloud connectivity, cloud computing, transmission bandwidth, data analytics etc. In our opinion, providing information regarding working of such patents in such stipulated time is difficult.

It is also possible that the market may not be yet ready for such technologies because of the costs and the volume.
b. Patents worked in products and assigning value to patented product:

Looking at the fast development of technologies in which we work and also looking at the technologies that are adapted across domains, it is possible that one product may involve many patents. Similarly one patent may be used in many products. Under such scenario, it is difficult to tag individual patent to individual product and assign value of patented product for each of the patents.

c. Meeting the public requirements:

As we are working in various advanced it is difficult to assess the public requirements for these patented technologies. Also meeting of the public requirements not only depends upon our technologies but also on the surrounding technologies, infrastructure available as a whole. Pl. refer point (a) for details.

d. Public requirements - Partly met/adequately met/met to the fullest extent:

Please refer above point.

e. Meeting the requirements at reasonable price:

For the above mentioned technological fields, it is difficult to assess what is the reasonable price for the patented products. The price not only depends upon our technologies but also on the infrastructural costs which may be provided by others, market demand etc.

In views of the above issues, we request you to revise the Form 27 to make it simple.

3. Proposal for revision of Form 27

We propose that Form 27 be made simpler and easier for the patentees to provide the information. A patentee may submit information what is available along with a self-declaration. The patentee should be allowed to explain/declare the extent of working rather than providing information on quantum of products sold/value realized from the sale of products/meeting of reasonable requirements etc.,

The Controller could on a need basis request for additional information from patentees, based on a third party requesting for the same/the Controller may restrict this to only to those patents, which are related to public interest/public health.
To encourage, foster and develop new technologies in India, it is important that the industry is relieved of the burden of tracking/mapping of technological patents to products and maintaining, providing information regarding value of the patented products. In our view, the requirement of form 27 is more relevant for patents related to public health and not for engineering and technology related patents.

If required, we respectfully request to meet and explain in person, the issues we are facing in specific and the issues faced by the industry in general.

Yours Sincerely

Prakash Balekundri
Deputy General Manager
Robert Bosch Engineering and Business Solutions Private Ltd,
Bangalore
BSA Submission
On
Working of Patents under the Patents Act, 1970
Proposal for Amendment of Form 27

Friday, March 16, 2018

Dr. W.M. Dhumane
Deputy Controller of Patents & Designs

Dr. Usha Rao
Assistant Controller of Patents & Designs,

Office of the Controller General of Patents,
Designs & Trademarks,
Government of India
Mumbai, India – 400 037

Cc: Shri. O. P. Gupta, Controller General of Patents

Dear Sir,

BSA | The Software Alliance (“BSA”)\(^1\) welcomes this opportunity to submit comments on issues regarding requirements to submit statements on the working of patents under Section 146 of the Patents Act of 1970 (“Patents Act”), in pursuance of the Circular issued by the Controller General of Patents, Designs & Trademarks (“CGPDTM”) on March 01 2018.

The current reporting requirements imposed on patentees and licensees through Form 27 under the Patent Rules are inconsistent with the goal of providing a consistent and efficient Intellectual Property (IP) framework that provides the foundation for investment

\(^1\) BSA | The Software Alliance (www.bsa.org) is the leading advocate for the global software industry before governments and in the international marketplace. Its members are among the world’s most innovative companies, creating software solutions that spark the economy and improve modern life. With headquarters in Washington, DC, and operations in more than 60 countries, BSA pioneers compliance programs that promote legal software use and advocates for public policies that foster technology innovation and drive growth in the digital economy.

in the innovation ecosystem. The Form 27 requirements make it harder for innovative software companies and other innovators to seek and receive patents in India.

As such, we offer the comments below in relation to amending the Form 27 requirement:

(a) Form 27 imposes impractical, and often, impossible reporting requirements: The following difficulties exist in the process of filing Form 27 statements:

• **No recognition of portfolio licensing** - The present Form 27 rests on an archaic assumption – it considers a single product to be a result of a single patent. Thus, it does not recognize portfolio licensing, which is the principal model for licensing of patents in the high-technology industry. While Form 27 presumes that a single product is equivalent to one patent, high-technology industries involve products with a portfolio of patents, often owned by different patentees. Therefore, it cannot be realistically fulfilled for software and other high-technology sectors.

• **Impinges upon confidentiality requirements** - Under a licensing model, IP owners are often required to keep business data regarding licensees confidential. Form 27 impinges upon this confidentiality obligation by imposing disclosure requirements that can hurt licensing models and expose IP owners to litigation for breaches of confidentiality, or for not being able to secure confidential business information, such as sales figures, anticipated revenues, etc.

• **Difficulty in determining working of patents in India** – Patentees often have large portfolios of patents and patent applications pending before the CGPDTM and other patent offices worldwide, and develop large portfolios of products which are sold in India and worldwide through licensees or otherwise. Accordingly, patentees often find it difficult to provide extensive details of how the invention of a given patent has worked in India, especially if their licensees have large operations cutting across jurisdictions. Apportioning each licensed patent, as well as estimating which licensed patents are being used in products in each jurisdiction is a significant and impractical task of collection and collation.

• **Vague or arbitrary requirements** - Another concern with the proposed revised Form 27 relates to the lack of clarity regarding the terms “Quantum” and “Value” in the Form. For patent applicants to understand how to accurately complete this form, they will require a better understanding of what these terms are intended to mean. For example, does “Quantum” refer to the number of licensees (sub-licensees) or some other information? Does "Value" refer to the royalty of patent license, the whole revenue of manufactured
products that implement the licensed patent, or the specific portion of revenue of manufactured products contributed by the licensed patent? These open questions make it difficult for patentees or licensees to determine how to best comply with Form 27 requirements, often producing inconsistent results across filings.

- Having such reporting requirements has a detrimental impact on the effectiveness of the patent system. The information requested, especially for high-technology industries, such as the software industry, is often difficult, if not impossible to provide, and the requirements of Form 27 serve as a disincentive to innovators considering to seek patent protection for their inventions in India.

(b) **Form 27 is a significant drain of resources for the CGPDTM:** Beyond the difficulties associated with filing of Form 27, the requirements also have a direct impact on the efficiency of the patent system.

- These requirements are mandated each year for all patents, even for those patents whose working statements have been filed for the previous year. This increases paperwork, as well as requires significant allocation of resources by the CGPDTM.

- For instance, as per the Annual Report for 2015-16 of the CGPDTM, 39,507 working statements were received, which must be verified by the CGPDTM officers. Assuming that each perusal of a Form 27 takes at-least 15 minutes and that a single work day is 10 hours, the total time required would be ~987 working days.

- If 10 Examiners are deputed for this task, then clearing the backlog of one year’s Form 27 filings would take ~4 months, assuming each Examiner works only on assessment of Form 27 statements. Thus, Form 27 requirements are a significant drain on time and resources, which could otherwise be directed to decreasing the backlog of pending patent applications.

(c) **Form 27 has a chilling effect on innovation and ease of doing business:**

- Having such reporting requirements directly impacts the approachability of India’s patent system, due to the following reasons:

- Form 27 requirements may also be called for under a Public Interest Litigation, allowing for confidential business information to be disclosed publicly through the judiciary. Licenses also tend to be unique, with licensees preferring to avoid publicly disclosing their confidential information to business rivals. However, due to the possibilities for public disclosure, licensees and
licensors are prevented from negotiating freely, which impacts the efficacy of India’s business environment.

- Further, due to stringent penal provisions under Section 122 of the Patent Act, coupled with the significant administrative burden and costs involved in calculation of requirements under Form 27, domestic patent filings by both start-ups and established players are deterred. This is both antithetical to ease of doing business in a digital economy, as well as to the aims of the Special Patent Regime launched in 2016 by the Finance Ministry, aimed at boosting domestic patent filings.

- These challenges can have a significant chilling impact on the filing of patents by domestic and global technology firms that would find completing the form too difficult, if not impossible, imposing unwarranted legal liability for any unintentional inaccuracies or unavoidable deficiencies in the information provided.

- This is particularly important given the fundamental role of patent protection in spurring investment and R&D in the very high-technology sectors that the Government of India is seeking to promote through the Digital India and other initiatives.

**Form 27 is not relevant for India’s digital economy:** Such requirements are outdated, and have outlived their original reasons for inclusion:

- The requirement for working statements dates back to the inclusion of Section 146 within the Patents Act of 1970 on the recommendations of the Ayyanagar Committee, constituted to address issues relating to the pricing and patenting of pharmaceutical products. The intention behind the need for such reporting requirements was to ensure the easy access to medicines for the public at large, and prevent the abuse of patent rights by a patent holder in this domain.

- However, India has witnessed significant economic transformations since 1970, with the advent of a significant software industry and innovation ecosystem focused on advanced technologies. Accordingly, India now requires an effective patent system that looks to foster innovation while protecting legitimate public interests and considers the implications of relevant requirements on other sectors beyond the pharmaceutical sector that are crucial for India’s economy.

- An effective patent system, one that grants high-quality patents to innovators in India and abroad in a timely manner, is a fundamental aspect of making India an attractive destination for investments in research and development
and the commercialization of the new products, methods, and services that will underpin India’s future economic growth and development.

• Moreover, several provisions of the Patents Act already exist to serve to check the abuse of patent rights by a patentee, such as those pertaining to compulsory licensing requirements under Section 84; the revocation of patents due to their non-working under Section 85; the use of patented inventions for Government use and acquisition under Sections 99 and 103; the revocation of patents in public interest under Section 66, etc.

• Therefore, the specific relevance of such reporting requirements is lost in today’s dynamic innovation ecosystem, especially given the presence of such alternative safeguards with the patent regime itself.

(e) Recommendations: BSA strongly recommends that the Government of India explore ways to remove Form 27 from the patent system, rather than simply amending it.

However, we recognize that this could require a change in the Patent Act and may not be an immediately practicable solution. In the interim, BSA recommends that the Government of India focuses on introducing amendments to make Form 27 practical and useful, by considering our subsequent submissions herein. Accordingly, BSA strongly recommends that:

• Form 27 may suffice for multiple patents if the working statement for each such multiple patents is the same.

• Further, Form 27 must not mandate the disclosure of revenues or license fees earned by working a patent, given that such information relates to business or commercial information and not necessarily on whether patents are being worked or not. Therefore, where patentees are required to provide such information, they should be asked to do so upon specific request, and within the confines of a confidentiality agreement with the CGPDTM.

• Requirements for providing quantum and valuation must be removed, due to difficulties in their estimation and calculation, as pointed out above.

• Finally, applicants should be allowed to file a simpler Form 27. In the online submission process, Form 27 should be flexibly designed to enable patentees to enter only that information which is suited to the requirements of their industry.
Conclusion

BSA thanks the CGPDTM for this opportunity to offer comments on India’s patent system. Our member companies have a long-standing commitment to India and are excited by the potential that India’s innovation ecosystem offers. We hope our contributions will help improve the system for examination of patents in India and stand ready to answer any questions regarding this submission or to provide any further information you may require.

Thanking you.

Yours sincerely,


Venkatesh Krishnamoorthy
Country Manager- India
BSA | The Software Alliance
March 16, 2018

Mr. O.P. Gupta
Controller General of Patents,
Designs & Trade Marks, India

Comments on the issues relating to a statement on working of Patents

We would like to submit comments on the issues relating to a statement on working of Patents as attached, upon receiving a notification of meeting circular dated March 1, 2018. We would greatly appreciate your consideration of our requests.

If you have any questions, please feel free to contact at the following address.

Sincerely yours,

CANON INC.

Kenichi Nagasawa
Managing Executive Officer
Group Executive
Corporate Intellectual Property and
Legal Headquarters
Canon Inc.
Email: adm-iporg@list.canon.co.jp
Comments on the issues relating to a statement on working of Patents

Canon Inc.

<Relevant provisions>
Article 146(2) and (3) of the Patents Act, Article 131(1) and (2) of the Patents Rules

<Request>
We would like to request a reduction of the burden on patentees and licensees, and also the protection of trade secrets described in the statements.

<Reasons>
(1) Preparing information necessary to submit a statement on the working of patents every year by confirming the status of working or bearing the cost of asking a representative to submit such statement forces patentees and licensees who have many patents to bear an excessive burden. Consequently, we would respectfully like to request the reduction of burden in relation to the submission of a statement on the working of patents.

Article 146(2) of the Patents Act obliges each patentee and licensee to "furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India." On the other hand, the aforementioned burden arises from the provisions of Article 131(2) of the Patents Rules, "The statements referred to in sub-rule (1) shall be furnished in respect of every calendar year within three months of the end of each year.

In consideration of the aforementioned circumstances, as a measure to reduce the burden of patentees and licensees, we would like to propose decreasing frequency of submitting a statement on the working of patents, for example, every three years.

(2) Form 27 includes question items regarding grant of license (i.e. "License Granted", "License Name" and "Sub License Name"). Being disclosed such information on the website of Intellectual property India leads to a situation such as "licensees and licensors are made clear", "intellectual property strategy in India is known by other companies".

Needless to say, trade secrets are very important intangible property in corporate activities, and are also sources of competitiveness.

Therefore, we would like to request that question items regarding grant of license are deleted from Form 27. In case this request is not accepted, we instead request such information to be kept undisclosed on the website of Intellectual property India or any other places.

EOD
COMMENTS ON THE FORM 27 OF THE PATENTS ACT AND SIMPLIFICATION

1. **Freedom available to the Controller General:** Under Section 146(1) the CG may seek information from patentees and licensees on working of patents in India in respect of patents granted to the patentees. We understand that the CG provides a choice to the CG that he can exercise his discretion in selecting patentees and nature of information being sought. We suggest that CG may consider exercising the choice which is closely in tune with the technological developments taking place at a rapid rate. For example, the same yardstick can be applied to drug related patents and patents related to artificial intelligence.

2. **Extent of information:** There should be a cap on the extent of the information to be published since the information pertaining to licenses, Country wise importation details, quantum and value of working of invention is very competitive and sensitive in nature. This kind of detailed information may compromise on business information and trade secrets of companies.

3. **DEADLINE TO FILE FORM 27:** Instead of calendar year the Statement of Working of invention should be filed for every financial year as it is to do with the financial data of a particular invention. The deadline i.e. 31st March should be mentioned in the Form itself.

4. **ENLIST REASONS OF NON–WORKING:** Conversion of patents into technology may require long time frame work and hence, during the intervening period the information will be nil and someone may seek compulsory license on account of non-working of patents. There should be distinct provision for sharing this kind of information. Therefore reasons for Non-working of an Invention can be enlisted in the Form such as Inadequate Capital Investment; Inadequate Technological Support; Inadequate Infrastructure; Inadequate cost; Inadequate effective labour; Unfavourable Environment; Social & Political Factors; Others factors.

5. **REASONABLE PUBLIC REQUIREMENT (UNDER SEC 84(7)):** Criteria’s to determine whether public requirement is met or not is not properly defined. Various
criteria’s like Commercial Scale; Fullest Extent that is reasonably practicable; adequate extent should be provided.

6. **OTHER POINTS:** Form 27 is designed for pharmaceutical inventions where you are either dealing with one molecule or a formulation for a disease. This establishes a direct relationship with a patent and its working. In case of engineering applications, one patent is generally not sufficient for conversion into known product. Sometimes the working of a patent may depend on other products. This aspect may be taken care of.

7. **MISCELLANEOUS:** The form 27 should be computerized.

A draft “sample form 27” modified with comments for a better understanding of the grievances is given below:
FORM- 27
THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENTS RULES, 2003
STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON COMMERCIAL SCALE IN INDIA
[ See section 146 (2) and rule 131 (1) ]

In the matter of Patent No. .......................of ........................................

I/We ........... name ........................................... of ................. address ..........................................., the patentee(s) or licensee(s) under Patent No. ....................... hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year ................................

(Year: This has to be for the financial year and not for the calendar year as stipulated by the Controller)

(i) The patented invention:

[ ] Worked [ ] Not worked

(a) if not worked: reasons for not working and steps being taken for working of the invention.

(b) If worked: quantum and value (in Rupees), of the patented product: ________

(For a patentee it’s not possible to provide the “quantum and value”, since one patent does not always equal one product. A product may have over one hundred patents some of which are owned and some licensed. This statement may apply to one blockbuster drug, and therefore relevant to some forms of pharma patents and NOT to all patents applied in other fields of technology)

(i) manufactured in India – Yes/No

(ii) Imported from other countries. (give country wise details)

(A clarification to the extent, if “importation” amounts to working of Patents. Logically it should not as there is evidence of employment through distributorship, packaging etc.)

(iii) the licences and sub-licenses granted during the year; - Yes/No

(iv) state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.
(The public requirement needs to be defined properly. With no clear cut definition, this can lead to frivolous admission since there is no approved way to quantify this. For example in case of a pharmaceuticals, how is one going to determine whether public requirements is met or not. In case of a tablet, where the market is created through advertising, how does one establish that there was a public requirement in the first place?)

The facts and matters stated above are true to the best of my/our knowledge, information and belief.

Dated this ____day of ________, 20

Signature

To,
The Controller of Patents,
The Patent Office, at ________.
This is a response by the Chartered Institute of Patent Attorneys ('CIPA') to the request for comments on the requirements for working of patents in India. The Chartered Institute of Patent Attorneys (CIPA) is the United Kingdom professional body which represents over 2000 UK patent attorneys. Most of our UK patent attorney members are also European Patent Attorneys. Our members not only play major roles in representing clients before the UK and European Patent Offices, but also work closely with patent attorneys in other jurisdictions (including India) to ensure the most effective outcomes for their clients.

We welcome the opportunity to respond to the Consultation for working/non-working statement of patents under the Patents Act 1970.

Form 27 requires every patentee of a granted patent to file a statement every calendar year, relating to the extent to which the patented invention has been worked on a commercial scale in India. Collecting and filing this data provides a very significant administrative burden both to patentees – including entrepreneurial Indian companies – and to the Indian Patent Office (IPO) itself. We think it is important to consider whether this burden is proportionate and corresponds to any benefit that the resulting data provides to the public.

Has any study been carried out as to how much of this data is actually used by the public? To what uses does the public put the data? What benefits accrue as a result? If there is any benefit, could it be achieved in a less burdensome manner? For example, could the data be requested simply when a competitor applies for a compulsory licence, or at least less frequently than every year?

Furthermore, certain aspects of Form 27 lack clarity, such that the mandatory information is unclear. As a result, this causes confusion amongst patentees required to fill out Form 27. As such, we welcome the present consultation as a step in the right direction to clarify these problems and optimise this process for both IPO and patentees.

Item (i)(b) of Form 27 requires the disclosure of the “quantum and value (in Rupees), of the patented product”. In cases where a granted patent corresponds to a single product, an account for the value of that single product will be disclosed.

However, this requirement is unclear for instances where the granted patent involves mechanical and electrical inventions, as the patented feature is likely to be just one module or feature incorporated into a number of different complex products or processes. Should the patentee disclose the sales figures for all complex products and processes that involve the
invention? The resulting information does not represent the value of the patented feature itself, and therefore we do not see how its disclosure provides any benefit to the public. The same is true for certain medical devices, e.g. inhalers, that may be used for different medicaments.

Additionally, there can be a difficulty in cases where the sales figures are confidential information to a patentee, or where their disclosure is prohibited under the terms of a contract with a third party. Guidance notes will be welcomed to set out how the requirement can be met when part or all the information requested must be redacted. There are also examples such as where the patentee has granted a royalty-free licence, and therefore is not entitled to request the sales figures of the licensee.

*Item (iii) of Form 27 also requires the patentee to “state whether public requirement has been met partly partly/adequately/to the fullest extend at reasonable price”.*

This is a particularly burdensome requirement for patentees as it is not at all clear on what basis this assessment is to be made and by what standard it is judged. Are patentees expected to provide some kind of statistical analysis in the field to be able to justify their response to this? It is difficult for patentees to state this on an official register without knowing what benchmarks are set by the Indian Government or the Patent Office for this.

In addition to this, there is a question as to whether Form 27 (clarified or not) is needed at all for India. India seems to be the only country that requires such statements of working for patents. This could be potentially damaging to innovation and investment in India since it remains a factor that discourages applicants from filing or continuing protection in India, for example, due to the requirement of disclosure of confidential information.

It also discourages applicants who are thinking of India of a potential market for the future from pursuing a patent, and risk having to offer a compulsory license to others in the event that the IPO is not happy that they have met with the public requirement.

There is no reason to believe that investment in India would be negatively affected, should this requirement for working of patents be repealed altogether.

Tim Jackson
Chair, CIPA Patents Committee

23 March 2018
To,
Shri. O P Gupta, IAS
Controller General of Patents, Designs & Trade Marks
Intellectual Property India,
Patents/Designs/Trade Marks/Geographical Indications,
Boudhik Sampada Bhavan,
Antop Hill, S.M. Road, Mumbai-400037

Sub: Circular No. CG/Meeting Circular-DIPP/2018/14 dated March 1, 2018

Dear Sir,

This is with reference to the subject Circular where the Controller General of Patents Designs and Trademarks (CGPDTM) has sought for feedback/comments on the changes in working requirement that the stakeholders would like to highlight.

CLG takes this opportunity to provide following inputs/comments on identified issues with suggested changes and the reasons/remarks thereof. We urge you to kindly consider the same. We also look forward to stakeholders’ consultations that is scheduled to be held on March 21, 2018 in this regard.

Table:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Issues</th>
<th>Suggested Changes</th>
<th>Reason/Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No definition of ‘Working’ in the</td>
<td>The definition of ‘working’ should be included in the Patents Rules, 2003 on the lines of the Judgment of the</td>
<td>Clear &amp; unambiguous definition will facilitate the patentees to comply with the working requirements and</td>
</tr>
</tbody>
</table>

1 wherein it was held that it is not at all necessary that for the product in question must be manufactured in India to meet the working requirements. Relying on an earlier decision of the Delhi High Court (*Telemecanique & Controls (I) Limited v. Schneider Electric Industries SA* 2), the DB held that all that is to be seen is that the imports are of a sufficient quantity so as to meet the demands for the product. | rule out subjectivity that that been cause around this issue till now. |
| 2. Requirement to disclose value of the patented drug that was worked in a given calendar year in addition to information on the quantum. | Sales figures may be confidential in nature and, therefore, Form 27 must seek information with respect to quantity of product only. Any requirement to furnish information on the value of patented product must be excluded from Form 27. | Due to licensing agreements or relevant business strategy, the information regarding sales may be required to be kept confidential. Patentees and/or licensees should not be subject to the Indian government’s determination of what information is confidential to the Patente and/or Licensee and whether such information could potentially be detrimental to the party(ies) if publicly disclosed. |

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1 2017 SCC OnLine Del 7393
2 2002 (24) PTC 632 (Del) (DB)
|   | Requirement to furnish information in respect of licenses and sub-licenses granted during the year | Explanation to Form 27 3 (ii) must be added to state that details of “licenses and sub-licenses” would only mean details in respect of date and particulars of the licensees and sub-licensees. Further, in case, the patentee has reservations in furnishing any detail, the same may be supported with reasons for consideration by the patent office. Disclosure of commercially sensitive information like the terms of license/sub-license agreement are proprietary in nature and could jeopardize or adversely impact the patentee(s) financially. Accordingly, Form 27 must be amended to preserve proprietary and/or sensitive business and operating information in line with the Hon’ble High Court’s clarification issued in this regard in Order dated February 7, 2018 passed in writ petition (WP) [W.P.(C) No. 5590 / 2015] titled Shamnad Basheer v. Union of India (UOI) & Ors.

Moreover, it is to be noted that Section 69(4) of the Patents Act requires the Indian Patent Office to keep confidential registered patent license agreements when accompanied by a confidentially request. Yet, Section 146 of the Patents Act appears to require the Patent Office to publish the same information as reported through Form 27. At a minimum, the Indian Patent Office must exempt confidential or proprietary information from its annual working statement disclosures. That means striking provisions of Form 27 that relate to “licensees and sub-licensees.” |
<table>
<thead>
<tr>
<th>4.</th>
<th>Form 27 of the Patents Rules, 2003 read with Section 146(2) of the Patents Act, 1970 require both, the Patentee and the Licensee to file working statements.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Form 27 should be amended to require filing of working statements either by the Patentee or the Licensee.</td>
</tr>
<tr>
<td></td>
<td>Provided where a Compulsory License is granted under Section 84 of the Act, it will be the responsibility of the CL holder alone to file Form 27 in respect of the Patent for which the CL has been granted. Further, the Patentee shall be exempted from filing the said Form 27 in respect of the Patent till such time the CL is in existence.</td>
</tr>
<tr>
<td></td>
<td>Filing of Form 27 by either the patentee or the licensee with respect to a particular patented product should suffice.</td>
</tr>
<tr>
<td></td>
<td>This would avoid an anomalous situation that may arise due to difference in information furnished by the Patentee and Licensee with respect to sales and quantities of a particular product <em>qua</em> the same patent.</td>
</tr>
<tr>
<td></td>
<td>If the intent of filing working statements is to ensure the invention is worked, fulfilling the requirement by either the Patentee or the Licensee should suffice.</td>
</tr>
<tr>
<td></td>
<td>Moreover, requiring filing of working statements either by the Patentee or the Licensee will reduce the burden on the Patent Office by mitigating duplicity.</td>
</tr>
<tr>
<td></td>
<td>Intent of granting CL is that the patented invention is worked to the fullest extent by the person to whom the CL is granted. If working statement is filed by the CL holder, then the Controller can determine whether the invention is worked to the fullest extent as per Section 90(1)(ii) of the Act by CL holder.</td>
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<tr>
<td><strong>5.</strong></td>
<td>Form 27 is ambiguous on whether or not information in respect of sales of a patented product manufactured/marketed by multiple companies (particularly infringers) is permitted to be included by the patentee in its Form 27 in respect of the given patented product.</td>
</tr>
<tr>
<td><strong>6.</strong></td>
<td>Whether Importation amounts to working of the patent in India.</td>
</tr>
</tbody>
</table>
given calendar year, whether manufactured locally or imported.

Form 27 may be amended to read as under:

“3. (i) The patented invention: ...

(b) If worked: Quantum of the patented product imported or sold in India…”

considerations determine whether manufacturing can be done in a cost-effective manner in one country or another; and supplied to one or more other countries. Having manufacturing facilities in all countries is not always feasible. The working requirement should suffice if the reasonable requirements of public are met either by manufacture in India, or through importation from one or more countries.

The fact that “working” has not been defined anywhere in the Patents Act, 1970 or in the Patents Rules, 2003, leads to ambiguity as to its scope. Working should therefore, be defined in line with Article 27(1) of the TRIPs that states that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced”.

We wish to point out here that because of the existing ambiguities in law, mere importation was not treated as meeting working requirements by Bayer in the Nexavar Compulsory Licensing (CL) case3.

We urge the Government to provide clarity on this issue through a Circular/Notification from the Government.

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3 Bayer Corporation vs. Union of India and Ors. [2014 SCC OnLine Bom 963]
7. Requirement of Patentee/Licensee to affirm compliance of public requirement in Form 27.

<table>
<thead>
<tr>
<th>Requirement of Patentee/Licensee to state whether public requirement has been met partly/adequately/to the fullest extent at a reasonable price must be deleted from Form 27.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement of Public Requirement will always be subjective so would be the statement on reasonableness of the price. Different interpretation (even if reasonable and submitted using due diligence by the Patentee/Licensee) of the above may expose the patentee or the licensee to a risk under Sections 122 of the Patents Act, 1970. In light of above, the requirement to make statement of meeting the public requirement at a reasonable price must be deleted from Form 27 as was proposed under the draft Patent (Amendment) Rules, 2015 that was published for stakeholders’ comments vide notification dated October 26, 2015.</td>
</tr>
</tbody>
</table>

8. Enforcement of Section 122(1)(b)

| Rule 131A may be added as below:  
*Rule 131A: Steps to be taken by the Controller in case of non-compliance of Section 146(2)*  
i. *In the event the patentee fails to file Form 27, the Controller may* |
<table>
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<tbody>
<tr>
<td>Such a provision may meet the concerns raised by the Hon’ble High Court’s in W.P.(C) No. 5590 / 2015 titled <em>Shamnad Basheer v. Union of India (UOI) &amp; Ors.</em></td>
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</tr>
</tbody>
</table>
9. Form 27 does not distinguish between product & process patent and simply requires the Patentee/Licensee to furnish information in respect of Working/non-working.

Process patents must be removed from the ambit of working requirement and Form 27.

It is to be noted that the same patented product can be made by several processes and each such different process may be patented by same or different companies. Filing Form 27 for each patented process by respective patentee(s) with accurate information about quantity and sales may be not be feasible, especially since certain processes may pertain to both patented and non-patented products, thus causing legitimate confusion for the patentee(s) in attempting to comply with Form 27 requirements.

Further, providing incorrect information about quantity and sales of the product in Form 27 (even if the patentee is reasonably and legitimately attempting to comply with the requirements) may expose the patentee(s) to punitive actions under section 122 of the Patents Act, 1970.

10. Form 27 provides for meaningless and vague details for showing invention is “worked” in the current form.

Simplify Form 27 to require patentees to solely state whether or not a patent was worked in India, e.g., the patented invention was or was not: made, used, offered for sale, sold, or imported in India.

The majority of disclosures required under Section 146 are either unnecessary to determining if the patented invention is “worked” in India or are so vague that they are nearly meaningless. The Patent Office should reconsider the need for Form 27 in its current form or at least significantly simplify Form 27 to require patentees to solely state whether or not a patent was worked in India, e.g., the patented invention was or was not: made, used, offered for sale, sold, or imported in India during the relevant period. In addition, the Patent Office should continue to exempt certain situations of non-working, i.e.,
regulatory delays or market conditions that would otherwise prohibit patentees from making, using, offering for sale, selling or importing the product in India.

Thanking you,

Yours sincerely,

Hrishikesh Raychaudhury

IN/PA 834

Corporate Law Group
14th March 2018

Controller General of Patents, Designs & Trade Marks
Boudhik Sampada Bhavan
S.M. Road, Antop Hill
Mumbai 400 037

E-mail to: wm.dhumane@nic.in; drusharao.ipo@nic.in

Dear Sir,

Re. Comments on the issues relating to the statement of working – Form 27

This is in response to the invitation dated 1st March 2018 inviting stakeholders to submit comments on the issues surrounding the statutory provisions relating to filing of statement of working. Our comments on the subject are provided below for your kind consideration.

**Background**

A patentee/licensee is required to furnish information on the working on his patent under Section 146 (1) and (2) of the Act.

Section 146(1) deals with the furnishing of information on working, when requisitioned by the Controller, while Section 146(2) provides for voluntary filing of an annual statement of working on Form 27 by the patentee/licensee for every patent.

In a PIL pending for disposal, before the Hon’ble Delhi High Court, the petitioner has extensively quoted from Ayyangar’s Report to justify his contention to ask the patentees/licensees to mandatorily submit detailed specific information on all matters relating to the working of their patents. The observations made by Justice Ayyangar were correctly quoted in the PIL, but one should not lose sight of the fact that those observations were for empowering the Controller when he calls for the information on working from the patentee under Section 146(1). Indeed, the wording of Section 146(1), as it stands today, was suggested by Justice Ayyangar himself.
Justice Ayyangar observed that the Controller must have before him all the information regarding the working of a patent by the patentee/licensee for proper disposal of a compulsory license application pending before him. But, this information is to be called for with respect to a particular patent, for which a contested compulsory license application is pending before the Controller and is to be furnished by the patentee/licensee under Section 146(1).

Justice Ayyangar also observed that, for statistical purpose, it may be useful to have working information on patents. It is submitted that the information required under Section 146(2) is to satisfy this statistical purpose.

It is further submitted that other than bare ascertainment of whether a patent is 'worked' or 'not worked', the following issues surrounding the working of a patent, namely,
(a) grant of compulsory license
(b) revocation under Section 85
(c) grant of injunctive relief
CANNOT be adjudicated upon on the basis of the information furnished in Form 27.

In some instances, the above three issues can be decided from the information provided in form 27, but in those instances, it suffices if Form 27 merely states whether the patent has been 'worked' or 'not worked'. But, in all the other instances, where the issues cannot be resolved only by knowing whether a patent has been worked or not, it is submitted that no amount of additional information contained in form 27 alone would be sufficient to fully dispose of the above issues. When those issues arise, the Controller or the court, as the case may be, would need to ask for additional information either under Section 146(1) [by the Controller], or otherwise [by the court].

To explain our contention, if a 'Not worked' statement on Form 27 has been filed, the Controller can straightaway proceed to fix the terms of the license in a compulsory proceeding before him, because it would no longer be necessary for him to decide on whether reasonable public demand at reasonable price has been met or not.

But, if a 'Worked' statement has been filed, it is not possible for the Controller to adjudicate the issue of "reasonable demand at reasonable price" on the basis of whatever additional information is provided in Form 27 alone. He has to call for additional details under Section 146(1), as indeed was done in the compulsory license procedure against the Bayer patent.
Similarly, the issue of revocation under Section 85 may be decided quickly, if a 'not worked' Form 27 is on file. But, no amount of information provided in a 'worked' Form 27, on file, can suffice for deciding on the 'reasonable demand at reasonable price' issue. The Controller will have to call for additional input under Section 146(1) to help him decide the issue.

Same consideration will also apply for deciding on an application for injunctive relief by the Court. If a 'not worked' Form 27 has been filed by the patentee, such may be enough for the Court to decide on the issue. On the other hand, if 'worked' Form 27 has been filed by the patentee, that may also suffice for the court for formulating its decision on the issue of providing injunctive relief. The court may not require further details of working regarding the issue, or even if it does require it, such can very well be called for from the patentee.

It is submitted that other than barely stating in Form 27 whether a patent is 'worked' or 'not worked', no other information contained in Form 27 impacts in any way the grant of compulsory license, the revocation u/s 85, or the grant of injunction.

**Difficulties in providing information on working/license**

It is further submitted that, in normal business environment, one keeps records of total sales. There may also be records of product-wise sales figures. But, seldom, if at all, does one keep any record of revenue earned against each patent held by him. If a person has very small patent portfolio, it might be possible for him to analyze his books of accounts in order to extract the relevant information on 'quantum and value' as may be assigned against each patent held by him; but it is an extremely onerous, if not impossible, task if the portfolio is fairly large.

There are various situations where again it is a huge and very difficult task to accurately provide the 'quantum and value' information in Form 27.

First of all, one must not lose sight of the fact that there has been a paradigm shift in the definition of 'invention' under Section 2 (1)(j), since the 1970 Act first came into force in 1972. With the amended definition of 'invention' which came into force from 20th May 2003, it is no longer necessary that the claimed invention must result in manufacturing of a tangible product. So, there are now patented inventions for...
cleaning, testing, monitoring, telecommunication process, air purifying and so on, where the machine or apparatus is not the subject matter and which does not result in any tangible product. In the absence of any clear cut product, assigning 'quantum and value' to such patented inventions is an impossibility.

The same is true for most of the computer implemented inventions too. Here again, it is not only not possible to provide the information relating to 'quantum and value', because often there is no product, in the normal sense of that term, it is equally difficult to even ascertain if the invention is implemented in India, or from abroad. So, in these instances, answering the question 'manufactured in India', or 'imported from other countries' is a further complication.

Then there are other complex problem situations. For example, if the patent relates to an improvement of a small part of an article or machine and where the patentee is selling, the machine as whole, it is not easy to apportion the 'quantum and value' of the patented invention. If the part is covered by a number of patents, which is often the case, the task is even more complicated.

Sometimes, the patent is for producing an intermediate and sale occurs for the final product. Here also it is difficult to provide apportioned 'quantum and value' for the patented invention.

There are so many other situations, where most of the information sought in Form 27 looks, on the face of it, rather simple, but, in actual facts, is far from being so.

In the present day business situations, it is also not easy to determine whether a patent is covered by a broad technology license agreement entered into by a patentee with many of its global partners, particularly when one has a large or a substantial patent portfolio. Then there are SEPs, where the number of licensees are sometimes so huge that it may be very difficult to list all of them accurately. There are lot of other complicated situations due to which it is not easy to determine whether or not a patent is under a license arrangement.

Consider all these also against the backdrop that the patentee may be accused of providing false information with the resultant application of the penal position under Section 122 against him, when, in point of fact, the situation, as it prevails, genuinely prevents him from submitting the information which is required of him, with any amount of accuracy. It is only when this perspective is kept in focus, the enormity of the problem faced by the patentee in this regard might be appreciated to some extent.
**How much information should go into form 27?**

One must also not lose sight of the fact that even if the patentee takes all the trouble to provide all the information in utmost details in Form 27, such will not serve any more useful purpose than would have been served, if he were to file a Form 27 with simple 'worked' or 'not worked' information for his patent.

The provision for grant of compulsory license and the provision for filing statement of working on Form 27 are there in the Act for the last 45 years.

During last 25 years, only one compulsory license has been granted. During 1980s, some seven or eight compulsory licenses were also granted. But, in none of those, Form 27 played any crucial role. So, trying to prove otherwise today, may not have any real justification.

Adequate deterrents are provided in the Act to induce the patentees to work their patents in India. But, to say that application of such deterrents is somehow tagged to whether or not detailed information of working is provided in Form 27 would seem to be wholly unfounded. If anything, a very stringent Form 27 regime is likely to act as deterrent for patent filing, as such, in India.

**Conclusion:**
To conclude Justice Ayyangar never envisaged that detailed working information for each and every patent held by each and every patentee is to be filed every year. His suggestion was that detailed information of working is to be furnished by a patentee in respect of a patent that has become subject of a compulsory license application so as to enable the Controller to decide on the issue judiciously and for this purpose, he wanted the Controller to have an effective tool in the form of the provision under Section 146(1).

For all the rest of the patents, which must satisfy the requirement of Section 146(2), we contend that it will fully serve the purpose of the Act, if the patentee/licensee simply informs the Controller annually through the Form 27 as to whether or not his/her patent has been worked in India.

Respectfully submitted for consideration on this 9th day of March 2018

Kind Regards
RP Bhattacharya / DJ Solomon
Regd. Patent Agents

*De Penning & De Penning*
Dr. Nidhi Buch,  
Assistant Professor of Law and  
Director, Centre for IPR, GNLU

Gandhinagar, Friday 16 March 2018.

To,
Mr. Ramesh Abhishek  
Secretary (IPP)  
Ministry of Commerce & Industry  
Udyog Bhavan,  
New Delhi, India  
E-mail: secy-ipp@nic.in

And

Shri O.P. Gupta, IAS  
Controller General of Patents  
The Indian Patent Office  
Mumbai, India  
E-mail: cgoffice-mh@nic.in

Dear Sir,

It gives me a great pleasure in introducing the Gujarat National Law University (GNLU), Gandhinagar, (www.gnlu.ac.in), one of the premier national law universities of India, established under the GNLU Act 2003 and recognized by the Bar Council of India and the UGC. GNLU aims to advance in dissemination of knowledge, learning and their role in national development. GNLU offers interdisciplinary legal courses in all the five faculties, namely B.A. LL.B, B.Com. LL.B, B.Sc. LL.B, B.SW. LL.B and B.BA. LL.B. Additionally, GNLU also offers LLM (full-time and distance), Ph.D. programs in law & inter disciplinary fields and Foreign Law and Languages Programs.

Further, recognizing the domestic and international growth of Intellectual Property Rights, GNLU has established a Centre for Intellectual Property Rights, in the year 2016, with an aim and vision to incentivize innovative and cutting-edge academic research in the field of IP Laws, and conducting various training and extension activities for creating more awareness in the field of IP laws. Over a short period of time, the Centre has emerged with various programmes focused on strengthening the level of awareness on IP laws amongst stakeholders; capsule courses, special lecture series and panel discussions on emerging issues in the field of IPR form part of the programmes. Research has also formed a core part of the Centre activities, wherein till date, substantial contributions have been made
to drafting of IP policies for other educational institutions in the State such as Central University of Gujarat. The Centre is also associated with the Education Department, State of Gujarat, for drafting IP policy for the colleges affiliated to various Universities of the State. Adding further, an empirical research project titled "Adding Life to Centuries' Dying Art: A Comparative Market Analysis between Tangaliya Shawls and Kutch work Shawls", is being undertaken wherein the GI Law as implemented in India, particularly in the State of Gujarat is being investigated. The Centre activities are performed by the Team consisting of myself as Director, Dr. Hardik Parikh- Assistant Professor of Law as member along-with Ms. Hetvi Trivedi & Ms. Vaishali Singh - Research Associates. This team is further assisted by a group of enthusiastic student members from Undergraduate and Post-graduate courses at GNLU.

Working under the Centre, is the GNLU-GUJCOST Research Centre for Excellence in IP Laws, Policies & Practices. Established by the Government of Gujarat in the year 2014, this Chair aims at developing a synergy between facets of Science and Technology with IP, to look at how the common man can be benefited. This aim is fulfilled by undertaking various awareness programmes and intense discussions on the developments in IP, various amendments brought to IP laws and how they affect scientific and technological advancements. These activities are combined with research papers, in order to maximize the reach of ideas among authorities at various levels. Thus, the Chair looks at various points of convergence between Science, Technology and IP to bring about an enhanced and in-depth knowledge of the same. Currently, Dr. Raj Dave - Chair Professor, is researching on a range of issues in domestic IP laws and as the future course of action, has planned on offering an Advanced Certificate Course on a Comparison of Patent Laws as implemented in India and U.S.A., where scholars from both countries will come together to provide a comprehensive understanding of both laws and draw necessary comparisons.

With this background, I take this opportunity on behalf of Gujarat National Law University to propose a formal submission on Form 27—India’s Opportunity for Tracking Patents Related to Drugs prepared by Dr. Raj S. Davé, Gujarat Council on Science and Technology IPR Chair Professor for Excellence at Gujarat National Law University (appointed) and Justice Asok Ganguly, Former Supreme Court Justice of India and Adjunct Professor at Gujarat National Law University (appointed).

Thanking You,

Dr. Nidhi Buch,
Assistant Professor of Law and
Director, Centre for IPR, GNLU.
March 16, 2018

Mr. Ramesh Abhishek  
Secretary (IPP)  
Ministry of Commerce and Industry  
Udyog Bhavan  
New Delhi, India  
Secy-ipp@nic.in

Shri. O P Gupta, IAS  
Controller General of Patents  
The India Patent Office  
Mumbai, India  
cgooffice-mh@nic.in

SUBJECT: Form 27—India’s Opportunity for Tracking Patents Related to Drugs

Through this submission, on behalf of Gujarat National Law University, we, Dr. Raj S. Davé and Justice Asok Ganguly, would like to bring to your notice the opportunity for tracking patents related to drugs through the working statement (i.e., Form 27) under Section 146 of The Indian Patents Act, 1970. In our viewpoint, the prevailing Form 27 does not fulfil the intent of law and, is particularly ambiguous and unclear. We believe that the time is right for India to develop an “Orange Book” type database like that of the United States Food and Drug Administration (maybe, we can call it India’s “Green Book”), to give generic pharmaceutical companies and the public a clear notice as to which patents are related to a particular drug. At the same time, Form 27 should be amended to minimize—preferably eliminate—disclosure requirements for, and the accompanying burden on, non-pharmaceutical drug patent owners.

We have undertaken and provided a legal analysis on Section 146 of The Indian Patents Act, 1970, the legislative intent for working statement, and suggestions for modifying Form 27 such that the objectives of creating greater access to affordable medicine in India and promoting innovation in India are simultaneously met. We request you to consider our submission in an unbiased manner.

We also request your office to allow us to participate in the Open House discussion on Form 27 scheduled at DIPP on 21st March.

Thank you very much.

Sincerely,

Dr. Raj S. Davé  
Gujarat Council on Science and Technology  
IPR Chair Professor for Excellence at Gujarat National Law University (appointed)

Justice Asok Ganguly  
Former Supreme Court Justice of India and Adjunct Professor at Gujarat National Law University (appointed)
Dr. Raj S. Davé is appointed the Gujarat Council on Science and Technology (GUJCOST) Chair Professor for IPR Excellence at Gujarat National Law University (GNLU). He is a registered patent attorney in the United States and the President & Founder of Davé Law Group (DLG), a full-service Intellectual Property law firm in the United States.

Dr. Davé’s vast experience in all aspects of Intellectual Property (IP) includes IP counseling, patent prosecution, dispute resolution, licensing, technology transactions, IP mining and enforcement, post-grant proceedings, pre-litigation opinions and patent litigation, including ANDA litigation. He also has extensive experience in several diversified technologies, including biotechnology, business method, chemical, electrical, hardware and software technologies, information technology and internet, materials and polymer science, pharmaceuticals and telecommunication.

Dr. Davé is recognized as an “IP Star” by Managing Intellectual Property and the Legal 500 U.S. He is an author of articles published in Duke Law & Technology Review, Yale Journal of Law and Technology, and Harvard Journal of Law and Technology, among others. He is a Board Member of the United States National Inventors Hall of Fame and other nonprofit organizations. He is the Founder of the George Washington University Law School India Project and has led 10 judicial delegations from the United States to India. He is a Board Member of WHEELS Global Foundation (www.wheelsglobalfoundation.org), whose mission is “Technology Enabled Philanthropy” to give back to India, the United States and to global communities by providing technological solutions to issues related with water, health, energy, education, livelihood, and sustainability. He is the Director of the Sustainability track of WHEELS Global Foundation.

In 2014, when India’s IPR Regime was under threat of being unilaterally downgraded under Section 301 by the United States Trade Representative (USTR) through an “Out of Cycle Review,” Dr. Davé, along with Professors Srividya Ragavan, Sean Flynn and Brook K Baker, submitted comments to the USTR that:

- India’s enactment and implementation of the India Patent Act of 1970 with subsequent Amendment of 2005 are fully in accord with the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

- Any unilateral sanctioning of India through Special 301 would be illegal under the World Trade Organization rules.

This submission was reported in SpicyIP, as follows:

Srividhya Raghavan’s comment submitted that Indian law was TRIPS compliant, and provided reasoning to support Section 3(d), compulsory licensing provisions.

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1 Dr. Davé’s LinkedIn profile is available at https://www.linkedin.com/in/raj-s-davé-6b918412/.
and the patent invalidation by Indian courts. The USTR Report had made unfavourable notes of the interpretation of section 3(d) and compulsory licensing provisions. Further, the Report stated that “in recent years, India has invalidated or otherwise attached patents on a significant portion of innovative drugs.” In response to this, the submission cited the patent invalidation rates in the US which were actually just as high or possible higher than Indian courts, thereby refuting the claim.

In the second part, the submission asserted that threats of sanctions in the nature of the Report were unjustifiable- citing precedents such as the Special 301 and the EC Tariffs case previously adjudicated at the WTO. Further, it stated that imposing unilateral sanctions was impermissible by Article 23 of the Dispute Settlement Understanding.

**Supreme Court Justice Asok Ganguly**⁴ is the former Chairman of the West Bengal Human Rights Commission and a former Judge of the Supreme Court of India. He is an eminent scholar of law and the author of the most eminent Indian opinion on patentable subject matter in *DIMMINACO A.G. VERSUS CONTROLLER OF PATENTS AND DESIGNS & OTHERS* in the High Court at Calcutta, heard on: 13.09.2001, 20.09.2001, 26.09.2001 & 04.10.2001; Judgment on: 15.01.2001. He is appointed Adjunct Professor at Gujarat National Law University. Along with Dr. Davé, he will be teaching two courses on IP law in the fall semester of 2018 at the GNLU.

He started his career in 1969 by teaching in the same school of which he was once a student. In 1972, he started practice in Calcutta High Court. On 10 January 1994, he was appointed a permanent judge of Calcutta High Court but within 3 months was transferred to Patna High Court. After remaining in Patna High Court for more than 6 years, he was transferred back to Calcutta High Court on 1 August 2000. There he subsequently became senior most puisne Judge in March 2005. He functioned twice as “Acting Chief Justice of Calcutta High Court”. Later he was transferred to Orissa High Court where he joined as the senior most puisne Judge on 21 April 2006. On 2 March 2007 he took oath as Chief Justice of Orissa. He joined Madras High Court as Chief Justice on 19 May 2008. Later he was transferred to Supreme Court of India where he joined on 17 December 2008 and remained in the apex court for more than 3 years. On 3 February 2012 he attained superannuation. Post his retirement, justice Ganguly worked as guest faculty at National University of Juridical Sciences, Kolkata. He also went on to be the Chairperson of the West Bengal Human Rights commission, where his role was highly appreciated.

**Disclosure:** Neither of the authors has been paid by any entity to make this submission to the Indian Government. The views expressed herein are solely those of the authors.

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PROPOSAL FOR AMENDMENT OF FORM 27 TO TRACK PATENTS RELATED TO DRUGS

Legal Basis for Form 27

Section 146 of the India Patents Act of 1970 as amended by Act No. 15 of April 4, 2005 (hereinafter “Section 146”) is the legal basis for Form 27. Section 146, entitled “Power of Controller to call for information from patentees,” states:

146. Power of Controller to call for information from patentees.
(1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.
(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.
(3) The Controller may publish the information received by him under sub-section (1) or sub-section (2) in such manner as may be prescribed. [Emphasis added.]

Under the plain reading of the law, the Controller may (not shall) “by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him” and “such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may (not shall) be specified in the notice” by the Controller. On the other hand, “every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.” Furthermore, the “Controller may publish the information received by him under sub-section (1) or sub-section (2) in such manner as may be prescribed.”

In short, the statute is unambiguously clear by using the terms “may” and “shall” in the same section of the statute that the Controller may exercise his powers under Section 146, but it is NOT mandatory for the Controller to do so. On the other hand, once the Controller decides to excise any power under Section 146, it is mandatory for the patentee to furnish the information required by the Controller.

Legislative Intent

To understand the legislative intent for promulgating Section 146, it important to delve into the historical background leading to the passage of the India Patent Act of 1970, and the subsequent Amendment of 2005.
Mr. Shamnad Basheer, in his article entitled *INDIA’S TRYST WITH TRIPS: THE PATENTS (AMENDMENT) ACT, 2005*, explains:5

The most prominent and controversial change [by the Amendment of 2005] has been the deletion of section 5 of the Patents Act, 1970, thereby paving the way for product patents in the area of pharmaceutical and other chemical inventions. Section 5 of the Patents Act, 1970 (as it stood after the 2002 amendments) had provided that, in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the *methods or processes of manufacture* of such substances could be obtained.

This deliberate strategy of denying product patent protection to pharmaceutical inventions is traceable to the Ayyangar Committee Report, a report that formed the very basis of the Patents Act, 1970. The Committee found that foreigners held between eighty and ninety percent of Indian patents and that more than ninety percent of these patents were not even worked in India. The Committee concluded that the system was being exploited by multinationals to achieve monopolistic control over the market, especially in relation to vital industries such as food, chemicals and pharmaceuticals. Medicines were arguably unaffordable to the general public and the drug-price index was rising rapidly. The Committee therefore recommended that certain inventions such as pharmaceutical inventions, food and other chemical inventions be granted only process patent protection. India’s well-developed generic industry today is testimony to the farsightedness of this report. [Italics in original; internal citations omitted.]

In short, back in 1969-70, 80-90% of the Indian patents were owned by foreign multinational companies and most of the patents were not worked in India. This led to the mandatory working requirement, the elimination of product patents in pharmaceutical and other chemical inventions, and incorporation of Sections 84 and 146 in the India Patents Act of 1970, with a goal of providing affordable medicines to the public.

Under Section 84(1)(c) of the Act, any person interested may apply to the Controller for grant of a compulsory license if the patented invention has not been worked in the territory of India. Such representation under Section 84 may be made any time after the expiration of 3 years from the date of the grant of the patent. The information in Form 27 under Section 146 is intended to provide public notice.

**Fast Forward to 2005 and Beyond**

Now, let’s fast forward to 2005. Mr. Basheer wrote, “The controversial Patents (Amendment) Act, 2005 (hereinafter ‘the 2005 Act’) was India’s last step towards achieving complete TRIPS

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The 2005 Amendment deleted Section 5 of the India Patents Act, 1970, thereby paving the way for product patents for pharmaceutical and other chemical inventions. However, the 2005 Amendment continues to include Chapter XVI entitled “WORKING OF PATENTS, COMPULSORY LICENCES AND REVOCATION.”

Voluntary licenses are those that are granted at will by a licensor and accepted by a licensee. The patentees can, at-will, typically license or permit a third party to manufacture a patented product and charge a fee for it. The parties mutually determine such fee and terms of the license. As voluntary licenses are negotiated between parties, they can be typically more easily available and flexible, and provide access to medicine far quicker than waiting for patent expiration and subsequent generic market entry. In contrast, a compulsory license is involuntary and granted to a third party for using or manufacturing a product without consent of the patent holder. In the case of a compulsory license, the government, and specifically the Controller of the Indian Patent Office, determines the royalty, compensation, and other terms on which such license is to be granted.

Thus, compulsory licenses interfere with the patent holder’s right to exclude others for the statutory life of the patent by ending such period of exclusivity prematurely. Clearly, such action can be used to compel and or incentivize voluntary license negotiations, that ultimately speed up access to patented medicine. Voluntary licenses are typically preferable by the generic pharmaceutical companies but are often not granted by the innovator pharmaceutical companies. In such circumstances, the government may impose a compulsory license only after the failure of negotiations between the applicant and patent holder on “reasonable commercial terms.”

However, in certain “exceptional circumstances” such as “national emergencies, other circumstances of extreme urgency or public non-commercial use (or “government use”) or anti-

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6 Id. at 16.
7 There is no authority for fixing the pricing of voluntary licensing; it is fixed by the parties. However, in case the product falls under the National List of Essential Medicines, i.e., scheduled formulations/drugs, the price of the licensed drug cannot be more than that of the fixed ceiling price. The ceiling price of the NLEM drugs is fixed by National Pharmaceutical Pricing Authority. Further, in case of non-scheduled formulations/drugs, NPPA monitors the annual increase in prices which cannot be more than 10%.
8 The unamended Patents Act 1970 provided for a ceiling of a 4% royalty to be paid to the patentee in the case of a compulsory license. However, this ceiling was removed by the Patents (Amendment) Act 2002 and it was left to the Controller to decide on a case-to-case basis as to the quantum of royalty or other remuneration to be paid to the patentee by the compulsory license holder.
9 1 Michael D. Scott, Scott on Multimedia Law, 18-21 (1995-12)
10 See Compulsory Licensing of Pharmaceuticals and TRIPS,
competitive practices, there is no need to try first for a voluntary license.”

A compulsory license is generally granted to accomplish a social objective (e.g., public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria, and other epidemics). That is, such licenses are imposed on the patentee when the public’s need for the patented invention outweighs the patent holder’s rights. Therefore, such licenses are typically granted when certain criteria are met which justifies prematurely ending the period of exclusivity of the patentee in the interest of the public.

In sharp contrast to the patent statutes of many nations, including Canada, China, Japan, India and Germany, the United States patent code does not include a general compulsory licensing provision or scheme. The United States has never imposed such duties on ordinary patent holders, particularly “worked in the country”-type obligations. In *Hartford-Empire Co. v. United States*, the United States Supreme Court noted that a patent owner “has no obligation to use [the patent] or to grant its use to others.” The United States Congress has repeatedly refused to create such provisions in United States patent laws despite their apparent accord with broader patent system objectives. However, non-patent laws in the United States include provisions that allow for the compulsory licensing of patented inventions, e.g., “march-in” rights by the United States government (such as that threatened against Bayer for ciprofloxacin during the Anthrax attack crisis), and the terms are set by a quasi-judicial process. In addition, circumstances that are arguably akin to a compulsory license may occur through antitrust enforcement, judicial determinations in patent infringement litigation, and activities of the federal government. A modest number of additional compulsory licenses exist with respect to the United States patents, each pertaining to specialized subject matter.

The inclusion of the power to grant compulsory license under the Indian patent statute is a good thing, though one might look at it as a “necessary evil” to protect public interest from other evils. Dr. Davé has co-authored a paper entitled *FRAND v. Compulsory Licensing: The Lesser of the Two Evils* in Duke Law & Technology Review. The abstract of this paper states:

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11 Id.
15 *Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176 n.21 (1980).
This paper focuses on two types of licenses that can best be described as outliers—FRAND [an acronym for “Fair, Reasonable and Non-Discriminatory”] and compulsory licenses. Overall, these two specific forms of licenses share the objective of producing a fair and reasonable license of a technology protected by intellectual property. The comparable objective notwithstanding, each type of license achieves this end using different mechanisms. The FRAND license emphasizes providing the licensee with reasonable terms, e.g., by preventing a standard patent holder from extracting unreasonably high royalty rates. By contrast, compulsory licenses emphasize the public benefit that flows from enabling access to an otherwise inaccessible invention. Ultimately, both forms of license attempt to create a value for the licensed product that can be remarkably different from the product’s true market value. Nevertheless, both forms ultimately benefit the end-consumer who pays less to access a product subject to either of these forms of license. In comparing these two forms of licenses, the paper hopes to determine whether one form is better than the other, and if so, from whose perspective—the consumer, the licensor or the licensee. In doing so, this paper compares the different prevailing efforts to embrace such licenses as well as the impact of such licenses on the industry.

A patent that controls any part of the technology used in a standard is called a “standard-essential patent” (hereinafter “SEP”). The FRAND license in the United States is a judicially created doctrine aimed at facilitating widespread use of a standard and to ensure that while the SEP owner benefits from use of the patent, the SEP owner cannot gain an unfair bargaining advantage or abuse the SEP. On the other hand, the power to grant a compulsory license in India, and in most countries, is statutory, with greater emphasis on public good than equitable and fair business dealings between competitors.

The 2005 Amendment also continues to include Section 146. This is good law too as Section 146 gives the Controller the flexibility to implement the compulsory licensing statute, i.e., Section 84 in the India Patents Act of 1970, as appropriate in time and circumstances, and without any mandatory requirements.

**Reality Regarding Grant of Compulsory Licenses in India**

Renowned author Janice M. Mueller asserts that, “India’s compulsory licensing provisions are undoubtedly the broadest and most comprehensive of all the world’s patent systems.”17 Despite this, until 2012, the compulsory licensing provisions envisaged in the Indian Patent Act were not utilized. In fact, compulsory license on only **one** pharmaceutical product (Bayer’s Sorafenib/Nexavar) has been granted in India under § 84 of the Indian Patents Act.18

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18 Discussed infra, Section 2(B).
On March 9, 2012, the Controller granted, via Order, Natco Pharma (a mid-sized Indian company focused on anti-cancer segment in generic drugs) non-exclusive and non-assignable rights for Indian Patent No. 2,157,58 to sell a generic form of Bayer AG’s kidney and liver cancer drug, Nexavar, on grounds of lack of affordability and lack of access to the general public. Nexavar was marketed in India in 2008 at Indian Rupees (INR) 280,000 (approximately United States $4,300) for a pack of 120 tablets required for one month of treatment.

The first compulsory license grant in India for Nexavar is considered historical as it demonstrated that India’s compulsory licensing regime is TRIPS compatible. Bayer lost on all legal grounds that it argued and ultimately the Intellectual Property Appellate Board and Bombay High Court found no justification for Bayer’s pricing and not manufacturing the drug in India.

One would have presumed that post-Nexavar, India would be quick to grant compulsory licenses, especially given the perception (albeit unproven) that compulsory licenses undercut prices of patented drugs. And indeed, many experts in the field certainly expected that there would be a rise in such grant given the price reductions through the generic version of Nexavar. However, since the grant of compulsory license on Nexavar’s patent, no other compulsory license has been granted in India. Post-Nexavar, there have been at least two other applications for granting a compulsory license.

The first was filed by an Indian generic pharmaceutical—BDR Pharma. BDR Pharma’s application pertained to Bristol-Myers Squibb’s cancer drug Dastanib. This application was rejected at the initial stage. According to the Controller, BDR Pharma failed to make a good faith effort to seek a voluntary license from Bristol-Myers Squibb prior to making a compulsory license application under § 84. A prior good faith effort to seek a voluntary license is a decisive factor in adjudging § 84 applications; a lack thereof automatically disqualifies the application. To date, BDR Pharma’s application has not been re-submitted, though there is a pending Section 92 case (under which the government would decide about issuance compulsory license to address a health emergency arising from lack of access to a patent medicine to the Indian public) for a compulsory license on Dastanib.

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19 Id.

20 Cost of Bayer’s patented cancer drug Nexavar, was Rs. 280,000 (about $4850) for a monthly dose whereas its generic version, Cipla, could be produced for about Rs. 8,800 (about $150). This was held to be not “reasonably affordable” by the Controller.

21 Natco could also produce more of the generic drug than Bayer could, and could thus increase the penetration of the drug thereby facilitating its access to the common man. Bayer argued that the sales of Cipla, a generic version of its patented drug Nexavar, should also be considered to determine penetration and facilitation of the drug to the public. However, this argument was dismissed. Further another argument was put forward by Bayer AG claiming that Natco had not entered into reasonable negotiations with it before applying for the compulsory license, which also stood rejected. The IPAB revised the royalty to be given to Bayer AG from 6% to 7% of the net sales by Natco until 2020 (the end of the patent term is 2020).

22 As of the date of this paper’s publication, the authors are unaware of any pending application under Section 84 of the Patents Act for grant of a compulsory license.

23 Note, on February 2, 2012, BDR Pharma sent a letter to BMS seeking a voluntary license. However, BMS replied to their letter seeking certain information. BDR assumed the raising of said queries as the rejection of their application to seek voluntary license and then proceeded with the S.84 application. This according to the Controller didn’t count as adequate effort to seek a voluntary license prior to making a S.84 application for compulsory license. See https://ipandlegalfilings.com/indian-patent-office-rejects-compulsory-licensing-application-bdr-pharmaceuticals-pvt-ltd-vs-bristol-myers-squibb/.
The second application was filed by Lee Pharma in January 2016 for a compulsory license on Astra Zeneca’s Saxagliptin diabetes drug. This application was also rejected for non-satisfaction of conditions prescribed under § 84 of the Act. The applicant failed to show that the drug was not affordable, unavailable, or that it was not “worked” in the territory of India.\(^{24}\) Also, Novartis’ Onbrez and Roche’s Herceptin were subject to compulsory license negotiations, but no licenses were issued.\(^{25}\)

As of 2017, there has been a negligible impact of India’s compulsory licensing law, despite protests by brand pharmaceutical companies and the United States government alleging anti-competitive decrease in prices and undercutting of patented innovations. Ironically, today, many jurisdictions, including the United States, Japan, the European Union, and other major markets including the United Kingdom, China, India, Brazil, Russia, and Canada, recognize at least some form of compulsory patent licensing under statutory or judicial schemes, even though the term used for such licensing might not be “compulsory licensing.” While the basic principles are similar in that the patentee is compelled to grant a license, the specific requirements and mechanisms for obtaining “compulsory” licenses differ widely between jurisdictions.

Regardless of the above, the minimal growth of compulsory licensing in India may just be due to the fact that patented drug products in India only account for about 6% of all those sold.\(^{26}\) Further, the impact of the Nexavar compulsory license on improving access has not yet been meticulously reviewed or analyzed, though Natco was directed to maintain accounts of sales and report the details to the Controller and Bayer on a quarterly basis.

The grant of the Nexavar compulsory license by the Indian government became an irritant in the eyes of multinational drug companies and the USTR. So, the USTR listed India in the “Special 301” Report of 2013 (the “Special 301” is an annual report issued by the USTR listing countries that cannot protect IP rights of United States companies\(^{27}\)). In this report, the USTR claimed that India needs to modify its IP rules and regulations, specifically on compulsory licensing and Section 3(d), and placed India on the “Priority Watch List” along with other countries. Furthermore, the USTR threatened to downgrade India in 2014 through an “Out of Cycle Review.” The first author, Dr. Davé, vigorously opposed this move as explained above under the heading “ABOUT THE AUTHORS,” and fortunately, India was not downgraded. The threat of


\(^{25}\) In June 2016, Cipla’s application for Revocation under Section 66 and compulsory licensing under Section 92 of the Patents Act of five of Novartis’ patents, covering its drug Onbrez®, was rejected by the Department of Industrial Policy & Promotion (DIPP), of the Ministry of Commerce, Government of India. Cipla did not file any new Section 84 application over Novartis’ Onbrez. The matter stands settled between the two entities. Further, Roche abandoned its patent in India over Trastuzumab/Herceptin in 2013 and therefore, no compulsory license could be granted in respect of the same. There are already several generic versions of Trastuzumab/Herceptin in the Indian market being manufactured by Biocon & Mylan.

\(^{26}\) A product patent regime was set up in India only as recently as 2005, yet, the domestic pharmaceutical industry has attempted several ways to penetrate the market of brand drugs via generics, as well as government-sanctioned routes using compulsory licensing under Sections 84 and 92, as well as Revocation under Section 66 of the Indian Patents Act.

\(^{27}\) The "Special 301" Report reflects the outcome of a Congressionally-mandated annual review of the global state of intellectual property rights (IPR) protection and enforcement. See [https://ustr.gov/issue-areas/intellectual-property/Special-301](https://ustr.gov/issue-areas/intellectual-property/Special-301).
sanctions against India by the United States may be one disincentive for a larger number of Indian government-granted licenses.

Form 27 Should be Used for Tracking Patents Related to Drugs

Having explained the importance of compulsory licensing regime, we now focus our attention on Form 27. What is the objective of Form 27? It is a public notice by the patent owner to allow the public in India to decide on what patent to apply for a compulsory license in India. However, history proves that only one compulsory license has been granted in India so far, and all applications for compulsory licenses in India have been for drug patents only.

Therefore, on a practical level, the real-value of Form 27 would be to use it for tracking patents related to drugs. However, the authors’ proposal is not “patent linkage,” which is the practice of linking drug marketing approval of a generic medicine to the patent status of the originator’s reference product and not approving the generic medicine prior to the expiration of patent term, unless consented to by the originator.28 The authors’ proposal is to create an “Orange Book”29 type database of the United States Food and Drug Administration (hereinafter “FDA”) that generic pharmaceutical companies or anyone can refer to determine which patents are related to a particular drug. Maybe, we can call this Orange Book type database as India’s “Green Book.”

A screenshot of the [home page of the Orange Book](https://www.accessdata.fda.gov/drugs/orangebook/index.cfm) is shown below:

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29 The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* is commonly known as the “Orange Book.” It identifies drug products approved based on safety and effectiveness by the FDA under the US Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.
Let us assume that someone want to know what patents are related to drugs containing the active ingredient PIRFENIDONE. Then, one would enter PIRFENIDONE in the search box and press Search. The next screen is shown below:

Next one must click one of the “Appl No” to see the next screen, which is shown below for N022535 (Dosage Form: CAPSULE):
Note that the brand name of branded company Genentech’s drug having PIRFENIDONE as the active ingredient is ESBRIET. Finally, to know which patents are related to Dosage Form: CAPSULE of ESBRIET, one clicks “Patent and Exclusivity Information” and the next screen is shown below:

Form 27 should be redesigned to require pharmaceutical companies to provide data on patents related to drugs. The patents related to a drug would be any patent that covers the making, using, selling, offering to sell, or importing of a drug. The pharmaceutical companies are used to providing some or all of this information to the FDA; therefore, providing similar information in Form 27 should not be excessively burdensome to the pharmaceutical companies.

The Indian public has a right to rely on the information provided in Form 27 to make important decisions that impact business and public welfare. The failure to identify a certain patent for making, using, selling, offering to sell, or importing a given drug should result in an “irrebuttable presumption” that the claims of the certain patent do not cover the given drug, and thus cannot afford the patent owner the right to exclude others from making, using, selling, offering to sell, or importing the given drug.30

30 Under Section 4 of the Indian Evidence Act, conclusive proof of a fact precludes any evidence from being given for the purposes of disproving that fact, i.e., it is an irrebuttable legal presumption. Section 115, 116 and Section 117 of the Indian Evidence Act 1872 deals with the rule on estoppel and considers estoppel as an example of irrebuttable presumptions. Estoppel is a judicial device in common law legal systems whereby a court may prevent, or “estop” (a person who performs this is estopped) a person from making assertions or from going back on his word. When a person by declaration (act or omission) makes/induces another to believe a thing, the person cannot deny its truth subsequently. The other person cannot be estopped from proceeding upon such declaration. Estoppel is rule of evidence, by which a person is not allowed to plead the contrary of a fact or state of things, which he formally asserted as existing.
Besides seeking data on drug patents, the information required to be submitted for non-drug patents under Form 27 should be minimal—preferably none. After all, what is the objective of collecting data on non-drug patents when history proves that no compulsory license has even been applied for world-wide until 2010 on a non-drug patent.

The table below reflects all compulsory licenses applied for, and their outcome, until 2010 on a world-wide basis. Until 2010, there was only one application for compulsory license in India, and this too was not granted (and as mentioned before, the compulsory license over Bayer’s Nexavar was initially issued later in 2012, and subsequently to additional generics in 2014, 2015, and 2016). On the other hand, applications for compulsory license have been filed in many other countries, including Canada and the United States.

<table>
<thead>
<tr>
<th>Year(s)</th>
<th>Nation</th>
<th>National Income Group</th>
<th>Disease</th>
<th>Disease Group</th>
<th>Total Products</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>Brazil</td>
<td>LAC</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>2</td>
<td>CL/discount</td>
</tr>
<tr>
<td>2005</td>
<td>Brazil</td>
<td>LAC</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>1</td>
<td>Discourge</td>
</tr>
<tr>
<td>2003</td>
<td>Brazil</td>
<td>LAC</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>1</td>
<td>Discourge</td>
</tr>
<tr>
<td>2004</td>
<td>Portugal</td>
<td>NCD</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>3</td>
<td>CL</td>
</tr>
<tr>
<td>2005</td>
<td>Brazil</td>
<td>LAC</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>1</td>
<td>Discourge</td>
</tr>
<tr>
<td>2005</td>
<td>Brazil</td>
<td>LAC</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>1</td>
<td>Discourge</td>
</tr>
<tr>
<td>2005</td>
<td>Indonesia</td>
<td>LIU</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>2006</td>
<td>India</td>
<td>LAC</td>
<td>Cancer</td>
<td>NCD</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>2007</td>
<td>Thailand</td>
<td>LAC</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>1</td>
<td>CL</td>
</tr>
<tr>
<td>2007-2008</td>
<td>Thailand</td>
<td>LAC</td>
<td>HIV/AIDS</td>
<td>NCD</td>
<td>2</td>
<td>CL</td>
</tr>
<tr>
<td>2007-2008</td>
<td>Thailand</td>
<td>LAC</td>
<td>Cancer</td>
<td>NCD</td>
<td>1</td>
<td>Discourge</td>
</tr>
<tr>
<td>2008</td>
<td>Ecuador</td>
<td>LAC</td>
<td>HIV/AIDS</td>
<td>HIV/AIDS</td>
<td>1</td>
<td>CL</td>
</tr>
</tbody>
</table>

Dr. Davé, the first author on this paper and a patent practitioner himself, has inquired with many companies and institutes in India and abroad as to what their biggest challenge is for getting patents in India. Consistently, companies and institutes state that their number one challenge is the annual ritual of completing and filing Form 27. In today’s day and age, this ritual has become

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31 See Reed Beall & Randall Kuhn, Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis, PLOS MED 9(1): e1001154 (2012) [https://doi.org/10.1371/journal.pmed.1001154](https://doi.org/10.1371/journal.pmed.1001154); the authors do not have data on all compulsory licenses applied for, and their outcome, post-2010 on a world-wide basis.
an incredible headache for patent holders in India, including Indian corporations and institutions such as the IITs—the alma mater of Dr. Davé.

It is time for India to take a fresh look at Form 27 and come up with a pragmatic solution. The authors believe that adopting the suggestions provided herein will not only be in the best interest of creating greater access to affordable medicine in India but would also promote innovation, entrepreneurship and growth of intellectual property in India.

The Economic Times of March 14, 2018, under the banner “US firms review plans to set up R&D units in India” reports that “Many US firms have begun to review their plans to set up or expand R&D centres in the India, in what industry experts see as a fallout of the Trump administration’s new additional tax on companies that move work to offshore subsidiaries.” R&D leads to innovation, and innovation leads to more patents. Thus, to create a healthy environment in India for promoting R&D, innovation and patenting, it is imperative for the Controller of the India Patent Office to modify Form 27 in a manner that the dual objectives of creating greater access to affordable medicine in India and promoting more innovation in India are simultaneously met.

**Lingering Questions**

If Form 27 is modified as proposed by the authors to seek information solely for tracking patents related to drugs and nothing more, then there will be certain lingering questions in people’s mind. Below, we address two questions:

1. **How should we curb patent abuses by a patent holder who owns a patent that controls a technological standard or creates a complete barrier for any competitor to enter a specific technical field?**

   An analogy to a patent that controls a technological standard or creates a complete barrier for any competitor to enter a specific technical field is a patent on an active pharmaceutical ingredient (API). To make a drug, irrespective of the dosage form, one must use the API; after all, the API is the active pharmaceutical ingredient in the drug. For example, one must use PIRFENIDONE to make a generic version of ESBRIET irrespective of whether the generic version is a capsule, tablet, or any other form. Generally, a similar situation occurs when a patent controls a technological standard such as a 3G or 4G transmission protocol.

   If faced with such a situation in India in the future, the solution to curtail this abuse by the patent holder is through FRAND licensing. The Indian judiciary can decide to grant FRAND licenses, just as this has been done in the United States, on a case-by-case basis.

   Furthermore, the Division Bench of the Delhi High Court in *Franz Xaver Huemer v. New Yash Engineers*, AIR1997 Delhi 79, held that “the plaintiff who has registered patents in India in 1984 but has not used them in India cannot, in equity, seek temporary injunction

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against the respondent.” The *Franz Xaver Huemer* decision was cited in *Sandeep Jaidka V. Mukesh Mittal*, 21 l (2014) DLT401 (Delhi High Court, 2014), to deny injunction to the plaintiff when “[t]here has been complete non-use of the patented invention by the plaintiff and *** the patented invention has not been used or licensed by the plaintiff to anyone in the world … .” In short, there are adequate safeguards in the Indian legal jurisprudence against patent abuse of non-working patents.

(2) **Should the submission of incorrect information in Form 27, knowingly or unknowingly, attract criminal prosecution and punishment of imprisonment?**

With the proposed changes in Form 27, limiting the request for information to that required for tracking patents related to drugs and with a provision that the failure to identify a certain patent related to a given drug would result in an “irrebuttable presumption” that the claims of the certain patent do not cover the given drug, there is no need for criminal prosecution or punishment even if there is incorrect information in Form 27. The party that would suffer from providing incorrect information would be the patent holder itself.

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33 The full decision is available at https://indiankanoon.org/doc/254672/.
34 The full decision is available at https://indiankanoon.org/doc/47594754/.
March 22, 2018

Mr. Ramesh Abhishek  
Secretary (IPP)  
Ministry of Commerce and Industry  
Udyog Bhavan  
New Delhi, India  
Secy-ipp@nic.in

Shri. O P Gupta, IAS  
Controller General of Patents  
The India Patent Office  
Mumbai, India  
cgoffice-mh@nic.in

SUBJECT: Supplemental Submission in Response to No.CG/Circular/2018/114 Dated March 16, 2016, on Working of Patents

On behalf of Gujarat National Law University, we, Dr. Raj S. Davé and Justice Asok Ganguly, made our first submission entitled “Form 27—India’s Opportunity for Tracking Patents Related to Drugs” on March 16, 2018, in response to the March 1, 2018, Circular entitled “Subject: Stakeholders Meeting regarding issues related to Working of patents under the Patents Act, 1970.” In our first submission we explained that in our viewpoint, the prevailing Form 27 does not fulfil the intent of law and, is particularly ambiguous and unclear. We proposed that India should develop a database called “Green Book,” to give generic pharmaceutical companies and the public a clear notice as to which patents are related to a drug and that Form 27 should be amended to minimize disclosure requirements for, and the accompanying burden on, non-pharmaceutical drug patent owners.

We forwarded our first submission to academics and stakeholders. We received outstanding comments. In this supplemental submission, we address these comments and suggestions.

We also request your office to allow us to participate in the Open House discussion on Form 27 scheduled at DIPP on April 6, 2018.

Thank you very much.

Sincerely,

Dr. Raj S. Davé  
Gujarat Council on Science and Technology  
IPR Chair Professor for Excellence at Gujarat National Law University (appointed)

Justice Asok Ganguly  
Former Supreme Court Justice of India and Adjunct Professor at Gujarat National Law University (appointed)
Comments

1. **Comment from Professor Srividhya Ragavan of Texas A&M University School of Law:** I like the idea of providing drug related information and creating a Green Book. But, I am not sure why it has to be provided under Form 27? I believe that Form 27 caters to a specific purpose of letting the India public aware of the supply of the drug within the Indian market. India can create separate requirement under the Drugs and Cosmetics Rules for creating what you are suggesting.

   **Our response:** We do not suggest deleting anything from Form 27 for drug related patents; instead, we suggest that Form 27 should ask for more information on drug related patents to create the Green Book. As the information contained in the Green Book is not intended for drug approval, but only to provide public notice as to which patents are related to a particular drug, we believe that there is no need to create the Green Book under the Drugs and Cosmetics Rules, though that is a possible option too.

2. **Comment from Professor Srividhya Ragavan:** I also think it is unworkable in India to have a FRAND type license for pharmaceuticals with the judiciary setting the fee, as you suggest. It may end up with endless appeals leaving the license fee to the predilections and perceptions of judges. I believe that such a license would merely be a system to avoid compulsory licensing. I would not advocate it when there is an abuse by a patent holder who controls a technological standard by not disclosing the patent information.

   **Our response:** We are advocating FRAND type licensing for non-pharmaceutical patents, not for Pharma patents.

3. **Comment from Professor Srividhya Ragavan:** I like the irrefutable presumption part for not providing all the information. I agree that it can hurt patent holders who do not provide all the necessary information. But, jurisprudentially, advocating no punishment for “knowingly abusing” by not providing information is not a good solution nor does it establish good governance standard. It sets a bad precedent.

   **Our response:** Attaching any type of criminal penalty for patent violation, whether it is against the patentee for patent misuse or against an infringer for patent infringement, is not a good idea. See paper entitled “Patent Infringement as Criminal Conduct” by Professor Jacob S. Sherkow of Law at the Innovation Center for Law and Technology, New York Law School. In the abstract of this paper, Professor Sherkow writes:

   Criminal law jurisprudence requires an intent element for three reasons: to ascribe a level of moral blameworthiness to an act, to separate criminal from civil liability, and to shield otherwise innocently acting defendants from criminal punishment. Patent

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1 Professor Srividhya Ragavan has published extensively on the Indian IP ecosystem. See [http://law.tamu.edu/faculty-staff/find-people/faculty-profiles/srividhya-ragavan](http://law.tamu.edu/faculty-staff/find-people/faculty-profiles/srividhya-ragavan).

infringement actions, by contrast, lack an intent element because they almost exclusively seek to remedy economic harms. The importation of criminal concepts of knowledge into the patent infringement statute may therefore lead to unwanted consequences, particularly, higher-than-warranted burdens of proof for patent holders. To this end, equating criminal mental states to civil ones risks treating patent infringement as criminal conduct.

4. **Comment from Professor Srividhya Ragavan:** If there is no criminal penalty, then what is the punishment for “knowingly abusing” Form 27 by not providing correct information?

5. **Our response:** If a patentee knowingly provides incorrect information on Form 27, then all patents listed on Form 27 and all related patents that claim priority to the patents listed in Form 27, such as divisional patents, should be held unenforceable. In the United States, the punishment for committing a fraud before the United States Patent & Trademark Office (hereinafter “USPTO”) is unenforceability of the patent. Unenforceability of a patent is a draconian punishment, but it is required for fair and honest dealing with the Patent Office. Under the heading entitled “Fraud, Inequitable Conduct, or Violation of Duty of Disclosure Affects All Claims,” the Manual for Patent Examination and Procedure (hereinafter “MPEP”) of the USPTO states:

   A finding of “fraud,” “inequitable conduct,” or violation of duty of disclosure with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid. [Emphasis added.]

6. **Comment from an industry stakeholder:** How should Form 27 address the issue where a patentee of a non-drug patent is genuinely not aware of which patents from a bundle of licenses are worked by the licensee?

   **Our response:** Dr. Davê, as a practicing patent attorney, is very familiar with this situation. To identify, for example, which patents out of a bundle of hundreds of patents related to a microprocessor is being worked is a daunting task to say the least. Thus, for non-drug patents, Form 27 should include the option “Not known to have been worked or not worked.” However, if the patentee ticks off the option “Not known to have been worked or not worked,” then the patentee should be obligated to provide information within a certain period, upon written request the Controller or any public, on the working or non-working of the patent for which the option “Not known to have been worked or not worked” has been exercised. The failure to provide this information should result in the patent at issue, i.e., the patent for which the option “Not known to have been worked or not worked” has been exercised and information on the working or non-working of the patent not provided, to be held unenforceable for fraud on the India Patent Office.

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7. **Comment from Professor Srividhya Ragavan:** I think abolishing Form 27 to establish a Green Book, by whatever name we call, is a bad idea. The purpose of Form 27 is very different from that of a proposed Green Book. Even if we establish a Green Book, Form 27 amended or otherwise, should stay.

**Our Response:** We are *not* advocating abolishing Form 27. To the contrary, we are recommending *more* information in Form 27 for drug related patents, but to minimize the information required for non-drug patents. For non-drug patents, the only information that should be requested in Form 27 should be:

The patented invention is:
[ ] Worked [ ] Not worked [ ] Not known to have been worked or not worked [Tick (√) mark the relevant box]

Attached is a proposed revised Form 27.
FORM 27
THE PATENTS ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON COMMERCIAL SCALE IN INDIA
[See Section 146(2); rule 131(1)]

| 1. Insert name, address and nationality. | In the matter of Patent No. ________, of ________________
|                                           | I/We _________________________________________________
|                                           | Nationality: ________

| 2. State the year to which the statement relates | The patentee (s) or licensee (s) under Patent No. ____________, hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year ________.

| 3. Drug related patent | The patent or patents listed herein are related to a drug (where “related to a drug” means that one or more claims in the patents cover (not just the specification describes) one of the following: active pharmaceutical ingredient (API), intermediate, drug product (i.e., finished formulation), process of manufacturing or use), then complete this section; if not, then skip this section and complete the next section under “Non-drug related patent.”
|                         | The patented invention is: 
|                         | [ ] Worked [ ] Not worked [Tick (✓) mark the relevant box]

(a) if not worked: reasons for not working and steps being taken for working of the invention: ____________________.

(b) If worked: quantum and value (in Rupees), of the patented product;
   (i.) manufactured in India
   (ii.) imported from other countries, (give country wise details)

(i) the licenses and sub-licenses granted during the year;
(ii) state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

Complete Table 1 entitled “Data on drug related patents for Green Book.”

The failure to identify a certain patent for making, using, selling, offering to sell, or importing a given drug shall result in an “irrebuttable presumption” that the claims of the certain patent do not cover the given drug, and thus cannot afford the patent owner the right to exclude others from making, using, selling, offering to sell, or importing the given drug.

To:
The Controller of Patents,
The Patent Office, At ....
4. Non-drug related patent

The patent or patents listed herein are not related to a drug as the term “related to drug” is defined above. The patented invention is:

[ ] Worked [ ] Not worked [ ] Not known to have been worked or not worked [Tick (√) mark the relevant box]

5. To be signed by the person(s) giving the statement.

The facts and matters stated above are true to the best of my/our knowledge, information and belief. A finding of “fraud,” “inequitable conduct,” or violation of duty of disclosure with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid.

Dated this

Signature........................................
Name:
Agent for Applicant Regd. No.: ....

Table 1: Data on drug related patents for Green Book

<table>
<thead>
<tr>
<th>Active ingredient:</th>
<th>Proprietary name of the drug:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage form and route of administration:</td>
<td></td>
</tr>
<tr>
<td>Strength:</td>
<td></td>
</tr>
<tr>
<td>Reference listed drug (Yes/No):</td>
<td></td>
</tr>
<tr>
<td>Reference standard drug (Yes/No):</td>
<td></td>
</tr>
<tr>
<td>Drug application number:</td>
<td></td>
</tr>
<tr>
<td>Drug approval date:</td>
<td></td>
</tr>
<tr>
<td>Drug applicant holder’s full name:</td>
<td></td>
</tr>
<tr>
<td>Marketing status</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patent Information</th>
<th>Claim number of claim that covers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent No.</td>
<td>Working</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To:
The Controller of Patents,
The Patent Office, At ....
COMMENTS ON ISSUES RELATED TO WORKING OF PATENTS UNDER
THE PATENTS ACT, 1970

INTRODUCTION:

The Lawyers Collective\(^1\), Delhi Network of Positive People\(^2\) and Medecins Sans Frontieres – Access Campaign\(^3\) working on addressing pharmaceutical monopolies to increase supply of affordable medicines to patients in India and across the developing world would like to make the following submission on the statement of working of patents for medicines in response to the Circular (No.CG/Circular/2018/114) dated 16.03.2018 issued by the Office of the Controller General of Patents.

Sections:

I. India’s commitment to right to health and access to medicines
II. Non-working under the Patents Act, 1970
III. Existing practice
IV. Example of Delamanid
V. Comments on Statement of Working of Patent
VI. Sample Form- 27 for Pharmaceuticals

I. India’s commitment to right to health and access to medicines

In the process of amending its laws to comply with the TRIPS Agreement, India faced the challenge of preventing price lowering generic competition from Indian generic pharmaceutical industry from being stifled. India utilized the flexibilities under the TRIPS Agreement to strike a balance between public health and monopoly rights of inventors. Such flexibilities *inter alia* included providing for pre-grant and post-grant opposition, stricter patenting standards in the form of Section 3(d) and provision for compulsory license.

In 2016, responding to a question in the Lok Sabha on 25.04.2016, the Minister of State (Independent Charge) of the Ministry of Commerce & Industry noted that, “*The government is committed to fully utilizing all the flexibilities provided under the TRIPS agreement to protect domestic pharmaceutical sector from pressure exerted by the foreign countries.*”

II. Non-working under the Patents Act, 1970

In order to ensure that patent rights are not abused the pioneer convention on protection of industrial property, viz. the 1883 Paris Convention for the Protection of Industrial Property provided for allowing legislative measures against patented invention that were not being worked sufficiently. The need to balance benefit to the society from the patented invention and patent rights was envisaged in the Patent and Design Act 1911 in India which provided for grant of compulsory licence.

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\(^1\) [http://www.lawyerscollective.org/](http://www.lawyerscollective.org/)
\(^2\) [https://dnpplusindia.wordpress.com/about/](https://dnpplusindia.wordpress.com/about/)
\(^3\) [https://msfaccess.org/](https://msfaccess.org/)
Later, the Justice N. Rajagopalan Ayyangar Committee Report, 1959 which examined the Patent law in India, discussed in detail, the requirement for working of the patent. The Committee Report had noted that the patents must fulfill the basic purpose of being worked in the country as soon as the patent is granted. The importance of working of patents related to medicines was also taken note of by the Ayyangar Committee Report which noted that, “...I would add in regard to these patents (for food and medicine etc.) is a provision for enabling them to be revoked if they are not adequately worked after a reasonable interval after they are sealed.”

A refusal or failure to share the working of the patent hinders scrutiny of trading practices that tend to be monopolistic, anti-competitive, and often detrimental to public interest.

The right of patent is based on the principal of quid pro quo. Therefore, in return for the exclusive right of patent, the patentee is expected to not only disclose the patent to the public but also work the patent.

Section 48 of the Patents Act vests in a patentee the exclusive right to prevent third parties making, using, offering for sale, selling or importing for those purposes the patented product, or product obtained from patented process, in India. This right is balanced against the requirement of disclosing the best method of performing the invention in Section 10 and requirement of submitting statement of working the patent as provided under Section 146 of the Patents Act.

Section 146(2) ensures that a check on working of patents is maintained by making it mandatory for a patentee and every licensee of the patent thereof to submit a statement of working of the patent to the Controller of Patents. Such statement is to be submitted periodically at an interval not less than six months. This statement, to be filed as per Form-27 provided under Schedule II of the Patents Act, 1970. The failure to furnish information such information, the same is punishable with fine extendable to ten lakhs under Section 122(1)(b).

Thus, Form-27 is instrumental in assessing whether the patentee is able to fulfill the reasonable requirement of the public with respect to the patented invention and ensuring that patents do not hinder public health related measures to be taken by the Central Government. Section 83(d)-(g) of the Patents Act also reiterate that general principles applicable to working of patented inventions include ensuring that the patents do not impede protection of public health. These provisions ensure that there is balance between India’s obligations under the TRIPS Agreement and interest of the Indian public. The Hon’ble High Court of Bombay in the matter related to grant of compulsory license in Bayer Corporation v Union of India AIR 2014 Bom 178 had observed that, “Manufacture in all cases may not be necessary to establish working in India as held by the Tribunal. However, the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India keeping in view Section 83 of the Act. This could be for diverse reasons but it would be for the patent holder to establish those reasons which makes it impossible/prohibitive for it to manufacture the patented drug in India.”

Thus, a requirement of submitting statement of working of patent ensures that any negative effect, such as unavailability of cheaper generic drugs, is mitigated by knowledge of the extent to which the patent is being worked, for effective application of the TRIPS flexibilities adopted under the Indian Patent Law.
In furtherance to fulfilment of its obligations under the TRIPS Agreement, India made several amendments to the Patents Act, 1970. Chapter XVI of the Patents Act in particular deals with “Working of Patents, Compulsory Licences and Revocation”. This chapter contains provisions related to non-working and compulsory license. Section 83 lays down general principles applicable to working of a patented invention. Relevant provisions are discussed below:

- Section 83(a) states that patents are granted to encourage inventions, and to secure that they are worked in India on a commercial scale, and to the fullest extent, and without undue delay.
- Section 83(b) states that patents are not granted merely to enable patentees to enjoy a monopoly for importation.
- Section 83(d) states that patents should not impede protection of public health or nutrition.
- Section 83(e) states that patents that are granted do not prohibit the Central Government in taking measures to protect public health.
- Section 83(f) states that patent rights should not be abused by a patentee by enabling practices which restrain trade or adversely affect international transfer of technology.
- Section 83(g) states that patents are granted to make the benefit of a patented invention available at reasonably affordable prices to the public.

To ensure that the patent is worked in India, the Patent Act under Section 85 provides that a patent for which a compulsory license has been granted may be revoked after two years from the date of grant of the compulsory license if the reasonable requirement of the public with respect to the patented invention has not been met or if the patented invention is not available to the public at a reasonably affordable price.

In fact, the intent of ensuring access to medicines and balancing patent rights with public health is clear in Section 92 of the Patents Act. Section 92 empowers the Central Government to notify a compulsory license in circumstances of national emergency, extreme urgency, or public non-commercial. The Act takes cognisance of the need to expedite access to the patented drug in case of a public health crises relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria and other epidemics and thereby allows the Controller under Section 92(2).

III. Existing practice

The statute vests in the Controller of Patents, the discretion to publish the information related to working of patent, as received by him. Third parties may access the Form-27 by filing an RTI application with the Controller of Patents. It is pertinent to point out that the Annual Report of 2014-15 published by the Office of the Controller General Of Patents, Designs, Trademarks and Geographical Indications reported that of the 43,256 patents that were in force, Form-27 of only 31,990 were filed. Of these only 7,900 patents were being worked. The numbers clearly indicate that patent rights are being used to merely create a monopoly that may harm the Indian manufacturers and market.
Further, even though the Patents Act provides for penalising the act of failure to file statement of working, till at least 2014, no action was taken by the Patent Office in this regard. In response dated 09.01.2014 to an RTI filed by Prof. Shamnad Basheer, the Asst. Controller, at Chennai Patent had noted that there was “no action initiated for non-submission of Form-27”. There is a clear lag in holding the patentee accountable for failure to work the patent.

In the context of public health and medicines, the information regarding the extent to which a patent has been worked is of utmost importance. Therefore, Form-27 becomes a source of information of non-working of patent that will facilitate any compulsory license related action for early access to medicines.

IV. Example of Delamanid

Delamanid is a recommended anti-TB drug which has been approved in the treatment for multi-drug-resistant (MDRTB) by the World Health Organisation (WHO). The 20th WHO Expert Committee further recommended including Delamanid to the WHO Model List of Essential Medicines (EML).

In India, Otsuka Pharmaceuticals holds six patents for Delamanid, its intermediate, formulation and combination. These are - patent no. 250365 that claims Delamanid, patent no. 219525 and 248249 that cover early nitroimidazole (used to make Delamanid) and methods of their preparation, patent no. 244643 that covers intermediaries to make nitroimidazole compounds, patent nos. 253642 and 268015 that cover pharmaceutical compositions comprising Delamanid. A perusal of the latest Form-27 (statement regarding working the patent in India) filed for each of the patents by Otsuka at the Patent Office, shows that Otsuka has not worked any of their patents on Delamanid in India.

<table>
<thead>
<tr>
<th>Patent No.</th>
<th>Date of grant of patent</th>
<th>Status of working the patent (date of Form-27)</th>
<th>Reason given for non-working in Form-27</th>
</tr>
</thead>
<tbody>
<tr>
<td>250365</td>
<td>December 29, 2011</td>
<td>Not worked (March 21, 2016)</td>
<td>Market under survey</td>
</tr>
<tr>
<td>219525</td>
<td>May 7, 2008</td>
<td>Not worked (March 24, 2015)</td>
<td>Not provided</td>
</tr>
<tr>
<td>248249</td>
<td>June 29, 2011</td>
<td>Not worked (March 15, 2013)</td>
<td>Conducting market research</td>
</tr>
<tr>
<td>244643</td>
<td>December 14, 2010</td>
<td>Not worked (March 24, 2015)</td>
<td>Not provided</td>
</tr>
<tr>
<td>253642</td>
<td>August 8, 2012</td>
<td>Not filed</td>
<td></td>
</tr>
<tr>
<td>268015</td>
<td>August 12, 2015</td>
<td>Not worked (February 15, 2016)</td>
<td>Under consideration for commercialisation of patented invention</td>
</tr>
</tbody>
</table>

Clearly, the Form-27 indicates that the patent has not been worked and gives incomplete reasons for failure to work.

V. Comments on Statement of Working of Patent

Section 146(2) of the Patents Act imposes a duty on every patentee and licensee to furnish statement on working of the patent. This obligation is imposed on exclusive and non-exclusive licensees as well as parties who have been granted a compulsory license.
We submit that this duty, particularly in case of pharma products should be strictly fulfilled. This requirement help identify whether the patent is helping knowledge transfer and/or providing means to introduce innovative and life-saving pharma products in the Indian market.

On Form-27

Attached with this submission is a proposed format for Form-27 for Pharmaceutical products. Below we detail out the rationale for including certain details to be furnished under the suggested format of Form-27.

Pharmaceutical products may be patented in the form of the basic API or the final formulation. Any new drug can only be marketed in India only post approval from the Drug Controller General of India (DGCI) after submitting the results of mandated clinical trials. Therefore, the working of a patent related to a pharmaceutical product is subject to regulatory approvals. The statement of working for a pharmaceutical product must therefore specify whether an application for approval has been made with the DGCI. If an application for regulatory approval has been made, the patentee must indicate at what stage is the application is. If the application for approval has been rejected, the same should also be indicated in the statement of working.

The form also seeks information on whether the patent has been worked to ensure that public requirement has been met partly/adequately/to the fullest extent at reasonable price. In order to ensure that requisite information is provided in this regard, the Patent Office must provide guidelines that information in this regard must include-

i. INN name and marketing name of the patented product (for facilitate identification of the drug);
ii. Price at which the patented product is made available to the public;
iii. units required per patient per month;
iv. Whether regulatory approval has been granted;
v. If not, whether such an application has been made;
vi. Details of regulatory approval application process;
vii. If regulatory approval has been refused, reasons for the same;
viii. Formulation/strength of dosage approved for marketing;
ix. Price per unit, if patent is for dosage form;
x. Price per pack and number of doses per pack;
xi. Number of packs sold annually;
xii. Price per kg if patent is for API form;
xiii. Quantity of patented (API) sold;
xiv. Quantity approved for sale (in case of API);
xv. Quantity of patented product manufactured by the patentee in India;
xvi. Quantity of patented product manufactured under contract manufacturing;
xvii. Quantity of patented product manufactured under voluntary license to generic manufacturers.

Often, the patent is made available to the Indian public by importing the patented product and not through local manufacture of the patented product. In such a scenario it becomes imperative to indicate:

i. the amount of the patented product that has been imported;
ii. country from where it is imported;
iii. Number of quantum of imported patented product sold.
Section 146(2) clearly provides that the statement of working has also to be provided by all exclusive and non-exclusive licensees. Therefore, either each of the licensees should file a separate Form-27. In the alternate, the patentee filing Form-27 shall provide every detail required under Form-27, with respect to each of the licensees.

**On imposing penalties**

Section 122 sets out penalties for non-compliance with Section 146, or for filing information knowing that such information is false or erroneous. However, there is no set guideline or infrastructure to ensure that is a constant review of compliance of duty under Section 146(2).

Therefore, it is imperative that the Patent Office sets up an internal committee which would annually review whether the statement of working has been filed and take action on failure to comply with the requirement under Section 146.

Further, the Patent Office may also consider taking cognisance of failure to file Form-27 on the basis of any complaint by any person who bonafide believes that Form 27 has not been filed. The Patent Office may thereafter give an opportunity to the patentee to respond to the complaint. After the hearing the patentee, the Patent Office may make decide to order payment of fine as under Section 122(1) (b) of the Patents Act.
VI. SAMPLE FORM 27 FOR PHARMACEUTICALS

<table>
<thead>
<tr>
<th>FORM 27 (PHARMACEUTICALS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>THE PATENTS ACT, 1970</td>
</tr>
<tr>
<td>(39 OF 1970)</td>
</tr>
<tr>
<td>&amp;</td>
</tr>
<tr>
<td>The Patents Rules, 2003</td>
</tr>
</tbody>
</table>

No fee

**STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON COMMERCIAL SCALE IN INDIA**

*See Section 146(2) and rule 131(1)*

In the matter of Patent No. ___ of __
I/We  .............................................................
                                                                                     .............................................................

The patentee(s) or licensee(s) under Patent No. ...... hereby furnish the following statement regarding the working of the patented invention referred to above on commercial scale in India for the year5 ....

The patented invention6:

<table>
<thead>
<tr>
<th>(___) Worked</th>
<th>(___) Not worked</th>
<th>[Tick (√) mark the relevant box]</th>
</tr>
</thead>
</table>

(a) If not worked: reasons for not working and steps being taken for working of the invention.

<table>
<thead>
<tr>
<th>Product name (INN name, if available)</th>
<th>Under clinical trials</th>
<th>Under regulatory review (details)</th>
<th>Approval refused due to safety/efficacy concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(b) If worked: quantum and value (in Rupees), of the patented product:

**For patented product that is marketed in dosage form**

<table>
<thead>
<tr>
<th>Product INN Name /Marketing Name</th>
<th>Formulation/strengths (Approved)</th>
<th>Single Per Unit price</th>
<th>Per pack price (mention how many doses per pack)</th>
<th>Packs sold annually</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**For patented product that is marketed in API form**

<table>
<thead>
<tr>
<th>Approved quantity for sale</th>
<th>Price per kg</th>
<th>Quantity of API sold annually</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(i) manufactured in India

<table>
<thead>
<tr>
<th>Patented medicine manufactured by Patentee</th>
<th>Patented medicine under contract manufacturing</th>
<th>Under voluntary license to generic manufacturer/s</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4 Insert name, address and nationality.
5 State the year to which the statement relates.
6 Give whatever details are available.
(i) Imported from other countries. (give country wise details)

<table>
<thead>
<tr>
<th>Name of the country</th>
<th>Quantity of API imported/Number of doses imported</th>
</tr>
</thead>
</table>

(ii) the licences and sub-licences granted during the year;

<table>
<thead>
<tr>
<th>Exclusive/Non-exclusive</th>
<th>List of API licensees</th>
<th>List of finished formulations</th>
<th>Royalty rate</th>
<th>Geographical scope of license</th>
</tr>
</thead>
</table>

(iii) State whether public requirement has been met partly/ adequately/ to the fullest extend at reasonable price.

The facts and matters stated above are true to the best of my/ our knowledge and belief.

Dated this ___ day of ____ 20__

Signature

To
The Controller of Patents,
The Patent Office,
at _____

Note: Strike out whichever is not applicable.

7 To be signed by persons(s) giving the statement.
Historical Background:

It is understood that there were 2,237 licensed drug manufacturers in India in 1969-70, of which 80-90% were foreign multinational companies and for various reasons most of the patents were not worked in India.

The government was of the opinion that the mandatory working requirement and the removal of the product patent regime in the pharmaceutical arena would make medicines available to the Indian people at large. This led Government to amend Indian Patents Act by incorporating provision (section 146) re submission of working statements.

The underlying Patent Policy providing impetus to the Indian Patent law has been mainly oriented towards the pharmaceutical industry since independence.

After independence, Indian Patent law was not changed and given the high prices of pharmaceutical components and medicines in the country a national-level committee was commissioned in 1948 under the chairmanship of Dr. Bakshi Tek Chand, a retired High Court judge. This was the first national committee which addressed the patent law and led to the formation of a number of national pharmaceutical companies (e.g. Hindusthan Antibiotics Limited in 1954 and Indian Drugs and Pharmaceutical Limited in 1961).

With the continued high prices of medicines, another national level committee was commissioned in 1957 under the leadership of Justice N. Rajagopala Ayyangar, which later became well known as the Ayyangar Committee. The Committee emphasized on Art. 21 of the Indian Constitution (which guarantees to its citizen the right to life and good health) in light of the medicine prices and studied Patent laws of different countries.

With inputs of the Ayyangar Committee the Patents Bill 1965 included provisions for the Working requirement (also removed product patents for pharmaceuticals, shortened process patents for pharmaceuticals to seven years and introduced compulsory licenses). The Patent Bill of 1965 was passed by the Lok Sabha (lower chamber) but lapsed in the Rajya Sabha (upper chamber) of the parliament and finally it was passed and the Indian Patent Act 1970 (Act No. 39 of 1970) became effective in April 1972 with the adoption of the Patent Rules in 1971.

Thus, the provision of statement of working was introduced primarily as a safeguard against abuse of patent rights by patent holders in the pharmaceutical domain, so as to enable availability of medicines in sufficient quantities and at reasonable pricing. The statement of working requirement combined with the compulsory license provision would serve as another safeguard to prevent monopolistic behavior of patent holders, and especially pharmaceutical patent holders, and enable easy access of medicines to public at large.
It has been over 45 years since the inclusion of section 146 in the Patents Act, which is outdated and is no more desirable in context of changing industry dynamics because today India has emerged as the world’s best pharmacy. There already exist sufficient provisions in the Patents Act that may be invoked in case of abuse of patent rights by patent holder (such as pre-/post grant opposition u/s 25; Compulsory license u/s 84; revocation of patent due to non-working u/s 85; use of patented invention for Government use and acquisition u/s 99 and 103); revocation of patent u/s 64; revocation of patents in public interest u/s 66). There is thus a need to re-look into section 146 and consider removing it from the patent statute.

Further, current Form 27 does not fit well with the way ICT patents are worked. In the context of ICT patents where one product may involve multiple (portfolio) of patent or one/multiple patents may be covered into multiple products. Thus, patent-wise apportionment of the product’s price is not possible, and hence the extent of working of each patent in terms of quantum and value made available in the Indian market is difficult to estimate.

Is it technically not feasible for a patentee to rip apart/disassemble each product (billions in number) to then find out which of the patents from the portfolio so licensed have been worked. There is no other country that has similar working requirements. Working Statement in India is potentially impacting foreign licensing deals too as there is always a potential threat of calling for detailed licensing terms and conditions under a PIL (Public Interest Litigation) which are confidential and contain business sensitive information. Considering immense/unnecessary burden (immense engineering working hours) and compliance cost besides increased risk of depriving licensees/licensors from retaining confidential business information will rather hurt public interest as diffusion of technology through licensing will become difficult. Licensees and licensors will not be able to negotiate freely and voluntarily being under constant threat that their confidential information can be easily accessed by third parties including business rivals.

Further, for SMEs/Startups, Section 146 coupled with penal provisions under section 122 not only impinges on ease of doing business but will also deter domestic patent filings. Compliance with Form 27 comes with huge administrative burden and cost. Start-ups are under continued threat of being exposed to legal repercussions in case any third-party mala fide raises allegations of non-compliance with existing Form requirements. Working statement requirements is also anti-thetical to the Special patent regime, launched by Finance Minister in year 2016 that aimed at boosting domestic patent filings.

**Existing Form 27 is not attuned to changing Industry Dynamics**

Basic principles of working of inventions are listed under Section 83. Thus Section 146 and Rule 131 empowers the Controller to request for information about working of patents in India strictly for the purposes mentioned under Section 83. However, nothing mentioned in Form 27 would enable the Controller in determining the considerations prescribed under Section 83.

Further, existing Form 27 is archaic, especially in the sense it considers one product would be a result of a single patent, and is not attuned to changing industry dynamics. Moreover, the provision of statement of working is aimed primarily towards ascertaining whether a patented invention serves the public benefit.
or not and brings in a socialistic approach to Indian patent law. However, there may be many inventions which may not relate to this approach. For example, working related information regarding an invention on the bearing inside an engine assembly which has no relevance in maintaining public health, safety and saving public life may have no real-world significance.

Existing Form 27 is not aligned to the afore-said changing Industry dynamics and deserves consideration for appropriate amendments by IPO. In addition, Form 27 needs to be amended in light of the purpose of usage of the information being sought and the end-consumer of the said information. For instance, working related information of a patent in ICT sector could only be useful for a potential licensee and is not as such required by an individual member of public as such. The vast extent of information asked for in Form 27 is at times unnecessary while being impractical to collate/collate. In view of the afore-said, we are highlighting below some of the concerns faced while complying with existing requirements and propose some changes.

Concerns:

i. Portfolio Licensing:
Existing Form 27 is based on presumption that one product is equivalent to one patent. However, such a model is non-existent in ICT sector where one product is not based on one patent but is actually covered in portfolio of patents and such portfolios are owned by different Patentees. For example, mobile phones, tablets, smart watches etc. which might incorporate multiple inventions covered in multiple patents. The existing working statement is required to be filed individually for each patent, which might suit in case of pharmaceutical inventions but not for ICT sector.

Solution Proposed:

a. Provision should be there in Form 27 for single statement for multiple patents. It may be kindly borne in mind that there may be cases where the patent portfolio, of which the patent in questions is a part, is huge and thus all numbers cannot be provided. It would be better to suggest that instead of providing the numbers of all patents being worked together, a simple statement may be given stating that the patent is worked not singly but in a portfolio, and details of all such patents can be provided when asked for.
b. Specifying that the single patent forms a part of the portfolio license.

ii. Existing requirements impinges upon Confidentiality:

Under a Licensing model, the IP owner is under a contractual obligation to keep important business data concerning licensees as confidential. Form 27 impinges upon that “confidentiality obligation” required to be maintained by licensors and licensees alike. Each license agreement is unique and no licensee would prefer its confidential information to be disclosed to third parties which are its business rivals. Any such disclosure in Form 27 with regard to commercial arrangements shall seriously prejudice interests of licensee as well as
licensor. Such information may be misused by unwilling licensees to gain competitive advantage over willing licensees. This can also be misused by unwilling licensees to get this important data out in public domain. This will increase litigation costs substantially where IP owner will be sued by licensees for the breach of confidentiality or for not been able to secure confidential business information such as sales figures, anticipated revenue/profit. This will threaten businesses, hurt global licensing model and will potentially chill innovation cycle.

PIL (Public Interest litigation) that calls for seeking much detailed information on licensing terms including payments/royalties, is against the letter and spirit of the Patents Act that respects confidentiality. Following points may be noted in this regard.

- In some recent patent infringement cases involving Standard-Essential Patents (SEPs-standards such as 3G/4G encumbered by patents held by multiple companies), Indian courts have ordered “confidentiality clubs” so that confidential information on licensing terms and other information such as claim charts may not be disclosed.
- Proviso to Section 69(4) mandates non-disclosure of registered PLAs when accompanied with a confidentiality request at the time of such registration through FORM 16.
- the Ayyangar Report emphasizes the importance of confidentiality of PLAs in Para 760 by stating that “[t]o allay any fears regarding disclosure of trade secrets the clause might provide that the terms of the agreement filed before the Controller should be kept confidential and should not be open to public inspection except under the orders of Court on the lines of Section 49 (5) of the Trade and Merchandise Marks Act, 1958 in respect of agreements as to registered user.

**Solution proposed:**

a. Given the fact that some of the information that need to be furnished are business/commercial information and not necessarily on whether the patents are worked or not (e.g. related to licenses and sub-licenses granted, etc). The working statements ought not mandate the disclosure of amount of revenue or license fee earned by working a patent. Thus, patentees should be asked to provide such information only if a specific request is made by patent office and that too under a confidentiality arrangement.

b. Further, while the requirement of notifying whether worked through manufacturing or licensing or by importation (discussed above in ii. & iii.) could be retained but the requirement for providing quantum and valuation needs to be removed.

iii. **Filing requirements increases burden of compliance and substantial work load and Paper work**

Filing of Form 27 for all patents is mandated every year even for those patents for which the working statements have been filed the previous year apart from paying the maintenance fees and other fees. This unnecessarily increases paperwork and engages considerable time. As can be seen from the data/table below, the rate at which ICT related filings are done at
IPO are growing at a substantial rate. Thus, filing working statements for each patent, so
grounded, until the time it is expired increases immense pressure on IP owners and also impacts
Ease of Doing Business in India. Furthermore, requiring patentees to spend enormous
resources to gather and provide detailed financial data every year, tilts the balance, as held
by The Delhi High Court in the Natco Pharma v. Bayer.

Table

<table>
<thead>
<tr>
<th>S. No</th>
<th>Year</th>
<th>No of Patent Application Filed</th>
<th>% Increase/Decrease over previous FY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2011-12</td>
<td>8615</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>2012-13</td>
<td>8587</td>
<td>0.3%</td>
</tr>
<tr>
<td>3</td>
<td>2013-14</td>
<td>8449</td>
<td>1.6%</td>
</tr>
<tr>
<td>4</td>
<td>2014-15</td>
<td>8665</td>
<td>2.6%</td>
</tr>
<tr>
<td>5</td>
<td>2015-16</td>
<td>11758</td>
<td>36%</td>
</tr>
</tbody>
</table>

Source: Annual Report 2015-16 of Indian Patent & Trade Marks Office – Appendix E. The numbers
indicated in the table is cumulative of the following fields of invention – Computers/Electronics” &
“Communication”

Solution Proposed 1:

There should be two sections of the form, one for first time filing (for patents granted within
the last three years) and another section for those cases where the working statement had
already been filed in the previous year and being continued. There might be a sub-section in
this section for those cases in which the mode of working has changed (e.g. from
Manufacturing to Licensing).

Solution Proposed 2:

It is suggested in the multiple options (in range form) in the Form, for entering the value of
quantum of goods sold as well as for the revenue achieved by the Patentee during the financial
year.

iv. Difficulty in determining whether the patented invention has been worked or not:

There are sometimes large portfolio of patent applications that are pending before the Indian
patent office for patentees and in respect of patents granted to the patentees worldwide, and
an equally large portfolio of products developed and sold in India and abroad. Thus, the
patentees often find it extremely difficult to provide extensive details of how the invention of a given patent has been worked in India in all the products of all its licensees.

Moreover, this practical difficulty is aggravated in a situation where patented invention(s) is/are being worked by licensee(s), especially those having worldwide sales in many jurisdictions. For licensees having huge scale of operation in each jurisdiction, it would be difficult to estimate which of the licensed patents are being used in products available in each jurisdiction, and also apportionment of each licensed patent being used in the product.

Solution proposed: Therefore, in case Form 27 is mandated, the Applicant should be allowed to file a simple FORM 27 indicating whether an invention has been worked or not along with providing exemplary details AND NOT EXHAUSTIVE. Further, a patentee can only provide details of adequate working and affordable pricing from its perspective and also the feedback received in general. Thus, a patentee ought to be permitted to aver that we have not received any feedback from anyone in India that the patented invention is not available in India adequately or at affordable price.

v. Difficulty in determining whether the patented invention met public requirement partly / adequately / to the fullest extent:

For reasons explained above, it is extremely difficult to collate the data that would enable the patentees to conclusively select any one of the categories mentioned in Form 27.

Therefore, in case Form 27 is mandated, the Applicant should be allowed to write the following: “patentee can provide the aforesaid details from its perspective and the feedback received by it”.

Solution Proposed- The Form - 27 declaration merely requires patentees to state whether or not the reasonable requirement of the invention to the public have been met. Further, the Government should require the Patentee to provide information in a yes or no format for the working of patents, without the need to provide the exact quantum of goods/revenue. The burden of proof of working should be left on the Patentee, if called upon by the Controller or application of third parties for Compulsory Licensing (CL) or on the discretion of the Controller.

Conclusion:

Laws and supporting Rules and Regulations are dynamic in nature and address the economic and social requirements of the people.

The filing of Form 27 is embedded in the Patent Rules and follows the statutory intent of the Controller obtaining information on how the Patents are worked within and after three years of the grant.
It is important to keep in view the fact that India’s innovation has expanded beyond pharmaceuticals and the contribution of other industries, e.g., ICT, electronics, automobiles, renewable energy, among others is significant. The case of ICT industry is worth noting since it has not only helped India to gain global prominence as a software major, but has enabled advanced wireless technology products to be available at the most reasonable prices.

Considering the changing industry dynamics and development of new business models, existing Form 27 requirement has become redundant, burdensome, hampers ease of doing business, makes commercialization of patented invention more difficult and is not aligned to international best practices. There is thus an urgent need to remove section 146 (working statement requirement from statute book). While, such a change in the law may take some time, meanwhile, may we request patent office to consider updating the Patent Rules and amend ‘Form 27’ in a manner that cater to the emerging technological fields.

*******
GNA/AF/123/17-18

16th March, 2018

To,

Shri Om Prakash Gupta,
Controller General of Patents, Designs & Trade Marks
Office of The Controller General Of Patents, Designs & Trade Marks,
Boudhik Sampada Bhavan, Near Antop Hill Post Office,
S.M.Road, Antop Hill, Mumbai – 400 037

Respected Sir,

Sub: Stakeholders Meeting regarding issues related to Working of patents under the Patents Act, 1970.

This has reference to the Notice bearing No.CG/Mtting Circular-DIPP/2018/14 dated 1st March, 2018 inviting stakeholders to submit comments on the issues relating to working of Patents i.e. Section 146 of the Patents Act 1970 (as amended) read with Rule 131 of Patent Rules 2003 including Form 27, and penal provisions provided in Section 122.

We are of the opinion that Section 146 and Rule 131 may be retained as such, without any amendments. As regard Form 27, we suggest as follows;

Under paragraph 3(i)(b) If worked: quantum and value (in Indian Rupees), of the patented product, the following criteria may be adopted to declare the values in Rs. (i) If manufactured in India

1. The invoice value excluding taxes and other levies may be declared as such against the quantum of sale. While the quantum of sale / number
of units is quantitative, the value may vary invoice to invoice, total of which may only be declared.

2. The total net value of invoices for the calendar year may be declared, if manufactured in India.

3. Declaration on ex-factory costs basis or on any other criteria (other than invoice value) may not be verifiable.

(ii) imported from other countries. (give country wise details)

Net import value in relevant foreign exchange country-wise converted into Indian Rupees on prevailing conversion rate may be declared for imported consignments (The declared value need to be NET of all levies and handling charges). It is suggested that such declaration may be counter-signed by chartered accountant.

Thanking you in anticipation.

Yours faithfully,

Dr. Gopakumar G. Nair
(Reg No. IN/PA 509)
Gopakumar Nair Associates

Pune (Mrs. Srividya Ravi - Mobile: 09860010252)

In Association with leading Patent and Trademark Attorneys globally.
REF: LHKAC/FOR-27- Suggestions/2018
March 16, 2018

To,
The Controller of Patents
Intellectual Property Office
Boudhik Sampada Bhawan
Near Antop Hill Post Office
S.M. Road Antop Hill
Mumbai-400 037

Kind attn.: Dr. W. M. Dhumane/Dr. Usha Rao

Subject : Comments or suggestions on the issues relating to working of patents i.e. section 146 of the Patents Act 1970 (as amended) read with Rules 131 of Patent rules 2003 including form-27 and Penal provisions provided in Section 122

Respected Sir,

With reference to the above stated subject, and as per circular of the Controller General of Patents, Designs and Trademarks dated March 1, 2018 with reference numbered CG/Meeting Circular-DIPP/2018/14; we are sending herewith our comments/suggestions as mentioned below.

1. Working of Patented invention requirement should not view with respect to healthcare point of view only. The working requirements which are going to be imposed by the amendment in Form 27 would be effective to the all technical fields.
2. If the invention is not work then in that case along with asking for reason for non-working the facility should be provided to the patentee whether the patentee wished to display his patent on list which shows about PATENT OPEN FOR LICENSING. This will encourage the Patentees who are not able to make the invention workable by themselves.
3. It is important to define whether the patent is for product or process.
4. We believe that as far as working or patent is concern the Patentee/Licensee has to disclose whether the patent is working or not instead of mentioning amount of manufactured product as Patentee/Licensee does not wish to disclose their confidential information to the public. According to our opinion one of the reasons for not filing working statement is that Patentee/Licensee does not wish to disclose their confidential information.
5. In the case of product patent (e.g. mechanical product patent) it may possible that only part of the whole product is patented. Hence, it is not possible to
provide “value” of the patented part and also providing “value” of whole product is also not correct.

Even for the pharmaceutical patent i.e. NCE / composition patent the term “value” is very vague as the patent might not relate to finished product that the customer buy from the market.

Hence, we believe that the “value” requirement varies case to case so on receiving demand from the third party the Controller should scrutinize the demand and ask for specific information from the Patentee as he deems to fit.

LICENCE AND SUBLICENCE INFORMATION

6. Following information should be asked if license has been issued:

- Name of the Licensee /Sub-Licensee
- License date
- License duration
- Type of License i.e. manufacturing, selling, marketing, importing, packaging or any other
- According to the License Agreement whether or not licensee is having duty to submit Form 27?

We are strongly in favour that Patentee/ Licensee should have reservation of right to disclose confidential terms of the agreement with the Patent office. Such confidential terms would only be disclosed when the dispute arises.

ONE PATENT ONE PRODUCT

7. We are strongly not in favor that working requirement should capture all potential manifestations of the patent i.e. the patentee should disclose all the technologies, applications and product where the patent is so deployed or used. The reason for that is such that in the case of pharmaceutical/biotechnological product there is least chance that one active ingredient / NCE/ Composition is deploy or used in any other product.

For, the rest of the technical field same thing is applicable for the patentee to provide such information.

U/S 10 (4) (a) it is mandatory that specification must fully and particularly describe the invention and its operation or use and the method by which is to be preformed. Hence, application i.e. use of the invention is mentioned in the
complete specification. So, there would not any doubt about the final product in which the invention is used.

Considering these it would be sufficient to provide information about product in which the Patented product/process is used rather than providing all the technologies, applications and product where the patent is so deployed or used.

DEMAND
8. Whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

a) “Reasonable Price” of the pharmaceutical/biotechnical drug should be in purview under the “National Pharmaceutical Pricing Authority”. For the other technical field it should be decided on case to case basis.

b) Regarding meeting the demand of the invention/patent the burden should not be on the shoulder to the Patentee. One has to keep in mind that alternative products are available in all the technical fields.

In case of pharmaceutical industry, different generations of drugs are available.

E.g.

*Therapeutic category: Antibiotic*

*Drug Name: Cephalosporin*

*First Generation: Cefazolin*
  - Cefalexin
  - Cefadroxil

*Second Generation: Cefuroxime*
  - Cefotiam
  - Cefuroxime axetil
  - Cefaclor
  - Laracarbet

*Third and Fourth Generation: Cefotaxime*
  - Ceftriaxone
  - Cefepime
  - Cefixime
  - Proxetil

*Fifth Generation: Ceftobiprole (Effective for MRSA)*

Further, the treatment with the drug is supervised by Doctors and requirement and type of the drug varies patient to patient and stage to stage. There are incidences the Patient may develop drug resistance of
the higher generation drug/patented drug. (See Attached Annexure-I
Resistance to sunitinib in renal clear cell carcinoma results from
sequestration in lysosomes and inhibition of the autophagic flux) Hence,
in those cases patented product might not be required.

Considering all these it would be better if the patentee has leverage to
provide information about the number/information of similar product/
alternate product available in the same technology.

**NO NEGLECTFUL CONDUCT**

9. We also strongly believe that the patentee should not demonstrate the
NEGLECTFUL CONDUCT as far as India is concerned. In that case on
receiving demand from the third party the Controller may ask for the foreign
patent working data.

Thanking you,

Sincerely yours,
For, Law Office of

\[HK\text{ \textregistered} \text{ACHARYA \& COMPANY}\]

Dr. Rajeshkumar H. Acharya
Advocates & Patent Agent
(IN/PA -134)

Encl.: Annexure-I
Resistance to sunitinib in renal clear cell carcinoma results from sequestration in lysosomes and inhibition of the autophagic flux

Sandy Giuliano, Yann Cormerais, Maeva Dufies, Renaud Grépin, Pascal Colosetti, Amine Belaid, Julien Parola, Anthony Martin, Sandra Lacas-Gervais, Nathalie M Mazure, Rachid Benhida, Patrick Aubger, Baharia Mograbi & Gilles Pagès

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Resistance to sunitinib in renal clear cell carcinoma results from sequestration in lysosomes and inhibition of the autophagic flux

Sandy Giuliani,1 Yann Cormerais,2 Maeva Dufes,1 Renaud Grépin,2 Pascal Colosetti,3 Amine Belaid,1 Julien Parola,4 Anthony Martin,5 Sandra Lacas-Gervas,5 Nathalie M Mazeure,1 Rachid Benhida,5 Patrick Aubéger,3 Baharia Mograbi,1 and Gilles Pagès1,*

1University of Nice Sophia Antipolis; Institute for Research on Cancer and Aging of Nice; UMR CNRS 7284; INSERM; Nice, France; 2Centre Scientifique de Monaco; Biomedical Department; Monaco, Principality of Monaco; 3University of Nice Sophia Antipolis; Center Méditerranéen de Médecine Moléculaire; INSERM; Nice, France; 4Centre Antoine Lacassagne; Nice, France; 5University of Nice Sophia Antipolis; Institut de Chimie de Nice; UMR CNRS 7272; Nice, France; 6University of Nice Sophia Antipolis; Center de Microscopie Appliquée; Nice, France

Keywords: angiogenesis, elacridar, Leu-Leu-O-Methyl, lysosome, proteasome inhibitors, renal cell carcinoma, resistance, sunitinib

Abbreviations: ABCB1, ATP-binding cassette, sub-family B (MDR/TAP), member 1; ATF4, activating transcription factor 4; CTSB, cathepsin B; CHL, chloroquine; EEA1, early endosome antigen 1; FACS, fluorescence-activated cell sorting; HBSS, Hank’s balanced salt solution; IC50, concentration of a drug that gives 50% inhibition of cell proliferation; LAMP1/2, lysosomal-associated membrane protein 1/2; MAP1LC3A/LC3A, microtubule-associated protein 1 light chain 3 α; MAP1LC3-II/LC3-II, lipidded forms of LC3; LLOM, Leu-Leu-O-methyl; MAPK1/2/3, mitogen-activated protein kinase1/2/3; mRCC, metastatic renal cell carcinomas; NAA10/ARD1, N(α)-acyetyltransferase 10, NatA catalytic subunit; PSMB8/9/10, proteasome (prosome macropain) subunit, β type 8/9/10; PSMF1, proteasome (prosome macropain) inhibitor subunit 1 (P131); SQSTM1/p62, sequestosome 1; V-ATPase, vacuolar-type ATPase; VEGFA/C, vascular endothelial growth factor A/C.

Metastatic renal cell carcinomas (mRCC) are highly vascularized tumors that are a paradigm for the treatment with antiangiogenesis drugs targeting the vascular endothelial growth factor (VEGF) pathway. The available drugs increase the time to progression but are not curative and the patients eventually relapse. In this study we have focused our attention on the molecular mechanisms leading to resistance to sunitinib, the first line treatment of mRCC. Because of the anarchic vascularization of tumors the core of mRCC tumors receives only suboptimal concentrations of the drug. To mimic this in vivo situation, which is encountered in a neoadjuvant setting, we exposed sunitinib-sensitive mRCC cells to concentrations of sunitinib below the concentration of the drug that gives 50% inhibition of cell proliferation (IC50). At these concentrations, sunitinib accumulated in lysosomes, which downregulated the activity of the lysosomal protease CTSB (cathepsin B) and led to incomplete autophagic flux. Amino acid deprivation initiates autophagy enhanced sunitinib resistance through the amplification of autolysosomes formation. Sunitinib stimulated the expression of ABCB1 (ATP-binding cassette, sub-family B [MDR/TAP], member 1), which participates in the accumulation of the drug in autolysosomes and favor its cellular efflux. Inhibition of this transporter by elacridar or the permeabilization of lysosome membranes with Leu-Leu-O-methyl (LLOM) resensitized mRCC cells that were resistant to concentrations of sunitinib superior to the IC50. Proteasome inhibitors also induced the death of resistant cells suggesting that the ubiquitin-proteasome system compensates inhibition of autophagy to maintain a cellular homeostasis. Based on our results we propose a new therapeutic approach combining sunitinib with molecules that prevent lysosomal accumulation or inhibit the proteasome.

Introduction

A large number of drugs currently used in the clinic are weak bases that make them lysosomotropic. These drugs are extensively sequestered in acidic lysosomes through an ion-trapping mechanism. Drug accumulation in lysosomes is driven by the large pH gradient that exists across the lumen of the organelle and the cytosol. Lysosomal sequestration can directly influence the activity of the drug by preventing its availability to bind with intended intracellular targets. In addition, some cancer cells have acquired an enhanced ability to sequester anticancer drugs in lysosomes, which constitutes a mechanism of drug resistance. The clear cell form of kidney cancers, the most represented one, is characterized...
by VHL/von Hippel-Lindau mutations and deletions which lead to stabilization of HIF1A (hypoxia inducible factor 1, α subunit [basic helix-loop-helix transcription factor]) protein and consequent overexpression of VEGFA (vascular endothelial growth factor A). This feature has rendered mRCC attractive targets for the treatment with antiangiogenesis drugs, particularly with the development of tyrosine kinase inhibitors targeting the VEGF (KDR, FLT1, FLT4) and the PDGF (PDGFRB) receptors, both implicated in proliferation of endothelial cells and pericytes. These inhibitors include notably sunitinib,\(^1\) which since 2006 is considered as the standard first line treatment option for this disease. Hence, we have analyzed the tumor cell fate with chronic exposure to the drug. Such a question may seem inappropriate since sunitinib was originally defined as an antiangiogenesis compound that inhibits endothelial cell proliferation. However, we and others have recently shown that sunitinib also inhibits mRCC cell proliferation probably because they aberrantly express the tyrosine kinase receptors targeted by the drug therefore leading to the selection of resistant cells.\(^2,3\) Sunitinib has been designed to disrupt major signaling pathways (HRAS-RAF1-MAP2K1/2-MAPK1/3 and MTOR pathways) that are responsible for the abnormal proliferation of cancer cells and tumor angiogenesis.\(^4\) However, sunitinib has not significantly improved the overall survival of the majority of patients compared to treatment with IFNA/interferon α or IL2/interleukin 2 (median time of survival after the diagnosis of about 20 mo).\(^5,6\) the standard treatments used before the development of antiangiogenesis drugs. Moreover, the fact that mRCC patients gradually become refractory to sunitinib represents an important obstacle to better outcomes for patients. Therefore, it is urgent to better understand the molecular mechanisms associated with resistance to sunitinib to improve the final outcome of the patients. In this context, we have analyzed the fate of tumor cells following chronic exposure to the drug. The selection pressure exerted by chronic exposure has led to the selection of resistant cells,\(^2,3\) but the mechanisms inducing resistance are unknown.

It was previously reported that sunitinib induces autophagy in bladder cancer cells,\(^6\) and that inhibition of autophagy potentiates the antiproliferative effects of sunitinib.\(^7,8\) However, in these experiments, cells are exposed to high doses of sunitinib and the cells are not representative of cancers for which sunitinib is the treatment of reference.\(^7\) Moreover, these reports do not investigate the molecular link between sunitinib treatment and autophagy. Lysosomal sequestration of sunitinib may be explained by the fact that it is a hydrophobic weak base (pKa 8.95).\(^9\) Sequestration in lysosomes may prevent access of the drug to the kinase domain of tyrosine kinase receptors present in the cytoplasm, thus participating in the loss of efficacy of the drug. However, the effect of sunitinib on autophagy has not been described for mRCC cells. Furthermore, the implication of autophagy and lysosome trapping in the mechanisms of resistance has not been addressed. In the present study we aimed at deciphering the link between autophagy and the mechanisms of resistance to sunitinib in mRCC. To overcome resistance we propose treatment with a combination of drugs preventing lysosomal accumulation.

**Results**

mRCC cells showed reduced proliferation in the presence of concentrations of sunitinib below the IC50 (suboptimal concentration)

Because of the abnormal vascularization of tumors, the core of primary mRCC or metastases is not exposed to optimal concentrations of the drug (Fig. 1A). We first determined the in vitro concentrations that resulted in progressive adaptation to sunitinib and final selection of resistant cells. The plasma concentrations of patients or mice exposed to sunitinib was low (0.1 to 1 μmol/L range) compared to the intratumor amount, which was 10 times higher (10 μmol/L range). Whereas the IC50 of endothelial cells for sunitinib was approximately 0.1 μmol/L,\(^10\) the IC50 of mRCC cells was approximately 5 μmol/L.\(^2,9\) In the presence of a concentration of sunitinib below the IC50 (2.5 μmol/L), mRCC cells (Fig. 1B, C and Fig. S1A, 786-O and RCC10, respectively) have a reduced proliferation rate, which was linked to prolonged S and G2/M phases of the cell cycle (Fig. 1D). A suboptimal concentration of sunitinib (2.5 μmol/L) did not affect cell viability (Fig. 1D, E) whereas exposure to a higher concentration resulted in cell death, as measured by cell counting or a clonogenic assay.

**Sunitinib accumulated in lysosomes**

To decipher the adaptation to suboptimal concentrations of sunitinib, the rest of the experiments were conducted at the concentration of 2.5 μmol/L.

Phase contrast microscopy highlighted a modification of the cell shape and the appearance of a yellowish color inside the cells after incubation with sunitinib for 2 d (Fig. 2A). The intracellular localization of sunitinib was confirmed by visualization of its autofluorescence. Sunitinib autofluorescence colocalized with a specific lysosomal staining (LAMP1 [lysosomal-associated membrane protein 1]; Fig. 2B) confirming that sunitinib accumulated in acidic lysosomal structures. Accumulation in lysosomes was also observed in 2 independent cell lines (RCC10 and A498) and 2 RCC primary cell lines (CC and TFE3) that we previously described (Fig. S1B).\(^2\) However, sunitinib did not accumulate in early endosomes (no colocalization with EEA1 [early endosome antigen 1]; Fig. S2). This result suggests accumulation of sunitinib in intracellular compartments with no major consequences to cell viability. This characteristic defines sunitinib as a lysomotropic agent.\(^11\) FACS analysis showed that sunitinib accumulated in lysosomes in a time-dependent manner and that there was an increase in the lysosomal mass (Fig. 2C), which coincided with increased expression of LAMP1 (Fig. 2D). Such accumulation of sunitinib was not dependent on the oxygen concentration since sunitinib sequestration was equivalent in normoxia or hypoxia (Fig. S3A). At the concentration of...
2.5 µmol/L of sunitinib, hypoxia did not modify the cell viability (Fig. S3B). Intracellular accumulation of sunitinib was also observed in experimental RCC in mice (Fig. S3C).

Sunitinib neutralized the pH of lysosomes and inhibited CTSB

Sunitinib is a weak base (pKa 8.95), which accumulates in lysosomes where it is protonated by a pH-partitioning process. Once ionized, sunitinib becomes membrane impermeable with the impossibility of diffusing out of the organelle, which results in lysosome trapping. Accumulation continues as long as the low pH is maintained by the vacuolar proton pump (V-type H^+ATPase) but ultimately results in buffering of the acidic pH of lysosomes. The LysoSensor Green DND-153 fluorescence (pKa 7.5) was intense in control conditions (this dye fluoresces in an acidic environment) but almost disappeared in the presence of sunitinib suggesting that the acidic pH of lysosomes has been neutralized (Fig. 3A, B). This correlated with decreased expression and activity of one of the major lysosome-associated proteases CTSB (Fig. 3C).

Suboptimal concentrations of sunitinib initiated incomplete autophagic flux

In physiological situations, autophagy is responsible for the degradation of dysfunctional organelles and proteins and allows cell survival during nutrient deprivation. So, autophagy is important in maintaining cell homeostasis, but if exacerbated, it can lead to cell death. Sunitinib treatment resulted in an increase in the lysosomal pH and inhibition of the lysosomal protease activity. Hence, we investigated the consequences of these modifications on autophagy. Autophagy is characterized by the accumulation of cleaved and lipidated forms of

![Figure 1](image-url)

**Figure 1.** A sunitinib concentration below the IC50 slowed down cell proliferation but did not induce cell death. (A) General schema illustrating the different concentrations to which RCC cells may be exposed to in a tumor. (B) The proliferative capacity of 786-O cells in the absence (Ct) or presence of increasing concentrations of sunitinib (sun) was evaluated by counting the cells at the indicated times. Data are the mean fold increase ±SD. The fold increase of untreated cells was taken as the reference value for statistics. Statistical significances of the results compared to untreated cells are indicated; *, P < 0.05; **, P < 0.01; ***, P < 0.001. (C) Clonal growth of 786-O cells in the absence (Ct) or presence of sunitinib (sun) (2.5 or 10 µmol/L). (D) The proportion of cells in each phase of the cell cycle was determined by DNA labeling with propidium iodide followed by FACS analysis. (E) Determination of viable cells in the absence (Ct) or presence of 2.5 µmol/L (2.5) or 10 µmol/L (10) of sunitinib (sun).
MAP1LC3A/LC3A (microtubule-associated protein 1 light chain 3 α; LC3-II) and the degradation of SQSTM1/p62 protein. Sunitinib treatment induced accumulation of LC3-II, which indicated either initiation or blockade of autophagy (in 786-O cells, Fig. 4A and in 2 additional cell lines [RCC10 and A498] and the above mentioned primary cells [CC and TFE3], Fig. S4A and S4B, respectively). However, sustained expression of SQSTM1 strongly suggested incomplete processing. To confirm incomplete autophagic flux, we evaluated the LC3-II level in response to sunitinib in 786-O cells incubated for 72 h. Sunitinib autofluorescence is shown. Merged fluorescence is also shown. (C) The autofluorescence of sunitinib and the localization of lysosomes in control or sunitinib-treated 786-O cells incubated for 72 h were tested for LAMP1 expression by immunoblotting. NAA10 is shown as a loading control.

Figure 2. Sunitinib accumulated in lysosomes. (A) Phase contrast microscopy showing modifications of the cell shape and accumulation of yellow granules in 786-O cell incubated with 2.5 μmol/L of sunitinib for 24 h. (B) Immunofluorescence to LAMP1 in control (Ct) or sunitinib-treated (2.5 μmol/L, sun) 786-O cells for 48 h. Sunitinib autofluorescence is shown. Merged fluorescence is also shown. (C) The autofluorescence of sunitinib and the localization of lysosomes (LysoTracker Red DND-99, Lyso) were followed by FACS analysis performed at the indicated times. (D) Cell extracts from control (-) or sunitinib-treated (2.5 μmol/L) 786-O cells incubated for 72 h were tested for LAMP1 expression by immunoblotting. NAA10 is shown as a loading control.

Sunitinib-resistant cells showed exacerbated, incomplete autophagy and a more aggressive phenotype

We hypothesized that sequestration of sunitinib in lysosomes and the subsequent inhibition of the autophagy flux participated in sunitinib resistance. To test this hypothesis, we generated sunitinib-resistant cells by chronic exposure of cells to the drug (786-OR and RCC10R). Incomplete autophagy in these cells was attested by accumulation of LC3-II and sustained expression of SQSTM1 (Fig. 5A). These results were confirmed with 2 other independent cell lines (RCC10 and A498 cells; Fig. S5).

Amino acid deprivation enhanced resistance to sunitinib

It is well known that cell starvation stimulates autophagy, which helps cells to resist this unfavorable environment. Autophagy is also used by tumor cells to survive when they have consumed all the nutrients easily accessible from the blood stream. Hence, the autolysosomes generated through this process may engulf sunitinib thereby amplifying resistance to the drug by preventing drug access to its targets. To test this hypothesis, we cultured 786-OS cells in a saline medium (Hank’s balanced salt solution; HBSS) deprived of amino acids, which initiates autophagosome and lysosomal formation. We questioned if this increased the capacity of the cells to store sunitinib in acidic intracellular compartments. Phase contrast microscopy clearly showed an enhanced accumulation of yellow granules when cells are cultured in HBSS medium (Fig. 5A). Quantification by FACS confirmed this qualitative observation (Fig. 5B). A high concentration (10 μmol/L) of sunitinib induces cell death, but at a lower concentration (2.5 μmol/L), it slows proliferation without inducing cell death, as expected. However, if the cells were first cultured in HBSS medium, cell proliferation was minimally affected by 2.5 μmol/L sunitinib and cell death was substantially decreased, even at a high concentration of the drug (10 μmol/L; Fig. 5C). These results were confirmed with 2 other independent cell lines (RCC10 and A498 cells; Fig. S5).
illustrated in Fig. 6A. As shown previously by Gotink et al., resistance (maintained several weeks) is not genetically acquired since it can be reverted by culturing the cells in the absence of the drug for a few passages. Electron microscopy showed that 786-OR cells accumulate bigger vacuolar structures, identified above as autolysosomes, compared to 786-OS cells when incubated in the presence of 2.5 μmol/L of sunitinib, a finding in favor of an exacerbated incomplete autophagy (Fig. 6B).

Previous reports have shown that treatment of tumor-bearing mice with sunitinib results in the selection of more aggressive cells. This has been observed in vivo, but we hypothesized that such selection did not involve cells from the tumor microenvironment but implicated an intrinsic phenotypic adaptation of tumor cells. We observed that 786-OR cells acquired greater anchorage independence illustrated by the formation of bigger colonies in soft agar (786-OR, Fig. 6C; and RCC10R, Fig. S8). In addition, the 786-OR cells showed an increase in their ability to migrate compared to 786-OS cells (Fig. 6D). These results suggest that incomplete autophagy correlated with the acquisition of the more aggressive phenotype of 786-OR cells.

We tested different markers implicated in epithelial/mesenchymal transition including CDH/N-cadherin, VIM/vimentin, and the transcription factors SNAI2 slug and SNA11/snail, but no significant changes were observed between the sensitive and resistant cells.

Inhibition of the ATP binding cassette (ABC) transporter ABCB1 and lysosomal permeabilization enhanced the efficacy of sunitinib

We hypothesized that sequestration of sunitinib in lysosomes is involved in resistance to sunitinib. If so, destabilization of lysosomes with LLOM may result in increased cell death in the presence of a suboptimal concentration of sunitinib since the drug inhibits the kinase activity of target tyrosine kinase receptors located in the cytoplasm. However, we observed that LLOM reduced accumulation of sunitinib inside the cells. Moreover, in the presence of LLOM, the amount of sunitinib in the culture medium was increased. These results strongly suggest that if sunitinib is not sequestered in lysosomal compartment, it is actively exported outside the cells.

Inhibition of the ABC transporters improves sunitinib accumulation in the brain suggesting that these transporters
participate in the efflux of the drug. These transporters are present at the lysosomal membrane and could participate in sunitinib accumulation in this cellular compartment. Moreover, sunitinib is a substrate of ABCB1. Hence, we hypothesized that ABC transporters could be present on the plasma and/or lysosomal membranes to mediate accumulation in specific cell compartments and/or to participate in sunitinib efflux out of the cells. Sunitinib treatment of 786-OS stimulated ABCB1 expression and increased accumulation in 786-OR cells (Fig. 7A). ABCB1 expression was also increased in A498, TFE3, and CC cells (Fig. S4). Whereas elacridar, an inhibitor of ABC transporters, induced slightly 786-OS cell death at a low concentration (1 µmol/L; Fig. S9A), it potentiated sunitinib activity on 786-OS cells (Fig. 7B). Elacridar did not significantly mediate 786-OR cell death when alone (Fig. S9A) but potentiated sunitinib activity (Fig. 7B). The lysosomotropic agent LLOM had little effect on cell death at a low concentration (1 µmol/L). Higher concentrations are needed to induce cell death probably through the release of cathepsins and induction of lysosome membrane permeabilization leading finally to apoptosis (Fig. S9B). A low concentration of elacridar and LLOM alone or in combination had no effect on TFE3 cell viability. Elacridar was more active in the presence of a concentration of 2.5 µmol/L sunitinib (55% cell death) but this was not the case for the LLOM and sunitinib combination. As for 786-OR cells, massive TFE3 cell death was obtained with elacridar plus LLOM had a strong detrimental effect on 786-OS cells even at low concentrations, but had little effect on 786-OR cell viability (Fig. S9C). Although less potent, bafilomycin A1 (BAF), an inhibitor of the V-ATPase pump, which is responsible for the maintenance of the low pH of the lysosomes, exerted a comparable effect to LLOM (Fig. S9D). Hence, the triple combination sunitinib, BAF and elacridar, was less potent than the sunitinib and LLOM-elacridar mix. Equivalent results were obtained with an independent cell line (RCC10, Fig. S10). These results suggest that blockade of sunitinib trapping in the lysosomes is an efficient way to increase the potency of the drug and prevent resistance.

Proteasome inhibitors induced the death of sunitinib-resistant cells

Autophagy and the ubiquitin-proteasome system are 2 linked mechanisms leading to the degradation of abnormal proteins and the recycling of amino acids. These 2 mechanisms compensate for each other when one is inhibited. Hence, we speculate that incomplete autophagy resulted in enhanced proteasomal activity. As a consequence, sunitinib and inhibitors of the proteasome may have additional effects on cell death. We observed that MG132, a proteasome inhibitor, or bortezomib, which is approved for the treatment of multiple myeloma, induced the death of sensitive and resistant cells. However, proteasome inhibitors combined with sunitinib induced a higher level of mortality of 786-OR cells than that induced by the individual compounds (Fig. 9). A
higher level of mortality was also observed for RCC10S, RCC10R, and CC cells when proteasome inhibitors, and especially bortezomib, was combined with sunitinib (Fig. S11).

**Discussion**

Most of the current research in the field of antiangiogenesis drugs has focused on the adaptation of the endothelial cells to these drugs, which target VEGFA or its receptors.\(^1\) However, it has been shown that other members of the VEGF family especially VEGFC are induced after exposure to anti-VEGFA antibodies.\(^2\) Research has also concentrated on modifications to the genetic program of tumor cells exposed to antiangiogenesis drugs, which lead to the expression of redundant proangiogenesis factors or the ability to migrate.\(^3,4\) Different reports have described the acquisition of a MET-dependent aggressive phenotype associated with sunitinib treatment, in particular in animal models.\(^5-7\) However, it is difficult to address this modification in patients since sunitinib is administered mainly after radical nephrectomy to challenge metastatic sites and metastatic cells are generally not sampled for ethical purposes. Dissemination of mRCC cells via the lymphatic system has also been reported but again in animal models.\(^8,9\) The role of the tumor microenvironment in the adaptation to treatments has also been addressed.\(^10\)

The major question was how to define the best treatment among the different ones that have been approved since 2007. A great hope was to use mouse avatars xenografted with fragments of a tumor to test the available treatments in vivo. With this experimental model, a correlation between the capacity of a tumor to develop in nude mice and tumor aggressiveness has been described. This model is also used to test the efficacy of a new compound.\(^11\) The results of many groups including ours show that the growth of these tumor fragments in mice takes 3 to 6 mo. Hence, testing various treatments with this method is not compatible time-wise for a rapid therapeutic decision between surgical removal of the tumor and the beginning of the treatment.\(^12\) Tumor-derived slice cultures of head and neck cancers have also been used to test the sensitivity to targeted therapies, a technique that may also be used for mRCC, but the procedure needs to be improved.\(^13\) Our recent study shows a good correlation between the response of the patient and the sensitivity to a FDA (Food and Drug Administration)-approved drug.\(^2\) We postulate that the antiangiogenesis treatment equivalently targets the blood vessels constituted of normal cells from one patient to another. However, we believe that tumor cell genetic plasticity was at the origin of the variation in tumor response. Our procedure consisted of testing cell survival and death in response to available drugs on isolated tumor cells grown in a specific culture medium. This technique is rapid and the procedure can be performed within one month after surgery. It may allow assistance in a therapeutic decision considering that the response to a given treatment on primary cells that represents tumor heterogeneity will reflect the general effect on patients.\(^3,14\)

Although all the aspects that lead to acquired resistance are of major importance, to become resistant the cells require chronic exposure to the drugs. So it would take several months before genetically modified tumor cells emerge that survive antiangiogenesis treatment.

The ability of cells to compartmentalize the drug in subcellular organelles to avoid accessibility to its target has not been examined in detail. Several reports have shown that certain weakly basic compounds (i.e., daunorubicin, doxorubicin) with pKa values near neutrality are selectively sequestered into lysosomes of multidrug-resistant cell lines. Alternatively, other weakly basic compounds, also with pKa near neutrality, specifically accumulate within mitochondria (i.e., rhodamine 123).\(^15\)
In our case, we have observed lysosomal sequestration of sunitinib but no accumulation in mitochondria, as previously shown. Among the different drugs that have obtained FDA and/or EMA (Food and Drug Administration and/or European Medicines Agency) approval for the treatment of mRCC, in addition to sunitinib, axitinib and dovitinib can be protonated at physiological pH and subsequently trapped in the lysosomes. Hence, resistance mechanisms equivalent to that described herein for sunitinib may be the cause of reduced efficacy of these drugs. Pazopanib, another ATP mimic approved for the treatment of mRCC is the only drug that cannot be protonated and trapped in the lysosomes, hence not concerned by this mechanism of resistance. However, sunitinib and pazopanib show the same overall survival, but pazopanib is preferred by physicians and patients mainly for its better quality of life. Several reports have previously shown that drugs that are lysosomotropic shared certain physicochemical properties, possessing a ClogP > 2 and a basic pKa between 6.5 and 11, predictably influenced their intracellular localization. Sunitinib enters perfectly into this category with a ClogP = 5.2 and a basic pKa = 8.95. We also observed that the amine group of sunitinib, added to improve the solubility of the drug is responsible for the high pKa value. Thus, the synthesis of an analog of sunitinib devoid of this amine group may prevent its accumulation in lysosomes.

Figure 6. Enhanced inhibition of autophagy and aggressiveness of 786-OR cells. (A) Determination of the percentage of viable 786-OS and 786-OR cells in the absence (Ct) or presence of 2.5 (sun2.5) or 10 μmol/L (sun10) of sunitinib after incubation for 24 h. (B) Electron micrographs of 786-OS cells incubated in the absence (Ct) or presence of sunitinib 2.5 μmol/L (sun) for 48 h and of 786-OR cells showing autolysosomes (arrows). Note the presence of autolysosomes of increased size in 786-OR cells. (C) Quantification of the number (left panel) and the size (right panel) of colonies obtained for 786-OS and 786-OR cells seeded in soft agar; *, P < 0.05. (D) Cell migration in real time was analyzed with the xCELLigence RTCA. The chart shows the outcome of the kinetics analysis of the cell migration for 786-OS and 786-OR cells (left panel). The right panel shows the average cell indexes at 24 h from 3 independent experiments. **, P < 0.01.

In the cytoplasm. This mechanism has been described in chronic myeloid leukemia for which agents that destabilize lysosomes revert resistance to imatinib. Among the different drugs that have obtained FDA and/or EMA (Food and Drug Administration and/or European Medicines Agency) approval for the treatment of mRCC, in addition to sunitinib, axitinib and dovitinib can be protonated at physiological pH and subsequently trapped in the lysosomes. Hence, resistance mechanisms equivalent to that described herein for sunitinib may be the cause of reduced efficacy of these drugs. Pazopanib, another ATP mimic approved for the treatment of mRCC is the only drug that cannot be protonated and trapped in the lysosomes, hence not concerned by this mechanism of resistance. However, sunitinib and pazopanib show the same overall survival, but pazopanib is preferred by physicians and patients mainly for its better quality of life. Several reports have previously shown that drugs that are lysosomotropic shared certain physicochemical properties, possessing a ClogP > 2 and a basic pKa between 6.5 and 11, predictably influenced their intracellular localization. Sunitinib enters perfectly into this category with a ClogP = 5.2 and a basic pKa = 8.95. We also observed that the amine group of sunitinib, added to improve the solubility of the drug is responsible for the high pKa value. Thus, the synthesis of an analog of sunitinib devoid of this amine group may prevent its accumulation in lysosomes.

Sequestration of chemotherapeutic agents in lysosomes is largely due to their lysosomotropic properties but sequestration within lysosomes may also be dependent on the ABC transporter activity. We observed an increase in the expression of the ABCB1 transporter after sunitinib treatment, but the regulatory mechanism implicated is unknown. Preliminary experiments suggest that the initiation of autophagy induces ATF4 (activating
transcription factor 4) expression. ATF4 is a major transcription factor implicated in the adaptation to nutrient stress of tumor cells.\textsuperscript{40} Moreover, ATF4 has also been implicated in resistance to cisplatin and cells overexpressing ATF4 showed multidrug resistance.\textsuperscript{41} Hence, ATF4 may be the driver of a transcriptional program leading to expression of ABCB1, as previously shown.\textsuperscript{42,43}

Moreover, accumulation of ABCB1 may be due to a lack of its degradation. Several membrane proteins, including receptors and transporters, recycle to the plasma membrane through the recycling endosomal system. Some cargo proteins sort cell membranes and discarded proteins into internal luminal vesicles of multivesicular bodies (early endosomes), and mature multivesicular bodies (late endosomes) that can fuse with lysosomes for proteolysis by lysosomal enzymes. In the context of this study, the lysosomal degradation pathway is impaired because of the modification of the lysosomal pH and could explain the decrease in ABCB1 degradation and its subsequent accumulation. Similar consequences were observed with CHL treatment, which resulted in NOTCH1 accumulation due to a decrease in the activity of lysosomes.\textsuperscript{44}

lysosomal sequestration is rapid, occurring as soon as the drug is in contact with the target cells, and does not modify the genetic program. Recent studies have also demonstrated that numerous cancer cells have defective acidification of their lysosomes. Hence, lysomotropic agents would be in contact with their targets in the cytoplasm of cancer cells devoid of lysosome trapping.\textsuperscript{45} This elegant approach would limit toxicity to normal cell and would concentrate the cytotoxic or cytostatic effects on tumor cells. However, we showed that the acidification of the lysosomes of mRCC cells was not defective. We observed that the TFE3 cells were resistant to a high concentration of sunitinib (IC50 = 10 μmol/L). However, we did not observe an increase in the number of lysosomes (Lysotracker Red labeling) in TFE3 cells compared to 786–0 cells. The pH of lysosomes dictates the predicted degree of lysosomal accumulation of sunitinib; the greater the lysosome-to-cytosol pH gradient the greater the extent of lysosomal sequestration. As long as the pH gradient is maintained, significant accumulation of the drug is possible. The proton pump, the vacuolar-type (V-) ATPase, which is located on the lysosomal membrane, maintains acidification of lysosomes.

Tumor cells with drug resistance exhibit an increase in V-ATPase activity, which may explain the resistance to sunitinib of TFE3 cells.\textsuperscript{46,47}

To prevent lysosomal trapping and avoid export of the drug out of the cells, we used lysosomal destabilizing agents and inhibitors of ABC transporters. This combination was very efficient in promoting cell death of cancer cell lines and cancer cells derived from a patient who progressed on sunitinib. The recapitulative schema we propose to prevent sunitinib resistance is shown in Fig. 10. Lysosome stabilizing agents are far from entering into the clinic, because of major toxic effects whereas clinical assays using inhibitors of ABC transporters are ongoing.\textsuperscript{48} Moreover, we found that proteasome inhibitors induced strong tumor cell death especially on cells resistant to sunitinib. As sunitinib and proteasome

\section{Figure 7. A combination of a lysosome destabilizing agent and an inhibitor of ABC transporters reverted sunitinib resistance of 786-OR cells. (A) Expression of ABCB1 was detected by immunofluorescence in control (Ct) or sunitinib-treated (2.5 μmol/L) sensitive 786-O cells (786-OS) for 48 h (sun) and in resistant 786-O cells (786-OR) in the presence of sunitinib (sun). (B) Determination of the percentage of dead 786-OS and 786-OR cells after incubation for 24 h the indicated combinations of drugs (sunitinib (sun) 2.5 μmol/L; LLOM (L) 1 μmol/L; elacridar (E) 5 μmol/L). *, P < 0.05; ***, P < 0.001.}
inhibitors have independent targets, the toxic effects should be manageable. In silico analysis of online-available microarrays highlighted a cluster of proteasome-associated genes that are overexpressed in primary and mRCC but also in paired pulmonary metastasis (Fig. S12A, Table S1, Supplemental Materials and Methods). The proteins encoded by these genes comprised a subset of the proteasome β subunits that affect the generation of peptides to promote efficient antigen recognition (PSMB8/9/10; proteasome [prosome, macropain] subunit 8/9/10), and a cellular regulator of proteasome formation and of proteasome-mediated antigen processing (PSMF1; proteasome [prosome, macropain] inhibitor subunit 1 [PI31]).

A slight increase in expression (1.4 [PSMB8, PSMB9, PSMB10] to fold2- [PSMF1] above the median) of each gene was associated with a decrease in overall survival (OS) with significant P values (P = 0.035 for PSMB8; 0.0006 for PSMB9; 0.018 for PSMB10; 0.036 for PSMF1) as revealed by data analysis at cbioportal. Moreover, overexpression of the genes of the cluster were indicative of both disease free survival (P = 0.0008) and overall survival is much more decreased for patients that overexpressed the different genes of the cluster (P = 0.0002). Overexpression of the genes of the cluster was also indicative of disease free survival for non metastatic patients (P = 0.007) and of overall survival for metastatic patients (0.006) (Fig. S12B). This in silico analysis clearly showed the prognostic significance of specific proteasome-associated genes. It corroborated our “in cellulo” analysis for the relevance of association of sunitinib and proteasome inhibitors.

The resistance to any targeted therapies is a constant debate between the presence of mutations within the primary tumor and acquired mutations under the selection pressure induced by the treatment. Tumor heterogeneity constitutes a major problem for defining personalized treatment. For mRCC, genomic sequencing highlighted an evolution of the metastatic niche that may refine tumor progression. As analyzed by cbioportal, proteasome genes were highly informative as prognosis markers of poor survival of nonmetastatic and metastatic patients while ATF4 and ABCB1 were not. A biopsy of metastases is rarely possible because it would threaten patients’ life. However, if it is possible, it would be interesting to test in metastases that become refractory to sunitinib treatment if ABCB1, ATF4 and PSMB8, PSMB9, PSMB10, and PMSF1 are upregulated compared to the primary tumor hence defining them as markers of resistance as suggested by our study.

Taken together, our study highlighted a primary mechanism of resistance to the major antiangiogenic compound used in the treatment of mRCC. Having deciphered this mechanism, we can now propose relevant therapeutic combinations that deserve testing in preclinical models but also putatively in phase I clinical trials.

Materials and Methods

Materials

Sunitinib and bortezomib came from residual materials given to patients (Center Antoine Lacassagne, Nice, France) and prepared as 2.5 mmol/L and 6.5 mmol/L stock solutions in dimethyl sulfoxide (Sigma, 472301) and stored at -20°C. CHL (C6628), elacridar (SML0486) and LLOM (L7393) were purchased from Sigma. MG132 was purchased from Calbiochem (474790) Anti-LC3 antibody (5F10) was obtained from Nanotools (0231–100/LC3–5F10). Anti-LAMP1 (H4A3, sc-20011) and anti-EEA1 (N-19, sc-6415) were from Santa Cruz Biotechnology, anti SQSTM1 was from BD Bioscience (610833), CTSB (Ab-1, IM27L) was purchased from Merck, anti-LAMP2 type, 8/9/10), and a cellular regulator of proteasome formation and of proteasome-mediated antigen processing (PSMF1; proteasome [prosome, macropain] inhibitor subunit 1 [PI31]). A slight increase in expression (1.4 [PSMB8, PSMB9, PSMB10] to fold2- [PSMF1] above the median) of each gene was associated with a decrease in overall survival (OS) with significant P values (P = 0.035 for PSMB8; 0.0006 for PSMB9; 0.018 for PSMB10; 0.036 for PSMF1) as revealed by data analysis at cbioportal. Moreover, overexpression of the genes of the cluster were indicative of both disease free survival (P = 0.0008) and overall survival is much more decreased for patients that overexpressed the different genes of the cluster (P = 0.0002). Overexpression of the genes of the cluster was also indicative of disease free survival for non metastatic patients (P = 0.007) and of overall survival for metastatic patients (0.006) (Fig. S12B). This in silico analysis clearly showed the prognostic significance of specific proteasome-associated genes. It corroborated our “in cellulo” analysis for the relevance of association of sunitinib and proteasome inhibitors.

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Taken together, our study highlighted a primary mechanism of resistance to the major antiangiogenic compound used in the treatment of mRCC. Having deciphered this mechanism, we can now propose relevant therapeutic combinations that deserve testing in preclinical models but also putatively in phase I clinical trials.
was from Abcam (H4B4, ab25631), anti-NAA10/ARD1 antibodies were produced and characterized in our laboratory,\textsuperscript{56} anti-actin (L-19, sc-1616) was from Santa Cruz Biotechnology, antiphospho-AKT1 (Ser473; 9271S), anti-AKT1 (9272), anti-phospho-MAPK1/3 (Thr185/Tyr187 and Thr202/Tyr204; 4370), anti-MAPK1/3 (137F5; 4695) and anti-ABCB1 (EY7B, 133442S) antibodies were all obtained from Cell Signaling Technology. HBSS was from Life Technologies (CRL-1932\textsuperscript{TM}).

Cell culture

Human 786-0 cells were purchased from the American Tissue Culture Collection (ATCC\textsuperscript{®} CRL-1932\textsuperscript{TM}). RCC10 cells were a kind gift from W.H. Kaelin (Dana-Farber Cancer Institute, Boston, MA) and were used in one of our published studies.\textsuperscript{57} RCC cells were grown in DMEM (Life Technologies, 61965–026) supplemented with 7% fetal calf serum at 37°C in a humidified atmosphere containing 5% CO\textsubscript{2}. For HBSS experiments, cells were preincubated in HBSS for 30 min before sunitinib treatment for 24 h for the determination of cell viability. For clonogenic assays, cells were incubated for 7 d in fresh medium after the same procedure. Resistant cells were obtained by chronic exposure to increasing concentrations of sunitinib up to 8 \textmu mol/L. An INVIVO\textsuperscript{2} 200 workstation (Ruskin Technology Biotrace International Plc, Sanford, FL, USA) set at 1% oxygen, 94% nitrogen and 5% carbon dioxide was used for hypoxic conditions.

Growth curves and cell viability

Cells were seeded in 6-well dishes and transiently treated with sunitinib the following day. Cells were next detached from d 2 to 6 and counted with a Coulter counter (Beckman, Pasadena, CA, USA) in duplicate to assess cell proliferation. Cell viability and cell death was assessed using the ADAM-MC apparatus (Nano-EnTek, Guro-gu, Seoul, Korea) based on fluorescent propidium iodide staining according to the manufacturer’s instructions.

Colony formation assay

RCC cells (500 cells per condition) were treated or not with sunitinib. Colonies were detected after 10 d of culture. Cells were then washed, fixed at room temperature for 20 min with 3% paraformaldehyde (PFA; Electron Microscopy Sciences, 15713) and colored by crystal violet (Sigma, C3886).

Kinetics of cell migration

Cell migration in real time was monitored by using the xCELLigence Real-Time Cell Analyzer (RTCA) DP Instrument equipped with a CIM-plate 16 (Roche, Indianapolis, IN, USA). Each well of the plate is composed of upper and lower chambers separated by a microporous membrane. Migration was measured as the relative impedance change (cell index) across microelectronic sensors integrated into the bottom side of the membrane. Ten \textsuperscript{5} cells were added in triplicate to the upper chambers. Migration and invasion were monitored every min for 48 h. For quantification, the cell index at the indicated time points was averaged from 3 independent measurements.

Immunoblotting

Cells treated with sunitinib and/or exposed to pharmacological inhibitors, were lysed in buffer containing 3% SDS (Euromedex, EU0660), 10% glycerol, 0.825 mM Na\textsubscript{2}HPO\textsubscript{4}. Samples (30 \mu g) were separated by 10% SDS-PAGE, transfected onto a PVDF membrane (Immobilon, Millipore, IPVH00010) and then exposed to the appropriate antibodies: anti-LC3, anti-SQSTM1, anti-LAMP1, anti-NAA10, anti-CTSB or anti-actin. Proteins were visualized with the ECL system using horseradish peroxidase-conjugated anti-rabbit (W4011) or anti-mouse (W4021) secondary antibodies (Promega).

Subcellular colocalization studies

Cells were incubated with sunitinib and LysoTracker Red DND-99 (Invitrogen, L7528) or LysoSensor Green DND-153 (Invitrogen, L7534). Viable cells were imaged in real time with EVOS Cell Imaging Systems (Life Technologies, Carlsbad, CA, USA).

Immunofluorescence

RCC cells seeded on glass coverslips (150,000 cells for 24 h or 60,000 cells for 48 h) in 6-well dishes were treated or not with sunitinib. Twenty-four or 48 h after, cells were then washed, fixed at room temperature for 20 min with 3% paraformaldehyde and permeabilized with phosphate-buffered saline (PBS; Euromedex, ET330-A) containing 0.2% Triton X-100 (Amresco, 0694–1L) for 2 min before being exposed to...
anti-LC3, anti-SQSTM1, anti-LAMP1, anti-LAMP2, anti-EEA1 or anti-ABCB1 (Sigma, P7965) for 1 h at room temperature. Cells were washed 3 times with PBS, and then incubated for 1 h at room temperature with 1:1000 dilution anti-mouse or anti-rabbit Alexa Fluor 488- (A21207) or Alexa Fluor 594-labeled (A21203) secondary antibody (Invitrogen, Life Technologies) and mounted using Mountant Permafluor (Thermo Scientific, TA-030-FM). Fluorescence images were examined and collected under a DeltaVision Microscopy Imaging System (GE Healthcare/Life Technologies, Carlsbad, CA, USA).

Subcellular fractionation
Subcellular fractionation was performed using a proteo-extract subcellular proteome extraction kit according to the manufacturer’s instructions (Calbiochem, 539790).

Flow cytometry– cell cycle distribution
Cells were trypsinized, washed, and resuspended in cold 70% ethanol overnight. After 2 washes with PBS, cells were resuspended in propidium iodide (40 µg/ml; Sigma, P4170) containing ribonuclease A (10 µg/ml; Sigma, R4642) for 15 min at room temperature and were analyzed using a fluorescence-activated cell sorter (BD healthcare FACSCALIBUR, analyzer, San Jose, CA, USA).

Transmission and scanning electron microscopy
For ultrastructural analysis, cells were fixed in 1.6% glutaraldehyde (Electron Microscopy Sciences, 16210) in 0.1 M phosphate buffer, rinsed in 0.1 M cacodylate buffer, postfixed for 1 h in 1% osmium tetroxide (Electron Microscopy sciences, 19170) and 1% potassium ferrocyanide (Sigma, 14459–95–1) in 0.1 M cacodylate buffer (Sigma, 124–65–2) to enhance the staining of membranes. Cells were rinsed in distilled water, dehydrated in alcohols and lastly embedded in epoxy resin (Sigma, 45345). Contrasted ultrathin sections (70 nm) were analyzed under a JEOL 1400 transmission electron microscope (JEOL Europe, Croissy sur Seine, France) mounted with a Morada Olympus CCD camera (Olympus-SIS Europe).

CTSB activity
RCC cells treated with sunitinib for 24 h were lysed for 30 min at 4°C in lysis buffer (400 mmol/L Na-phosphate, pH 6, 150 mmol/L NaCl, 4 mmol/L ethylene-diaminetetraacetic acid, 1 mmol/L phenylmethylsulfonyl fluoride (Sigma, 78830), 10 µg/ml aprotinin (Calbiochem, A21203) secondary antibody (Invitrogen, Life Technologies) or anti-ABCB1 (Sigma, P7965) for 1 h at room temperature. Cells were washed 3 times with PBS, and then incubated for 1 h at room temperature with 1:1000 dilution anti-mouse or anti-rabbit Alexa Fluor 488- (A21207) or Alexa Fluor 594-labeled (A21203) secondary antibody (Invitrogen, Life Technologies) and mounted using Mountant Permafluor (Thermo Scientific, TA-030-FM). Fluorescence images were examined and collected under a DeltaVision Microscopy Imaging System (GE Healthcare/Life Technologies, Carlsbad, CA, USA).

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Statistical analysis
Statistical significance and P values were determined by the 2-tailed Student t test.

Disclosure of Potential Conflicts of Interest
No potential conflicts of interest were disclosed.

Acknowledgment
We thank Dr M Christiane Brahimi-Horn for editorial assistance and Mr Benoit Front for the detection of sunitinib in experimental tumors.

Funding
This work was supported by the French Association for Cancer Research (ARC), the Fondation de France (SG and MD financial supports), the French National Institute for Cancer Research (INCA), the “Conseil Général des Alpes Maritimes,” the association Monégasque “Cordons de Vie” (www.cordonsdevie.com) and Novartis (Prime award for SG). This work was performed using the microscopy (PICMI) and cytometry (CYTOMED) facilities of I RM C. The materials of CytoMed were supported by the Conseil Général 06, the FEDER, the Ministère de l’Enseignement Supérieur, the Région Provence Alpes-Côte d’Azur and the INSERM.

Supplemental Material
Supplemental data for this article can be accessed on the publisher’s website.

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To,
The Office of The Controller General of Patents, Designs & Trademarks,
Boudhik Sampada Bhavan,
S.M. Road, Antop Hill
Mumbai - 400037

Subject: Stakeholders Meeting regarding issues related to Working of patents under the Patents Act, 1970

Respected Sir

We refer to the Circular no.CG/Meeting Circular-DIPP/2018/14 dated 01-03-2018 calling for comments from stakeholders on the issues relating to working of Patents, i.e., Sec 146 of the Act read with Rule 131 including Form 27, and penal provisions provided in Sec 122.

At the outset, we would like to inform you that Hindustan Unilever Limited (HUL) has been filing patent applications in India for over three decades and has always maintained a sizeable portfolio of patents. Of late, our parent company, Unilever PLC has started filing patent applications in India.

As a company, we always comply with the laws and regulations of the countries in which we operate. Therefore, HUL has always disclosed the information pertaining to commercial working of its...
patents. The following are the comments from our company and we hope that the Controller finds the comments useful and constructive.

**Comments on Sec 146 and Form 27**

Sec 146(1) empowers the Controller to call for information from every patentee or a licensee as to the extent [emphasis added] to which the patented invention has been commercially worked in India. Sec 146(2) puts the onus on every patentee and every licensee to furnish the information in a time bound manner, whether the Controller has called for it or not.

As far as Sec 146(1) and 146(2) is concerned, the main aim is to obtain information as to extent of working as explained above. This term “extent of working” has not been defined/clarified anywhere in the Act. However, the information sought through the Form-27 is presumably a step towards finding out the extent of working.

We believe that there is significant room for revision and simplification of the Form, whilst still being fully compliant with the scope of Sec 146 and the principles embodied in Sec 83 of the Act.

The following are few comments [pointwise as per Form 27] for your kind consideration for simplification of Form 27 while strictly adhering to the statute (Section 146):

I. Regarding point No. 1, we do not have any comments as it is asking for information relating to Name, Address and Nationality of the Patentee and the Patent Number, which is required for identification of the patent in question.

II. Regarding point No. 2, also we do not have any comments as it is asking for information relating to the year for which the statement is being submitted.

III. Point No. 3 in Form 27 starts with a statement “Give whatever details are available”. This statement is vague. It creates an impression that all the other sub-points under Point 3 are optional at the discretion of the patentee. This is in contravention to Section 146 (2) wherein it provides the mandate that the patentee should provide a statement that satisfies the “extent of working”. Therefore, either the legislative change has to be made to Section 146(2) making the details asked under point no 3 of form 27 as optional OR Form 27 needs to be amended and simplified for better compliance.

IV. Notwithstanding the above comments under para III, we do not have any other comments under point 3[i] as it is asking whether the patent has been worked or not which is the primary purpose of Section 146.

V. Regarding point no. 3 (i)[a], patentees are asked to submit the reasons for not working if the patent in question has not been worked. This question contravenes Section 146(2). According to said Section only “extent of working” is required NOT the extent or the reason[s] of non-
working. As the Patentee needs to sign off the Form stating that the facts and matters are true to the best of his knowledge, information and belief, the question puts an undue burden on the Patentee to find out why a particular patent is not worked. It is not always possible for the Patentee to find out the true reason despite best efforts on the part of the Patentee. However, as the question is included in the Form, the Patentee cannot avoid answering it. Therefore, to make it simple at the same time adherent to Section 146, this part could be removed from Form 27.

VI. Regarding point no. 3 (i)(b), it is asked to provide the quantum and the value of the patented product. The term "quantum" is vague and we suggest that the term be replaced by something more meaningful and easier to measure/ascertain on the part of the patentee. If it is not possible to replace the term with any other suitable and more appropriate term, then we suggest that the Controller should formulate some Guidelines which would clarify this. For example, if the patented product is sold as a discrete article like a toothbrush, a pack of toothpaste, a carton of tea leaves, a bar of soap or a water purification device, then it would be easier for the patentee to at least give a reasonably accurate number of the units that were sold during the year. On the other hand, if the invention pertains to a process for manufacturing, for example, a laundry detergent powder, then we suggest that it should be sufficient to indicate how many tonnes of the powder was prepared by the patented process and the "quantum" in such cases be equated to the tonnes of the product manufactured by the Patentee. Furthermore, we suggest the term "value" be replaced by something more concrete, meaningful and which can be easily ascertained by members of the public and at the same time adhere to Section 146 regarding extent of working. This whole thing become very complex and not accurately determinable when more than one patent relates to a single product or vice versa. Therefore, we suggest inserting a word e.g. "approximate" before the terms quantum and value (price) would give all Patentees some degree of relief as otherwise, we are required by the law to quote exact numbers and figures in the Form which is difficult to ascertain in the certain scenarios.

VII. We would further like to add that under point 3(iii), Form 27 also seeks information which is significantly more than necessary. We respectfully submit that it should be sufficient to know whether the working was by manufacture in India or by importation or by both. We genuinely believe that it serves no meaningful purpose to call for country-wise details of importation. Hence, we suggest this point should be removed from the Form.

VIII. The point 3 (iii) of Form 27 is superfluous and needs to be deleted. It asks every Patentee to state whether the public requirement has been met partly/adequately etc. From the point of view of any Patentee, it is but obvious that the Patentee would state that the requirements have been met to the fullest extent at reasonable price. The term reasonable price is inextricably linked to the product being sold. The price that is reasonable for a product A may not, and need not be reasonable for another product B. Usually consumer products are
priced differently based on the profile of the expected consumers and the features that are offered through the product. Moreover, these are not required by section 146 (2). Hence this part should be removed from Form 27.

Comments on Sec 122

Other than pecuniary penalty in the form of fine, imprisonment is also mentioned as one of the punishments under Section 122(2). We believe is way too much for the kind of information involved under Section 146. This should be relooked and handled appropriately.

Comments on Rule 131

As Rule 131 just lays down the procedure (form, timeline etc.), we do not have any comments. However, on procedural part of submission of Form 27 online, bulk upload option needs to be considered and enabled. Currently, the patentee (for each individual patent) has to fill up the details in the online system at the same time also needs to attach the hard copy of the Form along. This amounts to dual work. Therefore, it is required that the Patent Office should consider the possibility of making this better and reduce the burden on the patentee to comply with the requirement of Sec 146 and Form 27.

Based on the above submission, we request your kind self to extend the invitation to us for the stakeholder meeting scheduled on 21\textsuperscript{st} March 2018. We will be glad to attend the said meeting and provide any clarification or further explanation on the points raised in this letter. Further, we would be more than willing to extend any help or support to your Office to further deliberate on the matter and be part of any committee, should your kind self deem it fit and proper to do so.

Thanking You.

Truly,

For HINDUSTAN UNILVER LIMITED

Suman Kumar Bhattacharya

[Authorized Signatory]

IN/PA/2021
To: The Indian Patent Office

Huawei Technologies Co Ltd provides its comments in response to the CIRCULAR of 01 March 2018 on the subject of “Stakeholders Meeting regarding issues related to Working of Patents under the Patents Act, 1970”.

Huawei is a global leader of ICT solutions and products, with 180,000 employees including 80,000 R&D employees distributed over 15 R&D institutes and centres. Huawei products and solutions are available in over 170 countries. Huawei’s operations in India include our oldest and largest overseas R&D centre of Huawei in Bangalore, employing around 3000 software engineers out of a total of 7000 local employees in India. We have had local manufacturing in Chennai since 2011. Huawei believes in protecting its intellectual property, and as of 31 December 2017, Huawei and its subsidiaries holds 218 granted patents in India, and 74307 patents globally. Huawei is both a manufacturer and researcher.

The Indian Patents Act and Rules are unique in requiring the regular disclosure of patent working information concerning “as to the extent to which the patented invention has been worked on a commercial scale in India” (section 146(2)). The precise mechanism for collecting patent working information is by filing Form 27 which is referred to as a “patent working statement”. The form and content of Form 27 is determined purely by the Patent Rules. Huawei fulfils the requirements by timely filing Form 27 using the information readily available to Huawei.

The purpose of the provision is related to the limited monopoly – public disclosure bargain concerning patent rights. As the theory goes, by providing the patent working information, there is an opportunity to assess whether the public in India has adequate access to the patented invention in a concrete form that is affordable. Patent working information may also assist in evaluating the state of development of the domestic economy. Ultimately, under a separate section of the Indian Patents Act, sanctions are provided in the terms of compulsory licencing and patent revocation if the patent working requirement – as distinct from providing the patent working information - is not met. Such sanctions may be of particular relevance in certain industries, such as the pharmaceutical sector, where access to a patented medicine may be deemed a right available to all patients. Case law has shown that the situation is different where the products are not essential to life (decision of the IPAB in Bayer
Corporation v. Union of India, establishing that meeting to an adequate extent the public demand for a cancer drug is 100% meeting the demand, whereas for luxury products the test would be completely different).

Huawei believes that current practices associated with the patent working statement fall short of fulfilling the purpose of the provision.

Firstly, Huawei does not believe that the information provided by a patent working statement is of interest to those in the telecommunications sector, irrespective of the level of detail provided. On the contrary, if an interested party in this sector wishes to make use of a patented invention, there are already adequate means at their disposal, either via seeking a licence, or as a last resort via compulsory licencing or patent revocation.

Secondly, the Form inevitably captures inaccurate information. Imposing any stricter reporting requirements is unlikely to be assistance, because Form 27 requests information which in many cases is not available to the patentee. This is primarily because the questions in the Form assume that one patent equals one product. Whilst this may be true in other industry sectors, the situation for complex products is different, as the patented product of one patent may relate to only one part of a much larger product. In the case of telecommunications, each product, such as a server, router, or telephone handset, comprises many different components each of which may relate to one or more patents. As an illustrative example, a mobile phone may comprise many components, including different kinds of memory, display, application processor, baseband processor, RF chip, WIFI, amplifier, interface controllers, sensors, camera module and lens, driver ICs, speaker, battery, circuit board, navigational related chips to name but a few. A patent may relate to any one aspect of any one of these components, or even interworking of these components in the phone or with external systems. Further, the particular components may be substituted over a short period, and correspondingly the relevant patent(s) may change.

Moreover, it will be difficult to put a fixed definite value of each patented product in a complex product composed of multiple patented products. The value of the complex product is affected by various factors at different times.

Even if a patentee was able to assess which products had the patented feature(s), an additional hurdle would be updating that list to reflect old products being withdrawn (but perhaps still serviced i.e. worked) and new ones coming onto the market. The sales figures would then need to be calculated and at best an estimated number of the total value of the complex products sold, which would still not be that of each patented sub-component or feature.

Absent a specific court-imposed obligation to account for numbers and sale prices of a particular product it is common industry practice to not collect the information about products and map them to specific patents due to the complexity of tracking outlined above. The most similar exercise to tracking is accounting for damages in patent infringement. There, the only difference is that the patent belongs to a third party. The infringing products will already have been determined in a trial for liability, so the required action is only accounting for the sales. However, Huawei’s experience is that this is an onerous activity occupying many
man-hours of otherwise productive time, and even then the results are open to interpretation by third parties.

Thus, the third aspect is that providing the information is unduly burdensome.

**Form 27**

Huawei believes that the current Form 27 should be streamlined to reduce the burden on the patentee. Specific suggestions include:

- remove the questions which impose a high burden on the patentee, particularly the requirements as to quantum and value

- remove the question which imposes a near impossible burden on the patentee, i.e. the question “whether public requirement has been met partly/adequately/to the fullest extent at reasonable price”. This was removed in the draft Form 27 in the Rules 2015 but was not officially promulgated. As the patentee does not have access to the whole market information, it is not possible for the patentee to state with absolute confidence whether the extent to whether any public demand has been met. The corresponding penalty of penal provisions, as per current Section 122, is disproportionate given the inherent uncertainty in answering this question. The public may also vary with the product – and in some cases may only be a certain commercial circle of an industry sector. In any event, the “demand” is for the “complex product” which is not the same as the “patented product”. For similar reasons, it is also difficult to assess what is a “reasonable price”.

- remove the questions on licencee sales data: each individual licence may not provide for the collection of the data at this level of granularity (e.g. in the case of a royalty-free licence, or an upfront licencing or bulk fee) and as such has no means to compel a licencee to disclose such data. Further, various terms of the licence may be deemed confidential, disclosure of which may constitute breach of the licence.

**Guidelines**

The patent working procedure would benefit from updated official guidelines which illustrate what is acceptable, whilst balancing what is actually possible in a commercial context for each respective industry. One specific suggestion would be acknowledging that patent to product mapping is different for different industries, and that a one size fits all form is not suitable.

An additional welcome confirmation would be that “working” may include importation, as per the decision of the IPAB in Bayer Corporation v. Union of India and in accordance with TRIPS Article 27(1). It is not realistic in a globalised economy with multi-country supply chains to expect a patented product to be manufactured wholly in one jurisdiction. If it were so, it would be extremely disruptive, with various undesirable outcomes including potentially raised costs for consumers due to the development of cottage industries for local manufacture in each jurisdiction with an adjunct loss of economies of scale.
16th March, 2018

To,
Office of the Controller General of Patents, Designs and Trade Marks,
Boudhik Sampada Bhavan,
S.M. Road, Antop Hill,
Mumbai – 400 037
Email: wm.dhumane@nic.in
        drusharao.ipo@nic.in

Dear Sir,

Sub: Comments on issues related to working of patents in India
Ref: Circular from the Office of the CGPDTM dated 01st March, 2018 inviting comments on the above subject.

At the outset I greatly appreciate the efforts of the Office of the Controller General of Patents, Designs & Trade Marks in taking the initiative to invite feedback from stakeholders on working of patent requirements as envisaged in the statutory provisions of the Patents Act 1970 and corresponding Patent Rules 2003, including Form-27.

I herewith enclose my comments related to the working of patents in India with recommendations for the kind consideration of the Controller.

Thank you.

Kind regards,
Inkollu Sreenivasa Murthy
IN/PA 901
# 302, Sri Residency,
H. No. 29-164/1/A,
New Vidhya Nagar Colony,
Neredmet, Secunderabad – 500 056,
Telangana, India.
Email: sreenivasipr@gmail.com

Enclosure: Comments on issues related to working of patents in India.
COMMENTS ON ISSUES RELATED TO WORKING OF PATENTS IN INDIA

Introduction

It is important to understand compliance related to working of patents in light of objectives it tries to achieve while such compliance should not create undue burden on patentees. The fact that working of patents is part of Chapter XVI of the Indian Patents Act 1970, which also deals with provisions related to compulsory licenses, is an indication that these two aspects are interrelated. Any changes to the Patent Rules 2003 and Form-27 in connection with working of patents should take into account this fundamental correlation. It is very well known that every patent that gets granted does not end up being commercialized due to various reasons, and very often it is a very small number of patented inventions that reach the market. Of these, only a few patented inventions qualify for being granted a compulsory license. Experience from the last several years tells us that very few applications for compulsory license have been filed in India and only one has been granted, that too, in the pharmaceutical field. Therefore, it needs to be considered what is the outcome of an exercise requiring every patentee to provide extensive details in Form-27 on a yearly basis, when in reality, there has not been large number of applications filed for the grant of compulsory license. The factors that govern commercialization of a patented invention are often different from mere grant of patent (grant of patent being no guarantee of success of a product in market). Hence, a balanced approach needs to be taken in seeking information related to commercial working of patents from patentees ensuring that efforts do not exceed the benefits such an exercise would entail. Requiring patentees to provide extensive details about the working of invention may also have negative impact on the number of patent applications that may be filed in India.

Therefore, a more realistic approach should be taken in amending Rules related to working of patents and revising the format of Form-27 to balance the efforts required to provide such information compared to the intended goals of obtaining such information. I believe that the proposed amendments, as given below, to Form-27 and respective Rules will not only serve the objectives of Chapter XVI, but also not be an undue burden on the patentees.

Recommendations:

I, hereby, propose the following suggestions to streamline the procedure related to seeking information in respect of working of patents.

I. Sreenivasa Murthy – IN/PA 901
1. Since no compulsory license is granted in the first three years after the grant of the patent, I do not think it is warranted to seek statement of working during this period. At the most, it can be made optional. Suitable amendment may be made to the respective Rules.

2. Form-27 should be simplified to promote compliance. I herewith suggest the following amendments to Form-27.

a. Only seek information whether a patented invention is “worked” or “not worked”.

b. The requirement to provide reasons for not working and steps being taken for working the invention should be made optional/voluntary. In fact, it will be in the interest of the patentee to provide such information. The reasons for not working the invention or steps being taken for working the invention may be sought by the Controller by adopting the procedure outlined below in paragraph 2(d)(i) to adjudicate any application for compulsory license.

c. In certain technological areas where patent portfolio licensing is commonly practiced and licenses and sub-licenses are granted to multiple parties, it may be extremely difficult to know which patent has been worked or not worked. There should be a provision in Form-27 to accommodate such a scenario. A procedure outlined in the paragraph 2(d)(i) may be adopted when details about working of such patents are required.

d. Other provisions of Form-27 such as disclosing the “quantum and value”, providing details of “licensees” and “sub-licensees”, should be dropped from Form-27 and following procedure may be adopted to seek such information:

i. Controller to seek information from patentee under Section 146(1) when a third party notifies its intent to apply for compulsory license. Form-30 may be used by the third party for notifying its intent to seek compulsory license.

Explanation: Based upon the recent decisions that have emerged in connection with compulsory licensing provisions (for example Lee Pharma v AstraZeneca), it is not sufficient for the applicant to establish that provisions of compulsory license are attracted solely relying upon the information related to quantum and value of the patented invention furnished by the patentee in Form-27. The applicant is required to make its case relying upon independent information about the actual “reasonable requirements” of the “patented invention” in the country. Such information can be collected by the applicant from market as they practice in the same field and are aware.
of the market needs for the patented invention. Details of licensees and sub-licensees are irrelevant for such information. Once this initial burden is discharged by the applicant, Controller can seek the details of quantum and value of the patented invention worked in India from the patentee under Section 146(1). Appropriate guidelines/directions may be given by the Controller in the notice itself as to how the quantum and value should be calculated/determined in respect of the patented invention (considering the nature of the invention - process or method, product, intermediates etc.) and furnished in response to such a notice under Section 146(1). The applicant can use this information to establish if the conditions required for awarding compulsory license are satisfied and a prima facie case is made out, and subsequently can make a formal application for compulsory license after first making attempts to obtain voluntary license.

e. The provision in Form-27 requiring patentee to state whether public requirements has been met partly/adequately/to the fullest extent at reasonable price should be dropped from Form-27. This is a very vague requirement which makes the compliance extremely difficult. There is no guidance on the basis of which the patentee would be required to make such statement. At the minimum this would require a market study by patentee every year to make such statement, which is highly burdensome. In fact, the burden of proof is on the applicant for compulsory license to establish that reasonable public requirements have not been met with respect to the patented invention, and for this purpose the information about quantum and value sought as proposed above would be sufficient. Therefore, requiring patentee to make such statements serves no useful purpose.

f. Penal provisions should only be enforced when a patentee refuses or does not provide information in response to notice under Section 146(1).

Conclusion:
To conclude, I request the IPO not to reduce the statement of working more of an academic exercise by requiring patentees to furnish extensive details where the benefits do not commensurate with the efforts used in providing such information when the same can be easily sought from the patentees under the present scheme of the Patents Act. I, therefore, think that it would be sufficient to annually require the patentees to just state whether the invention has been “worked” or “not worked” to satisfy the requirements under Section 146(2).
16th March 2018

From:
In-House Intellectual Property Professionals (I-HIPP) forum
Shanthiniketan, 2nd Cross, Church Street, 6th Block, Koramangala,
Bangalore – 560 096, Karnataka, India

To:

Dear Dr. W. M. Dhumeaji; and Dear Dr. Usha Raojj.
Email (wm.dhumane@nic.in; drusharao.ipo@nic.in)

Respected Sir,

Sub: Proposal on the practice of filing Working of Patents Statements in view of the PIL (W.P.(C) 5590/2015)

I-HIPP makes the following submissions, which we respectfully request you to consider while responding to The Delhi High Court (DHC) in WP 5590/2015 (Shamnad Basheer vs. UOI) pertaining to the Working of Patents Statements, and also in considering any changes to the statutes, rules and forms as already directed by the Hon’ble Court in that WP.

We offer to meet your esteemed selves to explain our concerns and we request you to arrange or attend (hosted by I-HIPP) a roundtable to delve on this important subject matter. At I-HIPP, we look forward to working with your office on this issue. Kindly contact us for any clarification or discussion on our submission. I-HIPP will be honored to be of service GoI and IPO in an ongoing consultation on IPRs, policy, and practice in India.

Sincerely

Dr. S.K. Murthy (murthyipr@rediffmail.com)
Core-Committee Member, In-House IP professionals (I-HIPP)

About I-HIPP
I-HIPP is a platform for in-house IP professionals to network with each other, to share knowledge and best practices, and to be a cause in making positive contributions to the IP system in India by working closely with industry bodies, legal community, Government and the academia. I-HIPP has the vision to be a leading IP Think Tank and Advocacy Group in India. I-HIPP was formed in September 2009 and is represented by around 60 professionals who have been working for Indian and Multinational organizations covering diverse technology domains that includes semiconductors, telecom, IT industry, software, power and energy distribution, health care, diagnostics and medical devices and consumer electronics, control systems and automation, FMCG, oil and gas. I-HIPP Forum has been meeting once in every three months and brainstorming on various IP issues and working towards making positive contributions in building an effective IP eco-system in India. I-HIPP Forum has been addressed by global IP professionals.
Proposal on the practice of filing working statements:

I. Legislative intent:

The legislation has put in place a number of statutory checks as detailed below to check the misuse of patents.

<table>
<thead>
<tr>
<th>SL. No.</th>
<th>The Patents Act, 1970</th>
<th>Provision</th>
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<tbody>
<tr>
<td>1.</td>
<td>Section 3</td>
<td>What are not inventions (exclusions by statute)</td>
</tr>
<tr>
<td>2.</td>
<td>Section 47</td>
<td>Grant of patents subject to certain conditions</td>
</tr>
<tr>
<td>3.</td>
<td>Section 25</td>
<td>Opposition to the patent (pre-grant and post-grant)</td>
</tr>
<tr>
<td>4.</td>
<td>Section 64</td>
<td>Revocation of patents</td>
</tr>
<tr>
<td>5.</td>
<td>Section 53</td>
<td>Term of patent (limited term monopoly)</td>
</tr>
<tr>
<td>6.</td>
<td>Section 66</td>
<td>Revocation of patent in public interest</td>
</tr>
<tr>
<td>7.</td>
<td>Section 84</td>
<td>Compulsory Licenses</td>
</tr>
<tr>
<td>8.</td>
<td>Section 85</td>
<td>Revocation of the patents by Controller for non-working</td>
</tr>
<tr>
<td>9.</td>
<td>Section 99 – 103</td>
<td>Use of inventions by Government and acquisition of inventions by Central Government</td>
</tr>
</tbody>
</table>

The above-mentioned provisions clearly indicate that there have been certain checks and balances to ensure that the patentee does not misuse his/her patent rights. Further, the provision of submission of working statements imposes additional and certain “impossible to perform” burden on the patentee that could force the inventors to rethink whether to secure patents in India and this could have a negative impact on the Indian innovation and IP ecosystem. Intervention is only necessary when no provisions exist under the prevailing statute to address public good. Thus, no harm is caused to public and neither is innovation stifled under the existing process as the India Patents Act clearly provides remedies to address such situations.

The legislative intent underlying the practice of working statements was to empower the Patent Office to device an appropriate procedure to seek relevant information as a basis for administering compulsory licenses under appropriate circumstances. Guidance on what are and what are not appropriate circumstances is already provided in paragraphs 23 and 24 of IPAB Case OA/35/2012/PT/MUM Bayer Corporation vs. Union of India et al. As noted there, “the mechanism of compulsory licensing is mainly to balance patent rights with access to medicine.” As further noted there, “A situation of emergency or urgency or crises is hardly likely to arrive if an inventor sits tight on a new kind of mobile phones, or computers.” More significantly, the Patents Act 1970 itself empowers the Patent Office with two separate and distinct tools (i.e., Sub-sections 146 (1) and (2)) to seek pertinent information for administering compulsory licenses. While the annual statements are sought generally for all patents (covering medicines, mobile phones and computers referred to in the IPAB
decision noted herein) under sub-section 146(2), the Patent Office is empowered to seek more specific information under 146(1) as suitable for the corresponding patents.

Patentees invest crores of rupees in research and development to produce innovative technologies and this activity would come to a full stop if patentees cannot make returns on their investments. The limited time bound exclusive right granted to patentees is to ensure that they make reasonable returns on investments made in research and development and such inventions are disclosed to the patent office and subsequently to the public to move forward as a society. Imposing additional burden on inventors/patentees would make it almost impossible for the inventor community (which is very small in comparison to the society as whole) to make a reasonable return on the investment and such additional burdens would only diminish or extinguish an already miniscule sized inventor community. This would result in hampering innovation and thus would affect advancements in science and technology, which ultimately benefit the public at large.

The Controller has powers under Section 146 (1) to call upon the patentees to provide statement of working on a periodic basis, to ensure that the patent holder practices the patented technology. Section 146 already imposes a heavy burden on patentees and licensees in regards to working requirements by (a) seeking information, which is impossible to provide at least in some industry verticals; and (b) levying fines and criminal penalties. These requirements have caused humungous hardships to the patentees, already. Continuation of such restrictions and/or imposing any further restrictions will be counter-productive to innovation goals of the country and will severely restrict investments in research and development.

II. Problems with the current practice of submission of Form – 27 information:

The intent of submission of Form – 27 appears to be to ensure that patents granted do not impede protection of public health and nutrition. Thus, in our view, seeking FORM-27 should only (a) be restricted to ascertain such objectives are met; and (b) when there is data to support such impediment to public health has occurred. However, the present requirement is for every patentee and licensee to submit FORM-27 annually and such a requirement clearly places a “huge and many times impossible to perform” burden on all the patentees. It is our opinion that very few patents fall under the public health and nutrition domain which is a concern for the IPO. The IPO is seeking information from a much larger group (comprising patent holders from automobile, software, computer, IT, consumer electronics, semiconductors, telecom, power generation and distribution sectors) thereby burdening the larger group to submit statement of working which is unreasonable. It is much productive and efficient to seek FORM-27 only from relevant patentees when data merits such information.
The primary objective of the Indian Patent Office (IPO) is to receive patent specifications, publish, examine patent specifications as per the provisions of Indian Patent Act, grant/reject based on the merit, and maintain the patents. Seeking information through FORM-27 from every patentee will only burden the patent office as the patent office may not have the resources to ascertain the information provided in the FORM-27 for each patent and the license provided thereof. It serves no purpose to merely collect this information from each and every patentee, which will not be of use to the patent office or the country as a whole. Instead, it is much more productive and efficient and objective to seek this information only form relevant patentees when data indicates that such information needs to be collected. Also, it is efficient for the patentee to provide the data, to the extent practically possible, for the selected patents based on the data indications.

Thus, it is in best interest of the patent office, patentees, and the public to collect the information based on the objective criteria of (a) whether such information would help meet the public health and nutrition objectives; and (b) whether there is sufficient data to support that non-working of a patent has created such impediment to public health and nutrition.

Further, the patent holders have been submitting Form 27, however, Form 27 in its existing format is not attuned to changing industry dynamics. The problem lies in the fact that the information sought in Form – 27 is not concise, impossible to provide accurate information, impinges on confidential business information and lacks clarity. There are ambiguities in understanding and interpreting the information being sought. Some of the problems with providing the required information is outlined below:

<table>
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<tr>
<th>Existing Form 27 is not attuned to changing Industry Dynamics</th>
<th>Further, existing Form 27 is archaic and is not attuned to changing industry dynamics. Existing Form 27 is based on presumption that one product is equivalent to one patent. However, such a model is non-existent in ICT sector where one product is not based on one patent but is actually covered in portfolio of patents. For example, mobile phones, tablets, smart watches etc. which might incorporate multiple inventions covered in multiple patents. The existing working statement is required to be filed individually for each patent, which might</th>
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suit in case of pharmaceutical inventions but not for ICT sector.

It is generally difficult to identify the patented invention being worked out in a single product. The patented invention may not be worked in a single standalone product. It could have been worked in several products. In many fields of engineering such as semiconductors, mechanical, telecommunications, computers, it is highly difficult for the patent holder to utilize the inventions on an individual basis. Most often, one or more patented inventions may be used in a product and some patents may be used in multiple products. It becomes difficult for the patent holder to individually isolate the patents and tag it to a product.

Clarity needs to be established whether it is a must to identify each and every patent in each and every product. Is it possible to group a bundle of patents and list all the patent numbers in a single Form – 27 and indicate that one or more of these listed patents are worked in one or more of the listed products?

<table>
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<tr>
<th>Working of invention on a commercial scale</th>
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<tbody>
<tr>
<td>The working of a patent means the commercial exploitation of the invention that is embodied in the patent. Although the working of the invention within India at a commercial scale amounts to local working, it is still controversial as to whether the local working of the patent can only be satisfied by the local production within the territory of India and not importation. There is no statutory evidence to offer clarity as to whether only local manufacture amounts to working on a commercial scale; but as a signatory to TRIPS Agreement (Art. 27 (1)), India is under obligation to consider importation of a patented article as sufficient proof to constitute local</td>
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Working. Thus while non-working continues as one of the basis for revocation, it is no longer the case that domestic demand needs to be met to adequate extent or on reasonable terms from manufacture in India only. The scope of the word “commercial scale” needs to be clarified.

<table>
<thead>
<tr>
<th>Existence of requirements impinges upon Confidentiality</th>
<th>Under a Licensing model, IP owner is under an obligation to keep important business data concerning licensees as confidential. Form 27 impinges upon that “Right to Confidentiality”. Each license agreement is unique and there cannot be one-size fit all model and hence licensing terms and conditions varies and are market driven. Any such disclosure in Form 27 with regard to commercial arrangements shall seriously prejudice interests of licensee as well as licensor. Such information may also be misused by unwilling licensees to expose licensor to frivolous competition issues. Further, this can actually be misused by unwilling licensees to get this important data out in public domain. This will increase litigation costs substantially where IP owner will be sued by licensees for the breach of confidentiality or for not been able to secure confidential business information such as sales figures, anticipated revenue/profit. This will threaten businesses, hurt global licensing model and will potentially chill innovation cycle.</th>
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<tr>
<td>Quantum and value (in Rupees) of the patented product</td>
<td>It is difficult to determine the value of the patented product. Quantum here refers to the quantum of products manufactured in India. Generally organizations have the data related to the sales information of a product. The sales information relate to the sale price of the product and not the manufacturing price of the product. Whether the value of the patented product relates to the manufacturing price of the product or its sale price is unclear. Further, the</td>
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manufacturing price could vary over time, and expecting organizations to keep track of the manufacturing price during a year and then furnish the total manufacturing price which appears unreasonable. Would it be acceptable to cluster as many patents as possible that pertain to a single product and state in Form – 27 that the listed patents are worked in the product and the exact value of the individual patents is difficult to be determined accurately?

Further, in case the product is imported from different countries, how do we determine the value of the patented product? Does it refer to the importation value or to the selling price of the product?

It would be good if the patent office could provide more details to resolve such uncertainties. The patent office could provide detailed exemplary scenarios, it could aid the patent holder in furnishing the required information in an accurate, correct, complete and unambiguous manner.

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<th>Reasons for not working the patent invention</th>
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<tr>
<td>A CL application can be made any time after 3 years from the date of grant. In certain technology fields such as pharmaceuticals, nanotechnology, cancer therapies and advances in health care diagnostics, the minimum time period required is almost 6 – 8 years. The patentee has to wait for the other enabling technologies to develop before the patentee could bring out the patented invention in a product. So, would it be acceptable to state that the technology field is still embryonic and hence there is a delay to work the patented invention. It could also be the case that there is no market need at the time the patent is granted. The delay could be not in terms of the patented technology, but could be that the market is not yet ready, or the associated enabling technologies are yet to develop/mature. What is undue delay in one technology field may not be...</td>
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undue delay in a neighboring technology field. May be the market conditions are not conducive to the patentee and the patentee would like to hold on and watch how the market develops before he starts putting his patented invention in a product. Would it be acceptable to state that the patentee is exploring licensing opportunities as one of the means for working the patented invention?

It would be good if the patent office could provide clear, concrete explanations on the intent of seeking such information and the scope of the sought information. Due to lack of clarity, there appears to be an incorrect, non-uniform way of providing the information. If these concerns are well addressed, the patent holders could furnish the required information in an accurate and correct manner.

<table>
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<tr>
<th>Meeting the public requirements</th>
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<tr>
<td>The public requirements could differ from one industry sector to the other. As an example, the public requirement for a patented medicine is different from the public requirement for a patented improvement to a high-end camera. Furthermore, what is a reasonable public requirement in one technology field may be an unreasonable requirement in another. In such cases how does the patent holder ascertain the scope related to “public requirements”? Further, it would be an additional burden on the patent holder to do a market study and collect the information related to public requirements.</td>
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<table>
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<tr>
<th>Reasonable price</th>
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<tbody>
<tr>
<td>The words “reasonable price” is ambiguous and there is no clarity on what amounts to reasonable price. The literal meaning of reasonable means “showing reason or sound judgment”, “not excessive or extreme”. Generally, the patented product would be priced high during the early years of the launch of the product. Later on due to a number of reasons, the prices generally start falling over a couple of years. As an example, when mobile phones were first introduced in the</td>
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</table>
Indian market, they were made available at reasonably high prices. Later on the prices started decreasing. The various factors to be considered in determining the reasonable price is unclear.

<table>
<thead>
<tr>
<th>Partly met/adequately met/met to the fullest extent</th>
<th>These are relative terms and there is no unequivocal, generally accepted meaning existing to interpret the words partly met/adequately met/met to the fullest extent. A more precise wording would be good. These vague terms could be made slightly more understandable by adding practical circumstances so that the patent holder can better understand their meaning. It would be good if a few working scenarios could be detailed to provide more clarity on how to determine whether the requirements are partly met/adequately met/met to the fullest extent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>True to the best of our knowledge and belief</td>
<td>Section 122(2) states “If any person, being required to furnish any such information as is referred to in sub-section (1), furnishes information or statement which is false and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both. Further, Rule 131 (3) states that the Controller may publish the Form – 27 submitted information. In view of the RTI Act, any third party may attempt to prove that the information provided in Form-27 is inaccurate and false. First of all, the information sought is impossible to determine. Further, due to the ambiguous nature of the information being sought in Form – 27 and also lack of clarity, there is a high probability of providing incomplete information. Providing accurate information as required in Form – 27 is a real challenge. At the same time, unintentionally providing incomplete/incorrect information may result in enforcing Section 122 provisions. Hence the patent holder would be put in a dilemma on the manner in which</td>
</tr>
</tbody>
</table>
accurate, correct and complete information is to be submitted in Form – 27. Further, if a patent is not worked, the patentee is expected to provide reasons for not working. Sometimes, the reasons may be business sensitive, trade secret and confidential. Under section 8(d) of RTI those are exempted from disclosure to public. This is especially important for India as we do not have any law that protects trade secret.

In view of the above problems, a clear, concise and unambiguous Form – 27 supported by detailed description (with exemplary illustrations) would enable all the stakeholders to effectively comply with the submission of Form – 27. Hence, it is necessary to revise form – 27 and come up with a simple form.

III. Proposal for revision of Form – 27

In the unlikely event that the patent office decides to retain the current practice of seeking the FORM-27 from each and every patentee and licensee, we propose that Form – 27 be revised to make it simpler and possible to comply format such that the patentees/licensees can provide the information. A patentee may submit whatever information is available along with a self-declaration. The patentee should be allowed to explain/declare the extent of working rather than providing information on quantum of products sold/value realized from the sale and meeting of reasonable requirements etc.,

The Controller could on a need basis request for additional information under sub-section 146(1) based on any query or clarification deemed necessary by the Controller or a third party requesting for the same/the Controller may restrict this to only those patents, which relate to public interest/public health and safety in line with the legislative intent explained in the opening paragraph.

We propose the following approach for the submission of the working statements:

<table>
<thead>
<tr>
<th>Proposal: Form – 27: Submission of working statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Name, address and nationality of the patentee</td>
</tr>
<tr>
<td>2. Patent Number</td>
</tr>
<tr>
<td>3. The patented invention (tick the relevant one)</td>
</tr>
<tr>
<td>A. Worked</td>
</tr>
<tr>
<td>B. Not worked</td>
</tr>
<tr>
<td>C. Unknown</td>
</tr>
</tbody>
</table>

- IPO will approach the Patente if more information is required.
The approach thus proposed meets the statutory objectives of seeking relevant information for the purpose of administering compulsory licensing, and at the same time avoids unneeded burdens to the majority of patentees where there is clearly no demonstrated public interest.
15 March 2018

Dr. W. M. Dhumane and Dr. Usha Rao  
Government of India  
Office of The Controller General of Patents, Designs & Trade Marks  
Boudhik Sampada Bhavan  
S.M. Road, Antop Hill  
Mumbai-400 037, India

VIA EMAIL ONLY (cgoffice-mh@nic.in; wm.dhumane@nic.in; drusharao.ipo@nic.in)

Re: Working of Patents Under the Patents Act, 1970 (as amended)  
No.CG/Meeting Circular-DIPP/2018/14

Dear Dr. Dhumane and Dr. Rao:

Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the request for comments dated 3 January 2018 by the Office of The Controller General of Patents, Designs & Trade Marks regarding the working of patents in the Patents Act 1970 (as amended).

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO’s membership includes about 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights.

We suggest the removal of the working requirement and its supporting statement for the benefit of domestic and foreign owners of Indian patents alike. Although one policy position might be that the requirement exists to encourage commercialization or to prevent the frivolous assertion of a patent by an abusive non-practicing entity, IPO believes such a policy does little to influence commercialization as commercialization is ultimately driven by market considerations. Further, documentation in support of the working requirement requires the public disclosure of confidential business information that is detrimental to the interests of the patent owner — and failure to submit a “working” statement can result in harsh civil and criminal penalties. IPO suggests removing the working requirement altogether from existing law.
Although we suggest Form-27 should be withdrawn, below we address the issues identified in the orders by the High Court of Delhi: Lack of clarity in Form-27 and non-compliance by patentees/licensees of Form-27.

First, any Form-27 should be amended to remove the “value” portion of the requirement related to providing the “quantum” and “value” of the patented products manufactured in India and imported from other countries. Further, for the remaining portion of the requirement, \textit{i.e.}, for the quantum, the requirement should be satisfied by completing one of a set of prescribed numerical ranges (for example: less than \underline{___}; between \underline{___} and \underline{___}; greater than \underline{___}) for the “quantum” as opposed to a precise unitary number. This approach helps alleviate patentees’ concerns where precise financial figures are not available or are subject to confidentiality obligations, while also providing the Office with a tangible indication of the extent of the patent being worked in India. Furthermore, licenses often cover multiple patents related to a certain technology field. Under such arrangements, the individual value of a patent is oftentimes not available to the patentee. Therefore, providing numerical ranges for “quantum” of the patented products manufactured in India and imported from other countries and not requiring exact value figures would contribute to a better and more holistic assessment of the extent of a package of patents being worked in India, and would also reduce associated administrative burdens.

Second, the requirement of disclosing information regarding the extent to which the public requirement has been met and reasonable pricing should be removed. This information is generally subjective and it is very difficult to identify an amount supported by objective data.

Third, our current understanding is that Form-27 does not require disclosure of license terms, but we wanted to make clear that we believe any requirement to disclose the terms of the license/sublicense, beyond identifying licensees/sub-licensees and working information, would create substantial issues for licensors and licensees. Patent license terms are often highly confidential to protect the interests not only of the patent owner, but also of the licensee (which is often a domestic company).

Fourth, Rule 131 of the Patent Rules of India provides that “[t]he statements shall be furnished by every patentee and every licensee.” The word “and” should be changed to “or”, as it would be redundant to have the same information furnished by both patentee and licensee, leading to unnecessary administrative burdens.

For the reasons discussed above, IPO respectfully requests removal of the working requirement. To the extent that the working requirement and accompanying working statement continue to be required, IPO urges adoption of the above-mentioned changes to Form-27.
We again thank the Office of The Controller General of Patents, Designs & Trade Marks for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information.

Sincerely,

Mark Lauroesch
Executive Director
COMMENTS RELATING TO WORKING OF PATENTS

Submission by
INDIAN PHARMACEUTICAL ALLIANCE
(Email: dgshah@vision-india.com)

Mumbai
March 16, 2018
1. My name is Dilip G. Shah and I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I am making this submission to the Controller General Patents, Designs & Trade Marks on behalf of the IPA. The submission is in response to Circular dated 1 March 2018 calling for comments on Section 146 and 122 of the Patents Act, 1970 and Rule 131 and Form 27 of the Patents Rules, 2003 relating to the working of patents.

2. IPA’s membership consists of twenty pharmaceutical companies which collectively account for about 85 percent of private sector investment on pharmaceutical research and development in India, 80 percent of the country’s exports of pharmaceuticals and related services and 46 percent of the domestic market. We therefore have a vital interest in manufacture of generic medicines for India and the world. We also have an interest in the protection of our innovations, not only for developing cost-effective and useful improvements in existing medicines, but also for discoveries of new medicines.

3. The statutory provisions relating to the working of patents cover domestic as well as foreign patentees in all fields. However, our comments are limited to the perspective of the pharmaceutical industry.

4. Though the IPA represents a segment of the pharmaceutical industry in India, it is deeply conscious of its larger responsibilities and has always endeavoured to provide inputs relevant to policy making in the national interest, including in the area of Intellectual Property Rights. This submission is no exception.

The context

5. The power of the Controller to call for information S. 146(1) and the mandatory requirement for patentees to periodically submit the prescribed information under S. 146(2) read with R. 131 and Form 27 assumes significance in the context of Chapter XVI of the Patents Act (the Act) dealing with the working of patents, compulsory licensing and revocation. For the purposes of this Chapter the terms ‘patent’ and ‘patentee’ are in relation to ‘patented articles’ and ‘any article made with a patented process’ (S. 82). The term ‘patentee’ includes a licensee. The terms ‘patent’ and patentee’ are used in the same sense in this submission, unless the context requires otherwise.

6. Chapter XVI confers power to the Controller to grant compulsory licences on application by any person (S. 84) or on notification by the Central Government (S. 92) and to revoke patents for non-working (S. 85). The ‘general considerations’ for the exercise of these powers are set out in S. 83 extracted below:
Indian Pharmaceutical Alliance

(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

7. It may be noted that subsections (c) to (g) were added by the Patents (Amendment) Act, 2002 with effect from 20 May 2003. These additions were clearly intended to safeguard public health, prevent abuse of patent rights and ensure that patents contribute to the transfer and dissemination of technological knowledge. They were also intended to strike a balance between the grant of monopoly rights to incentivize innovation and the imperatives of public health, consistent with the Doha Declaration and the TRIPS Agreement.

8. Public health objectives are furthered by the availability of medicines at reasonable prices. When medicines are under patent, it is imperative that patents are adequately worked. Compulsory licences are a powerful mechanism to ensure adequate availability at reasonable prices. Contrary to general perception, the use of compulsory licencing is not unusual. A recent study shows that there were 100 instances of compulsory licences (including for public non-commercial or government use) for pharmaceutical products between 2001 and 2016, and six of these instances were in developed countries. These licences were largely for HIV (73), but were also issued for cancer (12) and other (15) diseases.¹

Indian Pharmaceutical Alliance

9. India has been very circumspect in exercise of powers under Chapter XVI. The first and only issue of compulsory licence under S. 84 (for Bayer’s Nexavar™) was in March 2012. No compulsory licence has been issued in the last five years. On the contrary, applications for compulsory licences (for AstraZeneca’s Onglyza™ and Kombiglyze™) have been rejected in 2016. No patent has ever been revoked under S. 85 and no notification of patents for grant of compulsory licence under S. 92 has ever been made. In addition, it may also be mentioned that no use of a patented invention by Government has ever been resorted to under S. 100.

10. The mandatory requirement for patentees to furnish information annually on the working of patents under S. 146(2) read with R. 131 in Form 27 has to be reviewed in the above context.

11. It may be noted that a writ petition in the public interest is pending before the High Court at Delhi.² Based on an analysis of Form 27 filings between 2009 and 2012 in three fields – pharmaceutical drugs, telecommunications and publicly funded research – the writ petition alleges that about a third of the patentees did not disclose the status of patent working and even for the disclosures made, about a third were defective and incomplete. The writ petition seeks a directive to the Government and the Controller to compel patentees and licensees to declare information on the working of their patents as required under the Act.

12. As Government is well aware, PhRMA (Pharmaceutical Research and Manufacturers of America) and BIO (Biotechnology Innovation Organization) have consistently made a grievance of the requirements under S. 146(2) and Form 27 in their annual Special 301 submissions to the USTR (United States Trade Representative). Their apprehension is that this information will be used to grant compulsory licences and further, that it imposes an unreasonable administrative burden on them. The USTR has consistently noted this grievance while continuing to place India on the Special 301 Priority Watch List.

IPA comments

13. Section 146(1): The subsection confers power on the Controller to call on patentees and licensees to furnish such information or periodical statements that may be specified on the extent to which a patent has been worked on a commercial scale for specified period(s).

IPA submits that this power is necessary and justified.

² Shamnad Basheer v Union of India, WP(C) 5590 of 2015, Delhi High Court

Indian Pharmaceutical Alliance

14. Section 146(2): The subsection requires the submission as prescribed (currently at annual periodicity in Form 27) by every patentee and licensee of statements on the extent to which the patented invention has been worked on a commercial scale in India.

IPA believes that information pertaining to working of a patent is crucial to assessing whether the balance that is sought to be achieved by the Act, between incentivising innovation and promoting public health by ensuring adequate availability of medicines at reasonable prices, is achieved. The exercise of the power (and the concomitant obligation) under Chapter XVI will be stultified without such information. When the product patent regime for pharmaceuticals was incorporated into the statute to conform to the TRIPS Agreement, the assurance that public health will be safeguarded was backed partly by the amendments to Chapter XVI in 2002.

IPA submits that the requirement mandated by this subsection is justified and should continue.

15. Section 146(3): The subsection provides that the Controller may publish information received by under subsections (1) and (2).

Patents are in the public domain. Our understanding is that Form 27 filings are made available under the Right to Information Act. Civil Society and NGOs can play a constructive role in aiding assessment of the extent to which patents are worked on a commercial scale if the information is made available routinely and efficiently.

S. 100 confers power on the Government to use an invention for the purposes of Government. Information on the working of a patent can be advantageous should Government exercise this power for the furtherance of public health without losing sight of imperative of preserving the incentive for engaging in such much-needed innovation.

The Controller has previously made public the filings of Form 27 for two years – 2012 and 2013 – in a searchable database.

IPA submits that the Controller may consider routinely digitising all Form 27 filings and placing them in a searchable database designed to permit convenient analysis and scrutiny by all persons.

16. Rule 131: The rule merely specifies that the statement filed under S. 146(2) shall be filed in Form 27 for every calendar year, within three months of the close of the calendar year. IPA submits that no change is needed.

17. Form 27: The primary purpose of submission of the Form is for the Controller and Government to exercise their powers (and the concomitant obligations) under the Act. It is for them to decide on what best serves their purpose, taking into consideration the views of all stakeholders.
Indian Pharmaceutical Alliance

The content of the Form has invited criticism from several quarters. The main issues seem to be:

- Lack of clarity on what should be the definition of ‘quantum’, as several filings have aggregated supplies under Patient Assistance Programmes with commercial sales. IPA submits that the Form should provide for separate reporting of commercial sales and supplies under Patient Assistance Programmes.
- Lack of clarity on the manner of computation of value; IPA submits that the value should represent the aggregate value of commercial sales to wholesalers/distributors net of discounts, direct sales to patients and institutional sales. Free supplies under Patient Assistance Programmes need not be ascribed any value.
- Vagueness in Sl. No. 3 of the Form (‘public requirement’, ‘met partly/adequately’, ‘reasonable price’). Clearly, these terms are subjective and difficult to define in general. It may serve no purpose to require such information as they have to be determined through a case-by-case assessment.
- Confidentiality of commercial information relating to quantum, value and licensees. Information of quantum and value re provided in aggregate and may not materially compromise commercial confidentiality. Licensees are also required to file Form 27, so their identity is known.

18. **Section 122**: S. 122(1)(b) provides for punishment that may extend to Rs. Ten Lakhs for failure to furnish information under S. 146 and S. 122(2) provides for punishment that may extend to six months imprisonment, or fine, or both for furnishing false information. IPA does not see any reason to modify the penalty.

19. **Administrative burden**: All patentees (and licensees) of a patented article or an article made by a patented process are required to file Form 27, without any limitation of field. The primary purpose of such filings is to enable the Controller to make an assessment of working of the patent for the purpose of granting a compulsory licence (S. 84), revoking a patent (S. 85), termination of a compulsory licence (S. 94) and the Government to make a declaration by notice that it is necessary to grant a compulsory licence (S. 92).

The primary administrative burden is therefore that of the Controller to scrutinize all the Form 27 filings for the purpose of exercising powers under Chapter XVI the Act and of Government for the purposes of S. 92 and S. 100. The Controller may also decide to undertake the burden of publishing all Form 27s in a searchable database.

It may be noted that the majority of patents would be in fields or for articles where their working or non-working are of no consequence to public health or public interest. The Controller and Government may wish to examine the possibility of reducing the administrative burden on themselves, without in any way compromising public health and public interest.

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16 March 2018

Mr O P Gupta  
Controller General of Patens, Designs & Trade Marks  
Boudhik Sampada Bhavan  
S M Road, Antop Hill  
Mumbai 400 037

Dear Mr Gupta,

IPA Submission on Working of Patents

We refer to Circular dated 1 March 2018 calling for comments on Sections 146 and 122 of the Patents Act, 1970 and Rule 131 and Form 27 of the Patents Rule, 2003 relating to the working of patents.

2. The Indian Pharmaceutical Alliance (IPA) is a premier association of the pharmaceutical industry in the country. It represents over US$ 18 Bn of the total revenue of US$ 32 Bn of the pharmaceutical industry in India.

3. We forward herewith a detailed five-page submission for your consideration and request you to acknowledge the same.

Thanking you and with regards,

Yours sincerely,  
For Indian Pharmaceutical Alliance

D G Shah  
Secretary General

Encl: a/a
Ref. No.: PC/233

The Controller of Patents
The Patent Office
New Delhi

Dear Sir,

Re: Comments from Stakeholders regarding issues relating to working of Patents

With reference to circular no. CG/Circular/2018/114 dated 16.03.2018 please note our comments:

1. That there should be no deadline to file Form-27
2. That in products that have multiple patents it becomes difficult to determine the quantum of each application.
3. That when there are multiple licensees for an invention it is difficult to get information from each and every licensee.

Kindly consider the above and invite us for the Stakeholders meeting.

Regards,

Ms. Neha Chugh
Patent Attorney
B.Engg., LLM
March 16, 2018

Dr. W. M. Dhume and Dr. Usha Rao
Office of The Controller General of Patents,
Designs & Trade Marks
Boudhik Sampada Bhavan
S. M. Road, Antop Hill
Mumbai-400 037 (India)

Dear Dr. W. M. Dhume and Dr. Usha Rao,

Re: JIPA Comments on the issues related to Working of patents under the Patents Act, 1970.

We, the Japan Intellectual Property Association "JIPA", are a private user organization established in Japan in 1938 for the purpose of promoting intellectual property protection, with about 940 major Japanese companies as members. When appropriate opportunities arise, we offer our opinions on the intellectual property system of other countries and make recommendations for more effective implementation of the systems.

(http://www.jipa.or.jp/english/index.html)

Having learned the Circular on your website which request stakeholders to submit their comments on the issues related to Working of patents under the Patents Act, 1970, we would like to offer our opinions as follows.

Your consideration on our opinions would be greatly appreciated.

Sincerely yours,

(Osamu IKEMURA)
Managing Director
Japan Intellectual Property Association
JIPA Comments on the issues related to Working of patents under the Patents Act, 1970.

It is an excessive burden to patentees who own many patents or licensees to investigate the condition of working of patents to prepare information necessary for the submission of a statement on the working thereof, and to pay the fees for entrusting the submission to agents every year. It may cause them to refrain from filing applications in India. If foreign companies, in particular, who intend to protect results of their technical development in India by patents, are forced to bear an excessive burden to maintain the patents, they may refrain not only from filing applications in India but also from investing in India, such as establishing research and development bases.

The CGPDTM of India discloses, on its website, the PDF files of statements on the working of patents submitted by applicants under Section 146(3) of the Patents Act. Most of the descriptions in the statement are companies’ trade secrets, such as sales quantity, price and license information. For patentees and licensees, disclosure of such information to their competitors may cause loss of their competitiveness in their future businesses.

Therefore, we would like to abolish the system of submitting statements on the working of patents.

If it is impossible, we would like to request that descriptions including trade secrets, in particular sales quantity, price and license information (License granted (Yes/No), and Licensee name), should be removed from statements on the working of patents.

If both requests are not accepted, we would like to request these descriptions are kept undisclosed in the statements, or to allow the descriptions to be undisclosed upon appeal as with the license registration system.
Japanese Intellectual Property Group in India

Mr. O P Gupta
Controller General of Patents, Designs & Trade Marks
Intellectual Property India,
Patents/Designs/Trade Marks/Geographical Indications,
Boudhik Sampada Bhavan, Antop Hill, S.M. Road, Mumbai

Sub: Opinions on the working statement requirement and its related system under the Patents Act, 1970

Dear Mr. O P Gupta,

The Japanese Intellectual Property Group (IPG), formed by Japanese companies in India, aims to protect and promote intellectual properties Japanese companies have in India through intellectual property-related activities. One of the activities is to hold regular meetings to share intellectual property-related information among member companies. The IPG also submits suggestions regarding intellectual property rights through the Japan Chamber of Commerce and Industry in India (JCCII) and regularly exchanges views with the Government of India.

1. The purpose of the working statement requirement and its related system

1) Related rules and provisions

i. Working statements

Section 146 of the Patents Act: (1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.

(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.

(3) The Controller may publish the information received by him under subsection (1) or sub-section (2) in such manner as may be prescribed.

131 of the Patent Rules: (1) The statements shall be furnished by every patentee and every licensee
under sub-section (2) of section 146 in Form 27 which shall be duly verified by the patentee or the licensee or his authorised agent.

(2) The statements referred to in sub-rule (1) shall be furnished in respect of every calendar year within three months of the end of each year.

(3) The Controller may publish the information received by him under subsection (1) or subsection (2) of section 146.

ii. Penalties

Section 122 of the Patents Act: (1) If any person refuses or fails to furnish—
(a) to the Central Government any information which he is required to furnish under sub-section (5) of section 100;
(b) to the Controller any information or statement which he is required to furnish by or under section 146, he shall be punishable with fine which may extend to ten lakh rupees.

(2) If any person, being required to furnish any such information as is referred to in subsection (1), furnishes information or statement which is false, and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both. (The subsection does not set any upper limit on the fine.)

*Neither the Patent Act nor the Patent Rules provide any procedure to appeal against application of the penalties.

2) The significance of the working statement requirement

The significance of submitting working statements is to furnish facts based on which the Controller determines the grant of a compulsory licence under Section 84 of the Patent Act. The Controller uses working statements to understand the extent to which the patented invention has been commercially worked in India on the grounds that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or that the patented invention is not available to the public at a reasonably affordable price, or that the patented invention is not worked in the territory of India.

As Section 83 states, patents are originally granted to encourage inventions, secure that the inventions are worked, promote technological innovations and public interest, and make the benefit of the patented invention available at reasonably affordable prices to the public.

The compulsory licence system was established for the purpose of keeping the balance between public interest and a patentee’s right by exercising public authority to prevent exclusive rights conferred on patentees from impeding the promotion of public interest.

Accordingly, working statements should be used to keep the balance between public interest and a patentee’s right. This means that while sufficient information should be provided through the statements to the Indian Patent Office to grant a compulsory licence, patent applicants should not be discouraged to apply for a patent by undue burden of providing more information than necessary.
3) The significance of Article 31 of the TRIPS Agreement

The article includes provisions to be respected where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder. Especially, Article 31 (b) provides that compulsory license “may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.” It clearly requires the effort of the potential licensee of compulsory license.

Therefore, if the rules of compulsory license are requiring the undue burden on the patentee only instead of the effort of the proposed user, there is concern that such rules are conflicting against the purpose of Article 31 (b).

[For reference]
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

2. Issues relating to the working statement requirement and its operation

1) The statement is required regardless of any application for a compulsory licence.

• The main purpose of the working statement is to use information disclosed in it to determine whether a compulsory licence should be granted. It will not be too late if disclosure of information is requested at the time of an application for a compulsory licence.

• To date, 5 applications for a compulsory licence were filed under the existing Patent Act. Given the situation, it is not necessary to request that information on all patents be disclosed.

• More importantly, we can expect that each concerned party will furnish information which they reasonably think is most necessary if the Controller requests the information from the party, considering appropriate sharing of burden of proof, when examining an application for a compulsory licence.

• It is therefore sufficient that the Controller requests necessary information from patentees at the time of an application for a compulsory licence, and such operation will effectively fulfil the purpose of working statements.
2) It is not clear whether partial disclosure is permitted.
   · Form 27 requires the quantity and value of patented products worked in India, as well as a declaration that the information stated therein is true to the best of the patentee's knowledge. However, it is not clear whether the form requires patentees to do everything to research and find out all the information that shows to what extent their patented inventions are worked or the form allows a partial disclosure. This leaves us with some concern that unintentional omissions in the statement might be considered as false information and lead to penalties on patentees.
   · It is almost impossible to furnish complete information regarding the extent of working of patents because the following cases make it extremely difficult to keep a complete track of the quantity and value of patented inventions being worked.

(1) A patented invention, which the patentee plans to use for a product, can actually be used or has been used for another product manufactured or imported by the patentee. In this case, there is a risk of breach of duty if the patentee fails to report on the quantity of such another product for which the patent is used.

(2) Licensees under a comprehensive licencing agreement, which licences a patent in a comprehensive framework, such as technology areas, corporate entities and regions, without any licence number specified. Most of the licensees are not able to find out which one of the licensor's patents has been used for which one of the licensee's products. This will likely be a cause of omissions in the working statement.
   · In order to obtain the exact number/value of patented inventions being worked in the above-mentioned and other cases, patentees or licensees need an investment large enough to set up a unit in their company specialised in doing so. It is an undue burden for patentees.
   · As, unlike when patentees fail to furnish any information, severe penalties will be imposed when they furnish any false information, it might encourage some patentees (especially startups who will lead India in the future) to refuse to furnish any information, rather than to furnish an insufficient information because they do not have enough money to do any research on working of their patents.
   · For the reasons above, Form 27 should allow patentees to declare that what is furnished by them is a partial information regarding the extent of working of their patented inventions in India.
   · It should be noted that the Patent Act requires "the extent to which the patented invention has been commercially worked in India," not "the complete information on the patented invention which has been commercially worked in India." Such modification in Form 27 suggested above will cause no inconvenience to the purpose of the working statement requirement as the Controller can request additional disclosures if he considers that the information furnished is insufficient to decide whether a compulsory licence should be granted.

3) It is unclear whether patentees do not have to disclose the number of the patented inventions worked by the licensee.
   · For the reasons mentioned in 2) above, it is unclear whether "the working of the patented invention" includes "the working of the patented invention by licensees."
· If it includes “the working of the patented invention by licensees,” the following issues will arise:

(1) In most of licencing agreements on a lump sum payment basis, licensees do not have to report to their licensors on the quantity of patented inventions being worked. If patentees try to perform their research duty, they will need to negotiate with their licensees, which will be a burden on the patentees in terms of time and cost.

(2) Similar issues arise in a case of comprehensive licencing as it does not usually require any report on the quantity of patented inventions being worked.

· Therefore, Form 27 should mention that patentees are required to only show the quantity of patented inventions being worked by themselves, not by licensees.

4) The statement requires a declaration regarding the reasonable requirements of the public.

· The reasonable requirements of the public is what the Controller should consider in order to determine whether a compulsory licence should be granted, not what patentees can and should determine.

· Patentees will be trapped in a dilemma: If they declare that the reasonable requirements of the public is met, the Controller might deem it to be false in considering a grant of a compulsory licence while, if they do not declare so, a compulsory licence might be granted at a later stage.

· Such risk could intimidate prospective patent applicants.

· For those reasons, the requirement for the declaration should be removed.

5) The information disclosed in the statement can be public.

· Most companies cannot strategically disclose information such as the number and total value of products sold. We do not think that sufficient information will be furnished unless appropriate measures are taken to keep the information furnished secret and require applicants for a compulsory licence to conclude an NDA to obtain the information.

· As such information is critical especially for pre-IPO startups, some of them might decide not to apply for any patent to avoid disclosing their information. It will impede a national development and technological innovation in India.

6) There is a lack of review on application of penalties and legislation on appeal procedures.

· Penalties that restrict individual’s properties should not be applied until appropriate procedures are put in place to check compliance with the obligation to file a working statement within the Patent Office, to fix the amount of the fine, to give patentees an opportunity for a hearing and to appeal against the Controller’s decision.

· Those penalties could also intimidate prospective patent applicants.

3. Requests

1) Abolition of the entire working statement system in the future

Patentees furnish information necessary to determine whether a compulsory licence should be granted when they are asked to at the time of determination after appropriately sharing burden of proof. It is unnecessary and imposes an undue burden to require all patentees to disclose their information. Therefore, the entire working statement system should be abolished in the future.
2) Amendment of 131(2) of the Patent Rules (as an interim measure until the abolition)

As it is originally sufficient to ask patentees to furnish their information when an application for a compulsory licence is filed, the Patent Rules should be amended to remove the timeline for filing the statement, which is within 3 months of the end of each fiscal year. The amendment does not contradict the intervals of 6 months stipulated in the Patent Act.

3) Modification of Form 27 (as an interim measure until the abolition)

As we assume that it is difficult to amend the Patent Act, we would at least like to request the following modifications in Form 27 because of the reasons shown in paragraph 2 of this document.

i. It should be clearly mentioned that partial information of the extent of commercially working in India has been disclosed by the Form 27. Or, the option that patentee/licensee can mention the disclosed information could be partial information shall be added in Form 27.

ii. It should be clearly mentioned that it discloses the number of the patented inventions worked by the patentee itself (in case of working statement by patentee) or the licensee itself (in case of working statement by licensee).

iii. The declaration should be removed regarding the reasonable requirements of the public (Removing Paragraph 3. (iii) of Form 27).

Sincerely Yours,

Yoshinobu Noda
Japanese Intellectual Property Group in India
Vice Chairperson
March 15, 2018

Shri. O P Gupta, IAS
Controller General of Patents,
The Indian Patent Office,
Mumbai, India.
wm.dhumane@nic.in
drusharao.ipo@nic.in

RE: Stakeholders meeting on issues related to Working of Patents under the Patents Act, 1970

Dear Sirs,

This is with respect to the circular dated 1st March 2018 issued by Indian Patent Office inviting comments regarding the issues on working of patents under the Patents Act 1970. Please find enclosed our comments and suggestions in this regard, and particularly some of the important concerns about “working of patents and filing of Form 27 annually”.

As you may be aware, K&S Partners (K&S) is an Intellectual Property (IP) law boutique, a registered partnership law firm. K&S is specially noted for the depth and wide range of expertise in matters relating to patents and for pioneering work in the protection of certain IP rights like geographical indications in India. Founded in 1994, K&S today has over 110 professionals and is amongst the top five IP firms in India.

K&S represents a large number of patentees (both domestic as well as International) and is an active member in most of the stakeholder’s meeting by IPO acting on behalf of our clients with respect to various issues which impact the patenting system in India.

We would be pleased to meet with your esteemed selves to explain our concerns on this important subject in the stakeholder meeting on March 21, 2018. Kindly contact us for any clarification you may need or further discussion you may wish to review and consider our submissions.

Thanking you,

Yours Sincerely,

Jyoti Sagar
Managing Partner

Enclosed: Comments and suggestions on requirement of annual filing of Form-27 in India.
A. Legislative Foundation

- Section 146(1) of the Indian Patent Act (“the Act”) empowers the Controller to direct any patentee or licensee to furnish a statement describing the extent of commercial working of the concerned patent in India.
- Section 146(2) imposes an obligation on all patentees and licensees to submit a statement describing the extent of commercial working of their patent in India, in a manner and form as may be prescribed.
- Rule 131 of Patent Rules (the Rules), prescribes that a patentee (and licensee, if any) must furnish annually, the statement under Section 146(2), in the form prescribed – and that is Form 27.
- Section 122(1) imposes a fine, which may extend up to INR Ten Lakhs if a patentee or a licensee does not comply with Section 146.
- Section 122(2) provides for punishable with imprisonment, which may extend up to 6 months, or with fine, or both if a person furnishes information or statement (as referred to in Section 146), which is false and which he knows or has a reason to believe to be false or does not believe to be true.
- The information provided in Form 27 is made available to the public at large by being published on the Indian Patent Office (IPO) website.

B. Legislative Intent

The legislative purpose and intent of Section 146 of the Act is derived from Section 83 of the Patents Act, 1970, empowering the Controller to obtain from the patentee/licensee (and thus requiring the furnishing of) certain details about working of patents in India.

With the 2002 amendments to the Act, non-working of patents was added as one of the grounds for compulsory licensing under section 84 thereby linking these two provisions.

C. Commercialization of patents: ground realities

The percentage of granted patents getting commercialized, in India or internationally, is very small. The reasons why patents may not be commercially implemented or used at “commercial scale”, are diverse. Mere patenting does not mean that a potential product using the subject matter of the patent may have any imminent need or demand in the market.

D. Effectiveness of Form 27 for achieving the intended objective – who does it help?

- Form 27 does not enable the Controller in determining the considerations prescribed under Section 83 for inventions from all fields of technology. For instance, inventions related to ICT, computers, automobiles, general domestic equipment, tools, instruments, do not relate to maintaining public health,
nutrition, socio economic welfare and safety.

- The quantum manufactured, and revenue generated therein, has no correlation in determining whether the patent is promoting and encouraging inventions in India or that there is adequate transfer of technology in the Indian technological ecosystem.

- Public affordability cannot be quantified by the value of profit earned by the patentee/licensee.

- Most of the information sought under Form 27 is irrelevant for the purposes of principal Sections 83, 84 and 85.

- It would be unreal to assume that “interested” persons would trawl Form 27s filed by thousands of patentees and make a list of patents which have not been “worked” in India and on that basis, seek a compulsory license for those patents!

- Whether the Patent was actually worked or not, can always be established by leading evidence in case of a contention between interested persons and patentee – recent cases of compulsory license (CL) applications are examples of this. Thus, irrespective of whatever are the statements made in Form 27; or whether the form was filed at all, in any CL proceedings, the patentee will have to provide all information under oath.

E. Is IPO equipped to scrutinize thousands of Form 27s?

- Form 27 compliance places onerous burden on the patentee almost to the extent of acting as a deterrent to patenting in India. However, what are the benefit offered by this to the Indian Patent system?

- Indian Patent Office (IPO) cannot possibly play watchdog and scrutinize all these thousands of working statements to see if patentee has adhered to the requirements. How would such information eventually benefit the public?

F. Form 27 and its architecture

Form 27 seeks the following information:

“1. Whether the patented invention has been worked or not worked;

   a. if not worked, the reasons for not working and the steps being taken for the working of the invention.
b. if worked, the quantum and value (in Rupees) of the patented product;
   i. manufactured in India;
   ii. imported from other countries along with the country-wise details;

“2. The licenses and sub-licenses granted during the year;

3. Whether the public requirement has been met, partly/adequately/to the fullest extent” at reasonable price.”

- The last paragraph of Form 27 is: “The facts and matters stated above are true to the best of our knowledge, information and belief. This is an affirmation from the person signing the form.

This implies that if such information provided by the patentee/licensee is false, it can lead to imprisonment.

- The most important question in the form, question no. 3, is an open-ended question - “Whether the public requirement has been met, partly/adequately/to the fullest extent, at a reasonable price”.

It is impossible to answer for a patentee/licensee, whether the public demand has been met at one of the three levels suggested in the form and that too at a “reasonable” price? What constitutes “reasonable price” and what is implied by “partly” (sic) or “adequately” or “fullest extent”? Wrong answers to these vague and subjective words potentially carry a threat of imprisonment! “I do not know” perhaps may be a defendable truthful answer!

Question 1 (b) of the form is designed on certain assumptions. These are:

a. “one patent” covers “one product”.

b. the patentee or the licensee is the seller of the product in India – whether it is manufactured in India or overseas.

c. There are no intermediate products, parts or components which the patentee or its licensee could be selling overseas, which are then incorporated in to end “products” which are finally sold in India by third parties.
March 16, 2018

The above simplistic assumptions are fundamentally and conceptually incorrect – thus leading to a flawed architecture of the form.

G. Differences in Form 27 in print form in the Rules published by the Patent Office and the “on-line” form.

Although the IPO has made improvements in the online Form 27 filing process and format, there are still some differences, some of which are listed below:

**Fig. 1 Key differences between Form 27 in the printed Rules and Online**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Details to be given</th>
<th>Printed in the Rules</th>
<th>Online</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Patent No.</td>
<td>Available in the form</td>
<td>Available in the form</td>
</tr>
<tr>
<td>2.</td>
<td>Year</td>
<td>Available in the form</td>
<td>Available in the form</td>
</tr>
<tr>
<td>3.</td>
<td>Quantum &amp; Value of patented Product commercially worked (in Rupees)</td>
<td>Can give both quantum &amp; value (in Rupees)</td>
<td>Only Value (blank) is made available in the Form. No option to give quantum in online Form 27.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Col. 3 of the Form states “Give whatever details are available”</td>
<td>No such statement available</td>
</tr>
<tr>
<td>4.</td>
<td>Whether Manufactured in India</td>
<td>Can give details in the manual form by way of remarks.</td>
<td>Even if we select <strong>Yes</strong> or <strong>No</strong>, the preview of the filled-in online form 27 does not indicate the response.</td>
</tr>
<tr>
<td>5.</td>
<td>Total Value of patented Product in other country (CURRENCY) (In case not manufactured in India)</td>
<td>Can provide the specific currency apart from the four currencies mentioned in the online form.</td>
<td>The currency options given are only in Rupees, USD, Euro, and Pound.</td>
</tr>
</tbody>
</table>
**WORKING OF PATENTS IN INDIA AND FORM 27 STATEMENTS**  
Issues and recommendations by  
K&S Partners, India  
March 16, 2018

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>6.</strong></td>
<td>Total Value of patented Product in other country (AMOUNT)</td>
<td>Can give amount details.</td>
</tr>
<tr>
<td><strong>7.</strong></td>
<td>Whether public requirement met</td>
<td>Can simply give explanation even if we don't select any one option. The option “Other requirement” is not present in the manual form.</td>
</tr>
<tr>
<td><strong>8.</strong></td>
<td>Whether License(s) Granted</td>
<td>Can provide information with details.</td>
</tr>
</tbody>
</table>

*Point 5 & 6 ask for the value in terms of the currency as well as the amount.

**H. Parallel provisions in other countries**

The requirement of Working of patents exists in patent laws of several countries. In most of these countries, non-working of patents is a ground for compulsory license. However, none of these countries imposed in India and in the format as Form 27.

**I. Serious compromise of sensitive commercial data and information of patentee**

- It is apparent that under the current structure of Form 27, there are no protections for the disclosure of patentee’s confidentiality and commercial information regarding quantum and value of products sold. That causes harm to the patentee or its licensee without any public benefit whatsoever.
- Section 153 of the Patents Act, lists only a few items with respect to which information may be sought by third parties. There is no public policy rationale offered for exposing such data.

**J. A rational approach as way forward**
March 16, 2018

- Section 146(2) imposes an onerous annual filing requirement on patentees which produces no beneficial results and serves no public purpose in reality.
- Form 27 must be simplified. The patentee could be required to submit, under confidentiality, whatever information is available with him regarding the commercial working of a given patent without the burden of stating whether the public requirement has been met partly, adequately/to the fullest extent at reasonable price. This is impossible for a patentee to assess.
- Ideally, the patentee could simply be asked to state whether the patent has been worked or not worked without disclosing any confidential information.
- In case a third party approaches the IPO for a CL of a particular patent, the Controller could simply use the power under Section 146(1) to seek such information from the applicable patentee.
- Patentee should be allowed to explain the extent of working rather than filling pre-determined columns giving numbers which are difficult to ascertain in many cases.
- Form 27 comes in public domain the moment it is filed and uploaded on the IPO website. Therefore, confidential data relating to commercial activities such as value of patented product should not be required to be disclosed in Form 27.

End of document...
To,
Controller General of Patents, Designs & Trade Marks,
Boudhik Sampada Bhavan,
S.M. Road, Antop Hill,
Mumbai – 400 037.

Dear Sir,

**Sub: Submission of Comments on Issues related to Working of Patents under the Patents Act, 1970.**

This is in reference to the captioned subject matter. We are hereby submitting our compilation of comments relating to working of patents with regards to circular dated March 16, 2018 vide No. CG /Circular /2018 /114.

We hope our comments shall prove to be a valuable input for the Stakeholders Consultation Meeting scheduled on April 06, 2018.

Thanking you,

**FOR KRISHNA & SAURASTRI ASSOCIATES LLP**
The requirement of filing of working statement is basically to make the public aware of the patents that are commercially worked/ not worked in India. The information would provide an opportunity to any interested person to obtain a license or collaborate with the Patentee/its Licensee to use the patented product or process. On the other hand, the working statement would also help to understand how efficiently various industries use patent system in the business.

According to us, Form 27 has to be amended so as satisfy the above requirements at the same time tailoring the information required to be submitted by a Patentee.

The following may be considered in amending the information to be provided by the Patentee in Form 27.

1. **QUANTUM & VALUE OF THE PATENTED PRODUCT**

   Under this section of Form 27, Patentee is required to provide the information regarding the working of invention in numbers and value in INR.

   The quantum and value of the patented product is not only confidential information, but also competitive information. Therefore, making this information mandatory may have to be reconsidered. For example, Patentee may sell the patented product based on the quantum ordered by the Customer meaning that the selling price may differ from customer to customer.

   Further, a difficulty in providing the quantum and value of information has also been considered. The following are some example scenarios where providing quantum and value of information becomes a challenge to the patentee.

   a. If the invention, for example, an apparatus or a system that is required to be installed in India only once and the same has been sold in India once during the tenure of the patent, it means that the Patent has been worked and is working in India. However, when the Patentee must declare every year the quantum sold, the patentee cannot provide data that was provided previously.

   b. In cases where a worldwide license is granted by the Patentee (For example, patented mobile parts, embedded systems or parts of the systems, intermediate products) for manufacturing the patented product at a cost-effective price and sold all over the world including India, quantifying such product licenses and specifying the value in INR would be a task.
Therefore, the requirement to provide the number and value of the worked Patent may have to be reconsidered. It should be sufficient to indicate whether the invention has been worked or not. In other words, a declaration by the patentee whether the Patent has been worked in India or not is sufficient to ascertain whether the patent is worked in India as providing quantum and value of the patented product worked in India is an additional information that should be provided if the patent is worked in India in circumstances where the extent of working of patent is required to be ascertained in specific instances for example when there is an application of a compulsory license. This would help to keep the information provided by the Patentee confidential and also able to help to ascertain the extent of working of patent.

2. **IMPORT / MANUFACTURED IN INDIA**

In case where the patent is worked, the Form 27 should be made simple to show whether it is by way of Import from other countries or Manufactured in India. In other words, Form 27 should include check marks for import and manufactured in India.

3. **EXTENT OF WORKING OF PATENT**

The terms partly/adequately/to the fullest extent worked in India is not defined in the Act and are not definitive. Requiring such information may not be relevant to ascertain the Working of Patent as even if the invention is worked partly, it should be considered as “worked”.

The extent of working of patent would arise only in cases of application of compulsory license where the Patentee must prove that the patent has been worked adequately. Ascertaining the extent of working of patent would depend on various factors on industry type, requirement of the product by the public, pricing of the product, licences etc. Therefore, even if the Patentee files a Form 27 as adequately worked, the Controller has to consider the very many factors to ascertain the extent of working of patent. Also, it may be difficult to devise the extent of working for different industries. Therefore, such information should not be kept as mandatory information that needs to be submitted on Form 27.

It may be considered that instead of requiring such information in all cases, the Controller may require the Patentee to provide such information on case by case basis.

4. **PUBLICATION OF INFORMATION ON FORM 27**

In view of the Delhi High Court order on Working of Patents dated January 10, 2017, Form 27 information has to be restricted only to information that can be made public. Confidential information that may affect the business of industries should not be required to be included in Form 27 – quantum and value especially.
5. **Online Form 27**

The drop list options and selection options on online Form 27 should be relooked. The electronic Form 27 (print version) does not reflect all the selections made on online Form 27. There is no option in online Form 27 to include the Quantum *only* (without the value in Rupees).

Online Form 27 option of “**Total Value of the Patented Product Commercially Worked in Rs**”, the same must be filled in with the **amount in Indian Rupees**. If the amount (in Rupees) is not provided, the option of “Details Attached” must be selected and a PDF Form 27 must be submitted.

Online Form 27 should be made consistent with PDF Form 27 and filing of PDF Form 27 should be avoided to simplify the process.
FORM 27

THE PATENTS ACT, 1970
(39 of 1970)
&
THE PATENTS RULES, 2003

STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON COMMERCIAL SCALE IN INDIA

[See section 146 (2) and rule 131(1)]

In the matter of Patent No:233052

I/We

Grantee Name: TATA STEEL LIMITED
Grantee Address: JAMSHEDPUR

The patentee(s) or licensee(s) under Patent No: 233052 Hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year 2017

Reason for making the above request are as follows-
(i) The patented invention:
(1.) Quantum and value (in Rupees) of the patented product:
(2.) Manufactured in India

I/We Declare that the facts and matters started herein are true to the best of my/our knowledge, information and belief

Signature

(........................................................................)

To,
The Controller of Patents,
The Patent Office
AT KOLKATA

This form is electronically generated.
Ref. No.: P-IN227

To,

The Controller General of Patents, Designs and Trade Marks,
Boudhik Sampada Bhavan
S.M. Road, Antop Hill,
Mumbai - 400037

Subject: Comments on the issues relating to submission of information relating to working of patents

Dear Sir,

This is with reference to your circular no. CG/Meeting Circular-DIPP/2018/14 dated March 01, 2018 inviting stakeholders’ feedback on provisions of working of patents in the Patents Act 1970 (as amended). At the outset we would like to thank the Ld. Controller General for taking this initiative and giving us the opportunity for giving our comments. Please find our detailed comments in the following pages.

We request the Ld. Controller General to kindly consider our submission.

Thanking you,

Yours truly,

Anju Khanna, Ph. D.
Director, Patents

Encls.
   i. Annexures I-IV
1. Working Statement Requirement: Background

The provision of grant of a compulsory license based upon non-working of an invention that has been patented in India found its way in the Patent Act, 1911 with the amendments of 1950 (Act XXXII of 1950). The primary reason behind the provision was to serve the public at large in terms of availability and affordability of pharmaceutical products. These provisions were further consolidated and strengthened with the amendments based upon the recommendations of the Ayyangar Committee Report. Further the principal behind the requirement of working of an invention, covered by a patent, has been articulated in paragraph 181 of the Ayyangar Committee Report. It states that when under developed and under industrialized countries start providing patent protection for securing inventions, it is the industrialized countries, with whom they have trade relations that take its advantage. The motive of the patentee may not be to harm the economy of the host country, but the effect may be the same. Hence this is the basic premise from which stems the need of having a working statement requirement.

Chapter V of the Report deals with the “working requirement” in detail. The Report first explains with the principal of dealing with the abuse of a monopoly right without the working requirement. Countries, it states, generally adopted two measures to redress this problem: either revoke patent for non-working or grant compulsory license on terms of royalty settled by an outside authority. The Report laid down the principle that the compulsory license to be granted for an invention that is not being factually worked in India and no relief be granted vis-à-vis this requirement to an invention that was not capable of being worked in India. And that the patent to be revoked only if two years had passed from the granting of such license and the patent had still not been worked. The Report was against the revocation for non-working for the following reasons: (i) if contested this would lead to complicated inquiries that the Controller would not be able to handle; (ii) since the country was progressing industrially, it could take 3 to 4 years from the date of filing of the complete specification for the patent to work and (iii) it would not be possible to predicate of any invention at the time when the application for patent was made that it was absolutely incapable of being worked in the country. The Report suggested

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1. [http://ipindia.nic.in/ipr/patent/patents.htm](http://ipindia.nic.in/ipr/patent/patents.htm); sections 22, 23, and 23A to 23G
that the license would also help transferring the ‘know-how’ associated with an invention.

The Report also suggested getting information with regards to the working of an invention from the patentees and a special wing/unit in the Commerce Ministry be entrusted to get such information\(^3\). The Act of 1911 was repealed and replaced with the Act of 1970 with extensive compulsory licensing provisions. The next amendments of 1999, 2002 and 2005 brought in the next wave of changes to the provisions of working, compulsory licensing and revocation.

### 2. Legal Requirements

Chapter XVI of the Indian Patents Act 1970 (sections 82 to 94) broadly deals with “Working of Patents, Compulsory Licenses and Revocation”. Section 83 provides general principles applicable to working of patented inventions. Section 146 read with rule 131 provides the legal requirement of filing a working statement by a patentee and section 122 elaborates the consequences of not complying with this requirement. In addition Article 5 of the Paris Convention for the Protection of Industrial Property deals with the working and compulsory licensing. Article 27 of the TRIPS Agreement covers the local production requirement. The said sections and articles can be accessed from Annexure I and for the sake of brevity are not repeated here.

### 3. Form 27

Form 27 is the prescribed form in which the information regarding “working” or “non-working” statement is provided. The Form states that the patentee give whatever details are available to him. It is required to submit if the invention has been worked or not worked in India. If a patent has not been worked then the patentee has to give reason for the same and also specify what steps are being taken by the patentee to work the patented invention in India. If however it has been worked in India, the patentee needs to give the following information:

- Quantum and value of the patented product being manufactured in India
- Quantum and value of the patented product imported from other countries.
- Licenses and sub-licenses granted during the period.
- The patentee has to state whether public requirement is met partly/adequately/to the fullest extent at reasonable price.

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\(^3\) This suggestion has not been applied so far and rather Patent Office has been burdened with collecting the information, which it eventually makes available publically.
With the advent of online filing portal of the Patent Office, the Form 27 is also required to be filed online. The online form differs from the paper form in the following respects (however all other information is to be provided as is required to be given in the paper Form):

- Online form allows only numbers and specific information, like names of licensees, countries of manufacture etc. to be entered.
- To overcome the above-mentioned problem, it allows details in Form 27 to be uploaded instead of giving information directly in the online form.

4. What is meant by ‘working’

The Patent Act does not provide the definition of “working” or “non-working” except for the general principles delineated in section 83 (Annexure I). Additionally the kind of information that is required to be provided by the patentee is to prove whether a patent is worked or non-worked is only by way of Form 27. This raised several issues with regards to what is meant by the word ‘working’ and these are listed below:

- Does working mean only local manufacture?
- Does working include imports?
- Does working mean sale on a commercial scale, whether locally manufactured or imported?

4a. Established legal position

Based on the jurisprudence that has evolved with regards to the working requirement in India, the legal position can be summarized as follows:

- Working requirement would be satisfied only if the invention has been sold on a commercial scale and would not include that which is distributed/made available to the public under subsidized or other programmes.
- The working requirement would be dealt with on a case to case basis as in some cases it would mean only importation and in others it would mean local manufacture
- The patentee is required to show why it could not be manufactured locally.

\[4\]in-delhc-CS-3812-2014-20150109; Delhi High Court, 09-01-2015; in-mumhc-WP-1323-2013-20140715; Bombay High Court; 15-07-2014; 2013 Indlaw IPAB 20
The non-working of a patent cannot be taken as a defense in a suit for infringement of patents but the Court, in equity, may refuse an interim injunction on the basis of non-working of an invention.

Reasonable requirement could be met through licenses.

If reasonable requirement is met to an adequate extent would depend upon the technology.

5. Working requirement in other countries

There are several countries that provide for a compulsory license (which is line with provisions of the Paris Convention and the TRIPS Agreement), and list non-working as a ground for grant of one. An exemplary list of such countries along with the provisions can be found in Annexure II. The following can be deduced from information gathered for other countries:

- no country demands the patentee to provide a working statement.
- information related to working is only required after a compulsory license application has been filed.
- no country burdens the patentee with giving such detailed and, more often than not, sensitive and confidential information which goes into the public domain, year after year.
- no country has penal consequences attached to any requirement related to grant of a compulsory license.
- in a few countries, for instance in China, even on filing of a compulsory license application, patentee may provide legitimate reasons for non-working.
- in Turkey the practice of filing a declaration of use of the patent is optional and up to the patentee. However, if filed, the declaration is published.
- in Mexico, if a compulsory license application is filed, the patentee has one year to show working either through export or directly or indirectly through licenses.
- in the Russian Federation there is no working statement requirement. Reasons justifying the non-working of patent may be provided by the patentee to avoid compulsory license.
- in Malaysia the patentee is not required to submit any evidence for “working”. The responsibility to prove the “non-working” of a patent is with the third party which intends to apply for the compulsory license.
- in Canada non-working of patents is not a ground for compulsory license. It used to be a ground before the provision was repealed in 1993.
• in Thailand the patentee is not required to submit any evidence for “working”. The responsibility to prove the “non-working” of a patent is with the third party which intends to apply for a compulsory license.

As is clear from Annexure II and the points mentioned above, India is the only country in the world that is demanding sensitive, financial, confidential and commercial information from patentees that has no place in today’s modern, industrialized India.

6. Recent Developments

The most recent controversy that has erupted in this area is due to a Public Interest Litigation (PIL)\(^5\) filed demanding strict adherence to the requirement of the working statement. The PIL raises several issues and claims that it is the Patent Office that is lacking in its duty towards strict compliance to this requirement.

The writ petition is being heard by the Ld. Division Bench of the Hon’ble Delhi High Court. The Ld. Division Bench has directed the Patent Office to submit a framework within which it will make new rules for compliance to Form 27 submission.

The Hon’ble Delhi High Court in its Order dated 7\(^{th}\) February, 2018 (Annexure III) recognizes following issues with respect to the information required to be provided in the working statements:

• The current format of Form 27 is difficult to comply with due to the way it is worded.
• The form “has failed to take into consideration the several scientific and technological requirements as well as the confidentiality issues relating to some of the patents”. (emphasis ours)
• Noting that 45 years had elapsed since Form 27 has been existing in its current form, the Court held “Be that as it may, expeditious steps regarding the working of the statutory provisions as well as the changes, if any, are required in the statute, rules and prescribed forms deserve to be taken”.
• Further recognizing the difficulties faced by patentees in furnishing information in Form 27, the Court observed “In case, any party has reservation of any kind in furnishing details, it would have to disclose the reasons for such reservation and the patent office would be required to take a view in the matter so far as its satisfaction regarding compliance with the requirements of Section 146 is concerned.”

7. Issues with Working Statement Information

7a. Working Statement Provision is Obsolete

The need which led to the inclusion of the provision under Section 146 into the Patents Act does not exist anymore. The entire premise of demanding working of a patented invention from a patentee was that no one should be allowed to nix the fledgling Indian industry in the bud at the time of independence. In his report Justice Ayyangar laments about the non-existent industry in India and the many failures of its patent system to foster its growth and identified non-working of patents in India as one of the main reasons of failure of the patent system.

This assessment would stand in stark contrast with modern-day India. India boasts of being the pharmacy to the world. Today, the Indian Economy has the 3rd Highest GDP (PPP), the 7th highest Nominal GDP and the 12th Highest GDP growth rate of nearly 7% (International Monetary Fund) and which, as per IBEF, is expected to either grow or remain stable for many years to come.\(^6\) According to the World Economic Forum, India also now ranks at No. 40 out of 137 countries on the Global Competitiveness Index 2017-18. According to the World Intellectual Property Indicators, 2017\(^7\), India is now the 12th largest patent filing office in the world and it rightly leads the regional ranking and is placed in the top half of the entire pool of countries on the Global Innovation Index. India is also ranked 2nd worldwide in terms of innovation quality, 10th in the category of graduates in science and engineering, 27th on e-participation, 14th on the presence of global research and development companies, 32nd in general infrastructure, 18th in creative goods exports, 30th in knowledge impact and 29th in intellectual property payments.

For the Patent Office to begin enforcing the patent working statement requirement with renewed vigour at this point would be to the detriment of patentees in India and would be like hitting the brakes on an admirable industrial growth story.

7b. Patent Office Not Equipped to Handle Working Statements

There is nothing in Section 146 or in the rest of the Act which authorizes the Patent Office to seek specific details of the Patentee’s business dealings such as the number of licenses granted as well as the names of individual licensees or sensitive

\(^{6}\) [https://www.ibef.org/economy/indian-economy-overview](https://www.ibef.org/economy/indian-economy-overview)  
business information. The inclusion of said requirement in Form 27 is a glaring example of administrative overreach on part of the Patent Office.

The mandate of the Controller under the Patent Act with respect to statement of working is only limited to calling upon the patentee to submit such information. The Act however, does not specify what needs to be done with the data submitted in these statements of working. There are no provisions in the Act as to the verification or application of the data for some purpose. There is no frame work of rules in the Patent Act by which the Patent Office can examine the working statements. The Hon’ble Delhi High Court has now directed the Patent Office to frame Rules in this regard.

Over 40,000 patents are applied for, and nearly 10,000 are being granted each year by the Indian Patent Office. The Patent office, in the current scenario where there is a constant shortfall of trained personnel for examination of patent applications, cannot afford to waste resources upon the verification of the tens of thousands of working statements being filed by patentees every year. Despite recruitment of over 450 new examiners by the Patent Office, there is still a backlog of over 2 lakh patent applications awaiting examination. Patent examiners may not be well trained, being techno-legal persons with minimal background to analyze financial data, to analyze the correctness or completeness of the data sought by the patent office from patentees in Form 27.

Justice Ayyangar in his report has suggested a special wing/unit in the Commerce Ministry be entrusted to get such information. However this was never followed and the Patent Office was burdened with collecting and managing such information.

As such, the submission of said data turns out to be a complete waste of resources and an unnecessary burden for patentees. It puts sensitive business data in public domain, much to the detriment of patentee’s business interests.

7c. Compulsory License

As mentioned above, non-working of a patented invention is not a ground for opposition or revocation of a patent. The only purpose working status of a patented invention serves is that it is a ground for granting compulsory license. If we look at the statistics, the picture is revealing. During the period 1950 to 1957, 17 applications were filed for grant of Compulsory License, out of which one was for pharmaceuticals and one for chemistry. It is not clear what the fate of these applications was. In the recent past (since 2005 when Indian patent law became

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8 Economic Survey 2017-18, Chapter 8
TRIPS compatible), only three applications have been filed for grant of a Compulsory License, out of which only one is granted. Applications for seeking a Compulsory License for Dasatinib\(^9\) and Saxagliptin\(^10\) were rejected, while for Nexavar (as mentioned above) was granted.

It astonishes that when it is being alleged that patentees are not complying or are giving incorrect/incomplete information with regards to working of a patented invention, there are no takers of a compulsory license. The purpose for which such information is required does not exist. Such rudimentary laws which place unnecessary burden on an inventor/business should be seriously revisited.

7d. Undue Burden on Patentee

The bargain in granting an intellectual property right to a patentee is that in return she will disclose the invention to public, which can then also improvise on the disclosure. Patent is only to exclude others from using the invention without the permission of the patentee. And to get this right the patentee has to pass the vigours of examination at the Patent Office that examines the invention on the basis of novelty, inventiveness, industrial applicability, subject eligibility, enabling disclosure and unity of invention, all of which are grounds of rejection. In addition to these there are several formal requirements that need to be fulfilled. And this granted patent has no presumption of validity. There are several grounds on which it can still be challenged.

While the patentee has already satisfied its onus in showing industrial applicability of the patent and hence being capable of commercially worked in the course of obtaining a grant, the onus of supplying information as to non-working of the patent post-grant ought to fall upon the seeker of the compulsory license. The requirement of supplying unnecessary details connected to the business of the patentee puts an undue burden and is also in contravention of basic legal principles. Even if it is assumed that the burden to supply information related to working is on the patentee, such information should be sought only when required, such as after a compulsory licensing application has been filed. Furnishing extant information related to working is neither practical nor desirable for patentees.

In fact most cases of non-working of patents are merely cases where the market for the patented invention hasn’t developed yet, but is expected to develop eventually at some point during the term of the patent. It just does not make any economic sense


for a patentee, especially an SME or an educational institute or an individual inventor to keep paying exponentially rising annuities year after year for a patent that it doesn’t even intend to work eventually.

For patentees owning portfolios consisting of several thousands of patents as well as a vast range of products or many licensees implementing said portfolio of patents, it is almost impossible to accurately track the quantum or value generated from working of each and every patent. For instance several standard essential patent owners with huge SEP portfolios tend to license their patents through portfolio licenses and therefore may find it impossible to assign specific unit sales or revenue information to specific patents. Further, several classes of products often implement several patents and therefore it becomes almost impossible to accurately attribute quantum and value, patent by patent. Any information provided in such a scenario in fact may amount to submission of false information by the patentees. This can lead to a flurry of frivolous litigation, despite the alleger not even being interested in seeking a compulsory license. In fact, any organization, big or small, is bound to feel the drain on its resources caused by the frivolous requirement of providing yearly statements, full of data which is of no apparent use to anyone but could still be used by busybodies to make allegations of non-compliance and seek penal relief under Section 122 of the Act against such innocuous mistakes.

7e. Onerous Requirements on Patentees go Against the Government Initiatives

An inventor who gets enthused by the various Government policies and schemes like Startup India, Make in India, Invest India, Innovate India and other such initiatives is likely to get highly demotivated if protecting her technology to gain competitiveness in the market becomes such an onerous task. The Government’s slogan “Government has no business to be in business” gets negated by the requirements like working statements be filed every year for each patent, a tall order for any individual or company. It is hoped that ‘ease of doing business’ is in consonance with the ‘ease of patenting’ in India. In continuing to enforce the working statement requirement India has clung to its past despite having no obvious advantages of the data being collected thereby. In fact, Indian policy in this regard has been giving mixed signals inasmuch as on the one hand, we are seeking to increase patent filings, and on the other hand we are imposing onerous obligations violative of patentees’ fundamental rights which would instead dissuade innovators from filing for patents in India.

7f. Sensitive Business Information
There is no reason why a patentee should give monetary and other sensitive business information, for instance regarding licenses, which is of highly confidential nature, on a platter to competitors. The very idea of competition is defeated if the Government seeks this information and then puts it in public domain.

The information sought in Form 27 violates the right to privacy of the patentee and requires the patentee to supply information which is confidential in nature and directly impinges upon the patentee’s right to a livelihood. Businesses in any competitive market require that information regarding sales units and profit margins be kept confidential. In a country such as India, unit prices are usually determined on a one-off basis depending upon negotiations between parties and price margins given by the manufacturer/patentee are often agreed to be confidential information. It is these confidential price margins given to dealers and distributors which can often prove to be the difference and can affect an increase in the market share of a certain product. These are the basic rules of economics and survival in a competitive market.

Patentees are equally governed by these rules of economics, which require that sensitive business related information such as the kind which is required to be furnished by the patent office in its form 27 be kept confidential. However, in view of Section 146 (3) of the Act, the sensitive information which may be provided by a patentee is published by the Controller which can have a direct effect upon the business interests of the patentee or the party working the patent. For instance, for a patentee who is involved in the business of producing and selling products which work its patent, the publication of the quantum as well as total value can reveal the confidential per unit price of the product and hence profit margins of the patentee in selling that product and can allow the competitor to severely undercut the patentee in the market thus hurting its business. Furthermore, in cases where information regarding licensees is protected under confidentiality clauses or have been held as confidential by judicial orders, the disclosures of the same in Form 27 can have disastrous consequences for the patentee's business.

It is pertinent to note that the Patents Act, 1970 by itself does not mandate the publication of the information provided by the patentee/licensee under Section 146, inasmuch as said provision grants discretion to the Controller whether to publish or not. The same has been reproduced herein for ease of reference:

“146. Power of Controller to call for information from patentees. -

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(3) The Controller may publish the information received by him under sub-section (1) or sub-section (2) in such manner as may be prescribed.
Therefore, even if any information were to be disclosed by the patentee/licensee under Section 146 read with Rule 131, it is well within the powers of the Controller to ensure this disclosure, which may often contain confidential information as explained above, is not published and is only relied upon or disclosed to a third party upon application for a compulsory license having been filed by said third party.

In litigation involving Standard Essential Patents (SEPs), the Hon’ble Supreme Court has already held that information pertaining to SEP licenses is confidential in nature and the same can only be revealed under a protective order of the Court. It is submitted that to demand disclosure of such confidential information under the garb of a statement of patent working can seriously weaken the negotiating position of the patentee in any future license negotiations and can jeopardize on going infringement litigations with such patents as the subject matter.

7g. An Inventor’s Journey at the Indian Patent Office

After spending several prime years of her life in inventing and bringing an innovative product to the market, an inventor seeks an exclusive right for a limited period of time in the form of a patent. In the current scenario her journey in the Patent Office starts in the year X and by the time patent gets granted it is year X+10. And this granted patent has no presumption of validity. From X+11th year she has to start filing the working statements, otherwise she faces heavy penalties, either in the form of fine or jail or both. In the meantime she has to manufacture or license the product and market it. The market may or may not accept the product. Even if the patentee’s product is cheap (reasonably priced), sufficiently and easily accessible (public requirement adequately met) and patented but the market rejects it, would she still be fulfilling the criteria of working the patent? How is this situation a failure to work the patent on the patentee’s part? The patentee may still like to continue with the patent and come with better marketing strategies to push the product in the market. How is the patent worked or not worked in these circumstances?

So in addition to facing the vagaries of the market, after investing so much in time and money in research and development and manufacturing, she has the additional burden of constantly reporting the quantum and value of each patent that has gone into making her product. As it is the Indian Patent system inordinately delays the grant of exclusive right to the invention, on top of that the post grant obligations on the patentee certainly dissuade an inventor to seek any protection at all. Such a protection becomes meaningless. This also flies in the face of all the Government initiatives that are aiming to encourage innovation, initiative and investment in India.
In fact the big Multi National or Indian companies have the deep pockets to continue to satisfy the endless demands of the Indian Patent system. It is the small innovators, educational institutes, MSMEs and SMEs who find these demands onerous. It is such demands and inadequacies of the Indian Patent system that have discouraged development of an innovation ecosystem in the country and can now derail the already precarious innovation climate in the country.

7h. Interest of the Patentee vs. Interest of Society/Public Interest

A patent solves a technical problem (as against an academic or theoretical problem) that exists in the society and therefore it must have industrial applicability or satisfy a commercial need. A patentee gets an exclusive right for a limited period of time for solving the problem and the solution must be disclosed to the public in an enabling disclosure. That is the bargain or incentive of the exclusive right. Had there be no patent, there probably would be no research, no invention and no solution to the problem that the granted patent solved. So the public and society at large would be still be suffering because of the lack of a solution rather than suffering because of a solution that the patent offers. The public interest is hence served in providing the solution as against not providing the solution.

Public interest is also being served by having access to products that serve particular needs and also since the patentee is disclosing the product/process in his patent. A competitor can always introduce a better product/process by improving upon the disclosure. It is naïve to think that competitors depend upon the working statements of their rivals to plan research and development in the highly competitive technology sectors or for that matter in any other sector. Researchers have a vision of next twenty or more years and the previous year’s working statement of a competitor have absolutely no effect on their research strategy. They certainly have several other and much more sophisticated tools at their disposal to figure out a competitor’s research strategies.

By putting obstacles in the path of a researcher/innovator, it is ensured that the innovator will refuse to disclose the invention, but keep it as a trade secret. That would really be harmful to the economic and intellectual growth of a society.

7i. Industrial Revolution 4.0 and Working Statements

Technologies pertaining to Artificial Intelligence (AI) and the Internet of Things (IoT), collectively hailed as the Industrial Revolution 4.0, are changing and will change the way we innovate, manufacture, live and do business. India is already way behind countries like the US, China, Japan, South Korea and Europe in innovation in these
technology areas. While countries like China and Japan have amended their patent laws to protect AI and IoT related technologies, Indian patent law is still stymied by the limitations imposed by section 3(k).

To put in simple words, IoT and AI tools use a number of technologies working in tandem with each other. These may and will encompass a number of Standard Essential Patents (SEPs) and non-essential patents vested in different devices working together. Some of these interactions may be known and decipherable and some of them may not be known and hence undecipherable. In fact in some instances such interactions may give birth to a new technology altogether. In such a scenario how is a patentee expected to show working of patent by patent. If a device, like a phone is talking to every other device at home, then the number of licensees of each device, technology, patent would probably go into reams and reams of paper. This kind of burden on the patentee will for sure deter any one from investing into Research & Development (R&D) in the country or even to bring their technology into India. As it is the current Patent laws (due to section 3(k)) will not grant patent in this technology area; and any that is granted will be too burdensome to maintain if this kind of information is required to be given year after year. We are ensuring that India stays far behind the innovation curve where our neighbors are taking massive strides and only because we continue to cut the branch we are sitting on.

7j. Global Scenario

As mentioned above, the provision of granting a compulsory license is prevalent in several countries, but none of the countries put the burden of such declarations (Annexure II). From a comparative study of compulsory licensing and patent working provisions across several jurisdictions it can be noted that over time explicit working requirements have been phased out in favour of other non-direct means of compliance. Moreover, India is the only jurisdiction, where there still remains a statement of working requirement.

8. Recommendations

- The first step towards making compliance to submitting information with regards to working or non-working of a patented invention simpler is to simplify the prescribed form (F 27).
- We recommend the following option (Annexure IV):
  - The F27 should contain only two columns that require the patentee to mention either the patent is working or non-working. No further details or
information or reasoning or declaration regarding extent of working should be sought.

- An example of Form 27 template can be found attached in Annexure IV. The online Form 27 can be modeled on the same lines.
- No confidential or sensitive business information should be sought from the patentee until there is essential requirement in case of compulsory license.
- Such commercial, sensitive and confidential information in the working statement to be sought in cases related to compulsory license but not compulsorily from all the patent holders as a routine in its current form. Such information must be allowed to be submitted under a cover of confidentiality and not published.
- The onus to prove that a patent is not working should be on the applicant of a compulsory license.
- As mentioned in clause 7f above, section 146(3) grants discretion to the Controller whether to publish or not the information gathered with respect to the working of a patented invention. The Controller should use his discretionary powers under S. 146 (3) wisely and not publish working statements, unless there is a dire need for it.
- As mentioned in clauses 5 and 7e above, there is no country that adopts punitive consequences attached to any requirement related to grant of a compulsory license as mentioned under section 122; any busybody can make allegations of non-compliance and seek penal relief under Section 122 of the Act against any innocuous mistake purporting it to be false information. Hence this must be removed, with immediate effect.
- Ideally the working statement requirement should be expunged from the Patents Act. If that is not possible, working statements should be required to be submitted only in case of compulsory license applications. The Controller can use his powers under Section 146 (1) to invite working statements from patentees/licensees once a compulsory license application is filed.
- As mentioned earlier it is serving absolutely no purpose and creating an unhealthy environment in the country vis-à-vis innovation and enterprise. There are enough safeguards in the Patents Act to prevent abuse of monopoly. The biggest safeguards are limited period of monopoly and disclosure to public.
The Indian Patents Act, 1970

Working of Patents, Compulsory Licences and Revocation

82. Definition of "patented articles" and "patentee".—In this Chapter, unless the context otherwise requires,—
(a) "patented article" includes any article made by a patented process; and
(b) "patentee" includes an exclusive licensee.

83. General principles applicable to working of patented inventions.—Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;—
(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

84. Compulsory licences.—(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably affordable price, or
(c) that the patented invention is not worked in the territory of India.

(2) An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the
public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88.

(6) In considering the application field under this section, the Controller shall take into account,—
(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;
(ii) the ability of the applicant to work the invention to the public advantage;
(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;
(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anticompetitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

Explanation.—For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—
(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,—
(l) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or
(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or
(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or
(iv) the establishment or development of commercial activities in India is prejudiced; or
(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or
ANNEXURE I

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; or
(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or
(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by—
(i) the patentee or persons claiming under him or
(ii) persons directly or indirectly purchasing from him; or
(iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

85. Revocation of patents by the Controller for non-working.—(1) Where, in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order revoking the patent on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.

(2) Every application under sub-section (1) shall contain such particulars as may be prescribed, the facts upon which the application is based, and, in the case of an application other than by the Central Government, shall also set out the nature of the applicant's interest.

(3) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that patented invention has not been worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may make an order revoking the patent.

(4) Every application under sub-section (1) shall ordinarily be decided within one year of its being presented to the Controller.

86. Power of Controller to adjourn applications for compulsory licences, etc., in certain cases.—(1) Where an application under section 84 or section 85, as the case may be, is made on the grounds that the patented invention has not been worked in the territory of India or on the ground mentioned in clause (d) of sub-section (7) of section 84 and the Controller is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, by order, adjourn the further hearing of the application for such period not exceeding twelve months in the aggregate as appears to him to be sufficient for the invention to be so worked:

Provided that in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made thereunder or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles or of the articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of adjournment ordered under this sub-section shall be reckoned from the date on which the period during which the working of the invention was prevented by such
ANNEXURE I

Act, rule or regulation or order of Government as computed from the date of the application, expires.
(2) No adjournment under sub-section (1) shall be ordered unless the Controller is satisfied that the patentee has taken with promptitude adequate or reasonable steps to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

87. Procedure for dealing with applications under sections 84 and 85.— (1) Where the Controller is satisfied, upon consideration of an application under section 84, or section 85, that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the official journal.
(2) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition.
(3) Any such notice of opposition shall contain a statement setting out the grounds on which the application is opposed.
(4) Where any such notice of opposition is duly given, the Controller shall notify the applicant, and shall give to the applicant and the opponent an opportunity to be heard before deciding the case.

88. Powers of Controller in granting compulsory licences.—(1) Where the Controller is satisfied on an application made under section 84 that the manufacture, use or sale of materials not protected by the patent is prejudiced by reason of conditions imposed by the patentee upon the grant of licences under the patent, or upon the purchase, hire or use of the patented article or process, he may, subject to the provisions of that section, order the grant of licences under the patent to such customers of the applicant as he thinks fit as well as to the applicant.
(2) Where an application under section 84 is made by a person being the holder of a licence under the patent, the Controller may, if he makes an order for the grant of a licence to the applicant, order the existing licence to be cancelled, or may, if he thinks fit, instead of making an order for the grant of a licence to the applicant, order the existing licence to be amended.
(3) Where two or more patents are held by the same patentee and an applicant for a compulsory licence establishes that the reasonable requirements of the public have not been satisfied with respect to some only of the said patents, then, if the Controller is satisfied that the applicant cannot efficiently or satisfactorily work the licence granted to him under those patents without infringing the other patents held by the patentee and if those patents involve important technical advancement of considerable economic significance in relation to the other patents, he may, by order, direct the grant of a licence in respect of the other patents also to enable the licensee to work the patent or patents in regard to which a licence is granted under section 84.
(4) Where the terms and conditions of a licence have been settled by the Controller, the licensee may, at any time after he has worked the invention on a commercial scale for a period of not less than twelve months, make an application to the Controller for the revision of the terms and conditions on the ground that the terms and conditions settled have proved to be more onerous than originally expected and that in consequence thereof the licensee is unable to work the invention except at a loss:
Provided that no such application shall be entertained a second time.

89. General purposes for granting compulsory licences.—The powers of the Controller upon an
application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,—

(a) that patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;

(b) that the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.

90. **Terms and conditions of compulsory licences.**—(1) In settling the terms and conditions of a licence under section 84, the Controller shall endeavour to secure—

(i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;

(ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him;

(iii) that the patented articles are made available to the public at reasonably affordable prices;

(iv) that the licence granted is a non-exclusive licence;

(v) that the right of the licensee is non-assignable;

(vi) that the licence is for the balance term of the patent unless a shorter term is consistent with public interest;

(vii) that the licence is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product if need be in accordance with the provisions of sub-clause (iii) of clause (a) of sub-section (7) of section 84;

(viii) that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use;

(ix) that in case the licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product, if need be.

(2) No licence granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee.

(3) Notwithstanding anything contained in sub-section (2), the Central Government may, if in its opinion it is necessary so to do, in the public interest, direct the Controller at any time to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among other matters to the royalty and other remuneration, if any, payable to the patentee, the quantum of import, the sale price of the imported article and the period of importation), and thereupon the Controller shall give effect to the directions.

91. **Licensing of related patents.**—(1) Notwithstanding anything contained in the other provisions of this Chapter, at any time after the sealing of a patent, any person who has the right to work any other patented invention either as patentee or as licensee thereof, exclusive or otherwise, may apply to the Controller for the grant of a licence of the first mentioned patent on the ground that he is prevented or
hindered without such licence from working the other invention efficiently or to the best advantage possible.  
(2) No order under sub-section (1) shall be made unless the Controller is satisfied—
(i) that the applicant is able and willing to grant, or procure the grant to the patentee and his licensees if they so desire, of a licence in respect of the other invention on reasonable terms; and
(ii) that the other invention has made a substantial contribution to the establishment or development of commercial or industrial activities in the territory of India. 
(3) When the Controller is satisfied that the conditions mentioned in sub-section (1) have been established by the applicant, he may make an order on such terms as he thinks fit granting a licence under the first mentioned patent and a similar order under the other patent if so requested by the proprietor of the first mentioned patent or his licensee: 
Provided that the licence granted by the Controller shall be non-assignable except with the assignment of the respective patents.
(4) The provisions of sections 87, 88, 89 and 90 shall apply to licences granted under this section as they apply to licences granted under section 84.

92. Special provision for compulsory licences on notifications by Central Government.—(1) If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public noncommercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect, that is to say—
(i) the Controller shall on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent on such terms and conditions as he thinks fit;
(ii) in settling the terms and conditions of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.
(2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.
(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in—
(i) a circumstance of national emergency; or
(ii) a circumstance of extreme urgency; or
(iii) a case of public non-commercial use,
which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immunodeficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section:
Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87.

92A. Compulsory licence for export of patented pharmaceutical products in certain exceptional
circumstances.—(1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

(2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

(3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.

Explanation.—For the purposes of this section, 'pharmaceutical products' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

93. Order for licence to operate as a deed between parties concerned.—Any order for the grant of a licence under this Chapter shall operate as if it were a deed granting a licence executed by the patentee and all other necessary parties embodying the terms and conditions, if any, settled by the Controller.

94. Termination of compulsory licence.—(1) On an application made by the patentee or any other person deriving title or interest in the patent, a compulsory licence granted under section 84 may be terminated by the controller, if and when the circumstances that gave rise to the grant thereof no longer exist and such circumstances are unlikely to recur:

Provided that the holder of the compulsory licence shall have the right to object to such termination.

(2) While considering an application under section (1), the Controller shall take into account that the interest of the person who had previously been granted the licence is not unduly prejudiced.

146. Power of Controller to call for information from patentees.—(1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.

(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.

(3) The Controller may publish the information received by him under subsection (1) or sub- section (2) in such manner as may be prescribed.

122. Refusal or failure to supply information.—(1) If any person refuses or fails to furnish—

(a) to the Central Government any information which he is required to furnish under sub-section (5) of section 100;
ANNEXURE I

(b) to the Controller any information or statement which he is required to furnish by or under section 146, he shall be punishable with fine which may extend to ten lakh rupees.

(2) If any person, being required to furnish any such information as is referred to in subsection (1), furnishes information or statement which is false, and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both.

69. Registration of assignments, transmissions, etc.—(1) Where any person becomes entitled by assignment, transmission or operation of law to a patent or to a share in a patent or becomes entitled as a mortgagee, licensee or otherwise to any other interest in a patent, he shall apply in writing in the prescribed manner to the Controller for the registration of his title or, as the case may be, of notice of his interest in the register.

(2) Without prejudice to the provisions of sub-section (1), an application for the registration of the title of any person becoming entitled by assignment to a patent or a share in a patent or becoming entitled by virtue of a mortgage, licence or other instrument to any other interest in a patent may be made in the prescribed manner by the assignor, mortgagor, licensor or other party to that instrument, as the case may be.

(3) Where an application is made under this section for the registration of the title of any person the Controller shall, upon proof to title of his satisfaction,—

(a) where that person is entitled to a patent or a share in a patent, register him in the register as proprietor or co-proprietor of the patent, and enter in the register particulars of the instrument or even by which he derives title; or

(b) where that person is entitled to any other interest in the patent, enter in the register notice of his interest, with particulars of the instrument, if any, creating it:

Provided that if there is any dispute between the parties whether the assignment, mortgage, licence, transmission, operation of law or any other such transaction has validly vested in such person a title to the patent or any share or interest therein, the Controller may refuse to take any action under clause (a) or, as the case may be, under clause (b), until the rights of the parties have been determined by a competent court.

(4) There shall be supplied to the Controller in the prescribed manner for being filed in the patent office copies of all agreements, licences and other documents affecting the title to any patent or any licence thereunder authenticated in the prescribed manner and also such other documents as may be prescribed relevant to the subject matter:

Provided that in the case of a licence granted under a patent, the Controller shall, if so requested by the patentee or licensee, take steps for securing that the terms of the licence are not disclosed to any person except under the order of a court.

(5) Except for the purposes of an application under sub-section (1) or of an application to rectify the register, a document in respect of which no entry has been made in the register under sub-section (3) shall not be admitted by the Controller or by any court as evidence of the title of any person to a patent or to a share or interest therein unless the Controller or the court, for reasons to be recorded in writing, otherwise directs.
ANNEXURE I

PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY

Article 5
[Article 5

A. Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses. —
B. Industrial Designs: Failure to Work; Importation of Articles. — C. Marks: Failure to Use; Different
Forms; Use by Co–proprietors. — D. Patents, Utility Models, Marks, Industrial Designs: Marking]

A.—

(1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non–exclusive and shall not be transferable, even in the form of the grant of a sub–license, except with that part of the enterprise or goodwill which exploits such license.

(5) The foregoing provisions shall be applicable, mutatis mutandis, to utility models.

TRIPS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:
ANNEXURE I

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 30
Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31
Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;
(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.
<table>
<thead>
<tr>
<th>S. NO.</th>
<th>COUNTRY</th>
<th>SUBSTANCE OF THE PROVISION</th>
<th>RELEVANT PROVISIONS</th>
<th>ANY SPECIFIC FORM/ REQUIREMENT CORRESPONDING TO FORM 27 UNDER INDIA’S PATENT RULES, 2003/ HOW WORKING IS PROVED</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Albania</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 50 of Law on Industrial Property No. 9977 of 07/07/2008</td>
<td>No such requirement found in the Law on Industrial Property No. 9977 of 07/07/2008</td>
</tr>
<tr>
<td>2.</td>
<td>Australia</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Section 133-135 of the Patents Act no. 83 of 30/10/1990 as last amended by Act No. 103 of 2013</td>
<td>No such requirement found in the Patents Act no. 83 of 30/10/1990 as last amended by Act No. 103 of 2013</td>
</tr>
<tr>
<td>3.</td>
<td>China</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 48 of the Patents Law of 12/03/1984 as last amended on 27/12/2008</td>
<td>No such requirement found in the Patents Law of 12/03/1984 as last amended on 27/12/2008. Even on filing of a compulsory license application, patentee may provide legitimate reasons for non-working.</td>
</tr>
<tr>
<td>4.</td>
<td>Croatia</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 68 of the Patent Act No. 173 of 2003 as last amended by Act No. 49/2011</td>
<td>Not found in the Patent Act No. 173 of 2003 as last amended by Act No. 49/2011. The compulsory license will not be granted if the patent owner provides legitimate reasons to justify non-exploitation or insufficiency of exploitation of the protected invention.</td>
</tr>
<tr>
<td>5.</td>
<td>Turkey</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 129 and 130/2 of the Code of Industrial Property 6769 (repealed the earlier law in 2017)</td>
<td>As per the new law, the practice of filing a declaration of use of the patent is optional and up to the patentee. However, if filed, the declaration shall be published.</td>
</tr>
<tr>
<td>6.</td>
<td>Japan</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 83 of the Patent Law No. 121 of 13/04/1959, as last amended by Act No. 109 of 2006</td>
<td>Not found in the Patent Law No. 121 of 13/04/1959, as last amended by Act No. 109 of 2006</td>
</tr>
<tr>
<td>7.</td>
<td>Brazil</td>
<td>Non-working of patents is ground for compulsory license</td>
<td>Article 68 of the Industrial Property Law No. 9.279 of 14/05/1996 as last amended by Law</td>
<td>No reporting requirement. But as per Arts. 69 &amp; 73 of the Industrial Property Law No. 9.279 of 14/05/1996 as last</td>
</tr>
<tr>
<td>Country</td>
<td>Patent Status</td>
<td>Relevant Law/Legislation</td>
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<tr>
<td>Argentina</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 43 of Law No. 24.481 of Argentina as amended by Law No. 24.572 of 1995</td>
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<tr>
<td>Finland</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Section 45 of the Patents Act No. 550 of 15/12/1967 as last amended by Act 684/2006</td>
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<tr>
<td>Chile</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Articles 51 to 51bis D of Law No. 19.039 as last amended on January 26, 2007</td>
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<tr>
<td>Denmark</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Sections 45-50 of the Consolidate Patents Act (Act no. 91 of 28 January 2009)</td>
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<tr>
<td>France</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article L613-11 of the Intellectual Property Code, Law No. 92-597 of 01/07/1992 as last amended by Law No. 2015-195</td>
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<tr>
<td>Costa Rica</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 18 of the Law No. 6867 of 25/04/1983</td>
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<tr>
<td>Germany</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Section 24 of the Patents Act as amended up to Act of October 19, 2013</td>
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<tr>
<td>Greece</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Articles 13 and 14 of Law No. 1733/1987</td>
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<tr>
<td>Italy</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 70, paragraph 1 of the Industrial Property Code, Legislative Decree No. 30 of 15/02/2005</td>
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<tr>
<td>Mexico</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Article 70 of Law on Industrial Property (as amended up to the Decree of December 26, 1997)</td>
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<td></td>
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<td>There is no express obligation or requirement to file evidence of working the patent in the Law on Industrial Property (as amended up to the Decree of December 26, 1997). If a compulsory license application is filed, the patentee has 1 year</td>
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<tr>
<td>20. Monaco</td>
<td>Non-working of patents is ground for compulsory license</td>
<td>Articles 33 to 43 of Law No. 606 of June 20, 1955</td>
<td>Not found in Law No. 606 of June 20, 1955</td>
<td></td>
</tr>
<tr>
<td>21. Oman</td>
<td>Non-working of patents is ground for compulsory license</td>
<td>Section 15 of the Royal Decree No. 82/2000 Promulgating the Patent Law</td>
<td>Not found in the Royal Decree No. 82/2000 Promulgating the Patent Law</td>
<td></td>
</tr>
<tr>
<td>22. Russian Federation</td>
<td>Non-working of patents is ground for compulsory license</td>
<td>Article 1362 of the Patent Act (Chapter 72)</td>
<td>There is no working statement requirement. Reasons justifying the non-working of patent may be provided by the patentee to avoid compulsory license.</td>
<td></td>
</tr>
<tr>
<td>23. Pakistan</td>
<td>Non-working of patents is ground for compulsory license</td>
<td>Section 58 and 59 of the Patents Ordinance, 2000 (as amended in 2002)</td>
<td>Section 93 of the Patents Ordinance, 2000 (as amended in 2002) provides for a working statement requirement similar to the one provided under Indian law.</td>
<td></td>
</tr>
<tr>
<td>24. Malaysia</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Section 49 of the Malaysian Patents Act 1983.</td>
<td>The patentee is not required to submit any evidence for “working”. The responsibility to prove the “non-working” of a patent is with the third party who intends to apply for the compulsory license.</td>
<td></td>
</tr>
<tr>
<td>25. USA</td>
<td>Non-working of patents is not a ground for compulsory license.</td>
<td>N/A</td>
<td>The patentee is not required to submit any evidence for “working”.</td>
<td></td>
</tr>
<tr>
<td>26. Canada</td>
<td>Non-working of patents is not a ground for compulsory license (It used to be a ground before the provision was repealed in 1993).</td>
<td>N/A</td>
<td>The patentee is not required to submit any evidence for “working”.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Thailand</td>
<td>Non-working of patents is a ground for compulsory license</td>
<td>Section 46 of the Patent Act B.E. 2522 of 11/03/1979</td>
<td>The patentee is not required to submit any evidence for “working”. The responsibility to prove the “non-working” of a patent is with the third party who intends to apply for the compulsory license.</td>
</tr>
</tbody>
</table>
1. During the course of hearing, all the learned counsels have pointed out that one of the major difficulties in ensuring compliance with the provision of Section 146 of the Patents Act, 1970 is the manner in which Form-27 has been worded. It is...
submitted that this form was notified in the year 1970, and though amended in the year 2003, has failed to take into consideration the several scientific and technological requirements as well as the confidentiality issues relating to some of the patents.

2. We are informed by Mr. Amit Mahajan, learned CGSC that he has been instructed that the matter needs a relook.

3. Given the fact that this writ petition complaining of several pitfalls, illegalities as well as the admitted position on the part of the respondents that Section 146 of the Patents Act, 1970 has not been effectively worked, was filed as back as in the year 2015, this matter ought to have engaged the attention of the respondents long ago.

4. It is also astonishing that the matter has proceeded in this manner for a long period of 45 years since the statute was enacted. Be that as it may, expeditious steps regarding the working of the statutory provisions as well as the changes, if any, are required in the statute, rules and prescribed forms deserve to be taken.

5. In view thereof, the respondent no.1 shall place before this court, within two weeks from today, the timeline regarding the manner in which the steps required for effecting the necessary modification to the prescribed forms would be undertaken. The same shall be placed on affidavit before us within this period with advance copy to all parties through counsels who are represented before us.
6. It is pointed out by Mr. Gopal Subramaniam, learned Senior Counsel that on account of confidentiality attached to the issues relating to patents and agreements entered into between patentees and their licensees and sub-licensees, it is not always possible to disclose the terms on which the license has been issued. Mr. Subramaniam submits that in view thereof, the observations made by this court in para 13 of our order dated 10\textsuperscript{th} January, 2018 may be treated as violation of Section 146 of the Patents Act, 1970 if a patentee furnishing Form-27 withholds the details of the contents and terms of the license granted by a patentee. There appears to be force in this submission. It is, therefore, made clear that the reference in para 13 of the order dated 10\textsuperscript{th} January, 2018 to “details of licensees, licenses and sub-licensees” is only the specification with regard to number, date and particulars of the licensees and sub-licensees. In case, any party has reservation of any kind in furnishing details, it would have to disclose the reasons for such reservation and the patent office would be required to take a view in the matter so far as its satisfaction regarding compliance with the requirements of Section 146 is concerned.

6. In this regard, Mr. Bhandari has drawn our attention to Section 67 of the Patents Act which requires a register of patents to be maintained which contains the names and particulars of licensees. The information which is required to be furnished must comport to the requirements of Section 67 of the Patents Act as well.
7. It is submitted by Ms. Rajshree, learned counsel appearing for the applicant in CM No. 2108/2018 that, in paras 7 to 9 of our order dated 10th January, 2018, this court has noted the submission on behalf of the petitioner that the applicant has not furnished the information in terms of Section 146 of the Patents Act, 1970. We may clarify that this court has only noted the submission of the petitioner in this regard and has not expressed any opinion on the merits of the petitioner’s contentions.

8. List this petition on 1st March, 2018.

Dasti to parties.

ACTING CHIEF JUSTICE

C.HARI SHANKAR, J

FEBRUARY 07, 2018/kr
FORM 27
THE PATENTS ACT, 1970
(39 OF 1970)
THE PATENT RULES, 2003
STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION COMMERCIAL, SCALE IN INDIA
[See Section 146(2); rule 131(1)]

In the matter of Patent No. __________

We, ___________________ of ________________________________

The patentee(s) or licensee(s) under patent No. ____________ hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the Year ____________.

(i) The patented invention:

{ } Worked { } Not Worked [Tick (√) mark the relevant box]

The fact and matter stated above are true to the best of my/our knowledge, information and belief.

Dated this ________ day of __________

____________________________
Signature
(To be signed by person(s) giving statement)

To,
The Controller of Patents,
The Patent Office,
At
To:
Mr. Ramesh Abhishek,
Secretary (IPP)
Ministry of Commerce and Industry,
Udyog Bhavan,
New Delhi, India
Secy-ipp@nic.in

Shri. O. P. Gupta, IAS
Controller General of Patents,
The India Patent Office,
Mumbai, India.
cgoffice-mh@nic.in

Date: 16th March, 2018

SUBJECT: Comments on issues relating to working of patents under the Patents Act, 1970

We appreciate the opportunity to provide comments on Circular No.CG/Meeting Circular-DIPP/2018/14, dated March 1, 2018. With this we request your good office to allow our representative to be part of stakeholders’ meeting scheduled at DIPP on 21th March 2018.

Recent developments in the Indian patent jurisprudence has clarified certain concerns regarding information indicating working of an invention. Still there are certain aspects which do warrant attention so that the perceivable burden may be minimized, without compromising either the interests of the patentee or violating the provisions of the Act. Few of the most pertinent issues surrounding the for working of patents under the Patents Act, 1970 are as below:

1. Section 146 from which the working statement requirement stems, is outdated. This requirement was introduced as a safeguard to prevent patent holders from abusing their patent rights in India. However, Form 27 has remained the same and has not been amended even once to take into account the technological advancement that has taken place in these 45 years.

2. No such requirement exists in any other jurisdiction. Neither are such requirements mandated through TRIPS. In fact, provisions for compulsory license across jurisdictions have been considered as an appropriate remedy for non-working. Considering that adequate mechanism already exists in the Act for keeping a check on the patentee, the overall utility of the working statement is reduced.

3. Since the working statement contains sensitive license information which is confidential publication of details from the working stamen leads to violation of the confidentiality requirement. This may result in dissemination of information which is to be kept privy under contractual obligations. This
is likely to expose the patentee to the risk of misuse of such information by its competitors to create adverse market conditions, or by entities who have little regard for patent rights to unnecessarily initiate frivolous proceedings for revocation or public interest litigation.

4. The IPO’s expertise lies in examining, granting, or refusing a patent application. The details which are required to be submitted by a patentee/ licensee under Form 27, such as quantum and value of the patented product manufactured in India or imported to India, are trade related information. Neither the IPO has the resources or the skills to analyze such information nor does the Act prescribe the mechanism based on which such assessment is to be conducted.

5. The proviso to Section 69(4) mandates non-disclosure of registered patent license agreements when requested. However, such information is published along Form 27 which runs contrary to the aforesaid provision which operates to keep such information secret.

Most of the above issues can be addressed by doing away with certain requirements listed in Form 27 without impacting the scope of section 146 or rule 131. We would like to offer the following suggestions and hope that the same may be considered by the Patent Office to better reflect and adapt to the changing technologies and business operations.

a  Simplification of Form 27:

b

- Column 3(i) of Form 27 – to be made simple requiring the patentee to only state whether the invention has been worked or not.
- Column 3(i)(a) of Form 27 – reasons for not working to be removed.
- Column 3(i)(b) of Form 27 – to be removed.
- Column 3(ii) of Form 27 – may be retained. Any obligation to disclose or provide the license agreements should be dealt away with.
- Column 3(iii) of Form 27 – to be removed as this requirement is too vague and subjective, in addition to being extremely difficult to answer.

c  Since there are other provisions which ensure that patent rights are not abused by the patentee, for instance Section 64 (Revocation of Patents), Section 66 (Revocation of Patent in Public interest), Section 84 (Compulsory Licenses), Section 85 (Revocation of Patents by the Controller for non-working), India, like other countries, can also consider removing the requirement all together.

Thank you

R. Parthasarathy
Principal Partner,
Lakshmikumaran & Sridharan
B-6/10, Safdarjung Enclave, New Delhi – 110029
Comments on the 'Issue of 'Working of Patents' by M R Gupta former Asstt. Controller of Patents & Designs

(14-03-2018)

ABOUT THE ISSUE & PRESENT SITUATION

- Perhaps before 2005 Patent Office was not particular on the filling of Form - 27 by the Patentee, however when Patent Office started sending notice(s) / reminders to comply provision of Section 146 (2) of the Act it pinched all who were not complying this requirement.

- The persons / Public who inspected the Register of Patents were disappointed, looking that this information of Form 27 was not available to him / her

- The Persons requesting information under Section 153 or RTI Act were disappointed

Relevant provisions of the ACT

BEFORE, I proceed further, some relevant provisions of the ACT are reproduced below:

A. Section 10 (4) - Every complete specification shall-
   a. (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;
   b. (b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
   c. (c) end with a claim or claims defining the scope of the invention for which protection is claimed;

B. Section 67 (1) Register of patents and particulars to be entered therein. -(1) There shall be kept at the patent office a register of patents, wherein shall be entered-
   a. (a) the names and addresses of grantees of patents;
b. notifications of assignments and of transmissions of patents, of licences under patents, and of amendments, extension, and revocations of patents; and

c. particulars of such other matters affecting the validity or proprietorship of patents as may be prescribed

C. Section 83 - General principles applicable to working of patented inventions.

Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;-

a. that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

b. that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

c. that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

d. that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

e. that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

f. that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
g. (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

D. Section 153 - Information relating to patents. - A person making a request to the Controller in the prescribed manner for information relating to any such matters as may be prescribed as respects any patent specified in the request or as respects any application for a patent so specified shall be entitled, subject to the payment of the prescribed fee, to have information supplied to him accordingly.

E. Section 146 - 146 Power of Controller to call for information from patentees. –
   a. (1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.
   b. (2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.
   c. (3) The Controller may publish the information received by him under sub-section (1) or sub-section (2) in such manner as may be prescribed.

F. Section 146(2) (2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.
G. Section 100 (5) - Where an invention has been used by or with the authority of the Central Government for the purposes of Government under this section, then, [except in case of national emergency or other circumstances of extreme urgency or for non-commercial use], the Government shall notify the patentee as soon as practicable of the fact and furnish him with such information as to the extent of the use of the invention as he may, from time to time, reasonably require; and where the invention has been used for the purposes of a Government undertaking, the Central Government may call for such information as may be necessary for this purpose from such undertaking.

H. Section 122 - 122 Refusal or failure to supply information. - (1) If any person refuses or fails to furnish-
   a. (a) to the Central Government any information which he is required to furnish under sub-section (5) of section 100;
   b. (b) to the Controller any information or statement which he is required to furnish by or under section 146, he shall be punishable with fine which may extend to [ten lakh rupees].

   (2) If any person, being required to furnish any such information as is referred to in sub-section (1), furnishes information or statement which is false, and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both.

I. Rule 131 - Form and manner in which statements required under section 146(2) to be furnished.—(1) The statements shall be furnished by every patentee and every licensee under subsection (2) of section 146 in Form 27 which shall be duly verified by the patentee or the licensee or his authorised agent.

(2) The statements referred to in sub-rule (1) shall be furnished in respect of every calendar year within three months of the end of each year.

(3) The Controller may publish the information received by him under subsection (1) or subsection (2) of section 146.
J. Form -27 -The patentee(s) or licensee(s) under Patent No. _______ hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year___________. The patented invention:

[ ] Worked                         [ ] Not worked

a. if not worked: reasons for not working and steps being taken for working of the invention.

b. If worked: quantum and value (in Rupees), of the patented product: _________
   i. manufactured in India – Yes/No
   ii. imported from other countries. (give country wise details)
   iii. the licences and sub-licenses granted during the year; - Yes/No
   iv. state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

The facts and matters stated above are true to the best of my/our knowledge, information and belief.

OBLIGATIONS OF A PATENTEE

Wisely said, that where there is right, there is a duty. The possession of patent does not only bestow certain monopoly rights upon the patentee but also certain duties, such as:-

1. To encourage and secure working of invention to fullest extent without undue delay.
2. Not to use monopoly to unfairly prejudice interest of public.
3. Failure to discharge duties reasonably, would lead to revocation of patent.
4. To furnish periodical statements to Controller, as to extend to which invention has been worked.
5. Failure to provide statement to Controller is a punishable offence.

A patent is a monopoly right conferred by the Patent Office on an inventor, with his right to exploit his invention for a limited period of time. During this period, the inventor is
entitled to exclude anyone else from commercially exploiting his invention. Once a patent is granted to the patentee, certain rights and obligations arises with respect of holding, using, exploiting, and working of a patent on a patentee. The author believes it to be a negative right because enjoyment of a patent by a patentee is subject to various restrictions and obligations, breach of which may result into heavy penalties as subscribed by the law.

OBLIGATIONS OF CONTROLLER OF PATENTS

The Controller of Patents is the principal officer responsible for administering the patent system in India. The powers of the Controller includes the power: to receive, acknowledge, accept, publish and examine a patent application, claim, description and specification, to make search and investigate for anticipation by previous publication and by prior claim to consider the report of the examiners; to refuse application or require amended application, in certain cases to make orders respecting division of application; to make orders respecting dating of applications; to make orders regarding substitution of applicants; to issue written permit to a person resident in India to make an application outside India for the grant of a patent for an invention; to grant patent to name a few.

REGARGING - SUJECT CIRCULAR

CG's office circular as asking comments on - Provisions related to Working of Patents only i.e.

i. Section 146 (1) & (2) ----- E & F
ii. Rule - 131--------              G
iii. Section 122 ------              H        and
iv. Form 27 ----------               I
POWERS OF CONTROLLER UNDER SECTION 77

The Controller has CIVIL COURT too under Section 77 of the Patents Act, 1970. He shall be exercising powers of a Civil Court under the CPC, 1908 while trying a civil suit. These include summoning of witnesses and enforcing the attendance of witnesses; Receiving evidence on affidavits; Issuing commissions for the examination of witnesses of documents; Awarding costs; etc.

This also includes power to Review his own decisions on application made within the prescribed time and in the prescribed manner and setting aside an order passed ex-parte on application made within the prescribed time and in the prescribed manner. Sub section - 2 makes it clear that orders passed by the Controller shall be executable as a decree of a Civil Court.

DISCRETIONARY POWERS OF THE CONTROLLER

Controller has discretionary power of the controller under Section 3(d), under Section 8(2) and under Section 17Section 81 gives power to the controller to extend time. And no appeal shall lie from the order of the Controller granting extension of course under Rules 137 & 138. These powers are not arbitrary and the general powers of the controller are that of a Civil Court under the CPC 1908.

There are a good number of decision of the various High Courts and Apex court to guide the Controller while deciding a case under Section 77 of the Act. A few are below:

1) In the case of Press Metal Corporation Limited v. Noshin Sorabji Pochkanwalla, it was held that the power to correct clerical errors under Section 78(1) does not extend to make amendments suo moto. Thus, amendments have to be strictly made only under Section 57 of the Act

2) In the case of AIA Engineering Ltd. v. Controller of Patents, it was held that, while purporting to exercise powers under Section 78 of said Act, there could not be any
amendment of application as in that eventuality procedure of Section 57 read with Section 59 of said Act must be followed

3) In the case of Novartis Ag v. Union of India, the court held that Section 3(d) did not violate Article 14 of the Constitution of India and was not vague or arbitrary and did not confer uncontrolled discretion to the Patent Controller.

SUGGESTIONS:

The salient features of the Act, that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. This salient feature of the Act is very much responsible for the development of our Country. All inventors / companies / Patentee must work hard to use the latest technology available in patents documents. They must avoid litigations and disputes and help those who are waiting justice due to backlog of cases in courts. It will be the endeavor of the Patent Office not to say 'Go to Court' and use its power judiciously.

CONCLUSION:

• The author is of the opinion that information asked for in Form 27 is justified and Patentee must comply Section 83 of the Act, there should be no problem to the Patentee to give such information.
• Further nothing is confidential as patent is granted for full disclosure of the invention as per Section 10(4).
• However, in case of delay or other problem the Patentee must request the Controller of Patents accordingly.
• In case Patentee is silent on his /her duties Controller must exercise his / her power under Section 122. - principle of natural justice must apply.
• Further Controller have to exercise its power under Section 146 (1) as and when required to discharge its other duties duties (including related to Form 27 - asked Under RTI Act ) under the Act.
• No change / guide lines to be framed / required as the present provisions under the Act are sufficient to take care of the all stakeholders and public at large.

------------ End of the Document ---------
Ankush Mehta  
B.E. (Hons.) Electronics & Communications, LLB, IPA, ITMA  
Attorney-at-Law  
Patents, Designs & Trade Marks Attorney

Our Ref.: WS/Comments/IPO  
Date: 23 March 2018

Kind Attn:  
Dr. W M Dhumane  
Dr. Usha Rao  
Controller of Patents  
The Controller of Patents  
The Patent Office  
Intellectual Property Building  
Plot No 32, Sector 14, Dwarka  
NEW DELHI-110075

Re: Comments regarding issues relating to working of patents

Hon’ble Controller,

We are writing further to circular dated 16 March 2018 inviting comments from stakeholders regarding issues relating to working of patents and filing of working statement. We submit as follows:

Confidentiality of contents of working statement in view of section 146(3) and Hon’ble Delhi High Court’s order of Shamnad Basher vs. Union of India (W.P.(C) 5590/2015)

The Hon’ble Delhi High Court under their recent Order of Shamnad Basher vs. UOI has stated as follows:

“All that the patentees submitting Form-27 are required to submit, is the details of the licenses and sublicenses. This information certainly cannot be termed “confidential” and therefore, the Patents Office has to treat such suppression as failure to comply with the requirements of Section 146 of the Patents Act, 1970 and to take action against the patentees who do not furnish the required information.”

It is evident that it is now compulsory for patentees and / or licensees to disclose all information required under working statement. Further, they cannot simply state that said information is confidential.

However, the Hon’ble Court has not given any clarity on section 146(3) which reads as follows:
“The Controller may publish the information received by him under sub-section (1) or sub-section (2) in such a manner as may be prescribed”

From simple reading of above provision, it is clear that publishing any information received by the Hon’ble Controller under working statement is at his discretion.

However, IPO as a policy publishes all information which is ultra vires particularly in view of Hon’ble Supreme Court’s Judgment in “Shri Rama Sugar Industries Ltd. vs. State of Andhra Pradesh and Ors. (1974) | SCC 534: AIR 1974 SC 1745”. In said judgment, it was held as follows:

"Generally speaking, an authority entrusted with discretion must not by adopting a rule or policy, disable itself from exercising its discretion in individual cases. There is no objection in its formulating a rule or policy. But the rule it frames or the policy it adopts must not be based on considerations extraneous to those contemplated or envisaged by the enabling Act. It "must not predetermine the issue, as by resolving to refuse all applications or all applications of a certain class or all applications except those of a certain class"

In view of above, it is clear that if it is mandatory on part of patentees / licensees to provide all information required under working statement, it is equally important that IPO publish only those working statements where after observing circumstances of each case it deems fit to publish the same.

**Filing by unauthorized agents:**

It has come to our notice that Firms / Patent Agents who are not address for service are filing working statements. Further, such statements are being taken on records. However, upon reading of rule 5 of Patent Rules, we understand that if such an action is not completed by such address for service, "the Controller shall be under no obligation either to proceed or deal with any proceeding, or patent or to send any notice that may be required to be given under the Act or these rules and the Controller may take suo motu decision in the matter”.

In view of the same, a clarification is requested as to what action will be taken by IPO in such cases.

**Way forward and our suggestions:**

- **Publications of Working Statements:** It is respectfully submitted that most of the information required under working statement are of commercial importance to a Patentees / Licensees and often may lead to disclosure of trade / marketing secrets. Hence, it is suggested that such information is kept confidential and is not published. However, if it becomes mandatory to publish such information, then an opportunity be afforded to the Patentees / Licensees to reason against the same, if required.

- **Amendment of information required under Working Statements:** After consulting with different stakeholders we have noticed that submitting value of patented products within 3 months is not only difficult but may also detrimental to business as same discloses
commercial secret (*pricing*) to competitors. In view of the same, it is suggested if under amended working statement format value of patented product produced is not called for. However, if such information is still required in proceeding like deciding grant of compulsory licenses, same can be requested separately.

- **Action against non-compliant patentees / licensees**: The Hon’ble Delhi High Court has also asked IPO to set guidelines how action against Patentees / Licensees who are non-compliant to requirement of Working Statement. It is respectfully suggested:
  
  - That before any severe action is taken; opportunity to re-file information within reasonable time is granted to all patentees / licensees to avoid panic.
  - A mechanism should be set-up to avoid filing of working statement by unauthorized agents.
  - Further, a clarification should be issued as to what steps will be taken by IPO to provide confidentiality under section 146(3).

As stakeholders, we request that we are called for stakeholder consultation meeting currently scheduled on 06 April 2018 to discuss above. Further, for ease of all stakeholders, meeting may either be conducted at all 4 Patent Offices individually or same may be conducted via video-conferencing facility at all 4 Patent Offices simultaneously instead of holding it at one office only.

Most respectfully submitted and Prayed as above.

Yours faithfully,

[Ankush MEHTA]
Patent Attorney for the Applicants

[Regn. No. - IN/PA-1911]  
Mehta & Mehta Associates
Dated: March 23, 2018

To,
The Controller General of Patents,
Designs & Trademarks
Boudhik Sampada Bhavan
S.M. Road, Antop Hill
Mumbai-400037 (India)

Subject: Comments on the issues relating to Working of Patents under the Patents Act, 1970.

Dear Sir/Madam,

This is with reference to Circular dated March 1, 2018 and further circular dated March 16, 2018 inviting comments from stakeholders regarding issues relating to working of patent. Please find herewith Mylan’s comments in context to issues relating to working of patents i.e. Section 146 of the Patents Act 1970 (as amended) read with Rule 131 of Patent Rules 2003 including Form 27, and penal provisions provided in Section 122.

Thanks & regards,

Mylan IP Legal Team,

Mylan Laboratories Limited
Plot No. 34 A & B, ANRICH Industrial Estate
Bollaram Jinnaram (Mandal), Medak District - 502 325
Hyderabad (Telangana State)
Tel (Board) : +91 8458 279301/302
Comments Relating to Working of Patents

1. Mylan is one of the world’s leading global pharmaceutical companies, with a significant and growing presence in India. We are making this submission to the Controller General Patents, Design & Trade Marks on behalf of Mylan Laboratories Limited. This submission is in response to Circular dated March 1, 2018 and further circular dated March 16, 2018 inviting comments from stakeholders regarding issues relating to working of patent. This submission includes the comments in context to issues relating to working of patents i.e. Section 146 of the Indian Patents Act, 1970 and Rule 131 and Form 27 of the Patents Rules, 2003 and penal provisions provided in Section 122.

2. Mylan’s commercial businesses based in India market high quality API to third parties around the world and antiretroviral products for people living with HIV/AIDS. Today, nearly 50% of those receiving treatment for the disease in the developing world rely on a Mylan product, all of which are made in India. In fact, Mylan is India’s third largest pharmaceutical exporter. In addition, Mylan has a growing commercial presence domestically. Mylan’s current franchises include Critical Care, Hepato Care, HIV Care, Onco Care and Women’s Care.

3. Further, Mylan’s presence in India goes beyond manufacturing, sales and marketing. Hyderabad is home to one of Mylan’s three global R&D centers of excellence. The center has extensive experience working with health authorities from multiple countries. It also is fully integrated with the company’s global R&D function, creating a unique and efficient, ‘round-the-clock research, development, clinical and regulatory capability.

4. In view of the fact that Mylan’s substantial presence in India and to support healthcare system in India and globally, this submission is a responsible effort of the organization to provide inputs relevant to policy making in the areas of Intellectual Property Management.

Background

5. The local working of patents is an important requirement in patent regimes all over the world – including India – as well as being a major source of contention. Section 83 of the Patents Act 1970 establishes the general principles regarding the working of patented inventions in India. Section 83 states that the grant of patents is not solely intended to enable patentees to enjoy a monopoly on the import of patented articles. The goal of granting a monopoly to patentees is to encourage invention and ensure that patented inventions are worked in India on a commercial scale and to the fullest extent reasonably practical without undue delay. In return for a 20-year monopoly over the patented invention for the rights holder, the patent rights should serve to promote technological innovation and enable the dissemination of technology to the advantage of producers and consumers, in a manner that is conducive to their social and economic welfare. Section 83 also requires
6. That granted patents not impede the protection of public health and nutrition, but rather act as an instrument to promote the public interest; hence, patented inventions must be available to the public at reasonably affordable prices. Patentees are thus obliged to work their patented inventions in India for social and economic welfare in return for their 20-year monopolies.

**Working statement: statutory provisions**

7. Section 146 of the Patents Act empowers the controller general of patents, designs and trademarks to call for information from a patentee or licensee. Accordingly, at any point during the life of the patent, the controller general may – by way of notice or in writing – require a patentee or licensee, exclusive or otherwise, to furnish information or periodical statements regarding the extent to which the patented invention has been commercially worked in India. This must be provided within two months of the date of notification or within the time allowed by the controller general. Section 146(2), read with Rule 131, requires every patentee and licensee to submit to the controller general an annual statement of commercial working of the invention within three months of the end of each calendar year (i.e., by March 31).

8. The working statement is made in a fixed form, Form 27, and must include the following information:

- whether the patented invention has been worked, and:
  - if not, the reasons why not and the steps being taken to work the invention; or
  - if so, the quantum and value (in rupees) of the patented product manufactured in India and imported from other countries, along with the details of each country;
- details of all licences and sub-licences granted during the year; and
- Whether the requirement to promote the public interest has been met partially, adequately or to the fullest extent possible at a reasonable price.

9. Section 83 of the Patents Act aims to ensure the local working of patents and avoid the misuse of patent rights by the mere import of patented products. However, Form 27 requires the quantum and value of a patented product imported from other countries and their details to be specified. If the import of a patented product is considered sufficient to meet the working requirement, this interpretation seems to contradict the general principles laid down under Section 83.

**TRIPs versus working requirements in India:**


10. The ‘working’ requirement of a patented invention has been a bone of contention among WTO member states for some time. The dispute has arisen mostly because ‘failure to work’ a patented invention in the territory of the issuing country is a ground for compulsory licensing. In view of this issue, it is important to understand the WTO provisions on local working of patents and how the Indian patent working requirement complies with TRIPs.

11. TRIPs Agreement does not explicitly address patent working requirements. However, Article 2.1 and Article 2.2, 27, 30 and 31 of TRIPs in view of Article 5A of the Paris Convention, it can be interpreted that the local working of patent is well within the scope of TRIPS.

12. Importantly, Section 146 of the Patents Act, which requires the working of patents, has existed since the act’s promulgation in 1970, before India signed TRIPs, and The Patents Act has since been occasionally amended in order to bring it into line with TRIPs.

**Working of patented inventions in other geographies:**

13. Brazil: The current Industrial Property Law, dated May 14, 1996, there is a provision under article 68(1)(I) of the IP law stating that if the product is not locally exploited within a three-year period from its grant, it becomes vulnerable to compulsory licences, except in specific cases when local manufacture is not economically viable. In these cases, importation is allowed.

14. Spain: Spanish Patent law 24/2015; TITTLE IX; “Obligation to exploit and compulsory licenses” Article 90 relates to “Obligation to exploit”, while Article 91 relates to “Assumptions of granting compulsory licenses” wherein Lack or insufficiency of exploitation of the patented invention is an assumption for grant of compulsory licenses.

15. Turkey: As per Article 96 of the Turkish Patent Law (Decree Law No: 551; Section IV: Obligation to Work), a patentee is obliged to work the patented invention. The obligation to work shall be discharged within three years from the date of publication in the relevant Bulletin of the announcement relating to the grant of the patent.

**Mylan’s comments**

16. Section 146
• Section 146(1): The subsection confers power on the Controller to call on patentees and licensees to furnish such information or periodical statements that may be specified on the extent to which a patent has been worked on a commercial scale for specified period(s).

• Section 146(2): The subsection states that 'Without prejudice to the provisions of subsection (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India'.

• Section 146(3): The subsection provides that the Controller may publish information received by under subsections (1) and (2).

Comments: Mylan believes that the requirement of working of patent is important in order to achieve balance between promoting innovation in one hand and accessibility of invented product to the public at large at the other hand.

Moreover, section 146(2) states that 'every patentee' and 'every licensee' shall furnish information regarding the working of the patented invention; such requirement is ambiguous and creates confusion. This requirement will lead to submission of multiple statements (by patentee and by all licensees) on the working of the invention, wherein submitted information may be inconsistent. Hence, appropriate corrections should be made so that only one statement is submitted in context to the working of one patent which should be by the Patentee/Grantee only. The patentee/grantee should collect information in context to working of the patented invention from all the licensees and submit the Form 27 with the compiled data for the quantum and value of the patented product.

Further, Mylan submits that the Controller may consider routinely digitizing all Form 27 filings and placing them in a searchable database designed to permit convenient analysis and scrutiny by all persons.

Therefore, Mylan submits that the requirements prescribed by the section 146 are justified and should be continue.

17. The Rule 131(2): Rule 131 (2) of Patent Rules 2003 states that the statement in context to working of patent invention shall be furnished in Form 27 in respect of every calendar year within three months of the end of each year.

Comments: The said Rule 131(2) refers to submission of the statement of working of patented invention for every calendar year which starts from 01st January and ends on 31st December. Mylan believes that this rule does not need any changes.
18. Form 27: Part (i)(b)(ii) of Form 27 states that for the worked patented invention the quantum and value of the patented product imported from other countries is to be given with details for each country and part (iii) of the Form 27 states that details are to be submitted for whether the public requirement has been met at a reasonable price either partly, adequately or to the fullest extent.

Comments: As per part (i)(b)(ii) of Form 27, one is required to submit country wise details of quantum and value of the patented product imported from other countries. Submitting such country wise detailed information becomes cumbersome and difficult; and accordingly, this section of Form 27 should be amended so that one has to submit an overall quantum and value of the patented product in India.

Mylan also believes that for manufacture of a product, if plurality of patents ought to be commercialized together, i.e., incorporated in a single product / process, then Form 27 requires amendment so that it would enable the patentee to incorporate a list of patents as annexure, and the same Form 27 could then be filed against all the listed patents.

The part 3(iii) of the Form 27 requires that the details are to be submitted for whether the public requirement has been met at a reasonable price partly, adequately or to the fullest extent. More details/provisions should be provided for how to decide and differentiate between the terms ‘partly’, ‘adequately’ or ‘to the fullest extent’ in context to the meeting of public requirement at a reasonable price.

19. Section 122 is too harsh to the patentee if he fails to timely submit the information. As this section or related rules do not provide any provision for extension of time. Some provision should be made wherein, if patentee could not submit the information by 31st March, he can still submit it by paying extra fee. Form-4 may be modified and provision for late submission of Form-27 should be included in Form-4.

Further, Section 122 is inconsistent with the Controller’s power under Rule 137. In case of any irregularity, patentee can file Petition under Rule 137 and request for condonation of the irregularity. So, if patentee fails or erroneously submits any incorrect information he can get it rectified by filing the Petition under Rule 137. This makes Section 122 irrelevant and Patentee will safeguard himself by filing Petition under Rule 137.

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To: The Hon. Controller General of Patents, Designs, and Trade Marks, Mumbai

From: Narendra R Thappeta, Patent Agent, Bangalore

Sub: Stakeholders Meeting ... Working of Patents Under the Patents Act, 1970

Respected Sir:

India Patent Office (IPO) is respectfully thanked for inviting the stakeholders input in relation to Working of the Patents under the Patents Act 1970.

I also state at the outset that I am an intervenor/respondent in WP 5590/2015: Shamnad Basheer vs. UOI at the Honorable High Court at Delhi. Below is our submission.

I. Construction of Relevant Sections of Patents Act

It is humbly noted that section 146 is believed to be merely an empowering provision for the Patent Office to seek pertinent information for administration of compulsory licenses and licenses as of right. The law does not mandate that Patent Office collect information under either section.

In this respect it may be noted that subsection (1) of section 146 states in pertinent parts, “The Controller may, …, require a patentee or a licensee, exclusive or otherwise, to furnish …” (Emphasis Added). Similarly subsection (2) of section 146 states in pertinent parts, “...such manner and form and at such intervals (not being less than six months) as may be prescribed ...” (Emphasis Added).

Similarly, subsection (3) also leaves it to the sound discretion of the Controller as to whether or not to publish the information collected under subsections (1) and (2) by use of the word ‘may’.

Attached as Annexure A are the relevant excerpts related to section 146 from the report of Hon. Justice Ayyangar.
II. What is Prayed For

P1. IPO is respectfully urged to reduce the burden on patentees holding patents covering areas of no public interest (e.g., in most CRIs) consistent with intent inherent to the structure of section 146. It is specifically suggested that only minimal information be asked of all patentees under Form-27 under sub-section 146(2) of the Patents Act. The IPO is urged to instead use sub-section 146(1) for more detailed information when patents cover areas of public interest. This way the IPO would have necessary information for administration of compulsory licenses and yet avoid unneeded burdens on patentees as a matter of good governance.

A sample of Form-27 corresponding to P1 is attached hereto as Annexure B. P2-P5 below are inapplicable should Form-27 suggestion of Annexure B be accepted.

P2. Current electronic version of Form-27 is designed under the assumption that working requirement is satisfied by ONLY ONE of two conditions: (A) Manufacturing in India; OR (B) Importing. Form-27 may be suitably modified to permit submission that working requirement is satisfied under NONE of the two situations, or BOTH situations. The ‘NONE situation’ is attracted when a Computer Related Invention (CRI) is deployed in adequate quantity during prior years and the public requirement is met by such CRIs. The ‘BOTH situation’ is attracted when some units are manufactured in India and some are imported.

P3. Form-27 may be revised to refer to ‘Patented Subject Matter’ instead of the current term ‘patented invention’. The current term used causes undue burdens on patentees in CRI areas (but not in pharma), given that the determination of scope of ‘patented invention’ entails complex analysis.

P4. IPO is respectfully urged to remove the fields requiring units/quantum and value from Form-27, at least if those fields are made applicable to CRIs and other similar
non-pharma areas (while retaining the option to seek that information under sub-section 146(1) instead). The problem with such fields is that CRI Patents often contain multiple claims directed to different parts of an end product (e.g., one claim towards a small circuit and another claim towards a system incorporating such circuit), and there is no clear way to measure ‘units’ for a patent in such contexts. Similarly method claims in CRIs add further to the complexity.

P5. Form-27 may be redesigned so that patentees are not required to make subjective assessments such as whether the public requirements are met adequately.

P6. Sub-section 146(3) makes it optional for the Controller to publish the information received under 146(1) and 146(2). The Controller may be pleased to formulate rules or other guidelines on what information will be made available to the public either as a matter of routine course or when specifically requested (e.g., in a RTI request).

P7. Plain language of Section 122 (“... shall be punishable...”) makes penal provisions there non-mandatory. Rules may me formulated to clarify that penal provisions are applicable only under clearly articulated exceptional circumstances, and to establish due process in the implementation.

I may be reached at thappeta@gmail.com or +91.98452.05343 if there are any questions in this respect.

Respectfully Submitted

Narendra R Thappeta
Patent Agent
Annexure A: Excerpt from Hon. Justice Ayyangar’s Report

Clause 105—Power of Controller to call for information from patentee

838. Opinion has been expressed that this provision enabling the Controller to call for periodical statements from the patentee or the exclusive licensee as to the commercial working of the invention in India might prove a burden rather than an advantage, and that for this reason this provision should be omitted. It is urged that the particulars as to the user submitted by the patentee or the exclusive licensee could not be the subject of scrutiny or cross-examination by the Controller so that one could not be sure that the statements furnished by the patentee or the exclusive licensee were correct. It was stated that it was possible that the patentee might furnish untrue or incorrect statements with a view to enable him to confront any applicant for compulsory licence with the incorrect statements when the time for this arose.

839. There were others who expressed the opinion that compliance with the provisions of this clause would compel manufacturers to disclose their trade secrets and that if this requirement were insisted upon, they would rather close down than to continue to work the patent. I am not inclined to take this threat seriously. I am also not satisfied that the provision would be either useless or would be of disadvantage to the general public. Most of the industries in which patents are worked are covered by the requirements of the Industries (Development and Regulation) Act of 1951 under which manufacturers are bound to furnish to Government particulars as to the working and other details of manufacture. Besides, Clause 94 provides for a sufficiently deterrent punishment for furnishing false statements as to the working of the invention by a patentee or the licensee. I feel that this provision will enable the Controller to have detailed particulars as to the actual working of the invention. It would enable him to dispose of quickly and efficiently applications for compulsory licences and endorsements of ‘licences of right’ under the relevant clauses of the Bill.

840. Further, particulars as to working of the invention would be useful for statistical purposes as at present no estimate can be made of the extent to which patents are being worked.

841. The latter objection seems to be rather exaggerated. The information which the Controller requires under this clause is as to the “extent to which the patent is commercially worked in India”, and such information is generally disclosed in the Directors’ Report and the balance sheets of the companies and do not involve the disclosure of any trade secrets. No legitimate exception could therefore be taken to any provision under Section 105.

842. On the clause as it stands the Controller might require information as to working only from a patentee or an exclusive licensee. I consider this insufficient to
achieve the purpose of the clause. The patent may be worked not by the patentee but by a non-exclusive licensee. In such case, it is possible that the patentee might not be in a position to furnish particulars as to the extent to which the patent has been commercially worked in India. If in such a case the Controller cannot require the non-exclusive licensee to furnish information the purpose of the clause would fail. There does not appear to be any logical principle behind the exclusion of the non-exclusive licensee from the operation of this clause. After all, the clause is designed to find out the extent of commercial working of every patent and as a patent could be worked by exclusive as well as non-exclusive licensees, there is no reason why the latter should be excluded from the scope of this clause. I would, therefore, suggest that for the words “an exclusive licensee”, the words “a licensee, exclusive or otherwise” may be substituted.

843. I would also suggest that for the words “the patent has been commercially worked”, the words “the patented invention has been commercially worked” may be substituted.

844. I would accordingly recommend the retention of this clause with the modification I have suggested which is carried out in the following draft.

“105. Power of Controller to call for information from patentees.—The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.”
### Annexure B: Suggested Questions in Form-27

160 (i) Are any medicines/drugs covered by the patented invention?
161 Yes [ ]  No [ ]
162 If Yes: Name the Medicine(s)/Drug(s)  ………………

166 (ii) Is the patent a standard essential patent?
167 Yes [ ]  No [ ]
168 If Yes: Name the standard(s)  ………………

170 (iii) The patented invention (subject matter) is:
171 { } Worked  { } Not worked  { } Unknown

From: Narendra R. Thappeta, Patent Agent, Bangalore, nt@iphorizons.com

Date: September 12th 2017

Subject: E-filing of Annual Working Statements Under Patents Act 1970

This memo notes the issues faced by some of the patentees in completing online FORM-27 during January-March 2017 (hereafter ‘Current FORM-27’), and prays the Honorable Controller to ensure that practices for future years address the issues noted herein.

It is specifically explained that the working requirements of Chapter XVI of the Patents Act, 1970 are satisfied in ways not contemplated by the Current FORM-27. It is accordingly respectfully prayed that Current FORM-27 be suitably amended to enable Applicant’s to specify the working information, as applicable to their business context. Specific suggestions on amendment to Current FORM-27 are provided at the end of this memo.

This memo is also necessitated by the recent redesign of FORM-30 which precludes Patentees from submitting FORM-27 using FORM-30 in appropriate circumstances.

I. Background

The Patents Act 1970 (as amended), in view of Rule 131 of the Patents (Amendment) Rules 2016, requires every patentee and licensee to provide annually a statement (FORM-27) on the working of patented invention in India. The forms are required to be filled and filed electronically if submitted by the agents of record.

In the previous calendar year (Jan – Mar 2017), some patentees have been forced to use FORM-30 to submit a **scanned copy of FORM-27** (instead of filling the FORM-27 provided by the IPO’s E-filing Portal) in several instances when the patent was worked to meet the public requirement at reasonable price. FORM-30 was used pursuant to Rule 8 since the then applicable FORM-27 in the e-filing portal does not allow the entry of suitable responses corresponding to technological/business scenarios of the corresponding patentees.

However, we have observed recently that FORM-30 has been redesigned and does not permit FORM-27 to be uploaded in scanned format.

In addition, in view of the requirement to file FORM-27 electronically, the Patentees are precluded from the option of using suitable variations of the form, contrary to the express provision of Rule 8(1).
Accordingly, the attention of the Hon. Controller General is drawn to some of the business/technological scenarios that have presented issues with FORM-27 practice in the past. It is then prayed that the FORM-27 related practice be defined keeping such requirements in mind as well, for the annual working statements to be submitted from January 2018.

II. Technological/Business Scenarios

A. Case One: Patentees of computer related inventions (CRI)s often rely on operation of product(s) deployed during several prior years as a basis for asserting that the patent is being worked, satisfying the reasonable requirements of the public.

In other words, the patentees often rely on the deployed products from previous years as a basis for satisfying the principles and requirements contemplated by Chapter XVI of the Patents Act, 1970 entitled, “Working of Patents, Compulsory Licenses and Revocation”.

Such reliance may be appreciated by understanding that CRI based products do not cease existence despite repeated use. This is in sharp contrast to pharmaceutical products which are consumable and cannot be reused in most scenarios. The current design of FORM-27 appears to be premised on the characteristics of pharmaceutical products, which are not shared by CRI.s.

Specifically, current (as of March 2017) design of FORM-27 is unsuited in requiring the Patentee to specify details of either ‘Manufactured in India’ or ‘Imported from other countries’ when the patent is worked in the applicable calendar year. In particular, a ‘No’ for ‘Manufactured in India’ causes the online FORM-27 to automatically force a ‘Yes’ for ‘Imported from other countries’.

It is accordingly respectfully submitted that the design of FORM-27 is unsuitable for providing the pertinent information for CRI.s in the corresponding instances of Case One.

B. Case Two: Patentees of CRI.s (typically component providers) often enter into global cross licenses covering India also, due to which the products (components) get incrementally developed globally by potentially several parties before the end product is sold to customers in India.

Many of the vendors operating in India can be further sub-licensees of the licensees of the Patentees, with whom the patentee has no direct relationship. Thus, the patentees in this scenario often do not have a relationship with or...
control over the sales specific to India in view of the dynamics of the global markets.

In this scenario, the patentee is clearly aware of the existence of the CRIs being in operation in India (satisfying the public requirements clearly), but does not control or know the specific vendors in India who are manufacturing in India, importing into or selling the products in India.

Accordingly, the Patentees would wish to assert that the Requirements of Public are fully met (based on knowledge of availability of products in India), but cannot provide details of the specific activities of the licensees or sub-licensees as related to commercial working in India.

Specifically, if the Patentee indicates that the ‘License Granted’ is Yes as a basis for concluding that the reasonable requirements of public are met, Current FORM-27 would require entry of the Licensee Name and Sub-licensee name, which the Patentee is unable to provide.

Similarly, the Patentee is sometimes aware of the general market dynamics causing imports, but has neither control over nor clear knowledge of the activities of independent third parties. Accordingly, the patentee is unable to provide the details of countries where the patented product is imported from and also value of the product in other countries.

Again, even in this case, FORM-27 appears to have been designed keeping in mind the dynamics of pharmaceutical industry (not shared by CRI markets), where medicines may not be developed incrementally in many levels before reaching an end-consumer. It is accordingly submitted that the design of Current FORM-27 is unsuitable for providing information for CRIs in the instances corresponding to Case Two also.

C. Case Three: There are many CRIs, which are substantially in the form of software instructions. Several challenges are presented in answering the questions of Current FORM-27.

Firstly, it is often unclear how to interpret the term ‘manufactured’ referred to in Current FORM-27 in such a context. It may be appreciated that, the software instructions are designed, tested and finalized with teams from various locations globally. Once the instruction set is finalized, the set may be dynamically downloaded or copied relatively easily from one medium to another. Software can be reused many times locally or from large servers in the cloud.
In such scenarios, it is unclear how to answer the question whether the patented product is ‘Manufactured in India’.

Similarly, in CRI space (unlike in medicines), the same end product sold to consumers can be covered by thousands of patents due to the very nature of the technology. The Patentees find it challenging to ascertain contribution of a patent to the revenue achieved by selling such a multi-patent embodied product.

Current FORM-27 is unsuitable for providing information for CRIs in the instances corresponding to Case Three also.

**D. Case Four:** Patentees of some CRIs (specifically in software product space) simply license products, without reference to specific patents. In other words, what is licensed in the market place is a product for use to specific customers, and there is no license granted expressly for any of the Patentee’s patents that may be covered by the product thus licensed.

It is fairly clear under those circumstances that the products licensed by the Patentee satisfy the reasonable requirements of the public.

In such a situation, the Patentee is best served by answering the ‘facts’ (noting licensing of the product) as opposed to stating conclusions on whether or not specific patents have been licensed (which they may not be). Current FORM-27 is unsuitable for providing information for CRIs in the instances corresponding to Case Four also.

**III. Suggestions**

The Hon. Controller General is respectfully urged to define the FORM-27 practice addressing the issues noted above.

One suggestion is to permit scanned copy of FORM-27 to be submitted (either by itself or in conjunction with FORM-30 as in 2017 January-March).

Another suggestion is to add a new field, which permits the patentee the flexibility to explain in free-text format their basis for assertion of having met working requirements. In essence, when the basis is other than manufacturing or importing, the patentee should be able to explain that basis in this new suggested field.
Ref. No.: PC/233

The Controller of Patents
The Patent Office
New Delhi

Dear Sir,

Re: Comments from Stakeholders regarding issues relating to working of Patents

With reference to circular no. CG/Circular/2018/114 dated 16.03.2018 please note our comments:

1. That there should be no deadline to file Form-27
2. That in products that have multiple patents it becomes difficult to determine the quantum of each application.
3. That when there are multiple licensees for an invention it is difficult to get information from each and every licensee.

Kindly consider the above and invite us for the Stakeholders meeting.

Regards,

Ms. Neha Chugh
Patent Attorney
B.Engg., LLM
COMMENTS ON PROVISIONS RELATED TO WORKING OF PATENTS UNDER THE PATENTS ACT, 1970

March 16, 2018

Obhan & Associates
Advocates and Patent Agents
N - 94, Second Floor
Panchshila Park
New Delhi 110017, INDIA

Phone: +91 11 40200200 | Fax: +91 11 40200299| E-mail: email@obhans.com
This is with reference to the circular bearing reference no. CG/Meeting Circular -DIPP/2018/14, dated March 01, 2018, issued by the Office of the Controller General of Patents, Designs & Trademarks, inviting comments on the provisions of working of patents under Section 146 of the Patents Act, 1970 (as amended) read with Rule 131 of Patent Rules 2003.

Our comments in matter are as follows:

1. Ayyangar Committee Report states that the primary objective of requesting for the working information is as follows:

   “I feel that this provision will enable the Controller to have detailed particulars as to the actual working of the invention. It would enable them to dispose of quickly and efficiently applications for compulsory licences and endorsements of “licences of right” under the relevant clauses of the Bill”. (See para 839 of Ayyangar Committee Report)

2. The additional purpose for requesting such information as stated by Ayyangar Committee Report is as follows:

   “Further, particulars as to working of the invention would be useful for statistical purposes as at present no estimate can be made of the extent to which patents are being worked” (Para 840 of Ayyangar Committee Report)

3. On the issue of what information is required to be submitted, the Ayyangar Committee Report categorically states that,

   “The information which the Controller requires under this clause is as to the “extent to which the patent is commercially worked in India”, and such information is generally disclosed in the Directors’ Report and the balance sheets of the companies and do not involve the disclosure of any trade secrets. No legitimate exception could therefore be taken to any provision under Section 105”. (See para 841 of Ayyangar Committee Report)

4. Given that the primary objective is to enable the Controller to quickly decide the application for compulsory license, the provision of Section 146 (1) is sufficient to meet this primary objective. Section 146 (1) empowers the Controller to issue notice and call for detailed particulars on commercial working of a patent in India and this provision can be evoked as and when the Controller receives an application for a compulsory license.
5. Requiring patentees to furnish such detailed information for each and every patent is to place an undue burden on both the patent office and the patentee.

6. In order to meet the secondary objective, i.e. gathering of statistical information of patent working, it is our view that this can be achieved in a far more efficient and less burdensome manner as elaborated below.

Specific Comments on Existing Form 27:

A sample Form 27, that is provided in the Patent Rules, 2003, raises multiple questions on clarity. Some of the issues are as follows:

1. Clause (i) (b) of Form 27:
   a. The Form 27 uses two (2) distinct terms “patented product” and “patented invention”. The term “patented product” is ambiguous as it is not necessary that the final product in which the patented invention is deployed would also be covered by patent rights.
   b. On the other hand, if the intention is to obtain the value of the final product, in which the patented invention is used, then clause (1)(b) should be suitably modified.
   c. In case a patented product is covered by multiple patents, then the true value of the patented invention will not be reflected in the Form 27. This is especially of concern in cases where the patented product is covered by multiple patents held by different patentees.

2. Clause (i)(b)(i) of Form 27:
   a. The term “manufactured in India” is not applicable to all categories of inventions for example, inventions pertaining to ICT.

3. Clause (iii) of Form 27:
   a. The Form 27 in clause (iii) requires the patentee to state “whether public requirement has been met partially/adequately/ to the fullest extent at reasonable prise”.


b. This clause is unnecessary and open to multiple interpretations. “Adequacy” “fullest extent” etc are relative terms and require careful consideration of evidence. It is not practical for a patentee to make this determination for each patent.

c. The patentee is also not in a position to assess “public requirement” as contemplated under the Patents Act.

d. It is also not for the patentee to assess on the reasonable price, but rather for the Controller to determine whether the price is reasonable or not.

e. It is suggested that this clause be deleted from the revised Form 27.

4. Rule 131, of the Patents Rules requires that the Form 27 be filed in respect of every calendar year within three months of the end of each year. However, no clarity is provided in respect of patent applications that are granted between 1st January till 31st March of a calendar year.

5. No clarity is provided in the Patents Act or the present Form 27, for cases where the patentee is manufacturing the product covered by the patented invention in India, but the manufactured product is only for exporting purposes.

**Frequency of Form**

Section 146(2) only requires that the information be submitted at certain intervals not being less than six months apart. Accordingly, requiring a yearly filing of such information places an undue burden on the patentee. It should be considered whether this requirement can be made every three (3) years, with the first statement due after three (3) years from the grant of the Patent.

We request the Ld. Controller to consider our comments and provide us with an opportunity to attend the stakeholders meets scheduled on March 21, 2018.
March 16, 2018

Shri OP Gupta
Controller General of Patents, Designs, & Trademarks
c/o Dr. W.M. Dhumane and Dr. Usha Rao
The India Patent Office
S.M. Road, Antop Hill
Mumbai, INDIA
wm.dhumane@nic.in
drusharao.ipo@nic.in

Dear Shri Gupta,

The Organisation of Pharmaceutical Producers of India (OPPI), Pharmaceutical Research and Manufacturers of America ("PhRMA"), International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA"), Japan Pharmaceutical Manufacturers Association ("JPMA"), and INTERPAT (collectively "the Associations") appreciate the opportunity to provide comments on Circular No.CG/Meeting Circular-DIPP/2018/14, dated March 1, 2018. Collectively, our associations represent the world’s leading research-based biopharmaceutical companies, and are devoted to advancing public policies around the world that support innovative medical research, deliver progress for patients, and provide hope for tomorrow’s treatments and cures. Our industry is a partner in healthcare solutions around the world and is ready to continue constructively working with the Indian Government to address patient needs.

The rationale underpinning Section 146 of the Patents Act, 1970 is outdated, vague, and creates significant uncertainty for patent owners in India. Our member companies have expressed continued concern to the Department of Industrial Policy and Promotion regarding issues related to annual working statements in India. Even India’s judiciary has voiced frustration determining the purpose and scope of disclosures required under Rule 131 and Form 27 of India’s Patent Rules.1 In fact, other existing sections of India’s intellectual property laws adequately safeguard against non-practicing entities.

The Associations encourage the Government of India to reassess Section 146 to ensure that disclosures under that section complement other provisions of India’s patent laws, foster ongoing efforts to increase the ease of doing business in India, increase patent office efficiency, and do not burden Indian patent owners.2 For the reasons below, we urge the India Patent Office to take immediate steps to eliminate the significant burden and legal uncertainty created by Section 146 of the Patents Act, 1970. At a minimum, that includes clarifying that “worked on a

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1 See, e.g., Basheer v. Union of India, Del. High Ct., Order No. W.P.(C)5590.201 (Feb. 2, 2018).
2 See, e.g., Section 48, India Patents Act, 1970.
commercial scale” means “act[s] of making, using, offering for sale, selling or importing” a patented invention in India.

Eliminate vague and unnecessary annual working statement disclosures

The majority of disclosures required under Section 146 are either unnecessary to determining if a patented invention has been “worked” in India or are so vague they are nearly meaningless. The India Patent Office should reconsider the need for Form 27 in its current form, or at least significantly simplify Form 27 to require patentees to solely state whether or not a patent was worked in India – e.g. the patented invention was or was not: made, used, offered for sale, sold, or imported in India during the relevant reporting period. In addition, the India Patent Office should continue to exempt certain situations of non-working; i.e. regulatory delays or market conditions that would otherwise prohibit patentees from making, using, offering for sale, selling or importing the product in India.

As the Delhi High Court appropriately acknowledged, the scope of Form 27 has not been updated or amended in nearly 45 years, and therefore does not reflect the realities of today’s globalized nature of innovation and patenting activity. In fact, India is an outlier in requiring patentees to disclose the extent and manner in which they “work” their patent. That is likely due to the fact that this information is already available to the patent office (i.e., through the market place) and there are other legal mechanisms better equipped to address non-working.

In addition, filing Form 27 is burdensome because many of the requested disclosures are vague and unclear. Form 27 currently requires patent owners to disclose unnecessary information to seek assurance that a patented invention has been “worked,” including:

1. Whether the patented invention has been worked or not worked in India:
   a. If not worked, the reasons for not working and the steps being taken for the working of the invention;
   b. If worked, the quantum and value (in rupees) of the patented product;
      i. Manufactured in India;
      ii. Imported from other countries along with details of each country.
   c. The licensees and sub-licensees granted during the year;
   d. Whether the public requirement has been met, at a reasonable price either partly, adequately or to the fullest extent.

Collecting and auditing such information for international biopharmaceutical companies is complex. In fact, our member companies report that India’s annual working statement disclosures require significant human and capital investments. The information requested may not be available or is so vague that the scope of disclosure is not understood. Therefore, the Associations request, at a minimum, that the India Patent Office amend Form 27, and relevant regulations, to limit patentee statements to whether or not a patent was worked in India.

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3 Section 146, India Patents Act, 1970.
4 Section 48(a-b), Indian Patents Act, 1970.
5 Form 27 (emphasis added).
Section 146 of the Patents Act, 1970 creates legal uncertainty

Information currently sought under Section 146 can be abused by competitors and third parties if not adequately protected from disclosure. Due to the highly competitive and globalized nature of research, development, and supply chain management, confidentiality of product specific information is critical for our member companies. In addition, the required Form 27 disclosures seem to conflict with other provisions of the Patents Act. For example, Section 69(4) of the Patents Act requires the India Patent Office to keep confidential registered patent license agreements when accompanied by a confidentially request. Yet, Section 146 of the Patents Act appears to require the Patent Office to publish the same information as reported through Form 27.

Further, anyone may access the published Form 27 for each patent in India through the India Patent Office website, with no precautionary means for redacting or ensuring confidentiality of the submitted information that is required by Form 27. At a minimum, the Associations urge the India Patent Office to exempt confidential or proprietary information from its annual working statement disclosures. That means striking sections of Form 27 that relate to the “quantum and value” of the patented product and “licensees and sub-licensees.”

In addition, current information requested under Form 27 may be misused by third parties by initiating actions that are frivolous or intended for pecuniary gain under various public interest provisions of the Patents Act. The Associations are concerned that third parties can abuse Form 27 disclosures to misappropriate legitimate intellectual property rights. For example, in 2013, the Intellectual Property Appellate Board (IPAB) held that importation does not satisfy the working requirement. 6 The Bombay High Court inappropriately upheld the compulsory license granted by the IPAB, citing in part the fact that the patented anti-cancer medicine was not being manufactured in India and that “the patent holder” had not “satisf[ied] the authorities under the Act as to why the patented invention was not being manufactured in India.” 7 In that case, third parties relied on the patentee’s Form 27 filing to petition the Government of India that the medicine was imported into India and did not meet the working requirements under Section 84 of the India Patents Act.

Administering Form 27 unnecessarily burdens the India Patent Office

The Associations welcome the Government of India’s ongoing efforts to increase the ease of doing business in India and implementing policies outlined in the National IPR Policy that would further that work. We commend the India Patent Office for taking seriously India’s patent application pendency issue. The average age of a granted Indian patent application has steadily increased from less than 6 years in 2005 to nearly 8 years in 2015. 8 Through recent efforts to modernize the patent office, we are encouraged that the India Patent Office has committed to nearly doubling the number of patent examiners from 337 to 589. 9

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6 Bayer Corp. v. Union of India, No. OA/35/2012/PT/MUM, ¶ 52 (IPAB, 4 Mar. 2013).
9 Id.
Similarly, our industry has engaged constructively with the Department of Industrial Policy and Promotion (DIPP) to address the significant burden created by disclosures required under Section 8 of the Patents Act. We are encouraged that India has joined as a receiving member of the World Intellectual Property Organization’s Centralized Access to Search and Examination system. We look forward to continue working together to fully address that concern.

DIPP and the India Patent Office can take additional and immediate steps that would increase patent office efficiency, the ease of doing business in India, and incorporate corresponding elements of the National IPR Policy. The Associations urge the India Patent Office to eliminate the burdensome annual working statement requirements by simplifying their “manner and form.” That should include amending Form 27 to require patentees to simply state whether or not a patent was worked in India. Similarly, the India Patent Office should assess whether the current frequency of filing Form 27 is necessary. One way to limit the burden on patentees and the patent office would be to decrease the frequency of reporting periods.\(^\text{10}\)

* * *

The Associations appreciate the opportunity to submit these comments and would hope that OPPI will be invited to participate in the hearing scheduled for 21 March 2018 on behalf of the innovative biopharmaceutical industry.

Kanchana TK,  
Director General  
OPPI

Chris Moore  
Deputy Vice President, Int’l PhRMA

Thomas B. Cueni  
Director General  
IFPMA

Akihiko Matsubara  
Managing Director  
JPMA

Andrew Jenner  
Executive Director  
INTERPAT

\(^{10}\) For example, to the extent that the Form 27 reporting requirement is tied to the working language in Article 5.A.4 of the Paris Convention for the Protection of Industrial Property, it would be appropriate to reduce the reporting frequency to every three years.
Dear Dr. Dhumane and Dr. Usha Rao,

The Organisation of Pharmaceutical Producers of India (OPPI), Pharmaceutical Research and Manufacturers of America ("PhRMA"), International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA"), Japan Pharmaceutical Manufacturers Association ("JPMA"), and INTERPAT (collectively "the Associations") appreciate the opportunity to provide comments on Circular No.CG/Meeting Circular-DIPP/2018/14, dated March 1, 2018. Collectively, our associations represent the world's leading research-based biopharmaceutical companies, and are devoted to advancing public policies around the world that support innovative medical research, deliver progress for patients, and provide hope for tomorrow's treatments and cures. Our industry is a partner in healthcare solutions around the world and is ready to continue constructively working with the Indian Government to address patient needs.

Kindly find attached our official submission on the said topic. The Associations appreciate the opportunity to submit these comments and would hope that OPPI will be invited to participate in the hearing scheduled for 21 March 2018 on behalf of the innovative biopharmaceutical industry.

Regards,

https://mail.nic.in/iwc_static/layout/shell.html?lang=en&3.0.1.2.0_15121607

3/16/2018
Mr Ramesh Abhishek  
Secretary  
Department of Industrial Policy & Promotion  
Ministry of Commerce & Industry  
Government of India  

Dear Sir,  

The Organisation of Pharmaceutical Producers of India (OPPI), Pharmaceutical Research and Manufacturers of America ("PhRMA"), International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA"), Japan Pharmaceutical Manufacturers Association ("JPMA"), and INTERPAT (collectively "the Associations") collectively, our associations represent the world’s leading research-based biopharmaceutical companies, and are devoted to advancing public policies around the world that support innovative medical research, deliver progress for patients, and provide hope for tomorrow’s treatments and cures. Our industry is a partner in healthcare solutions around the world and is ready to continue constructively working with the Indian Government to address patient needs.  

Recently CGPDTM office issued Circular No.CG/Meeting Circular-DIPP/2018/14, dated March 1, 2018, inviting stakeholders comments on working requirements of patents in India. We would like to share a copy of our submission made on the said topic. We will be grateful if you could please give us some time on March 28, 2018 at your convenience to meet a joint delegation of PhRMA and OPPI to discuss our concerns and objections on the said topic.  

Members of the delegation are as follows:  
- Rich Verma, US Ambassador  
- Dr. Shailesh Ayyangar, Immediate Past President, OPPI  
- Kate Beale, Associate Vice President, International Affairs, PhRMA  
- Kanchana TK, Director General, OPPI  
- Dr. Ajay Sharma, Director - Government Affairs, OPPI  
- Nitika Garg, Director - Research, OPPI  

Mr Prem Singh Rawat, our Manager – Government Affairs will be in touch with your office to schedule this meeting.  

Kanchana TK  
Director General  

Tel: +91 22 2491 8123/2486, Fax: +91 22 2491 5168  
E-mail: kanchana.tk@indiaoppi.com  
Peninsula Chambers, Ground Floor, Peninsula Corporate Park, G.K. Marg,  

https://mail.nic.in/iwc_static/layout/shell.html?lang=en&3.0.1.2.0_15121607  
3/16/2018
Dated: 16.03.2018

Dr. W.M. Dhume/D. Dr. Usha Rao
Deputy Controller
The Patent Office
Boudhik Sampada Bhawan
Plot No. 32, Sector 14, Dwarka,
New Delhi - 110072

Sub: Comments concerning working statement.

Dear Sir/Madam,

Below are some suggestions concerning Form-27/working of patents:

a. **Form-27 - enable physical and electronic filing:** currently Form-27 can only be filed electronically. It is suggested that physical filing of Form-27 be enabled even for patent agents. This would facilitate easy filing of Form-27.

b. **Additional information be enabled:** currently Form-27 is in a format which is tightly controlled by the manner prescribed. It is difficult to provide additional information. The rules may be amended so that entities desirous of adding any additional information may do so either in the same form or by way of a separate attachment.

c. **Non-working statement be accepted by the Patent Office:** Many inventions take time to get marketed and worked. Hence, many times Patentees file working statement stating clearly that the invention is not worked. The Patentee may be given liberty to explain why the invention is not being worked.

d. **Failure to file working statement:** It is observed in many cases that the Patentee has not filed working statement or has neglected to file working statement for one or more years. In such cases, it is suggested that if this lapse is brought to the attention of the Controller or if the Patentee realizes the same on his own, the Patentee may be given a chance to file the working statement. This is already provided for in Section 146; In case the Patentee still does not file any working statement, then penal action may be considered.

e. **Simplify Form-27:** The Form-27 as currently exist cause for several details such as Quantum and value in Rupees and whether the requirement of the public has been satisfy or not. Satisfaction of the requirements of the public is a subjective requirement and there is no need for such details in Form-27. Similarly, with regard to licenses, the number of licenses granted may be disclosed; however the parties and further details including royalty arrived at between the parties need not be called for as the same may often be Confidential Information.

*Also at: Amsoft Business Centre, Unitech Trade Centre, Sector 43, Gurgaon - 122002, Haryana, India*
f. **Redacted documents:** In case the Patent Office calls for any documents in support of the working statement, parties may be allowed to submit redacted documents as some of them would be uploaded on the website of the Patent Office and made public.

Your sincerely,

(Rajeshwari H.)

Advocate
FORM 27

THE PATENTS ACT, 1970
(39 of 1970)

&

THE PATENTS RULES, 2003

STATEMENT REGARDING THE WORKING OF THE
PATENTED INVENTION ON COMMERCIAL SCALE IN INDIA
[ See section 146 (2) and rule 131 (1) ]

In the matter of Patent No. [•] of [••]

I / We

The patentee(s) or licensee(s) under Patent No. _______ hereby furnish the following
statement regarding the working of the patented invention referred to above on a commercial
scale in India for the year___________.

(i) The patented invention:

[ ] Worked [ ] Not worked:

(a) if not worked: reasons for not working and steps being taken for working of the invention.

(b) If worked: provide details per: Annexure A

(i) manufactured in India – Yes/No

(ii) imported from other countries. (give country wise details) Annexure B

(ii) the licences and sub-licenses granted during the year; - Yes/No

(iii) state whether public requirement has been met partly/adequately/to the fullest extent at
reasonable price.

The facts and matters stated above are true to the best of my/our knowledge.

Dated this ____day of ________, 20

To

The Controller of Patents,

The Patent Office, at ________.

Rajiv Kr. Choudhry, Advocate | D/841/2006 |
ANNEXURE A

Portfolio specific questions

• Is the patent part of a patent portfolio? If yes, then how many patents are in the global portfolio?

• What is the global portfolio licensing rate?

• Out of the global number of patents, how many patents of the global portfolio are in India?

• What is the India licensing rate?

• If the global portfolio licensing rate is the same as the India licensing rate, what is the reason to have the same licensing rate?

• If the global portfolio licensing rate is different than the India licensing rate, what is the reason to have the different licensing rate?

• How long has the portfolio rate been maintained at the current rate?

• How many patents have been added to the existing portfolio of which the current patent is a part

• How many patents have been removed from the existing portfolio of which the current patent is a part?

• How many patents have expired from the portfolio of which the Indian patent is a part.
Patent specific questions

- Is the patent or patent application ranked internally?
- What is the ranking process – scale of 1 – 5 or any other. Provide details.
- Is there a separate ranking or licensing rate for the litigated patent / counterpart, provide both details.
- Has the patent / global counterpart ever been litigated. If yes, give details of the litigation including case number, court name, pending / decided, and any order available publicly.

For Standard Essential Patents / Applications

Provide a complete list of applications, patents covered in the standard essential patent portfolio for all technologies where the patent is applicable with corresponding disclosure given to standard body.

What is the royalty rate for global portfolio / India portfolio?

Whether the rate proposed is a fixed price per unit or a percentage royalty;

If it is an ad valorem (i.e., percentage royalty), then disclose:

- the basis upon which the royalty is to be calculated;
- whether there is to be a maximum monetary amount of royalty (i.e., a cap);
- whether there is a minimum monetary amount of royalty (i.e., a floor) - any territorial restrictions that may be imposed;
- any branding restrictions that may be imposed;
- any grant-back requirements;
- the types of products which will, and will not, be licensed
ANNEXURE B

Whether a complete product is based on the patent, provide details?

Whether a complete product is based on multiple technologies having multiple patents, applications, provide details about the patents / portfolio owned by the same assignee

If the complete product is imported into India -

• provide the details of the part where the patent is applicable OR
• What is the component / part or sub-component in which the patent is incorporated?
To,
The Controller of Patents
The Patent Office
Mumbai

March 16th, 2018

Subject: Comments regarding Issues related to working of Patents under the Patents Act, 1970

We thank Indian Patent Office for inviting comments on the issues relating to working of patents. We have humble submissions on the topic, as detailed below. We have categorized the challenges faced by patentees in furnishing information in the present Form 27 and the strategies as suggestion/s for easing out the situation for Patentees.

Challenges:

- The details of licenses and sub-licenses granted, the quantum and value of patented product, needs to be furnished by the Patentee if the patent is selected as worked. The patentees consider this as commercially sensitive / confidential Information. It is also particularly of concern as the information is published on Indian Patent Office website and thus can be accessed by the public generally (including the competitors as well).

- The Form does not have options for the situations where a bundle of patents is used in a single product.

- The situations where nature of Invention is such that working of a patent in a product cannot be accurately determined.
The parameters to quantify the working of patent are limited i.e. in the present Form, quantum and value are the parameters to measure the scale of working of the Patent, whereas it may not be possible for all patents to quantify value.

The Patentees finds it difficult answering if the public requirement has been met (partly/adequately/full). The question is quite subjective.

Our Suggestion:

We observe that different Industries have peculiarities in terms of how they use technologies and manner of use of with respect to their resulting products e.g. mechanical Industries product would differ from the software Industries and ICT and other hi-tech industries. Thus, it is obviously challenging to have a single/common Form that would apply to all industries/sectors. Further it is common for a bundle of Patents to be used in a product. Thus, retrieving the working details of each patent is challenging as well.

As a solution to this, the Form may be structured in two broad heads of ‘working’ or ‘not working’.

In case, where the patentee selects patent worked in India as a guideline he may be asked to provide following specific details:

a. Quantum of the patented product in a range.
b. Value of the patented product in a range.
c. Specify if the bundle of patent are used in a single product
d. If the patent is for the product which is not sold independently in the market. In that case, to provide details of the final products where the patent will find its place
e. Number of license and sub-license (without insisting on the name and specific particulars of the licensees)
f. If patentee is not able to answer the above, he may be required to mention other details for substantiating that the Invention is worked

The ‘Non- working’ of Invention would require following specific details:

a. Reason for not working
b. Efforts taken by Patentee to work the Invention.

We hope the above suggestions would help higher authorities in finalizing Form 27.

Yours faithfully

Ranjan Narula
Managing Partner
Of RNA, IP Attorneys
COMMENTS FOR REPRESENTATION ON
“INDIA’S WORKING REQUIREMENTS”
Pursuant to the circular dated March 1, 2018 inviting comments on the issues relating to working of patents under the Patents Act, Remfry & Sagar, on behalf of its clients, submits the following comments, observations and recommendations for consideration by the Department.

GENERAL OBSERVATIONS

India is possibly the only country that has a “reporting” obligation for patentees to disclose the manner and extent to which a granted patent is worked in India. The intent behind the reporting obligation is to facilitate the dissemination of technical know-how into the Indian industry so as to spur domestic growth and global competitiveness. As with many other jurisdictions, third parties can seek compulsory licenses if inventions are not being worked. However, under the present scheme, the fundamental intent is not being satisfied and, perhaps, the process is being used as a tool to make an otherwise rewarding process of obtaining a patent into an intimidating non-value adding process. Specifically, the threat of imprisonment and monetary fine may intimidate patentees across the spectrum (multi national corporations, mid-sized entities, small scale entities and individual inventors) and dissuade patent applicants from filing patent applications in India – which defeats the intent behind this scheme. It also sends a signal which is contrary to the Government’s endeavour to make the patent system in India applicant-friendly and to encourage more domestic and international filings.

The disclosure requirement needs a relook since the present requirements are excessively burdensome and vague and do not meet the intended statutory objectives. The present scheme fails to recognize that patentees make working decisions based on business factors not on the threat of a reporting obligation. Existing Form 27 requirements do not take into account the complexities of technology, dynamic nature of the industry and practical difficulties faced by patentees.

We present below suggested changes in the current reporting requirement, which will meet the statutory objectives while balancing the interest of all parties.

CHANGES SUGGESTED IN FORM 27:

1. The initial filing of Form 27 should be delayed - A compulsory license can be applied for only if a patent, inter alia, has not been worked for three years from the date of grant of a patent. Therefore, a Form 27 should not be required to be filed for the first three years after grant.

2. Frequency of Form 27 filings ought to be reduced – Section 146 of the Patents Act does not mandate a specific time period between two consecutive statements of working (six months is the minimum). The department should consider reducing the frequency of filing statement of working to once in every three years instead of annually.

3. Form 27 ought to be restricted to a declaration of working/non-working – Practically, to achieve its intended purpose, it is sufficient for the statement of working to be restricted to a declaration as to whether the patent is being worked or not worked. This may be supplemented by reasons for not working. Further details are unnecessary and should be made optional.
4. **Requirement of specifying whether public requirement has been met partly/adequately/to the fullest extent and at a reasonable price should be removed from Form 27**

This requirement is very subjective and places an unnecessary burden on the patentee/licensee. A patentee is required to conduct a market survey each year to ascertain whether public requirement has been met at reasonable price. While this information may be useful in a compulsory licensing proceeding, it serves no practical purpose on Form 27. How should a patentee identify whether public requirement has been met? And what qualifies as “reasonable price”?

Moreover, the burden of making a statement that (i) reasonable requirements of the public with respect to the patented invention have not been satisfied, or (ii) the patented invention is not available to the public at a reasonably affordable price, should be placed on the applicant for a compulsory license – not the patentee.

Additionally, the requirement of submitting a declaration as to whether public requirements have been met is, perhaps, relevant for the purposes of public health and safety and should not (and cannot) be “required” information for every patentee.

5. **Information regarding quantum and value of the patented product should be dispensed with**

*Quantum* and *Value* are also not easily discernible. For example, for multi patent products how does one make this determination? Even in cases where collection of this data may be possible, it is extremely burdensome to require confidential/business sensitive information to be disclosed on Form 27.

Once again, this requirement is, perhaps, useful in a compulsory licensing proceeding and should not (and cannot) be “required” information for every patentee as it compromises confidential business sensitive information.

In ICT sector, where worldwide multiple-patent portfolio licensing and cross-licensing between different patentees is a norm, it is extremely difficult to ascertain whether a patent has been worked or not. Moreover, to determine the quantum and value attributable to each of the patent is impracticable in most instances.

Furthermore, the quantum and value of the product is proprietary business sensitive information, disclosure of which can harm the competitive position of the patentee. By virtue of Form 27, the trade competitors have easy access to confidential information which they might not have otherwise probably even after conducting market intelligence.

There is a need to rationalize the format of Form 27 and the requirement imposed by Form 27 to disclose the quantum and value of the patented product should be dispensed with.

6. **Information regarding licenses and sub-licenses granted should be dispensed with**

Existing Form 27 requires the patentee to disclose the licenses and sub-licenses granted during the year. At best, this requirement should solicit information regarding whether a license or sub-license has been granted.
Further, any suggestion that the patentee is required to publicly disclose the identity (and terms) of a license/sub-license is discriminatory and contravenes the statutory mandate provided under section 69(4) of the Patents Act which states that “in the case of a licence granted under a patent, the Controller shall, if so requested by the patentee or licensee, take steps for securing that the terms of the licence are not disclosed to any person except under the order of a court.”

Accordingly, details of the licensees/sub-licensees should not be sought. Information relating to only **number** of active licenses during the year could be sought.

7. **Obligation to file Form 27 should be either on patentee or licensee, not on both** - If a patent has been worked only via licensee, the burden should be placed on either one party and not on both parties.

8. **Form 27 should be amended to allow filing a single statement of working for multiple patents**- In order to reduce paperwork, there should be provision for filing single Form 27 for multiple patents (portfolio of patents).

**OTHER RECOMMENDATIONS**

1. **Form 27 should be published judiciously**- Section 8 (d) of the Right to Information Act, 2005 (RTI Act) exempts the disclosure of “information including commercial confidence, trade secret or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information”. The current Form 27 requires the patentee to submit business sensitive information (quantum and value), disclosure of which has potential to harm the competitive position of the patentee. Section 146 (3) of the Patents Act bestows the Controller with the discretion to publish information received under sub-section (1) and (2) of section 146, however, such discretion should be used judiciously **only** in cases where the public interest of disclosure outweighs any possible harm or injury to the interests of the patentee. In fact, the procedure as laid down in section 11 of the RTI Act should be followed as RTI Act has an overriding effect over the Patents Act (section 22 of the RTI Act).

2. Information such as **quantum** and **value** should be required only in response to third party petitions for compulsory licenses. Instead of asking every patentee and licensee to furnish burdensome information such as quantum and value, this information should be sought under section 146 (2) only in response to a petition seeking compulsory license or revocation of patent (under section 85 of the Patents Act).

3. Form 27 should be amended to allow filing a single statement of working for **multiple** patents.
4. Form 27 should include a column to indicate whether the patent relates to a SEP - If any patent is part of any standard then the same should be indicated along with the name of the SSO (Standard Setting Organisation) and corresponding Standard.

5. Measures such as imprisonment and monetary fine to the tune of INR 10,00,000 prescribed under section 122 of the Patents Act are vague and non-enforceable.
   a. There is no mechanism of enforcement - the Patents Act and the Rules do not provide any mechanism for the Patent Office to ascertain the correctness of the information submitted by the Patentee. Therefore, on what basis can they levy a penalty for allegedly disclosing incorrect information.
   b. Criminal sanctions ought to be removed - Since the Patents Act does not prescribe any criminal sanctions in case of infringement of patent rights, it is only fair that the criminal sanctions imposed on the patentee be removed. In case of false declaration, the sanction of revocation of patent can be prescribed instead of imprisonment.
   c. Non-compliance of the working requirement is a ground for a compulsory license. That should be a sufficient deterrent to the patentee. Any further penalty is not required. A potential licensee should be able to identify if a Form 27 has been filed and use that to take its case forward for a compulsory license or any other information.
We welcome the move from the Patent Office to issue a circular requesting comments from stakeholders on the working of patents and submissions of working statements and fixing a stakeholders meet for the same.

The information on the working of patents is required to be provided under law so that information may be available to all concerned whether the applicant is making good use of the monopoly right conferred by the Government. The working statement can be used in proceedings relating infringement of a patent or even a compulsory right application in the event the patent holder is seen to abuse the monopoly by non working or by selling the patented products at unrealistic prices. The working statement ought to reflect the true state of working. This was the objective of the legislators originally to provide for such a provision.

All inventions are not like pens or pencils

Complexities

However, with the passage of time and the complexity and diversity of the nature of the inventions and manner of implementation it is always not possible to provide specific numbers. Due to the intertwining of various inventions in the same field as well as allied fields it is not always easy to provide exact information on working of patents in terms of value or quantity of working for a specific patent. For example, an electric shaver has 50 components of which 20 are patented. The product has 5 variants in which say 12,14, 15, 18 and 20 of the patented products are used. Now the question is what should the patentee put as the value of the products in the 20 patents when none of the components are sold separately but form part of the complete device. In such cases it is only possible to submit a Statement of Case along with Form 27 describing the true position and indicating the number of the variants sold in India. So the accurate value of sale or the specific number of the products made or sold with respect to a particular patented item can never be specified. These are cases which one would often come across in products of different categories and the filling of Form 27 can only be done by providing a statement and the Courts have to appreciate the position and prescribe a realistic format.

Possible change in Form 27

A possible change in Form 27 may be to amend the form and state where the actual number of products made or sold cannot be quantified the patentee should submit a statement of case providing the actual position. The Patent office is the custodian of such statements and the parties are open to obtain copies and initiate appropriate steps where they have a specific grievance and produce evidence against the case made out by the patentee in Form 27. This can done by way of moving a Court. In a given case even a case of compulsory license can be filed where the Controller can appreciate evidence filed by the parties and decide a matter. As a matter practice the Patent office has never commented on a single Form 27 and merely keeps on record the Forms 27 filed by the parties.

Given the situation we suggest that the Form 27 in the present form be amended to reflect a more realistic approach.

1. Provision to be included to refer to related patents in the Form 27 because in most cases it is not one patent equivalent to one product but multiple patents relate to a single product.
2. When the patent is not worked the information required by 3(1)(a) in Form 27 is sufficient requirement and it is for the patentee to provide reasons if required by way of a statement of case. Whether the statement is incorrect or inadequate is something which can only be scrutinized in contested proceedings.

3. The value for quantum of sales from a patent should not be made mandatory but the requirement be amended so that the total sales of the product which includes the patents be provided in approximate value. It is difficult of ascertain the value in sales figure in view of a single product employing a number of patents not only for the components thereof but also in arrangement of the components in the form of process patents.

4. It is not possible to answer the question as to whether the requirement of the public is met for all kinds of patents across any and all fields of technology. Meeting requirement of the public may be true for pharmaceutical products that too for one patent-one product and for life saving drugs. But patents for FMCG, or electronics products there cannot be any requirement as such products do not include a bare necessity. A patent related to a part of air conditioner cannot be regarded as necessity and meeting public expectation. It is for the aggrieved party to come forward and initiate appropriate proceedings where he is aggrieved. It would not be a realistic move to make the submission of the Form 27 a great burden for the patentee and that would be disincentive for the stakeholders to come forward to apply for patents in India. The position of India as a business friendly country would be at serious stake.

5. Licensing often involves many confidential information and no patentee would reveal all details in public domain. The requirements for filing of such statement ought not be an obstruction free and fair trade practices. The litigations pending on the issue of Form 27 are mainly by people who are not involved in industrial activities. It needs to be placed by the counsels of the Central Government that adequacy and veracity of the statements of the patentee can only be appreciated in the facts and circumstances of a specific case.

We had circulated the Notice from the Patent Office to our clients and requested their inputs. We provide below some inputs/ concerns/ suggestions of our clients which include pharmaceutical and engineering sector.

- Imposing any stricter reporting requirements is unlikely to be of assistance, because Form 27 requests information which in many cases is not available to the patentee. This is primarily because the questions in the Form assume that one patent equals one product. Whilst this may be true in some industry sectors, the situation for complex products is different, as the patented product of one patent may relate to only one part of a much larger product. In the case of telecommunications, each product, such as a server, router, or telephone handset, comprises many different components each of which may relate to one or more patents. As an illustrative example, a mobile phone may comprise many components, including different kinds of memory, display, application processor, baseband processor, RF chip, WIFI, amplifier, interface controllers, sensors, camera module and lens, driver ICs, speaker, battery, circuit board, navigational related chips to name but a few. A patent may relate to any one aspect of any one of these components, or even interworking of these components in the phone or with external systems.

- Further, the particular components may be substituted over a short period, and correspondingly the relevant patent(s) may change.
Moreover, it will be difficult to put a fixed definite value of each patented product in a complex product composed of multiple patented products. The value of the complex product is affected by various factors at different times.

Even if a patentee was able to assess which products had the patented feature(s), an additional hurdle would be updating that list to reflect old products being withdrawn (but perhaps still serviced i.e. worked) and new ones coming onto the market. The sales figures would then need to be calculated and at best an estimated number of the total value of the complex products sold, which would still not be that of each patented sub-component or feature. Thus, providing the information is unduly burdensome.

Form 27 Specific suggestions include:

- A facility to club multiple patents may be provided, since one product may involve multiple patents, and sale value of that product would cover all those such patents. This would make the submission simple and realistic.

- Questions which impose a high burden on the patentee, particularly the requirements as to quantum and value may be further evaluated. There are no specific valuation guidelines “How to describe Sales.” i.e. whether to add/minus taxes and import duties and sales margins of intermediaries so that the end price of the drug is the reflection of the value that the patient is charged.

- Question which imposes a near impossible burden on the patentee, i.e. the question “whether public requirement has been met partly/adequately/to the fullest extent at reasonable price” may be reconsidered and clarified. This was removed in the draft Form 27 in the Rules 2015 but was not officially promulgated. As the patentee does not have access to the whole market information, it is not possible for the patentee to state with absolute confidence whether the extent to whether any public demand has been met. The public requirement may also vary with the product – and in some cases may only be a certain commercial circle of an industry sector. In any event, the “demand” is for the “complex product” which is not the same as the “patented product”. For similar reasons, it is also difficult to assess what is a “reasonable price”.

In any event the meaning of the terms “partly, fully or adequately” meeting public requirement is not clear. More clarification is required about this point and may modify this phrase to include clearly measurable parameters.

- Questions on licencee sales data may be further clarified: each individual licensee may not provide for the collection of the data at this level of granularity (e.g. in the case of a royalty-free licensee, or an upfront licencing or bulk fee) and as such patentee has no means to compel a licensee to disclose such data. Further, various terms of the licensee may be deemed confidential, disclosure of which may constitute breach of the licensee.

- For pharmaceutical patents one can include points that may enable patentee to mention detailed reasons for Non-working of patents or the exact reason if the patentee is not sure or has no information whether patent has been worked in India.
a. The pendency of regulatory approval/ongoing clinical trials – in such case, provisions should be made for patentee to incorporate stage of clinical study, clinical data or clinical trial Number (CTR) for ongoing studies.

b. Patentee is still exploring the Indian market for determining need/demand of the product.

c. The patentee is still working on the product to make it economical for the Indian market conditions.

d. Unavailability of License due to lack of demand for the product.

- The patent working procedure would benefit from updated official guidelines which illustrate what is acceptable, whilst balancing what is actually possible in a commercial context for each respective industry.

- One specific suggestion would be acknowledging that patent to product mapping is different for different industries, and that a one size fits all form is not suitable.

- Where the patentee has failed to file working statements the Controller may publish a list of such patents an automated monitoring and alert system warning patentees that they have not filed required Forms 27 can be established.
To,

Controller General of Patents, Design and Trade Marks,
Boudhik Sampada Bhavan,
Mumbai, India

Date: 16-March-2018


Dear Sir/Madam,

This is in response to your circular dated 1st Mar 2018 and we humbly submit our comments towards "Working of Patents" practice in India, enumerated herein as under:

1. Abolishment of Submission of Working Statement:

   We recommend that the mandate for the annual submission of Working Statement (Form 27) be abolished, since,

   (i) it imposes significant and undue administrative burden on patentees and IP stakeholders in India.

   (ii) for multi-national organizations, where multiple teams in worldwide locations are involved in product designing & implementation, many times it becomes tedious task to be certain about a patent's implementation in products and services in India with the same patented concept.

   (iii) receiving commercialization information from licensee(s) on individual patents from among a bundle of patent licenses, poses further challenges.
(iv) working statement runs counter to global trends toward harmonizing patent law

(v) due to competing interpretation by the patentees, the performance of the clause relating to Form 27 in the provisions of Indian Patent Act, cannot be sufficiently met by the patentees, and hence such clause including Form 27 should be abolished.

We do hereby further submit that if our submission as enumerated above cannot be accepted, then our comments as mentioned hereinunder may be considered:

1.a Limiting the Information sought in Working Statement:

We humbly submit that amount of information sought in working statement requires significant efforts to assess the quantum and financial information. It also poses challenges for information disclosure required by licensees, specially the financial information. We recommend to abolish pt. 3(i)(b)i), 3(i)(b)ii), and 3(ii) from the current format of Form-27.

We recommend to limiting the information requested in the working statement to just “worked” or “not-worked”.

2. Comments on Section 122 in The Patents Act, 1970

We recommend that the current penal provisions relating to fine and imprisonment for non-submission and/or wrong information in working statement as given in Section 122 (1)(b) and Section 122 (2) must be abolished.

Section 146 could be amended as follows:
(i) based on an application made by an interested party, the Controller may request the applicant to furnish the information as to “worked” or “not worked” within a period of 3 months from the date of such request.
(ii) In the event of failure of the applicant to submit the working information, the Controller must invite the parties for a hearing and thereafter pass an order on the patent based on the merits of the case.

We would further like to submit that our aforementioned comments may also be treated as comments of our Parent Company, Samsung Electronics Co., Ltd as well as our other Indian group companies.

We sincerely hope that your good self, will address our contentions, as raised herein and would decide the issue considering facts and circumstances qua instant issue.

We look forward to an improved and balanced intellectual Property system in India.

Yours Truly,

For SRI-Delhi (a division of Samsung India Electronics Private Ltd)

[Signature]

Name: Sanggi Jin
Title: Vice President-SRI Delhi
Date: 16th March 2018
Respected Sirs,

**Sub: Comments with respect to issues related to Working of Patents and Form 27**

This is with reference to the circular dated 01.03.2018 regarding stakeholders’ meeting with respect to issues related to Working of Patents in India.

The Patent Working requirement in India is considered as a tool to ensure knowledge transfer and consequent commercialization of patented technology in India. To satisfy the Patent Working requirement, Form 27 attempts to determine whether the patentee has made an effort to implement the patented technology in such a manner that the product or service including the patented technology is made available at to the public at large on a commercial scale at reasonably affordable price. Further, the current Form 27 seeks the reasons for not implementing the patented technology in the product or process.

While the intention of the Patent Working requirement stems from the goal of improving the technology landscape in India, it appears that the current Form 27 is designed keeping in mind a specific technology area, such as pharmaceutical. Therefore, we believe that there is a need to revisit the existing Form 27 keeping in mind different technology areas and nature and complexity of these technology areas such as electrical, mechanical, electronics, computer, ICT, medical, chemical and their combination. It is important to understand, as a matter of fact, that not every patented invention can be realized into a product or a service and cannot be made available to the public on a large scale due to various reasons such as changing business conditions and fast changing technology landscape. Also, it is important to consider that there are patented inventions which are not directly implemented in a single product and yet are made available on commercial scale. For example, there exist patented inventions which can contribute to process of making one or more products including manufacturing system and process, materials management, quality management, energy management, and maintenance management. In some cases, the patented inventions may be implemented in a server outside India but still can be used in India as a service for analyzing/visualizing product and process data (using cloud computing technology), thereby adding to the complexity.

In light of the aforementioned issues, we suggest that a revision shall be made to existing Form 27 to:

1) Encourage Patentees to submit the information in Form 27 with ease, irrespective of technology area; and
2) Enable ‘easy of IP protection’, thereby motivating Patentees to file more and more applications in India.
Therefore, we propose that the Form 27 be amended on following lines:

1) A simplified approach is proposed which:
   i. enables Patentees to indicate working of patented invention in India.
   ii. enables the Patent Office to reach out the patentees in case additional information on
       working of specific patents is required (for example, when compulsory licensing
       application is received).
   The revised Form 27 can have following fields to indicate the working of patented invention:
      a. Product or process comprising the patented invention is worked in India.
      b. Product or process comprising the patented invention is being worked in India.
      c. Product or process comprising the patent invention is not yet worked in India.
      d. Product or process comprising the patent invention is cannot be worked in India with
         reasons.

2) A field in the revised Form 27 which enables submission of details of other related patented
   inventions associated with the same product or process.

3) A declaration that “The Patentee hereby declares that the information provided above is true
   to best of my/our knowledge. The Patentee would provide additional details on working,
   non-working or inability to work patents upon application of compulsory license or on
   special request from the Controller.”

4) Fields which reflect a list of conditions where the above mentioned “special request” is
   evaluated. For example, the list of conditions can include:
      a. Technology of patented invention
         The Patent Office can regularly notify what technologies fall under “special request” in
         view of public interest.
         For example, technologies in the area of pharmaceutical, medical, renewable energy, etc.
         may fall under public interest and therefore qualify as a “special request” from the
         Controller.
      b. Issuance of a compulsory license for the corresponding patent in any other country
         outside India.

We request you consider above recommendations/proposals during revising the Form 27. In case
any clarifications are needed on the above, we would be happy to provide the same during the
stakeholders meeting. We look forward to receive the invitation for attending the stakeholders
meeting scheduled on 23rd March 2018 for discussing issues related to the Working of Patents.

Yours faithfully,

Chammika Subasinghe
Head of IP department, Siemens India

CC: Our representatives in India:
   L S Davar & Co., Remfry and Sagar, Bhatnagar and Associates
To:

Dr. W. M. Dhumane,
The Office of the Controller General of Patents, Designs and Trademarks

Via email: wm.dhumane@nic.in

Respected Sir,

Sub: Comments on working of patents under the Patents Act, 1970

This is in reference to the Circular (DIPP/2018/14) issued by the Patent Office dated 1st March 2018 to address issues relating to working of patented inventions in India. Singh and Singh Law Firm LLP commends the Patent Office in taking active steps to improve the provisions relating to working of patented inventions in India. We are enclosing our comments as desired. Singh and Singh Law Firm LLP would also like to be part of the stakeholder delegation scheduled on 6th April, 2018.

Sincerely

[Signature]

Saya Choudhary Kapur
Partner
Singh & Singh Law Firm LLP

CC
Dr. Usha Rao
Email: drusharao.ipo@nic.in
Comments
Provisions relating to working of patented inventions in India

I. Legislative intent behind working requirements
The basic object behind the requirement of working of patents in India is to implement the fundamental principle of patent law i.e. ‘quid pro quo’. The concept of working requirement was introduced under the Patents Act to ensure that a patentee commercially exploits his patented technology which in turn would lead to the technological development of society. This section was introduced at a time when the local industry in India was at a nascent stage post-independence and needed a boost and inflow of latest technological developments/innovations. Accordingly, to ensure that Indian industries have the advantage of the latest innovation and technology, the requirement of working was added in the statute to propel socio-economic development. Section 146 provides for implementation of the practice to furnish working statements in India. As evident from the reading of said provision, the Controller has powers under Section 146 (1) to call from a patentee/licensee such information/periodic statements as to the extent to which the patented invention has been commercially worked in India to ensure that the patent holder disseminates the patented technology to the public.

The rationale for working requirement, as per the present law, for a granted patent is captured under Section 83 of the Patents Act, 1970 (as amended by Patents (Amendment) Act, 2002). It is described as under:

- patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale.
- they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.
- the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of

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1  Section 146: Power of Controller to call for information from patentees-
(1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.
(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.
(3) The Controller may publish the information received by him under sub-section (1) or sub-section (2) in such manner as may be prescribed.
producers and users of technological knowledge and in a manner conducive to social economic welfare, and to a balance of rights and obligations.

The Ayyangar Committee Report laid great emphasis on working of patent invention in India. However, the rationale was development of the Indian patent law and availability of patented inventions at reasonable prices to the local population since Indian industry was still in the development phase. As per the Report, the information was meant to be restricted to the "extent to which the patent is commercially worked in India", and such information is generally disclosed in the Directors’ Report and the balance sheets of the companies and do not involve the disclosure of any trade secrets.

Thus, the requirement of submitting working statements, as presently prescribed by the Act empowers the Controller to call for necessary information to ensure that the patents are being commercially worked which in turn would lead to technological development of society. Thus, only such information should be sought by Patent Office which enables it to ascertain as to whether or not a patented technology is being commercially exploited. At the same time the Patent Office should also be mindful of the commercial realities of different industrial sectors and ought not to ask for information which may prejudice the legitimate commercial interests of a patentee (for instance, asking for disclosure of any information which may be a patentee’s commercially sensitive and confidential information).

Provisions relating to working in other jurisdictions:

It is submitted that in almost all European countries, there is no requirement for the patentee to show working or use of his patented invention. When the Paris Convention was signed in 1883, it stated that “the patentee [was to] remain bound to work his patent in conformity with the laws of the country into which he introduces the patented objects”. Ultimately, in the Final Protocol to the 1900 Brussels Revision of the Convention, the signatory countries agreed that a forfeiture for non-working could not occur before three years from the date of filing of a patent application and could occur only if a patent owner could not justify the non-working.

As indicated earlier, the main argument for enforcing working of the invention in a particular country is the consideration that, in order to promote the industrialization of a country, patents for invention should not be used merely to block working of an invention

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2 Report on the revision of the Patents law by Shri Justice N. Rajagopala Ayyangar September, 1959
3 Supra Note 2 at Page 266
4 Paris Convention art. 5(A)(2), 1883: Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
5 Paris Convention, as revised at Brussels on Dec. 14, 1990
in a country or to monopolize importation of a patented article by patent owners. They should rather be used to introduce the use of new technology into a country. Whether a patent owner can really be expected to do so, is first of all an economic consideration and then also a question of time. Working in all countries is generally not economical. Moreover, it is generally recognized that immediate working in all countries is impossible. Article 5A therefore tries to strike a balance between these conflicting interests\textsuperscript{6}.

It is submitted that it was not the intention of the legislature to obtain working statements for all patents granted by the Patent Office. It is clear that working requirement was introduced to ensure patents are worked in India on a commercial scale and to check possible abuse of patent rights by granting compulsory licenses. The current Indian law is compliant with all such requirements. Thus, the working requirement needs to be limited to the extent that it requires the patentee to disclose whether a patent is being worked in India or not. It is also to be noted that non-working is a ground for grant of a compulsory license\textsuperscript{7} and ideally it is in such proceedings that extensive information regarding working should be asked for, i.e., only a third-party prima facie establishes that patent technology is not being worked in India. Otherwise, asking for extensive information from a patentee to establish working of his or her invention on a periodic basis results in expenditure of extensive resources not only for the patentee but also for the Patent Office in verifying or scrutinizing such information. In this regard, it is also imperative to note that provisions relating to the grant of a compulsory license exist not just in India but other jurisdictions as well (for example U.K). However, the provision relating to periodic filing of working statements has not been mandated by any other jurisdiction. Thus, the current provision relating to periodic filing of working statements, as it exists today, is unique to India.


\textsuperscript{7} Section 84(1) of the Patents Act, 1970: (1) At any time after the expiration of three years from the date of sealing of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely: –

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.
Current U.S. and UK patent law does not include a general patent working requirement per se. The U.S. Supreme Court has rejected the proposition that the non-working of a patent, taken alone, may justify a denial of injunctive relief. The TRIPS Agreement also does not include provisions that specifically address general working requirements.

**Problems with existing provisions**
Some of the problems with providing the required information are outlined below:

- **Local Working and importation on a commercial scale**
  It is now a settled proposition of law that both local manufacturing and importation of a patented article satisfies the requirement of working as far as Form-27 is concerned. In this regard, reliance is placed on the judgment of the Bombay High Court in *Bayer Corporation v. Union of India and Ors.* in which the Court explicitly laid down as under:

  "...*where a patent holder satisfies the authorities, the reason why the patented invention could not be manufactured in India then the patented invention can be considered as having been worked in the territory in India even by import.... the contention of Union of India that 'worked in India' must in all cases mean only manufactured in India is not acceptable.*"

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8 U.S. law never required that U.S. nationals work their patents, but for a short period of time from 1832 to 1836 the U.S. Patent Act did include a working requirement for patent owners who were foreigners (Act of July 13, 1832, ch. 203, 4 Stat. 577 (1832) (repealed 1836)). When the existence of a patent working requirement was questioned in the context of equitable considerations, the U.S. Supreme Court in 1908 confirmed that no patent working requirement had existed in U.S. law since 1836. The Court concluded that Congress knew of working requirements that existed in other countries and consciously opted to adopt and maintain a different policy (Contiental Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 429 (1908). Repeated attempts thereafter failed to introduce a general scheme for compulsory licensing into U.S. patent law for nonworking (Hartford-Empire Co. v. U.S., 323 U.S. 386, 433 n.26, 433 n.27, clarified in 324 U.S. 570 (1945)). In 1988, Congress confirmed that a refusal to license or use rights to a patent is not grounds for the denial of relief to a patent owner for infringement; such a refusal is not sufficient to deem the refusal an instance of patent misuse. (35 U.S.C. § 271(d) (2012)) While some components of the current U.S. patent system encourage patent working (19 U.S.C. § 1337(a)(3) (2012)) and provisions do exist for a limited compulsory licensing of patents, 7 U.S.C. § 2404 (2012); the U.S. patent system does not include a general patent working requirement per se. (Quoted in Patent Working Requirements: Historical and Comparative Perspectives, Marketa Trimble, UC Irvine Law Review, Vol. 6:483. Accessible at http://www.law.uci.edu/lawreview/vol6/no3/Trimble.pdf)

9 In *Badische Anilin und Soda Fabrik v. W. G. Thompson & Co., Ltd.*, [1904] EWHC (Eng.), concerning chemical inventions, a judge of the High Court of Justice rejected the notion that the nonworking of a U.K. patent in the United Kingdom could lead to the revocation of a patent.


11 AIR 2014 Bom 178
The above observation of the Bombay High Court was also adopted by the Ld. Controller in Lee Pharma Ltd. v. AstraZeneca AB\(^\text{12}\) wherein the Patent Office held that manufacture in India is not a pre-condition in all cases to establish working in India.

As a member of the World Trade Organisation (WTO) and a signatory to the General Agreement on Tariff and Trade, India has committed to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS Agreement provides no specific obligations regarding the working of patents. However, Articles 27 to 31 can be interpreted in terms of local working of patents. Article 27(1), which is titled as ‘Patentable Subject matter’, states that patent rights will be enjoyed without discrimination as to whether a product is imported or produced locally\(^\text{13}\). Thus, while a patent in relation to which a compulsory license has been granted can be revoked under Section 85 of the Patents Act, 1970, it is no longer the case that domestic demand needs to be met to adequate extent or on reasonable terms from manufacture in India only. It is already well established in India that a patentee can work a patent through the importation of a patented product. Commercial working of a patent by way of importation, therefore, should not be regarded as non-compliance with the requirements for working a patent under the Patents Act, 1970.

- **Confidentiality obligations of the patentee**

Patent licensing plays a vital role in technology commercialization. The Form i.e. Form 27, which prescribed under the Statute for furnishing working details of patents has the potential to encroach upon commercial sensitive information of an entity. Most license agreements have confidentiality clauses that restrict the parties to disclose the terms of the license agreement, except under very limited circumstances. In such cases patent owners are legally bound to maintain confidentiality with regard to important business information of its licensees. A breach of confidentiality may increase the risk of potential litigation against the patentee.

Since Section 146(3) allows for public disclosure of a document, any such disclosure in Form-27 with regard to commercial agreements shall seriously prejudice interests of a licensee as well as a licensor. Public disclosure of such information may provide an unfair competitive edge to the unwilling licensees over the willing licenses, more so in cases

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\(^{12}\) (C.I.A. 1 of 2015)

\(^{13}\) Article 27(1): Patentable Subject Matter: Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
relating to Standard Essential Patents. This will threaten businesses, hurt global licensing models and will potentially have a chilling effect on innovation cycle.

Furthermore, proviso to Section 69 (4) of the Patents Act clearly recognises that a patentee can request for a confidentiality protection in respect of its license agreement with a third party. However, Form 27 in its current form does not provide any such options to a patentee which is not only contrary to spirit of Section 69 of the Act but also goes against mandates of various judicial dictums wherein the courts have constituted confidentiality clubs in relation to the production of patent license agreements in judicial proceedings.

In a recent judgment\(^4\), the Delhi High Court while laying down great importance on protection of confidential information and trade secrets, observed that the issue of constitution of confidentiality club is no longer res-integra as has been dealt with in various judgments. It was held that trade secrets may make or break a company and hence need to be protected as once such disclosure is made or is misused by a competitor, no order of the Court can save the company from loss or could retrieve it to its original position.

Accordingly, it is imperative for the Patent Office to adopt a flexible approach for cases where there is a claim of confidentiality by the patentee. Non-submission of such information ought not to be regarded as non-compliance of Section 146 of the Act.

- **One product-one patent approach**

  In the past few decades, the pace and speed of technological advances has resulted in an increasing trend of products and services being rapidly commoditized by new products and services, which create new markets. This trend is more visible in industries such as Information and Communication Technology (ICT), Electronics, Semi-conductors etc. Much conventional wisdom in the patent system is built on the unstated assumption of one product-one patent approach. However, in many industries, a single product may be covered by numerous patents. For example, a computer, television set, video technology may be protected by hundreds of patents. Such a situation may not have been anticipated by the legislature at the time of enactment of the said provision.

  In such situations, it becomes almost impossible for the patent holder to isolate the patents in a product for the purposes of apportioning the exact value of sales attributable to each of such patent. Thus, such difficulties are required to be acknowledged and ought not be considered as instance of non-compliance of the relevant provisions of the Patents Act, 1970.

• **Rigid Requirements regarding valuation of a patented product**

The current Form-27 requires a patentee to provide the exact quantum and value (in INR) of the patented product. However, the vast majority of the products developed by the patent holders in various industries are technologically complex, incorporating hundreds of thousands of different components which are covered by numerous patents. In such cases, it becomes impossible to assess the exact value attributable to a single patent.

• **The present requirement goes against various government initiatives**

It is to be noted that the present day strict compliance requirement of working of patented inventions in India goes against the government’s objectives of *minimum government, maximum governance* and also goes against the spirit of other initiatives taken by the government to promote patent filings in India such as *Start-Up India*. Such a strict and rigorous compliance of the working requirement, though ideal and well intentioned in prospect, will in fact discourage patent filings.

• Further, the requirements relating to ‘reasonable price’ and ‘public requirement being met’ are ambiguous and vague. Section 122(2) states “If any person, being required to furnish any such information as is referred to in sub-section (1), furnishes information or statement which is false and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both”. Providing such information can become really difficult for a patentee. Further if a patentee unintentionally providing incomplete/incorrect information, the same may result in penal provisions under Section 122. Hence, despite acting with utmost *bona fide*, a patent holder would be put in a dilemma on the manner in which accurate, correct and complete information is to be submitted in Form-27. Accordingly, an undertaking to the said effect ought not to be required from a patentee.

II. **Possible revisions in the existing Form-27**

Form-27 should be made clear and concise for the patentees to provide the relevant information. The existing Form 27 should be amended to meet the objectives for which it was enacted—to ensure that the patents are commercially worked by the patentee. It should not be misused as a tool for conducting patent valuation. Furthermore, as stated above, extensive information qua working of patented technologies should only be asked in proceedings relating to the grant of compulsory licenses and should not be made a norm for all inventions. Accordingly, we suggest following format for submitting information relating to working of the patent:
Form-27

The Patents Act, 1970

And

The Patent Rules, 2003

STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON A COMMERCIAL SCALE IN INDIA

1. Name, address and nationality of the patentee:
2. Patent Number/License Number:
3. Nature of Invention: (Chemical/Information Technology/Mechanical):
4. The patented invention (tick the relevant one)
   A. Worked ☐
   B. Not worked ☐

Additional comments (if any):

To be signed by person(s) giving the statement:
NOTE ON
ISSUES RELATED TO WORKING OF PATENTS UNDER THE PATENTS ACT, 1970

RELEVANT PROVISIONS OF THE LAW:
- For filing of information: Form 27 under S. 146 read with Rule 131
- Penal provisions: Section 122

PRINCIPLES GOVERNING THESE PROVISIONS:
The Principles that govern the granting of patent is encapsulated in S.83 which states that patents are granted to encourage invention and to ensure that the patented inventions are worked in India.

In order to monitor that patentees are working their inventions in India, Section 146 read with Rule 131 requires the patentees to file the details of commercialization on Form 27. This is also useful in order to provide a check and balance on the misuse of the Compulsory Licence provision under Section 84 of the Patents Act.

INFORMATION REQUIRED ON FORM 27
Section 146(2), read with Rule 131, requires every patentee and licensee to submit to the Controller General an annual statement of commercial working of the invention within three months of the end of each calendar year. The information must include the following:
1. whether the patented invention has been worked, and:
   a. if not worked, then the reasons thereto, and the steps being taken to work the invention;
   b. if worked, then the quantum and value (in rupees) of the patented product
      i. manufactured in India and
      ii. imported from other countries, along with the details of each country;
2. details of all licences and sub-licences granted during the year; and
3. whether the requirement to promote the public interest has been met partially, adequately or to the fullest extent possible at a reasonable price.

THE PENALTY:
Failure to provide such voluntary information is fine which may extend to INR 10 lakhs under S. 122(1)(b).

ARE THESE PROVISIONS TRIPS COMPLIANT?
The working of Patents is within the scope of TRIPS Agreement (Art 5A of the Paris Convention read with Articles 2.1, 2.2, 27, 30 and 31 of the TRIPs Agreement.

ARE THESE PROVISIONS BUSINESS SAVVY
No. Form 27 requires the information on assumptions which can be very detrimental to a company especially where market competition works on trade secrets and confidentiality pertaining to business information.
Problem point 1: Calendar year is not = Fiscal year
- Requiring information for one calendar year is unreasonable since in India, one calendar year is not consonant with the fiscal year.
- The calendar year is the period from January to December of a year while the Fiscal Year is the period from April of one year to March of the following year.
- Companies do not have the information compiled at the end of calendar year.
- Further collating information from January to March of one fiscal year and April to December of the next fiscal year to provide information is not practical and creates unnecessary confusion.

SOLUTIONS:
Amend the term “calendar year” in Rule 131 to read as “fiscal year” and corresponding amendment in Form 27

Problem point 2: The principle of 1 patent = 1 product is not a reality
- Form 27 applies to patents in diverse fields of technology
- In all fields of technology that are not pertaining to pharmaceutical patents, there is a likelihood of one product having a multitude of patents all at different stages in the life cycle of patents; some patents being granted earlier and some later in time.
- Each of these patents have different valuation depending on the significance and/or obsolescence of a given technology.
- The assumption in the Form 27 for the value of the patent in proportion to the price of the product is a major pain point. There cannot be any accuracy in such estimation or information which can have a major impact on the exercise of other provisions of patent law especially where a patentee has a compulsory licence filed against him in that patent.

SOLUTIONS:
To be discussed

Problem point 3: Trade Secrets and/or confidential commercial information
- Information such as pricing policy, licensee information, area of operation, quantum of unit sold per annum etc are confidential commercial information of a company.
- Since this information is put out in public domain there is a likelihood that information on Form 27 may not be relevant.

SOLUTIONS:
To be discussed: Part of the information to be kept confidential with the Patent Office; which may be difficult until such time that India enacts a Data Protection Law.
RE: U.S. industry comments on provisions of working of patents, with reference to CGPDTM Circular no. CG/Meeting Circular-DIPP/2018/14, dated March 1, 2018

Dear Mr. Gupta:

Greetings from the U.S. Chamber of Commerce’s U.S.-India Business Council (USIBC) and the Global Innovation Policy Center (GIPC) in Washington D.C. Together, we represent the top global investors in India’s innovative sectors. We appreciate the timely opportunity to comment on the issues relating to the working of patents, specifically, Section 146 of the Patents Act 1970 (as amended) read with Rule 131 of the Patent Rules 2003 including Form 27, and provisions in Section 122.

We understand that Section 146 of the Patents Act, through Form 27, requires every patentee and every licensee of a granted patent to file a statement as to the extent to which the patented invention has been “worked” on a commercial scale in India. Today, as your review suggests, changing business models and dynamism in the innovative sector make this practice out-of-date and duplicative as well as out of step with global best practices. Furthermore, Form 27 adds to sensitivities around the disclosure of working requirements of patents in turn deterring foreign investment in India’s innovative sector – a key component to bolster and sustain India’s economic growth and job creation, and boost the U.S.-India economic relationship.

For the reasons outlined below, we recommend a reassessment of Section 146 of the Patents Act and subsequent elimination of the existing manner and form of working statement requirements. In the interim, USIBC, GIPC and its members believe that simplifying Form 27 to address ease of doing business concerns can serve as a step in the right direction.
**Obsolete Nature:** As noted by our members, it’s been more than 45 years since the inclusion of section 146 in the Patents Act, which is outdated and undesirable in context of changing industry dynamics. Innovative products are likely covered by multiple patents, especially products in technology areas such as information and communications technology (ICT) and computer-related inventions (CRI). For example, information related to working of patents in the ICT sector could only be useful for a potential licensee and may not be required by member(s) of public, making information collection not only difficult but also impractical to collate and report accurately.

**Disregarding Innovation:** In the context of ICT patents, one product may involve one or multiple patents licensed via patent portfolio, for which the patent owner may not be aware of which specific patent is used in the product. Form 27 does not cover portfolio patent licensing, and therefore, it’s difficult (if not completely impossible) to apportion each patent with a revenue earned. It is impractical for a patentee to rip apart/disassemble each product (millions in number) to then find out which of the patents from the portfolio so licensed have been worked. There is no other country that has similar working requirements.

**Compromising Confidentiality:** Business/commercial information pertaining to sales and quantities of the product may be contractually covered by confidentiality agreements as part of a global licensing agreement between the parties, or a business strategy. Hence confidential information should not be required to be disclosed. More specifically the sales amount could be required to be maintained confidential. However, providing the quantity and the sales amount provides clear information to the competitor on the business strategy. To this extent, the patentee-licensee should not be forced to provide information which they feel is confidential. Disclosure, if any required in the interim to reassessment of Section 146, should be limited to either “worked” or “not worked.” Confidentiality is further compromised with conflicting legal requirements – for instance, Section 69 (4) versus Section 146 of the Patents Act.

**Licensing Bottlenecks:** Working Statement in India is potentially impacting foreign licensing deals too as there is always a potential threat of calling for detailed licensing terms and conditions under a public interest litigation (PIL). Considering immense/unnecessary burden (immense engineering working hours) and compliance cost, in additional to increased risk of depriving licensees/licensors from retaining confidential business information, the continued use of Form 27 will actually hurt public interest as diffusion of technology through licensing will become difficult. Licensees and licensors will not be able to negotiate freely and voluntarily to strike a win-win licensing deal.

**Duplicative Effort:** There are several provisions offered in the Patents Act that already check and balance any potential abuse of patent rights. Conflicting legal requirements further exacerbate duplicity. For example, Section 69(4) of the Patents Act requires the Patent Office to keep registered patent license agreements confidential when accompanied by a confidentiality request. This conflicts with Section 146 of the Patents Act that appears to require the Patent Office to publish the same information as reported through Form 27.
Furthermore, in such cases wherein both the patentee and the licensee need to furnish working statements, any difference in the sales and quantities of both could be construed as a false statement by either party. This could also attract penalties under Section 122 of the Patents Act. The logic of filing the working statement is to ensure that the invention is worked in India which is already satisfied by one working statement either by patentee or licensee, if not by the checks and balances mentioned in the paragraph above.

**Arbitrariness:** Questions on Form 27 also include a list of open-ended questions which could be interpreted in an arbitrary manner. For example: “State whether public requirement has been met partly/adequately/to the fullest extent/at reasonable price.” This affirmation by the patentee/licensee is not logical since no patentee/licensee will mention that the public requirement is not met. Furthermore, it is difficult to ascertain compliance or the lack thereof given the vagueness of the definition of “working” as well as the arbitrariness around when and under what specific conditions the Form would be invoked during the course of the year.

**Disproportionate Penalties:** The nature of arbitrary questions could lead to further misinterpretation if meeting the public requirement may be construed as a false statement which may lead to punishment with fine and/or imprisonment under Sec 122. Since Form 27 is unclear regarding many issues, the applicant might wish to be safe and avoid filing Form 27 so that the applicant is not penalized under section 122(2). However that option is also taken away from the applicant with a fine levied of up to INR ten lakhs (approx. US$ 16,666) for every statement not filed. Such a penalty is not only disproportionate, but unnecessary. We recommend that such a question/statement be deleted.

**Defying Ease of Doing Business:** Form 27 must be filed annually by the patent holder apart from paying the maintenance fees and other fees. This step is an extra burden on the patentee. Non-compliance to Form 27 post patent grant may lead to penal liability for the patentee which discourages innovation.

Furthermore, the burden of compliance imposed under Section 146 coupled with Section 122 not only affect large foreign investors but will also deter domestic patent filings, including for small and medium enterprises (SME) and startups. Compliance with Form 27 comes with huge administrative burden and cost, and startups are under continued threat of being exposed to legal repercussions in case they are found to have not been able to comply with existing Form requirements. On the contrary, working statement requirements deter the initiatives launched by the Government of India (GOI) aimed at boosting domestic patent filings and innovation, negates their ongoing efforts to increase patent office efficiency, and ultimately defeats the good intentions of the GOI’s 2016 National IPR Policy.
Overall, Form 27 compliance is not only detrimental to the success of the Government of India (GOI)’s National Intellectual Property Rights (IPR) Policy but also critical government initiatives such as Digital India, Make in India and Startup India, which aim to promote technology transfers, innovative development, and licensing.

Given that patent abuse is mitigated via other existing checks and balances, USIBC and GIPC recommend a complete reassessment of working requirements under Section 146 of the Patents Act and subsequent withdrawal of the outmoded Form 27 as its imposition undermines domestic innovation, undercuts existing and future innovative foreign investment, and their cross-collaboration. In the interim, we believe that simplifying Form 27 to address the issues outlined in this submission will constitute a step in the right direction.

USIBC, GIPC and its member strongly believe that pro-innovation policies, including ease of doing business initiatives, can fuel the growth of domestic innovative industries, attract greater foreign investment, accelerate India’s transition into a knowledge-based economy and bolster its economic prosperity and global competitiveness.

Thank you for your leadership and for your team’s tireless efforts. On behalf of the U.S. Chamber of Commerce’s USIBC and GIPC, we look forward to working with you.

For any questions, please feel free to contact our policy leads in Washington DC: Hemal Shah at bshah@uschamber.com and Jay Gullish at jgullish@usibc.com; or Abhishek Kishore at akishore@usibc.com in New Delhi.

Sincerely,

Nisha Biswal
President, U.S.-India Business Council

Patrick Kilbride
Vice President, Global Innovation Policy Center

CC:
Dr. W. M. Dhumane, Office of the Controller General of Patents, Designs and Trade Marks
Dr. Usha Rao, Office of the Controller General of Patents, Designs and Trade Marks
The United States appreciates the opportunity to provide views on the circular issued by the Controller General of Patents, Designs and Trademarks regarding issues related to the working of patents in India. We hope that our comments will be helpful to India as Form 27 and its related issues are studied.

An unfavorable evaluation of patent working information provided in Form 27 has significant consequences for innovators under the Patents Act. U.S. industry stakeholders cite India's patent working requirements and related notifications to the Government of India as a key IP and ease of doing business concern in India. They indicate that current requirements for information are both burdensome and a threat to protecting commercially sensitive information. The current Form 27 system of annual working statement submissions to the Government of India has been a source of consternation among stakeholders, who have expressed deep concern over costs involved in producing these statements, uncertainty over the information required, and apprehension over the sensitive business information that may be sought. These concerns are exacerbated by potential penalties under Section 122 of the Patents Act, which include significant fines or imprisonment for failure to furnish Form 27. Consequently, patentees are forced into a vexing choice between satisfying the patent office and disclosing valuable information that may jeopardize commercial interests or provide opponents with grounds to challenge current or future patents.

India's current system of requiring annual working statements through Form 27 to give effect to Patents Act Section 146(2) and Patent Rule 131(1) is excessively onerous and costly for patentees and ill-suited to the reality of patented technology. The current Form 27 includes ambiguous and subjective fields, such as "commercial scale," "value," and "public requirement." Even the fundamental concepts of "working" and "non-working" in this context are not fully understood by many patentees. We also question the utility and appropriateness of requiring the nationality of the patentee to be disclosed.

Form 27 does not align with current trends in the commercialization of innovation. Across a broad range of technologies, it is rare that a single patent covers the entirety of an individual product. It is far more common that a product may comprise several patented and unpatented elements. This complex reality makes it difficult for patentees to ascertain the "quantum" and "value" of a patent as contemplated by Form 27. For example, imagine a vehicle that contains a patented mechanism for adjusting the windows, but otherwise contains no other patented elements. Should Form 27 reflect the full value of the vehicle? If not, how should a patentee that does not sell her product separately from the vehicle assess the value of the patented mechanism? In another imagined example, consider an umbrella that consists of several patented and unpatented components (e.g., the inventor secured patents for a novel opening mechanism and for the protective fabric, but the rest of the umbrella is unpatented). How is one to determine the value of each patent to the whole of the larger product?
In addition, for some companies, licensing arrangements for their technologies can amount to some of the most sensitive and valuable business information. If that information is revealed, it may put a company at a competitive disadvantage in the future. Also, given the subjectivity of many of Form 27’s fields, if patentees, licensees, and sub-licensees submit conflicting statements because they use differing standards of assessing value and quantity, would this pose a risk to any of the parties?

Finally, companies must invest significant amounts of time, effort, and money to produce the information necessary to maintain compliance with Form 27. For MSMEs and those with large patent portfolios in India, the legal and institutional costs can be excessive. If these costs—coupled with uncertainty over how to properly fill out the form and exposure to criminal penalties—outweigh the expected market potential, the unintended consequence may be a decrease in R&D and experimentation in India. This situation would likely make it more difficult for India to achieve the innovation objectives contained in the National IP Policy, Start-up India, and other high-level initiatives. To this end, recent initiatives to improve India’s IP administration, including through increased hiring at the Indian Patent Office and reducing pendency, could be facilitated by divesting the Indian Patent Office with overseeing and evaluating regular submissions of Form 27.

The United States thanks the Controller General for providing interested parties with the opportunity to share views on patent working requirements. If the Government of India is soliciting these views with the intention of reforming the Form 27 system, the United States urges India to take the opportunity to significantly improve the ease of doing business, enhance predictability and certainty for innovative industries, align with international best practices, and help achieve National IP Policy, Start-up India, and other national initiatives by eliminating the requirement for patentees to regularly file Form 27 statements. At the same time, India should refrain from applying such onerous penalties to violations of this type.
March 16, 2018

Mr. OP Gupta
Controller General of Patents, Designs and Trademarks
Intellectual Property India,
Patents/Designs/Trade Marks/Geographical Indications,
Boudhik Sampada Bhavan,
Antop Hill, S.M. Road,
Mumbai-400037

Dear Mr. Gupta,

Greetings from United States Patent and Trademark Office.

Thank you for giving us the opportunity to provide our feedback on Form-27 and related issues. Please find enclosed our submission. We hope you would consider them and invite us for the discussion on March 21, 2018.

We have provided a hard copy at New Delhi to Mr. Rajiv Aggarwal, Joint Secretary, the Department of Industrial Policy and Promotion. Should you have any queries or clarifications, please feel free to reach our office on the office number 91-11- 23472259; Mobile: +91 7042573377 or Email at Komal.Kalha@trade.gov.

With warm regards,

Komal Kalha
Senior Counsel
United States Patent and Trademark Office
Office of South Asia

Cc:
Mr. Rajiv Aggarwal
Joint Secretary
Department of Industrial Policy and Promotion
Udyog Bhawan
New Delhi.
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With warm regards,

Komal Kalha
Senior Counsel
United States Patent and Trademark Office
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22 March 2018

To

Mr. Ramesh Abhishek
Secretary (IPP)
Ministry of Commerce and Industry
Udyog Bhavan
New Delhi, India
Secy-ipp@nic.in

Shri. O P Gupta, IAS
Controller General of Patents
The India Patent Office
Mumbai, India
cgoffice-mh@nic.in

Submission in Response to No.CG/Circular/2018/114 Dated March 16, 2016, on Working of Patents

In furtherance to the circular published by your office on 01.03.2018, I wish to submit the following comments on the issues related to working of patents under the Patents Act, 1970, and in particular the format of Form 27.

The year 2018 must be distinguished for developing countries in India under the established and negotiated global trade norms. As many of us are aware, the norms for World Trade are changing rapidly. Even the United States, which was a leader in pushing the globe towards a harmonized trade regime, has imposed steel and aluminium tariffs, under Article XXI of GATT primarily to safeguard its local producers and to ensure that domestic manufacturers and jobs are not disadvantaged. For developing countries, this move alone underscores the primacy of taking care of the national obligations, by catering to areas of domestic strength. I have written much about the importance of trade norms to cater to national obligations apriori in my book titled Patents & Trade Disparities in Developing Countries, published by the Oxford University Press. Importantly, for India, it is time to deploy wisely trade flexibilities to prioritize national issues.
It is time for India to re-look at the issue of Form 27 disclosure from the perspective of its national access to medication debate. India has already taken a stand on the inclusion of the local working requirement. There is no compelling reason to shy away from it. If anything, making it clearer will allow India to assume a leadership role amongst developing nations on the use of this requirement. In any event, I support the underlying broad proposition that patent working norms lie at the very heart of patent systems of developing countries such as India. There is an inherent *quid-pro-quo* in requiring the patentees to disclose whether they are locally working their patented invention in exchange for the conferred benefits. Such disclosures should be required as part of a national strategy to improve innovation and further technology transfer into the country where the patent is being worked and in the case of pharmaceuticals, to support India's burgeoning generic drug industry and ensure supply of the medication nationally.

In this regard, requiring licensees to make a full and complete disclosure of the patent working information through Form 27 would not be considered out of the norm. It is equally important to appreciate that the WTO rules does not prohibit getting information on the local working. In this regard, it is indeed true that the current format of Form 27, under which the patentees and their licensees are required to disclose the patent working information remains insufficient to accomplish the task of getting complete disclosures on the working of the patent.

The objective should be to amend Form 27 in a manner: a) rectifying the deficiency of not requiring exhaustive information from the patentee, and, b) to encourage transparency from the patentee. Considering that we are dealing with life-saving medications, transparency of working of the patent can justified under the Doha Declaration under public health criterion as well Article XXI, on the grounds of national security. Thus, Form 27 needs to seek exhaustive details about a) local working details, b) the compositions or details of a prior patent on any element of the application material, and c) preserve the discretion of the Controller to seek more information if required. I strongly believe that Form 27 should be an important statutory mandate that ensures public scrutiny of the true extent to which the patent has been licensed and worked nationally. I believe that the detailed amendments to the Form that Mr. Shaminad Basheer has requested is fully warranted. In the light of the detailed survey evidence submitted by Mr. Basheer, I agree that the information that is suggested in his submission should be specifically requested in the amended Form 27.
I am also aware of the idea of creation of a Green Book. I believe that this issue is distinct from seeking information on the local working of a patent, which is Form 27. The Green Book, if India adopts it, would be concerned with information on other related patents. India has clearly taken a stance on patent linkage issue. The question of creation of a Green Book should be separately considered under the broad umbrella of patent linkage or, under, Section 122A of the DPCA for creating what you are suggesting. It is an important issue and deserves full consideration separately.

I also wish to discuss the question of whether a patentee who “knowingly abuses” the requirement by not providing information should be subject to punitive measures.

I would like to respectfully submit that the objective of the exercise is access to medication. Hence, it is in India’s benefit to not include statutory criterion that requires proof of whether the non-disclosure of the local working details by the patentee is “knowingly or otherwise.” I believe that liability should be strict civil liability if there is non-compliance. That is, if the patentee has not exhaustively disclosed information, knowledge should be presumed and the patent (and related patents, if any) should be subject unenforceable. Non-disclosure in Form 23 should create a strong presumption that “reasonable requirement of the public” under Section 84 has not been fulfilled, thus leaving the patent open for compulsory licensing.

In this regard, the paper titled “Patent Infringement as Criminal Conduct” by Professor Jacob S. Sherkow of Law at the Innovation Center for Law and Technology, New York Law School widely advocates the imposition of strict civil liability. The paper outlines that:

“patent infringement is a strict liability civil offense. It does not matter whether the conduct of the alleged infringer was malicious or innocent of heart; the patent infringement statute imposes liability on all those who make, use, sell, or offer to sell a patented invention without the authority of the patent holder. In a typical action for patent infringement, the mental state of an accused infringer is irrelevant.”

I agree and support the idea that India should institute specific strict civil liability for not fulfilling all the details of Form 27.

As for the question of whether such a patentee should also be subject to criminal liability, I do not think that the Sherkow paper\(^2\) deals with the question of whether criminal liability is warranted. It is upto India to determine whether to impose criminal penalties in addition to civil liabilities. If sophisticated patent owners/holders who violate patent filings are not be subject to criminal penalty, I believe that it dilutes the system and will result in rampant misuse.

Importantly, I wish to note that Professor Sherkow’s paper, does not advocate that such patentees should not be criminally prosecuted. Instead, Professor Sherkow’s paper specifically addresses the requirement of the US Supreme Court *Global-Tech Appliances, Inc. v. SEB S.A.*\(^3\). In any case, the paper does not stand for the proposition that patentees should not be left punished if a sovereign jurisdiction determines the need for criminal sanctions to enforce disclosures.

I do agree that with regard to a non-drug patent, if a patentee is genuinely not aware of which patents from a bundle of licenses are worked by the licensee, then Form 27 may “include the option “Not known to have been worked or not worked.” However, if the patentee ticks off the option “Not known to have been worked or not worked,” then the patentee should be obligated to provide information within a certain period, upon written request the Controller or any public, on the working or non-working of the patent for which the option “Not known to have been worked or not worked” has been exercised. The failure to provide this information should result in the patent at issue, i.e., the patent for which the option “Not known to have been worked or not worked” has been exercised and information on the working or non-working of the patent not provided, to be held unenforceable for fraud on the India Patent Office.

**Conclusion:**

The Indian statute’s provision incorporating the local working requirement is a reflection of a negotiated flexibility fully authorized by the Doha Declaration. India needs to stand-by this requirement. Considering the failed Doha Round of talks in 2015 and considering the


imposition by the US of steel and aluminium tariffs imposed on imports, India’s needs to have renewed sense of confidence in its incorporated flexibilities. A robust generic drug industry is a national need for a developing country like India. Given its own violations of the WTO, the United States, which always lacked the legal standing to impose its unilateral Special 301 findings, will also lack the moral standing to require other nations to open its market to the detriment of its own public. In any case, in light of the invocation of Article XXI, any scrutiny of negotiated flexibilities such as the local working requirement will fall under India’s nation security requirement to ensure that public health is maintained.

Should you wish further details, clarification or information in this regard, I would be happy to provide clarifications that you may need using Webex or the phone.

Sincerely,  

Srividhya Ragavan  
Professor of Law  
Texas A&M University School of Law  
Fort Worth, TX  
Ragavan.sri@tamu.edu
COMMENTS ON THE PROVISIONS FOR ‘WORKING OF PATENTS IN INDIA’

1. Information required under 3(iii) of Form-27: “State Whether public requirement has been met partly / adequately / to the fullest extent at reasonable price.”

**Comment:** I suggest deleting this reference in Form-27 altogether. The nature of such 'information' often tends to be view-based rather than objective and fact-based. To try to provide fact-based and meaningful information would entail substantive business studies involving public surveys and research into the demographics of target consumers, the buying power of consumers, the alternatives available in the market, etc. This can be a particularly onerous and cost-intensive burden, and one that would be more suitable to be carried out by government bodies that are better equipped to meaningfully derive such public-interest-oriented information to the extent the same may be required. This is particularly so when there are no specific guidelines for determination of meeting public requirement, and deducing reasonable pricing. The usefulness of self-attestation by patentees/licensees on public requirement being met and reasonable pricing is anyway debatable.

2. Information required under 3(i)b of Form-27: “Whether patented invention worked in India or not; If worked – quantum and value (in INR) of the patented product manufactured in India, and imported from other countries (with country-specific details).”

**Comment:** I suggest that it should be possible to provide the *quantum* and *value* in terms of selecting between pre-set ranges or slabs. Data provided in this form (of range, instead of exact numbers) would achieve an increased ease of compliance without compromising on the objectives behind seeking this information.

3. **Filing of Form-27:** Currently a separate Form-27 is required to be filed in respect of each granted patent.
**Comment:** It should be possible to file a single Form-27 for multiple (related) patents. Companies license its patents in blocks, which are often used in respect of same/similar product(s). In such case, it is inconvenient (at times, near impossible) to bifurcate the data for each such related patents.

4. Information required under 3(ii) of Form-27: “the licences and sub-licences granted during the year.”

**Comment:** I suggest that it should not be made mandatory to disclose the terms of license/sublicense granted by the patentees. The details of licensees/sub-licensees along with the details of working (such as the quantum of products imported/manufactured by the licensees/sub-licensees, and the market value of such products) will be more than good to achieve the objectives behind seeking this information. The Patentees/Licensee are anyway under an obligation under the Patents Act to register any instrument of transfer/creation of rights in a patent (such as for assignment, license, mortgage, etc.), without which the instrument is inadmissible as evidence in any court of law or Patent Office.

5. Information required under 3(i) of Form 27: “The patented invention worked or not worked”.

**Comment:** In the absence of a clear definition of 'Working of Patent' and also ambiguities in whether import amounts to working or not, there are challenges in trying to meet the requirement (viz. providing information of whether the patent was worked in India). Whether the patented invention was worked in India or not should be determined by the Patent Office on the basis of other information provided in the form.

6. Rule 131 of the Patent Rules, 203: “The statements shall be furnished by every patentee and every licensee under …..”
Comment: I recommend that "and" (emphasis added) be changed to "or" in the above rule, as it is not only redundant to have the same information being furnished by both the patentee and licensee, but it also amounts to an added responsibility on the licensees.

Regards,

Ashwani Balayan
Partner
ALG India Law Offices LLP
A-2, First Floor, Neeti Bagh, New Delhi - 110049
T +91.11.2656.2545 | F +91.11.2656.2546
E ashwani.balayan@algindia.com
Ayyangar’s Ghost and the Indian Patent System: Preserving Confidentiality of Patent Licensing Agreements

Yogesh Pai
Assistant Professor, NLU Delhi

The Context:

The Indian Patents Act, 1970, [hereinafter: “the Act”] is largely an outcome of a comprehensive review of the patent system by Late Justice N. Rajagopala Ayyangar as it prevailed in the early and mid-20th century. The report on the ‘Revision of the Law in India Relating to Patents for Inventions’ (1959) advocated strong reforms on compulsory licensing and commercial working of patented inventions in India. Under the Act, any patented invention which is not commercially worked by way of local manufacturing may trigger the grant of a compulsory licence by the Government on an application made by any interested third party after three years of the patent grant. The patent subjected to such a compulsory licence (which in essence is a forced contract) may finally be revoked for the same reason after two years from the date of grant of the compulsory licence. While importation of products embodying the patented invention may satisfy the requirement of working, the patentee must be able to justify (on case-by-case basis) why local manufacturing is not possible within India.

It is clear that the intent of the Act is not to allow patentees to merely exploit the Indian market without providing the incidental benefits of local manufacturing. So a textual disclosure of an invention is clearly not the only quid pro quo underlying the Indian patent system. In many ways, the social bargain in the Act is designed to force vertical integration by requiring the patent holders to ‘work’ (produce/import/licence) the patented invention on a commercial scale and to the fullest extent possible in India. Although India has amended her patent law thrice since the signing of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS- 1995), Justice Ayyangar’s scepticism that public interest may be defeated without provisions to ensure full, commercial and territorial working of the patent still informs the public policy debate on patents in India.

To ensure that sufficient information on working is made available by the patentee or her licensee, Section 146(2) of the Act requires an annual disclosure about the extent of commercial working of the patent through FORM 27. Section 146(3) read with Rule 131(3) of the Patents Rules 2003 [hereinafter: “the Rules”] provides discretion to the patent office to publish the information received by them in FORM 27. The refusal or failure of the patentee/licensee to furnish the information is punishable with a fine, which may extend to ten lakh rupees or with imprisonment (up to six months) in cases where such information is found to be false. FORM 27 requires the patentees to provide details pertaining to the status of working, the extent of working (quantum and value of patented product
manufactured/imported), the licences and sub-licences granted during the relevant year, and the extent to which public requirement has been met at a reasonable price. But patentees have often provided very broad and ambiguous information fearing that any detailed disclosure in FORM 27 may act as a trigger for a compulsory licence or may lead to public disclosure of confidential terms in Patent Licensing Agreements (PLAs).

**A PIL(L!) to Induce Working or Disclosure of Confidential PLA Terms?**

In a Public Interest Litigation (PIL) filed by Prof. Shamnad Basheer against the Union of India, the Delhi High Court has recently directed the Union Government to suggest steps and a timeline for enforcing the requirements of the Act against errant patentees. As per the petitioner, the patent office has failed in its statutory duty to seek adequate information through FORM 27 and initiate prosecution where such information has not been provided or has been wrongly provided. It is pertinent to note that the Counsel appearing for the Government agrees with the petitioner on the need to enforce the mandate under the Act. This has provoked many patent owning firms to file intervention petitions in the current matter.

So far, so good! However, what the petitioner demands in the context of disclosure of licensing details are deeply problematic for several reasons, which I argue are also against the letter and spirit of the Act. The petitioner states that the existing requirements in FORM 27 lack precision due to which a number of submissions by the patentees do not provide adequate details of licensees or licensing arrangements. It is true that many patentees have pleaded confidentiality terms involved in PLAs and may have agreed to share it in confidence with the Indian Patent Office upon a specific request. It is certainly not the case that patentees/licencees cannot provide such privately available information. But the core question is if such confidential information contained in PLAs can and ought to be subject to public disclosure under Section 146(3) of the Act.

In order to make the disclosure of licensing information more effective, the petitioner has demanded that FORM 27 must require disclosure of specific details viz., “whether the patent has been licenced in the first place; if so, it must then call for more elaborate details, such as the names of licensees, broad terms of licence, whether products are being manufactured under the licence, whether such licenses are exclusive or not, etc.” Not surprisingly, such a requirement to disclose the terms of the licence will include licensing rates and other terms and conditions contained in PLAs. While such information may be readily available with the patentees/licensees in PLAs, it is damaging to require them to disclose confidential information contained in them. As I explain below, this will risk making the patent rights redundant in India and in all those jurisdictions where patentees are engaged in licensing activities involving similar patent portfolios. Requiring elaborate disclosure of terms contained in PLAs may not only harm individual parties, but may have a cascading effect on an entire ecosystem of patent licensing activities world-wide. This
is especially true of critical sectors such as Information and Communication Technologies (ICT), which involve extensive licensing of patented technologies on a global scale.

**Why Confidentiality of PLAs Matter:**

Patents are private property rights with exclusivity at its core. There is a great deal of debate on the nature of exclusivity in the context of awarding remedies such as injunctive relief and damages. However, it must be clear that the function of exclusivity is not simply to stop infringement by exclusion, but also to allow patentees to enter into a voluntary exchange (voluntary licence) and diffuse the patented technology. Private ordering allows patent holders to monitor the value of their inventions by offering differential rates and other terms and conditions to different licensees based on actual and prevailing market conditions. Hence PLAs are often a subject-matter of confidentiality by way of non-disclosure agreements (NDAs) among different market players.

The exclusivity underlying a patent provides the patent holder with the power to control the output (by forcing a demand-supply mismatch) in order to realise a value that the market can bear. Price discrimination allows the patent holder to realise such a value based on prevailing market conditions. There are various reasons why licensing information, specifically on price and non-price conditions, can be considered as sensitive for both the parties involved in a licensing deal. All licensees do not see confidentiality as an impediment to manufacturing or distribution of the patented product. It allows downstream manufacturers and vendors to compete in the goods market. Although a large number of patentees may not practice the patent themselves (non-practising entities- NPEs) but agree to licence upon payment of royalties, some patentees do enter into long-term licensing deals with specific players in the downstream markets that allow such licensees to engage in a lot of value addition and compete for higher market shares. Thus differentiated licensing conditions achieved through confidentiality of PLAs have important benefits for the industry as a whole.

Price discrimination is achieved through several ways such as granting volume discounts, cross-licensing arrangements with smaller or zero royalties, and differential pricing based on conditions of purchase depending on buyers’ or products’ characteristics. Consumers also benefit from differential pricing since it allows the same patented technology to be used in differentiated products produced by various manufacturers. Unless such terms and conditions in a licence are specifically limited by a voluntary contract (specific commitments that may be undertaken by the patentees under SSO IPR policies), contract law (prohibition on certain types of contracts), regulation (patent law in India prohibits the inclusion of certain restrictive conditions), or competition law (where unfair and discriminatory condition in purchase or sale of goods or service may amount to abuse of dominance), there is no economic justification to prohibit price discrimination that may be achieved by preserving the confidential nature of PLAs.
Therefore, any forced disclosure of confidential terms contained in PLAs through FORM 27 defeats the voluntary bargain that patentees and individual licensees can strike based on prevailing market conditions. Disclosure of confidential licensing terms and conditions may have an irreversible impact on the bargaining power of the parties and how licenses get negotiated in the ICT sector, which has witnessed wider diffusion of patented technology through non-exclusive patent licenses (unlike in case of pharmaceuticals where there may be very few instances of non-exclusive licensing). Perhaps, it is for this reason (i.e., to preserve bargaining power between the patentee and several existing and potential licensees) that the current format of FORM 27 does not seek specific details of a license and leaves it to the patentee/licensee to give any available details.

**Does the Patents Act Mandate Confidentiality of PLAs?**

There are legal reasons why terms of licence contained in PLAs could be considered as confidential within the framework of the Act. It is very clear from the proviso to Section 69(4) of the Act that in case of a licence granted under a patent, the controller shall, if so requested by the patentee or licensee, take steps for securing that the terms of the license are not disclosed to any person except under the order of a court. This proviso stems from the requirement in section 69(4) to supply to the Controller of Patents copies of all agreements, licenses and other documents affecting the title to any patent or any license. Registration of a patent assignment/license or any other kind of document connected to the transmission of ownership or entitlement is mandatory under 69(1) and (2) (read with Rule 90 and 91). FORM 16 provides a mechanism through which such registration is made possible. It is pertinent to note that FORM 16 must be accompanied by a certified copy of a PLA. Any failure to register such a contractual document shall not be admitted by the Controller of Patents or by any court as evidence of title, unless for reasons to be recorded in writing [section 69(5)].

Pertinently, the Ayyangar Report emphasises the importance of confidentiality of PLAs in Para 760 by stating that “[t]o allay any fears regarding disclosure of trade secrets the clause might provide that the terms of the agreement filed before the Controller should be kept confidential and should not be open to public inspection except under the orders of Court on the lines of Section 49 (5) of the Trade and Merchandise Marks Act, 1958 in respect of agreements as to registered user. Needless to say that this last provision can apply only to voluntary licenses.” In fact, the Ayyangar Report did suggest a provision exactly identical to Section 69(4) proviso of the current Act. From a historical perspective, it is clear that confidentiality has a strong grounding in the Indian Patent Act, 1970.

There is no readily available information to ascertain if patentees/licensees in India regularly file FORM 16 to register their licenses. It is doubtful if the Indian patent office has put in place an apparatus to maintain the confidential nature of PLAs. Furthermore, the Act or the Rules do not suggest how a request for non-disclosure of PLAs must be accompanied with FORM 16. However, it is clear that the
proviso to Section 69(4) mandates non-disclosure of registered PLAs when accompanied with a confidentiality request at the time of such registration through FORM 16. Hence, any contrary requirement in FORM 27 to disclose the otherwise confidential terms of license contained in PLAs that is secured through a request made the patentee under the proviso to Section 69(4) militates against the clear mandate of the Act. Furthermore, in such cases the patent office may already have access to the confidential terms of PLAs, thereby negating the need for an additional disclosure under FORM 27 of specific details of licensing terms contained in those PLAs.

There could be a large number of cases where patentees may not have submitted FORM 16 along with a confidentiality request. Perhaps, it is for this reason that Section 146(3) of the Act and Rule 131(3) vests discretion in the Controller to publish information received by him under FORM 27. Even where the Controller requires such disclosure from time to time during the continuance of the patent under Section 146(1) (different from the annual disclosure requirement under Section 146(2)), it is clear that the Controller has discretion not to publish such information, which may include the confidential licensing terms of PLAs.

**Broader Implications of Disclosing Confidential PLAs terms in FORM 27**

In some recent patent infringement cases involving Standard-Essential Patents (SEPs- standards such as 3G/4G encumbered by patents held by multiple companies), Indian courts have ordered “confidentiality clubs” so that confidential information on licensing terms and other information such as claim charts may not be disclosed. Such confidentiality clubs have a limited number of nominees of the litigating parties and few external experts. The members of the club are bound by confidentiality orders passed by the Court, which requires them not to disclose “…patent license agreements to anyone else or anywhere else, including in other legal proceedings, oral and written communications to the press, blog publications etc., so that the spirit of the confidentiality regime would be preserved.” [Ericsson v. Lava Delhi High Court 2016]. Any contrary requirement to disclose the confidential licensing terms under FORM 27 beyond the current requirements would nullify the need for confidentiality clubs ordered by the Hon’ble courts in some of these SEPs matters.

Patentees have often used different techniques to gain an upper-hand in licensing negotiations by providing inadequate information to potential licensees without the signing of NDAs a pre-requisite. While valid concerns could be raised in the context of courts considering pleadings and other documents as confidential, the licensing terms that are disclosed only under NDA are a subject-matter of confidentiality. The argument that patentees by subjecting themselves to courts have implicitly waived their confidentiality is not in the spirit of civil commercial litigation. In such a case, we may not have had adequate safeguards under the Act against such disclosure.
It is not clear why the petitioner states that the public disclosure of working information (which may potentially include confidential terms contained in PLAs) is “absolutely critical” for pending SEPs investigation at the Competition Commission of India. It is clear that the investigating authority under the Competition Act, 2002 has powers to call for any document, including confidential PLAs, to seek any critical information. Hence FORM 27 disclosures on licensing terms are not critical, if not redundant, in the context of CCI proceedings. Importantly, Section 57 of the Competition Act provides remedies against disclosure. The Commission or the Appellate Tribunal can deal only with previous permission in writing of the enterprise, disclose information obtained by them, otherwise than in compliance with or for the Competition Act or any other law for the time being in force.

Furthermore, the “Competition Commission of India (General) Regulations, 2009” elaborately deals with confidentiality of information submitted to the Commission. Under Regulation 35(2), a request for treating the confidentiality of any document can be made if public disclosure of such documents “will result in disclosure of trade secrets or destruction or appreciable diminution of the commercial value of any information or can be reasonably expected to cause serious injury.” It is pertinent to note that the Delhi High Court has upheld the validity of Regulation 35 by noting the denial of access to confidential information at investigation stage by the CCI does violate natural justice or the party’s ability to defend itself [Somi Conveyor Belttings Ltd. & Anr. v. Union of India & Ors., (2016)]. Since the use of NDAs for differential pricing is the crux of the matter in the SEPs investigations before the CCI, it remains to be seen how mandatory public disclosure of confidential information through FORM 27 may play out in such cases in the future.

**Can FORM 27 be amended to seek confidential PLA terms?**

The petitioner’s prayer to enforce compliance with FORM 27 is definitely laudable. However, a request to amend FORM 27 to require further details on confidential licensing terms or force mandatory public disclosure of such licensing terms raises some difficult questions, which could potentially be a subject of an Ultra Vires challenge. Any change in FORM 27 to adduce more information on commercial working, such as requiring the disclosure of confidential terms of PLAs, runs into the risk of violating other provisions of the Act. This is specifically when such confidential terms in PLAs may be publicly disclosed by the patent office. Such information has been previously requested under RTIs. Even if the Central Government unilaterally or under a judicial order agrees to amend FORM 27, it will have to take the parliamentary route to bring in any irreversible change in FORM 27 since it primarily affects the nature of confidentiality of licensing information preserved by the proviso to Section 69 of the Act. It is pertinent to note that any demand for additional disclosure of licensing terms contained in PLAs in FORM 27 cannot be done without legislatively fixing the discretionary nature of public disclosure allowed in Section 146(3) of the Act.
It is prayed by the petitioner that the Patent Office must mandatorily publish the entire information relating to commercial working (which could potentially include confidential licensing information) of all patents on the website of the patent office as per Section 146(3) of the Patents Act, 1970 read with Rule 131(3). It is very clear that 146(3) of the Act vests discretion in the Controller to publish information received through FORM 27. It is not through a judicial action but through legislative amendment alone that such a requirement can be made mandatory. As discussed above, there are cogent reasons why confidential licensing information cannot be disclosed without violating other provisions of the Act.

The petitioner has prayed that a committee of experts may be constituted to suggest reforms to “improve the public disclosure norms around the commercial working of patents.” Perhaps, it is also apt to suggest that the Government of India must float a discussion paper and invite wider stakeholder consultations before making irreversible changes to FORM 27. The bargain struck by the Patents Act in India must not be defeated by diluting the confidential nature of terms contained in PLAs.

*******
To

Dr.W.M.Dhumane  and Dr.Usha Rao
Office of The Controller General of Patents, Designs & Trademarks,
Boudhik Sampada Bhavan
S.M.Road, Antop Hill
Mumbai- 400037 (India)

Dear Sir/ Madam

Sub: Inviting comments from stakeholders regarding issues relating to working of patents- Reg’

Ref: Circular No.CG/Circular/2018/114 Dt. 16.03.2018

Here are some comments/ suggestions on issues related to working of patents under Section -146 of Indian Patents Act 1970 read with Rule 131 of Patents rules 2003 including Form-27

<table>
<thead>
<tr>
<th>No.</th>
<th>Suggested additional inclusion</th>
<th>Reason for the suggestion</th>
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<tbody>
<tr>
<td>1</td>
<td>Complete particulars of the parties, licensees, sub-licensees including address, email, phone numbers etc., who practiced the subject patent in India during the year.</td>
<td>Brevity in where the patent is actually being worked</td>
</tr>
<tr>
<td>2</td>
<td>Particulars of new parties, if any, approached during the year for the subject patent license.</td>
<td>To understand the dynamic status of working of patent</td>
</tr>
<tr>
<td>3</td>
<td>Have you denied the license of the subject patent to anyone? If so state the particulars of the parties and the grounds/reasons with particulars for denial.</td>
<td>Fair working of patent in concurrence with Section.83</td>
</tr>
<tr>
<td>4</td>
<td>State whether the revenue particulars provided for the subject patent also involve any other product or process patents granted in India including cross licensing of patents.</td>
<td>To bring transparency in the disclosures as pertaining to revenue share of particular patent. This gives clarity to stakeholders at large involved in several commercial transactions pertaining to the product / process patents</td>
</tr>
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</table>
| 5   | Whether the patent is also commercialized outside India, If so  
   a) pricing particulars in other countries and Indian pricing | Ensure that the working of patent is on par with the similar geographies in the public interest |
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<th>b) whether pricing in India is it at equitable level, give particulars</th>
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<td></td>
<td>c) Justify in the public interest how it is reasonable pricing in India</td>
</tr>
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<td>6</td>
<td>Justify whether the patentee complied the principles laid down under Sec.83 of the Patents Act, 1970.</td>
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<td></td>
<td>To put some obligatory responsibilities on the patentee to follow the General principles laid down under Sec.83 in the national interest. Not contrary to public order</td>
</tr>
<tr>
<td>7</td>
<td>State the particulars of field of invention and industry(ies) practicing the patent.</td>
</tr>
<tr>
<td></td>
<td>Most of the patentees have invention being protected in a particular field, yet they are trying to monopolize on fields not relevant in guise of application. Very classic examples of many biotechnology patents are visible.</td>
</tr>
<tr>
<td>8</td>
<td>In working of patents, whether the patentee is not claiming the product / process outside that the claims granted under the patent.</td>
</tr>
<tr>
<td></td>
<td>This is to have clarity from the patentee that the product / process is worked upon only in the scope of claims granted and not outside.</td>
</tr>
<tr>
<td>9</td>
<td>If patent is licensed, describe what was provided to the licensee to license the patent.</td>
</tr>
<tr>
<td></td>
<td>In the public interest, this is asked for to have more clarity as to what is actually given to the licensee in the subject matter</td>
</tr>
<tr>
<td>10</td>
<td>Provide the particulars of infringement proceedings, if any, filed during the year against the subject patent.</td>
</tr>
<tr>
<td></td>
<td>Has the patentee come across any unauthorized working of patents during the year. If so, provide the details of the parties and the action taken against them</td>
</tr>
</tbody>
</table>

I kindly request you to consider these points in the national interest.

Thanking You
O.K. Tara
(IN/PA 2849)

O.K.Tara - (IN/PA 2849)
Manager- IP& PPV
NSL
Hyderabad
Contact: 9949030701
ear all,

As per the circular no. CG/Circular/2018/114, I hereby submit my comments regarding issues related to working of patents under the Patents Act, 1970.

Please consider an example for better understanding of the problem

Suppose we have the following situation:

Consider there is one patentee and several non-exclusive licensees under the same patent. The patentee is currently not working the patent because the product covered by the patent did not yet pass all the different steps of Indian regulatory approval. However, the non-exclusive licensees might have reached the stage of approval but the patentee does not have full knowledge of that. Can the patentee state that the patent is not worked because the “patent covers a product which is under development. For said product, regulatory approval from Indian authorities is pending. Status of the patented invention is likely to be worked in the near future subject to all pending approvals.”

But what if one of the licensees obtained full approval of which the patentee is not aware?

Can the patentee make the statement that the patent is not worked by the patentee?

Who carries the responsibility of correctly submitting the form 27? Is that the patentee or is that the licensee?

If the licenses provided under the patent are listed in form 27, does that shift the burden for correctly informing the Indian authorities on the working status of the patent partially to the listed licensees?

If the patentee does not have full knowledge of the status of development by a licensee of a product covered by the patent, can the patentee incorporate some appropriate wording in its form 27 to safeguard him against potentially incomplete statements made? For instance, can the patentee state “to our knowledge the patent is not worked because.....”?

If both the patentee and the licensee can submit a form 27, detailing the status of their development stage of a product covered by the patent, can a patentee be liable for incorrect statements made by the licensee on the licensee’s form 27 for the licensed patent of the patentee?

I really hope that the issues will be understood correctly and will be looking forward for the issues to get addressed in the upcoming meeting to be held on April 06, 2018.

Thanks & Regards,
Varun Sharma
Patent Analyst

You never have (Y) in HAPP-Y-NESS, However there is always an (I) in HAPP-I-NESS
DONT SEARCH FOR HAPP-I-NESS, JUST LOOK WITHIN
22 March 2018

To

Mr. Ramesh Abhishek
Secretary (IPP)
Ministry of Commerce and Industry
Udyog Bhavan
New Delhi, India
Secy-ipp@nic.in

Shri. O P Gupta, IAS
Controller General of Patents
The India Patent Office
Mumbai, India
cgoffice-mh@nic.in

**Submission in Response to No.CG/Circular/2018/114 Dated March 16, 2016, on Working of Patents**

In furtherance to the circular published by your office on 01.03.2018, I wish to submit the following comments on the issues related to working of patents under the Patents Act, 1970, and in particular the format of Form 27.

The year 2018 must be distinguished for developing countries in India under the established and negotiated global trade norms. As many of us are aware, the norms for World Trade are changing rapidly. Even the United States, which was a leader in pushing the globe towards a harmonized trade regime, has imposed steel and aluminium tariffs, under Article XXI of GATT primarily to safeguard its local producers and to ensure that domestic manufacturers and jobs are not disadvantaged. For developing countries, this move alone underscores the primacy of taking care of the national obligations, by catering to areas of domestic strength. I have written much about the importance of trade norms to cater to national obligations *apriori* in my book titled *Patents & Trade Disparities in Developing Countries*, published by the Oxford University Press. Importantly, for India, it is time to deploy wisely trade flexibilities to prioritize national issues.
It is time for India to re-look at the issue of Form 27 disclosure from the perspective of its national access to medication debate. India has already taken a stand on the inclusion of the local working requirement. There is no compelling reason to shy away from it. If anything, making it clearer will allow India to assume a leadership role amongst developing nations on the use of this requirement. In any event, I support the underlying broad proposition that patent working norms lie at the very heart of patent systems of developing countries such as India. There is an inherent *quid-pro-quo* in requiring the patentees to disclose whether they are locally working their patented invention in exchange for the conferred benefits. Such disclosures should be required as part of a national strategy to improve innovation and further technology transfer into the country where the patent is being worked and in the case of pharmaceuticals, to support India’s burgeoning generic drug industry and ensure supply of the medication nationally.

In this regard, requiring licensees to make a full and complete disclosure of the patent working information through Form 27 would not be considered out of the norm. It is equally important to appreciate that the WTO rules does not prohibit getting information on the local working. In this regard, it is indeed true that the current format of Form 27, under which the patentees and their licensees are required to disclose the patent working information remains insufficient to accomplish the task of getting complete disclosures on the working of the patent.

The objective should be to amend Form 27 in a manner: a) rectifying the deficiency of not requiring exhaustive information from the patentee, and, b) to encourage transparency from the patentee. Considering that we are dealing with life-saving medications, transparency of working of the patent can justified under the Doha Declaration under public health criterion as well Article XXI, on the grounds of national security. Thus, Form 27 needs to seek exhaustive details about a) local working details, b) the compositions or details of a prior patent on any element of the application material, and c) preserve the discretion of the Controller to seek more information if required. I strongly believe that Form 27 should be an important statutory mandate that ensures public scrutiny of the true extent to which the patent has been licensed and worked nationally. I believe that the detailed amendments to the Form that Mr. Shamnad Basheer has requested is fully warranted. In the light of the detailed survey evidence submitted by Mr. Basheer, I agree that the information that is suggested in his submission should be specifically requested in the amended Form 27.
I am also aware of the idea of creation of a Green Book. I believe that this issue is distinct from seeking information on the local working of a patent, which is Form 27. The Green Book, if India adopts it, would be concerned with information on other related patents. India has clearly taken a stance on patent linkage issue. The question of creation of a Green Book should be separately considered under the broad umbrella of patent linkage or, under, Section 122A of the DPCA for creating what you are suggesting. It is an important issue and deserves full consideration separately.

I also wish to discuss the question of whether a patentee who "knowingly abuses" the requirement by not providing information should be subject to punitive measures.

I would like to respectfully submit that the objective of the exercise is access to medication. Hence, it is in India's benefit to not include statutory criterion that requires proof of whether the non-disclosure of the local working details by the patentee is "knowingly or otherwise." I believe that liability should be strict civil liability if there is non-compliance. That is, if the patentee has not exhaustively disclosed information, knowledge should be presumed and the patent (and related patents, if any) should be subject unenforceable. Non-disclosure in Form 23 should create a strong presumption that "reasonable requirement of the public" under Section 84 has not been fulfilled, thus leaving the patent open for compulsory licensing.

In this regard, the paper titled "Patent Infringement as Criminal Conduct" by Professor Jacob S. Sherkow of Law at the Innovation Center for Law and Technology, New York Law School widely advocates the imposition of strict civil liability. The paper outlines that:

"patent infringement is a strict liability civil offense. It does not matter whether the conduct of the alleged infringer was malicious or innocent of heart; the patent infringement statute imposes liability on all those who make, use, sell, or offer to sell a patented invention without the authority of the patent holder. In a typical action for patent infringement, the mental state of an accused infringer is irrelevant."

I agree and support the idea that India should institute specific strict civil liability for not fulfilling all the details of Form 27.

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As for the question of whether such a patentee should also be subject to criminal liability, I do not think that the Sherkow paper² deals with the question of whether criminal liability is warranted. It is upto India to determine whether to impose criminal penalties in addition to civil liabilities. If sophisticated patent owners/holders who violate patent filings are not be subject to criminal penalty, I believe that it dilutes the system and will result in rampant misuse.

Importantly, I wish to note that Professor Sherkow's paper, does not advocate that such patentees should not be criminally prosecuted. Instead, Professor Sherkow's paper specifically addresses the requirement of the US Supreme Court Global-Tech Appliances, Inc. v. SEB S.A.³ In any case, the paper does not stand for the proposition that patentees should not be left punished if a sovereign jurisdiction determines the need for criminal sanctions to enforce disclosures.

I do agree that with regard to a non-drug patent, if a patentee is genuinely not aware of which patents from a bundle of licenses are worked by the licensee, then Form 27 may "include the option "Not known to have been worked or not worked." However, if the patentee ticks off the option "Not known to have been worked or not worked," then the patentee should be obligated to provide information within a certain period, upon written request the Controller or any public, on the working or non-working of the patent for which the option "Not known to have been worked or not worked" has been exercised. The failure to provide this information should result in the patent at issue, i.e., the patent for which the option "Not known to have been worked or not worked" has been exercised and information on the working or non-working of the patent not provided, to be held unenforceable for fraud on the India Patent Office.

Conclusion:

The Indian statute's provision incorporating the local working requirement is a reflection of a negotiated flexibility fully authorized by the Doha Declaration. India needs to stand-by this requirement. Considering the failed Doha Round of talks in 2015 and considering the

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imposition by the US of steel and aluminium tariffs imposed on imports, India's needs to have renewed sense of confidence in its incorporated flexibilities. A robust generic drug industry is a national need for a developing country like India. Given its own violations of the WTO, the United States, which always lacked the legal standing to impose its unilateral Special 301 findings, will also lack the moral standing to require other nations to open its market to the detriment of its own public. In any case, in light of the invocation of Article XXI, any scrutiny of negotiated flexibilities such as the local working requirement will fall under India’s nation security requirement to ensure that public health is maintained.

Should you wish further details, clarification or information in this regard, I would be happy to provide clarifications that you may need using Webex or the phone.

SrividhyRavan=
Professor of Law
Texas A&M University School of Law
Fort Worth, TX
Ragavan.sri@tamu.edu
Dear Sirs,

I write in furtherance to circular number DIPP/2018/14 issued on 01\textsuperscript{st} March 2018.

In-light of the issued circular, we are enlisting the major issues we are facing related to submissions of Working of patents under the Patents Act, 1970:

- For some of the patented inventions which are worked in India, it is difficult to provide the total value of the patented product. (Such as inventions pertaining to process, data transmissions, authentication of products, etc.).

- When manufactured in another country, it is not possible to provide Total Value of Patented product manufactured or sold in that country.

- In some of the patented invention, It has been observed that some part of the patented invention is manufactured in India and remaining part(s) are manufactured in other countries; however, there is no such provisions on IPO online portal of F-27 to fill such information. (Such as in case of Automobiles inventions, etc.).

- When the patentee is using his technology in their product(s) or is licensing his technology to other(s), it generally comprises of multiple patents to form a single product and therefore it is not possible for the patentee to calculate the commercial value of an individual patent. (Such as in case of telecom industry, automobiles, etc.).

- For some of the patented inventions which were licensed, it is not possible for the patentee to keep track of the further sub licensee(s).

- In some scenarios we have observed that a worldwide assignment is made on the patented technology (such as in composition used in making lubricants, part of a product such as in aerodynamic inventions, etc.) with a licensee, who thereafter may or may not sub license/use the patented technology in the countries mentioned in the worldwide license. Further, we also observed that it is difficult for the licensor (i.e. patentee) to obtain information pertaining to working of invention in some specific country (such as in India) from the licensee. In such scenarios, it is difficult for the patentee to fill details regarding working of invention or commercial value of the patented technology in India.
In some of the patented invention because of the confidentiality agreement between the licensor (i.e. patentee) and licensee it is not possible to disclose the name of the licensee(s). (Such as technology pertaining to anti-counterfeiting, confidential license agreement with Governments, etc.).

In view of the above issues, being faced by us (i.e. agent on records for the patentee(s)), in order to furnish the mandatory details of the working of patented invention (Form-27), we request the Indian Patent Office to allow us to attend the stakeholders meeting of 21st March 2018. We would be keen to discuss the issues/scenarios in the submission of Form-27 so as to find an appropriate solution.

We look forward to hearing from you.

Best regards,