7 THE ISSUE OF WORKING OF PATENTS AND ITS IMPLICATIONS FOR DOMESTIC TRADE, ECONOMIC DEVELOPMENT AND TECHNOLOGY TRANSFER

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ABSTRACT

This article analyses issues related to working of patents and the unique statutory requirement of periodic reporting on the working of patents in India via Form 27 by the patentee and any licensees. The consequence of failure to report, late reporting, and wrong reporting of working of patents in India is discussed. It is concluded that the current Form 27 is outdated and out of context in the framework of present day international business practices and an immediate revision of Form 27 is recommended in India.

Key words: Working, Patents, Form 27, reporting, compulsory licence, Indian, 'non-practising entities'

I. INTRODUCTION

The world of patents has undergone metamorphic changes since its inception. The TRIPS Agreement through its tortuous negotiating history has attempted to harmonize intellectual property laws within its Member states. However, contentious

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issues involving diverse interest groups have kept debates alive regarding balancing the interests of inventors, intellectual property right owners and business groups on the one hand, and making the benefits of the patent system timely and affordably accessible to the public on the other. This tug-of-war between seemingly non-converging parties becomes complicated due to its multidimensional features, as is best enunciated and recognized in the preamble of the TRIPS Agreement, thereby capturing the sentiments and spirit of the agreement and laying the foundation for a holistic interpretation and understanding of its nuances.

The proceedings at the WTO in these bygone years have demonstrated that the last word acceptable to all Members of the WTO on the harmonious interpretation of the rights and obligations of a patentee has not yet been inscribed.

The preamble of the TRIPS Agreement is fairly comprehensive in its effort to reduce distortions and impediments to international trade by recognizing diverse aspects and interests related to the creation of adequate standards for intellectual property rights, which are private rights, including: effective intranational enforcement, policies, governmental agreements, conventions (such as those administered by WIPO), special needs of least developed countries, and multilateral procedures for disputes between governments. The preamble additionally recognizes the further need for a multilateral framework of principles and rules for dealing with international trade in counterfeit goods.

The various articles of the TRIPS Agreement therefore are to be read and interpreted in conjunction with the provisions of other agreements and/or conventions. Specifically, in the case of patents, the TRIPS Agreement has to be considered together with the provisions in the Paris Convention and the other conventions administered by WIPO.

II. CONTOURING THE ISSUES

A patent grants a negative right by way of a monopoly to the patentee for a limited period of time in the country of the grant to stop others from making, using, selling or vending the patented invention without the patentees consent.

One of the central points in the current debate continues to be whether the TRIPS Agreement precludes the possibility of legislated local working in certain Member states. The key questions raised are therefore 'whether the patentee is obligated to work the patent that has been granted to him', and if so, 'is the patentee obligated to local working of the patent granted to him in the country of grant' and further, if local working is an obligatory requirement, then, what is the interpretation of the expression 'local working' and further, 'the consequences of not having locally worked the granted patent'.

Historically 'local working' has been viewed as a device for the transfer of technology and industrialization, a means for foreign investments, for generating partnerships between the 'technology haves and have-nots', and the like. From a utilitarian perspective, arguments have mostly been in favour of the local working of patents, though there have been counter arguments from a bargain theory standpoint. Local working requirements have generally been considered as a tool to balance the exclusive rights of a patentee with his obligations towards contributing to public interests. Critical examination of local working brings forth several 'for and against arguments' to be considered. A recent study provides a checklist of elements to be considered in evaluating the benefits of local working requirements and suggests that below a certain threshold, which is malleable to the principle of graduation, exceptions to obligations under the TRIPS Agreement should be made.2

There is yet another dimension to the issue related to 'local working'. A legitimate question that may be posed is whether periodic reporting on 'local working' is a statutory requirement in the country in which the patent has been granted and what are the implications of non-reporting, insufficient reporting, wrong reporting and delayed reporting of the 'local working' to the appropriate authority in the country in which the patent has been granted. Further, what are the detailed statutory requirements of reporting of local working of patents?

The answers to these questions have major implications on trade-related and societal issues, especially when addressing the complex and strategic management of such patents/patent portfolios.

A patent grants the patentee the monopoly over his patented invention. However every system certainly discourages any monopolistic practices that would discourage or reduce competition in society. It ought to be appreciated that overuse of the monopoly could cross into the forbidden zone of monopolistic practices, a problem which anti-trust or competitive

¹ Adam Bierylo, 'Importing Doesn't Work: Justifying Local Working Requirements through a Historical, Theoretical, and Contractual Perspective' (2013) Volume 3, Issue 1

">http://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1065&context=uwojls>">http://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1065&context=uwojls>">http://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1065&context=uwojls>">http://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1065&context=uwojls>">http://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1065&context=uwojls>">http://ir.lib.uwo.ca/cgi/viewcontext=uwo.ca/cgi/viewcontext=uwo.ca/cgi

laws could address. 'Failure to work a patent' may be deemed to be abusive and, thus, may become a subject to the remedy of compulsory licensing.

III. IDENTIFYING THE RELEVANT PROVISIONS FOR CONSIDERATION

Working the patent is not mandatory as per US patent law. However this requirement features prominently in several other countries where 'failure to work the patent' in the country of grant, in a specified time-period, makes the granted patent vulnerable to the grant of a compulsory licence or even leads to the cancellation of the patent in that country.

A historical perspective of a few pre-TRIPS provisions is of significance:

- As early as in the 15th century, the Venetian Patent Act of 1474 mandated the active working of patents, and any failure to do so, could result in the cancellation of the patent.
- As early as 1623, the English Statute of Monopolies mandated provisions for the working of a granted patent.
- Article I, Section 8, Clause 8 of the US Constitution also provides the philosophical backdrop for the patent system as it considers it: 'To promote the Progress of Science and useful Arts'.
- The American Patent Act of 1790 provided Americans with monopoly rights to import foreign technology, without any obligation to protect foreign inventors' rights.
- The Bayh-Dole Act in the United States provides for march-in provisions for the government, if a federally funded invention is not worked in a specified time.
- Article 5(A)(2) of the Paris Convention states that each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

The TRIPS Agreement in Article 27(1) 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.

² Cottier Thomas, Lalani Shaheeza and Temmerman Michelangelo, 'Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements' Working Paper n 2012/11| June 2013, NCCR Trade Regulation,

http://www.wti.org/fileadmin/user-upload/nccr-trade.ch/wp3/Use it or Lose it June 2013.pdf

The key issue is whether the provision of Article 27(1) of the TRIPS Agreement is to be interpreted in isolation to the other provisions, such as Articles 2(2), 7, 8, 30, 31, 66³ of the TRIPS Agreement and other related international conventions and agreements, and what would be its ramifications?

A combined reading of the above interrelated provisions leads to the conclusion that Article 27.1 is to be read alongside all the other provisions and therefore 'local working' is an essential precondition for the patentee to meet his obligations to the

³ TRIPS Article 2.2:

'Nothing in Parts I to IV shall derogate from existing obligations that members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits'.

Article 7 of TRIPS

Objectives

'The protection and enforcement of intellectual property rights should 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'.

Article 8 of TRIPS

Principles

- '1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement'.
- 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'.

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 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: Subclauses (a) to (I)'. Article 66

Least-Developed Country Members

'2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base'.

society and to the country in which the patent is granted. Cottier $et\ al^3$ argues that an analysis of the apparent legal conflict between Article 5 of the Paris Convention and TRIPS Article 27 and whether countries should impose the local production of inventions, for which they grant a patent, should take into consideration broad concepts such as 'made in the world', a calculation of the costs and benefits of a local production for local communities, regions and technology sectors, and the economic reality.

The question of whether mere importation should be considered to be 'local working' would have to be responded to in a contextual manner, based on the nature of the patented product, the manufacturing capabilities in the country in which the patent has been granted, the cost of production, and several other business-related issues, and whether the mere act of importation would meet the reasonable requirements of the public in the country in which the patent has been granted without compromising national interests.

A recent article provides a detailed analysis of the diverse issues related to this debate.⁴ The matter related to *United States v Brazil* in the Dispute Settlement Body (DSB) led the WTO to consider the legality of local working requirements. In support of its arguments, Brazil claimed that Article 5.A(2) of the Paris Convention explicitly grants a right to make use of local working requirements. Further, it claimed the validity of Article 5.A(2) was reaffirmed by its incorporation into TRIPS Article 2.2, which requires that the Paris Convention's obligation should not be derogated. Interestingly, in July 2001, the case was mutually settled before a final decision could be reached. The settlement required that Brazil provide US officials with advance notice, prior to invoking Article 68 of the Brazilian Industrial Property Law. The legal position of this provision has remained unsettled.5

IV. OTHER EXTERNALITIES OF NON-WORKING REQUIREMENTS

Mandatory 'local working' may be considered as a corrective measure against the growing menace of 'Non-Practising Entities' (NPEs) and 'Patent Trolls'.

⁴ Bierylo Adam, 'Importing Doesn't Work: Justifying Local Working Requirements through a Historical, Theoretical, and Contractual Perspective', (2013) 3:1 online: UWO J Leg Stud 2 <http://ir.lib.uwo.ca/uwojls/vol3/iss1/2>

⁵ Champ Paul and Attaram Amir, Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of US-Brazil Patent Dispute, The Yale Journal of International Law 365-393, Vol 27 (2002); SSRNID 348660 : http://papers.ssrn.com/sol3/papers.cfm?abstract_id=348

The United States is already facing the heat of the proliferation of NPEs and 'Patent Trolls' as abusive patent litigation drags on its economy in terms of the wasted capital that could have been used to create new jobs, fund research and development (R&D), and create new innovations and technologies that would promote the progress of science and useful arts. This recognition has led to the passing on 5 December 2013 by a sound margin of 325 to 91 of the 'Innovation Act' (H.R. 3309), which is principally aimed at curtailing certain patent infringement litigation practices of Non-Practising Entities.

An exhaustive and illustrative study of US jurisprudence on patents and their non-use by Tyler⁶ makes cautionary remarks on the existing US patent system and strongly argues that utilizing compulsory licensing to combat patent non-use and technology suppression can help to better achieve the primary goal of the intellectual property clause of the US Constitution. Compulsory licensing that compensates inventors through reasonable and marketplacebased royalty rates will ensure that inventors continue to develop and disclose their research and discoveries to the public. Furthermore, by weakening intellectual property rights on a limited scale, Congress can ensure that patents are made available to the highest value users who can best use these patents to achieve efficient societal innovation and progress. Tyler therefore questions why patentees are not required to at least make good faith efforts to practice their patents.

A report entitled 'Patent Assertion and US Innovation' prepared by the President's Council of Economic Advisers, the National Economic Council, and the Office of Science and Technology Policy summarizes the present concerns in the US system as follows:

Patent Assertion Entities (PAEs) often abuse the US intellectual property system's strong protections by using tactics that create outsize costs to defendants and innovators at little risk to themselves. The PAE business model is based on the presumption that, in many cases, targeted firms will settle out of

court rather than take the risky, timeconsuming course of allowing a court to decide if infringement has occurred.

The practices of this group of firms, which has come to file 60 per cent of all patent lawsuits in the US, act to significantly retard innovation in the United States and result in economic 'dead weight loss' in the form of reduced innovation, income, and jobs for the American economy.

Improving policy in this area is challenging because maintaining the incentives for innovation provided by patents requires allowing litigation when patents are infringed, and because practicing firms sometimes act badly as well.

A key factor in the rise of patent assertion by non-practicing entities in each of these cases was a change in law or technology that led to uncertainty about whether a patent had been infringed (for example, the granting of large numbers of patents that were broadly written or that met only a low standard of non-obviousness). History suggests that it should be possible to address these challenges. There have been two periods when conditions arose for the PAE or "shark" business model to be profitable (Lamoreaux et al 2013). In both instances, once the underlying conditions were changed, this business model was no longer profitable and litigation of this type fell dramatically.

Thus, the best approach to resolving today's patent troll problem is not to ban firms specialized in patent assertion, but rather to reduce the extent to which legal rules allow patent owners to capture a disproportionate share of returns to investment (Lemley 2008). We see three main areas for improvement: clearer patents with a high standard of novelty and non-obviousness; reduced disparity of litigation costs between patent owners and technology users; and greater adaptability of the innovation system to challenges posed by new technologies and new business models.

Another recent report⁸ that summarizes studies from diverse sources, using different methodologies and

⁶ Tyler Neil, 'Patent Non-use and Technology Suppression: The Use of Compulsory Licensing to Promote Progress, 162 U. PA. L. REV. 451 (2014),

http://scholarship.law.upenn.edu/penn law review/vol162/iss2/5

⁷ 'Patent Assertion and US Innovation' prepared by the President's Council of Economic Advisers, the National Economic Council, and the Office of Science and Technology Policy and issued in June 2013 by the Executive Office of the President.

https://www.whitehouse.gov/sites/default/files/docs/pat ent report.pdf>

⁸ Bessen James, 'The Evidence Is In: Patent Trolls Do Hurt Innovation' Harvard Business Review, November 2014, https://hbr.org/2014/07/the-evidence-is-in-patent-trolls-do-hurt-innovation

performed by different researchers, concludes that a consistent picture is emerging about the effects of patent litigation initiated by patent trolls:

- It costs innovators money;
- many innovators and venture capitalists report that it significantly impacts their businesses;
- innovators respond by investing less in R&D; and
- venture capitalists respond by investing less in start-ups.

Rajkumar⁹ presents a multijurisdictional analysis of issues related to trolls and legitimate actors in diverse patent systems. He concludes that an open post-grant review system with punitive measures for non-working within a reasonable period after grant and reformulation of criteria for indemnifying patent holders could discourage the practice of 'patent trolls'.

Hildreth¹⁰ reviews the pros and cons of working of patents and Non-Practising Entities from the US and European perspectives. He concludes that introducing a statutory working of patents would be a positive step that would benefit the society at large and discourage hoarding of inventions by the Non-Practising Entities.

V. SPECIAL PROVISIONS IN THE INDIAN PATENT LAW ON WORKING OF PATENTS AND ON MANDATORY REPORTING OF WORKING OF PATENTS'

Several countries have a statutory requirement concerning 'working of patents'. In such countries, the failure to work a patent within three to four years without reasonable justification after the grant has been considered to be an 'abusive' act by the patent holder, making the patent vulnerable to the issuance of a compulsory licence³.

In Turkey, to satisfy the working requirement the patentee must file a 'one-time' certificate of use or file importation documents making an offer for licensing with the Turkish Patent Institute.¹¹ The

⁹ Rajkumar.V 'The Effect of Patent Trolls on Innovation : A Multi-Jurisdictional Analysis

http://www.nalsar.ac.in/IJIPL/Files/Archives/Volume%201/5.pdf

minimal specific action a patentee would need to take in order to fulfil the working requirements is filling a request with the Turkish Patent Institute for the publication of an offer for licensing in the Official Turkish Patent Bulletin. In the absence of the prosecution of any course of action regarding the working requirements, it is to be noted that the patent cannot ex-officio be revoked by the Turkish Patent Institute on grounds of non-use or failing to meet the working requirement of a patented product and/or process. The Turkish patent is not abandoned or invalided due to the fact that no working requirement is met in the prescribed deadline of three years as from the publication date of the grant decision. The possible consequence of not fulfilling the working requirement either by filling a 'Certificate of Use' and/or importation documents would be a compulsory licence granted by the courts upon request of third parties. Until now, there is only one case for which the court has granted a compulsory licence.

Interestingly, India is the only country that has a statutory requirement of 'working of a patent by the patent holder' and also statutory annual reporting of working of patents.

This unique feature in the Indian Patents Act is an outcome of the detailed analysis of Justice Aayyangar¹², whose report formed the basis of the Indian Patents Act 1970.

The most scholarly document that became the basis of the Indian Patents Act 1970 and subsequent amendments was the 'Report on the Revision of the Patent's Law' by Shri Justice N. Rajagopala Ayyangar, of September 1959, who had foreseen the value of 'working of patents' and recommended its mandated reporting in paragraphs 33-36 and 165-167. A few sentences from these paragraphs are of immense significance, even in the complex business ecology of today:

If for the maintenance of a patent in force the law requires that the invention should be adequately worked in the country, the patentees would be as anxious as licensees to ensure adequate working in their own interests. (paragraph 166)

Clause 105 of the Bill enables the controller to obtain information from patentees regarding the working of patents. Besides the Government, the Controller is in a position to know

Hildreth Heather, 'Should an Inventor be Required to "Work" the Patent?' December 2012.

<hr/>http://www.slideshare.net/hph5sr/should-inventors-be-required-to-work-the-patent>

^{*}http://www.deris.com.tr/faqs-for-patent-in-turkey.aspx

^{12&}lt;a href="http://www.scribd.com/doc/201678355/Ayyangar-Committee-Report">http://www.scribd.com/doc/201678355/Ayyangar-Committee-Report and
http://spicyip.com/wp-content/uploads/2013/10/ayyangar-committee-report.pdf>

whether the commercial working of a patent relevant to such industry has been started, and if so, what the current level of working is. In these circumstances, if the commerce minister is entrusted with the task of obtaining information regarding such working of patents, the Central Government would be well positioned to be a central gathering point for information regarding the working of patents. I would accordingly recommend the setting up of a unit in the Government for this purpose. This unit might also have the function assigned to it of selecting 'approved persons' for the grant of licences to work patented inventions relating to food and drugs etc. (paragraph

Section 146 of the Indian Patent Act 1970 (as amended in 2005) mandates the submission of a statement of 'working of patent' either when directed by the controller or annually, even without the controller's direction:

- (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 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.
- (3) The Controller may publish the information received by him under subsection (1) or subsection (2) in such a manner as prescribed.

Under Rule 131, the annual statement is to be submitted in Form 27 at the latest within three months from the end of the calendar year:

(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.

Details to be furnished in Form 27 are:

- (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:
- manufactured in India;
- ii) imported from other countries (give country wise details);
- (ii) licences and sub-licences granted during the year;
- (iii) State whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

If a patentee or licensee refuses or fails to furnish information required under Section 146, the patentee or licensee will be punished with a fine, which may extend up to ten lakh rupees under Section 122(1)(b). Further, in the event of wrongful information or statement, the patentee/licensee, can face up to six months imprisonment or a fine or both.

The expression 'working of patents' has not been defined in the Indian Patents Act 1970 (as amended in 2005). However the submission of the mandated Form 27 requires the patentee/licensee to fill out the details regarding working of patents, which have serious implications for decisions related to the meeting of a patentee's obligations in India.

The title of Section 83 of the Indian Patents Act is 'General principles applicable to working of patented inventions', which states:

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) 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) they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- (c) 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) patents granted do not impede protection of public health and nutrition and should act as an instrument to promote public interest, specially in sectors of vital importance for socioeconomic and technological development of India;
- (e) patents granted in no way prohibit Central Government in taking measures to protect public health;
- (f) the patent right is not abused by the patentee or the person deriving title or interest on patent, by, for example, resorting to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
- (g) patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."

It ought to be appreciated that lawmakers in India have clearly defined terms and expressions in the Act. However, Section 83 provides only 'Guiding principles', meaning all the factors will have to be taken into consideration when deciding 'whether a patent has been worked'. Therefore no single factor such as 'local manufacture' ought to be considered alone to arrive at the decision on whether a patent has been worked or not. Failure to file Form 27 or an incomplete Form 27 can lead to a possible presumption of non-working for the purposes of a compulsory licence

The recent decision on the granting of a compulsory licence to Natco in the *Bayer v Natco* case with respect to Indian Patent No. 215758 ought to be viewed from such a perspective. The question addressed in that case was 'whether Bayer had met the reasonable requirements of the public at affordable prices'. The arguments put forth by Bayer, as are apparent from the judgement of the

Controller General of Patents¹³, Trademarks, Designs and Geographical Indications and the subsequent judgements of the IPAB¹⁴ and the High Court¹⁵ were not convincing and hence the compulsory licence in favour of NATCO was upheld. The details of 'working of the patent' via Form 27 by Bayer were one of the factors considered in deciding whether Bayer had met the requirements of 'working of the said patent'.

The details of Form 27 provided in the Controller's judgement [paragraph 10(a)] are reproduced below:

Table 7.1

	Total Patients	Demand for 80 per cent of patients	Bottles per month required	Bottles imported in 2008	Bottles imported in 2009	Bottles imported in 2010
Liver Cancer	20,000	16,000	16,000	Nil	200 bottles	Unknown
Kidney Cancer	8,900	7,120	7,120			

The Controller, based on the details available in Form 27 as declared by Bayer and other arguments presented before him by both the parties in the matter, observed in paragraph 10(b) of the judgement:

Bayer imports the drug into India but has not taken adequate steps to manufacture the product in India to make full use of the invention. The drug is exorbitantly priced and out of reach of most people in India. The product is available in pharmacies attached to certain hospitals and in metro cities such as Mumbai, Chennai, Kolkata, and Delhi. The product is often out of stock or not available in common pharmacies even in metro cities. The product in question is not a luxury item but a life-saving drug and it is highly important that substantial part of the demand be met strictly. In the present case, even 1 per cent of the public does not derive benefit of the patented drug.

The information submitted in Form 27 has yet another function in infringement-related proceedings. Under Section 108 of the Act, a patent owner may file suit for infringement, including seeking an injunction and at the option of the plaintiff, either damages or an account of profits. The information submitted in Form 27 may be used

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<http://bombayhighcourt.nic.in/generatenewauth.php?aut h=cGF0aD0uL2RhdGEvanVkZ2VtZW50cy8yMDE0LyZmbmFt ZT1PU1dQMTEyODEzLnBkZiZzbWZsYWc9Tg== >

¹³<http://www.ipindia.nic.in/iponew/compulsory license 12032012.pdf> (see page 13 of the controller's judgement).

http://www.ipab.tn.nic.in/045-2013.htm

by the court to arrive at the amount of the appropriate relief.

VI. RECOMMENDATIONS

The argument in this article so far analyses that 'working of a patent' by the patentee/licensee and its structured annual reporting ought to be statutorily mandated. Such a mandatory 'working of patents' reporting system would have a positive influence on society and the business ecosystem at large, as it would encourage 'technology haves' to service the markets in which they hold patents, and simultaneously allow the 'technology have nots' to identify the technologies they wish to acquire. Such a self-alert system would also promote technology transfer and possibly create a self-regulated system, where the need for compulsory licensing would be minimized. Further, it would minimize the growth of undesirable patent trolls and expensive timeconsuming litigations. If structured appropriately, such a framework would also deliver the unfinished agenda of the TRIPS Agreement especially those agenda items related to innovation, technology and socioeconomic development.

Such mandated 'working of patents' reporting would also seamlessly interface with clauses in national competition laws to monitor possible abusive conduct of patentees or the creation of unfair dominant positions in the marketplace that are detrimental to public interest and competition.

The issue that remains to be addressed is whether the content and nature of disclosure, uniquely mandated in the Indian Patent Act, is useful to serve the purpose for which it was enacted.

The business ecosystem has remarkably changed since 1970 when the Indian Patents Act was fist enacted. The concept of one product linked to one patent is fairly outdated. The innovation system creates patent portfolios that include several inventions to create a domain of protection in an aggressive competitive environment. In its present form, Form 27 in the Indian Patents Act and Rules fails to live up to the present day business realities and hence needs to be redesigned such that its content and structure are relevant in today's global business and realities.

Global businesses in today's context are largely governed by a framework that attempts to minimize the barriers to crossborder trade, keeping in mind the national interest by the respective member states. The TRIPS Agreement has also been driving the political and socioeconomic agenda and occupies a significant status in most bilateral and multilateral negotiations. In such a demanding platform, it is recommended that the following factors be taken

into consideration in redesigning mandatory disclosures regarding 'working of patents' disclosure by the patentee/licensees:

- The quantity and quality of patents in the relevant market sector;
- the extent to which those patents have been put to practice and/or incorporated in local products;
- the portion of the market segment being serviced by those patents and whether those patents have been licensed and properly registered;
- whether the patented invention is produced through local manufacturing or created through imports; and
- whether the patented invention is not being used for local manufacture and the reasons for importation, if not.

Many such questions need to be addressed when redesigning Form 27 which will, on the one hand, meet the requirements of the patent system, and on the other hand, meet the modern demands of management practices of domestic trade, economic development and technology transfer.

A constructive debate on 'working of patents' and associated issues is now imperative in view of the ever increasing challenge to deliver 'the most from the least' and the metamorphic changes in internations' knowledge-led business transactions and trade. Is there any option other than a globally functioning cooperative fast delivering innovation chain, coupled with real-time optimized shared use of global physical, fiscal and human resources?

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