

THE ROAD AHEAD AFTER PATENT GRANT

The number of patents granted in a country does not contribute as much to its economic and technological development or to its standard of living as “working of patents” does.



Lucy Rana

Patent is a strong right, granting the patentee an exclusive right to prevent any unauthorized person from making, selling, offering for sale or importing the patented product or process provided that the invention satisfies the criteria of novelty,

inventive step and industrial applicability. In return, the Patent Office expects the patentee to disseminate the inventive knowledge to the public and work the patented invention to the fullest extent.

LEGAL OVERVIEW

Section 83 of the Indian Patents Act refers to the general principles applicable to

working of patent and assists in understanding the term “working” in India. Section 83 (a) states that the patents are granted to encourage inventions and to secure that the inventions are worked in India on commercial scale to the fullest extent without undue delay. Further, as per Section 83 (b), the patents are not granted merely to enable the patentees or licensees

	2009-2010	2010-2011	2011-2012	2012-2013
Patents in Force	37334	39594	39989	43920
Form 27 received	24009	34112	27825	27946
Reported as working	4189	6777	7431	6201

Source- Annual report 2012-13 published by the Indian Patent Office

to enjoy monopoly for importation of the patented article. Section 83 (c) and Section 83 (f) also discuss promotion of technology innovation, technology transfer and prevention of abuse of patent rights to unreasonably restrain international transfer of technology.

The Controller General of Patents in his notification on December 24, 2009 made it obligatory on the part of patentee and licensee (whether exclusive or otherwise) to submit a commercial working statement of a patented invention to the Controller in India. However the requirement for filing the information about commercial working of patents already existed but it is only now insisted by the Controller due to irregularity in filing of such statements.

According to Section 146 read with rule 131 of the Patents Act, the Controller may request for information from the patentee or the licensee(s) (exclusive or otherwise) of a granted patent to submit a statement regarding commercial working of the patented invention in India in a prescribed manner. The Controller may issue a notice in writing, intimating the patentee or licensee to furnish such information in Form 27 within a period of two months from the date of issue of such notice. Such statements must specify the extent to which the patent has commercially worked in India. As per Rule 131 this statement or declaration must be voluntarily submitted to the Patent Office within three months of the end of each calendar i.e. by March 31st of the following year. It is imperative to note

that the statement may be filed earlier than this “deadline” but the interval between two such statements should be at least six months. The Controller may publish such the information for public viewing. (<http://ipindiaonline.gov.in/workingofpatents/>).

Failure to submit the said information is punishable with a fine which may extend upto INR One Million. Further providing false information regarding working of an invention is considered an offence and is punishable with imprisonment upto six months or fine or both.

In the year 2012-13, as per the annual report published by the Indian Patent Office, it received 7946 statements of working of which 6201 were shown to be working.

TRIPS AND PARIS CONVENTION COMPATIBILITY

India is TRIPS and Paris Convention compliant and has provisions to check the misuse of monopoly over an invention. Article 27 of TRIPS discuss that patent rights shall be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. Also as per article 5 of Paris Convention, importation of the patented articles should not result in forfeiture of the patent and each convention country shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the patent rights abuses and the right to make laws providing for the grant of compulsory licenses in case of non-

working of a patent.

The Indian Patents Act does not bar the importation of patented article to India, however, if such an act prevents or hinders the working of the patented invention in the territory of India, then it would be deemed that the reasonable requirement of the public is not met, and would be considered as a ground for the grant of compulsory license

THE NEED AND BENEFITS

Apart from encouraging development in science and technology, the statement of commercial working of patents offers several advantages to the patent-holders.

• **BUSINESS SENSE**

Statement of working pertaining to a particular patent can help in estimating the strength/value of the patent. This valuation of a patent builds the patent portfolio and is important to analyze the commercial viability of the invention. Thus the patentee is better prepared to negotiate the cost while out-licensing his patent to a prospective licensee. Similarly, a licensee can also recognize the potential licensor based on the extent to which an invention is worked in the country. Additionally, by knowing the economic strength of a patent, the patent-holders can strategically identify their competitors and any opportunity for mergers & acquisitions.

• **INVESTMENT ESTIMATION**

The working of invention data may be helpful for small-scale industries to understand the effectiveness and

commercial viability of an invention so that they may customize their research and development (R&D) investments.

• ESCAPE COMPULSORY LICENSING AND REVOCATION

By commercializing his invention in the country, the patent-holder can avoid the risk of getting wedged by any party who's looking for an opportunity to obtain compulsory licensing based on the fact that the invention is not worked in the territory of India, 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 u/s 84(1) of Indian Patents Act. Furthermore, a patent may be revoked two years after the grant of compulsory license u/s 85 (Revocation of Patent for Non-working) of the Patents Act if any of the aforesaid reasons are still not met.

Conversely, the generic pharmaceutical companies can spot the patent-holders who are not being able to work their invention. Hence it's a possibility for them to acquire compulsory licensing on that particular invention and thus expand their business in the country.

IN THE CASE: NATCO PHARMA LTD. V. BAYER CORPORATION

The generic drug company Natco requested Bayer for a voluntary license for their patented cancer drug SORAFENIB TOSYLATE but the request was denied. Accordingly Natco filed an application with the Indian Patent Office for grant of a Compulsory License.

The Controller Of Patents, by considering the statement of working filed by Bayer found that all the three criteria for the grant of Compulsory License as per Indian Patents Act were satisfied in this case, namely:

1. Since Bayer supplied the drug to only 2% of the patient population, the reasonable requirements of the public with respect to the patented drug (Nexavar) were not met.
2. Bayer's pricing of the drug (Rs 280,428 per patient per month) was excessive and did not constitute a "reasonably affordable" price.
3. Bayer did not sufficiently "work" the patent in India.

Hence, Natco was granted a compulsory license to manufacture and sell a generic version of Nexavar under the conditions that it would pay a 6% royalty on the net sales (every quarter) to Bayer. Further, it could only charge Rs 8800 for a monthly dose (120 tablets) of the drug and would donate free supplies of the medicines to 600 needy patients each year.

Later Bayer challenged the order passed by the Intellectual Property Appellate Board (IPAB) in High Court. The Bombay High Court upheld the IPAB order.

• PATENT LITIGATION

In case of infringement, the patent owner, as relief, can seek injunction and damages or an account of profit under Section 108. The information submitted in statement of working can be used by the court to estimate the damages that may be awarded. On the other hand, in case statement of working is not filed, the alleged infringer may argue that the patent owner might not have encountered any damages in view of the missing statement of working.

Hence the direction to file the statement of working not only checks the misuse of exclusive patent rights but also drives an invention to satisfy the criteria of industrial applicability.

Ms. Lucy Rana is the Managing Associate Advocate of S.S. Rana & Co., a premier Intellectual Property Law Firm of India. She has read law at the University of Delhi with specialization in Intellectual Property Laws and is enrolled with the Bar Council of Delhi (2007). She spearheads the firm's IP team managing IP portfolios of several national and international corporations and advises clients on a range of contentious and non contentious IP matters.



Working for over 17 years in the legal and corporate world, she has an in-depth understanding of the micro and macro factors influencing businesses and aptly provides practical business legal advice to clients.

She also holds a Bachelors Degree in Japanese language from Jawahar Lal Nehru University, New Delhi. Additionally, she holds an Executive Diploma in International Business Management with specialization in Foreign Trade from the Indian Institute of Foreign Trade (IIFT), New Delhi (2004). She is actively involved in raising awareness of IP rights by penning articles and speaking on IPR issues in seminars organized by trade bodies and organizations such as FICCI, etc. She was nominated as "**Rising Lawyer of the Year**" by Legal Era, a leading national IP Journal. She is a member of several national and international IP organizations such as International Trademark Association (INTA), Asian Patent Attorneys Association (APAA), Inter Pacific Bar Association (IPBA), International Association for the Protection of Intellectual Property (AIPPI), **Supreme Court Bar Association and Delhi High Court Bar Association.**

She is also an avid adventure sports enthusiast and likes to play the piano in her spare time.

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