

COMPULSORY LICENSING UNDER THE PATENT SYSTEM IN INDIA

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I. Introduction

Scientific development rapidly invented new inventions in various fields worldwide. These inventions were infringed earlier, taking the rights of the innovator. In order to provide the rights of the patentee patents were granted. Indian also enacted Patent Act 1970, guaranteeing protection and enforceability for patent. This grant of patent created possibilities of lack of accessibility causing difficulties to poor population. Being very strict with the implementation of protection of patent, the TRIPS Agreement incorporated the flexibilities as a mechanism to enable countries for accessibility. On the basis of flexibilities, India adopted compulsory license to third parties for public interest and public policies.

I.I Patent License

Patent licence is a contractual agreement between the patent holder and licensee. It is an exception of exclusive patent right guaranteed under Patent Act, 1970. The patent licence plays a significant role and contributes potential economic development to the nation. The licence also generates new products or processes and dissemination of invention. It creates competition energizing the market principle and attains the ultimate goal of affordability to the people. There are two types of licences in patent law: voluntary and compulsory license.

I.II Voluntary License

Voluntary licence means arrangements between a patent holder and another party in a country, or serving the country's market, may afford opportunities for significant cost-containment. With negotiated discounts, the benefits of voluntary licensing arrangements depend crucially on the terms of the licence. For voluntary licenses, the capacity of the licensee is also critical. Several studies have found evidence that important patented inventions are generally not licensed voluntarily for financial considerations,

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except in exchange for patents or technical information of equal importance.²

The patent holder may at his discretion allot more voluntary licence to others, on exclusive or non-exclusive basis. The terms and conditions depend mainly between the parties. The price may be fixed according to the ratio of profit. Further, in voluntary licence, price will be fixed equal or above the sale price of the deal with profit motive among the parties.

II. Compulsory License

Compulsory licence is neither explained by Paris Convention nor by TRIPS Agreement but allows it at domestic and international level. Compulsory licence is a tool whereby nation allows itself or third parties to access to produce, use or sell the patented product or process without the consent of the patent holder. Compulsory licence is an extraordinary legal instrument mechanism provides when the patent holder lacks the use of patented product or misuse of patent holder's monopoly rights towards the protection of public interest or public policy.

Compulsory is defined as grant of license by government to use a patent without the patent holder's knowledge. Compulsory licenses are "involuntary contracts between a willing buyer and an unwilling seller imposed or enforced by the state".³ It is a right granted by the government allowing parties other than the patent holder to produce and sell patented product or use a patented process, without the consent of the patent holder.⁴ It is an authorisation granted by national authority to exploit without the consent of the patentee.

Compulsory licenses is an important sources by which the patented invention can be made available at a competitive price. The patent system in India provides the traders other than patentee to involve themselves to play a competitive role against the exclusive rights of patent holder in meeting the demands at the local and international market. Compulsory licensing is an integral part of patent system allowing third party to produce and market patented product or process without the consent of patent owner. This mechanism enables two objectives, rewarding the inventor and access to product at public desire during the patent period. Intervention of this

² Watal, Jayashree, *Intellectual Property Rights in WTO and Developing Countries*, Oxford University (2003), p. 317.

³ *Compulsory Licensing: Bridging the Chasm between Competition Policy and Intellectual Property Law*, www.legalserviceindia.com, accessed 07/10/2010.

⁴ 'Compulsory Licensing of Pharmaceutical Patents', *Economic & Political Weekly*, Vol. XLV, No. 39, 25 September 2010.

mechanism not only promotes dissemination of technology but also reduces price of the product.

International conventions and treaties on patent system envisaged strong protection and enforcement of patent system. In spite of its strong protection, international conventions and treaties recognised compulsory license. Paris Convention of Industrial Property (Paris Convention) in 1925, incorporated compulsory licence and stipulated members to adopt under valid circumstance. Thereafter, nations introduced compulsory licence into their respective patent law. Right to utilise the compulsory license by the World Trade Organization (WTO) members were further recognized by WTO Agreement on TRIPS in 1994. Concerning the impact of scientific and technology sector, the WTO member in its ministerial conferences recognized the grant of compulsory licence. TRIPS recognising the right to compulsory licence as flexibilities allowed the WTO members to determine the grounds upon such licences that are granted.⁵

Earlier compulsory licence was allowed under Paris Convention for non-working. Further in 1967, the convention determines the issue of compulsory licence under Article 5(A). Article 5(A) of Paris Convention stipulates that 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. Compulsory licence under the Paris Convention remains applicable even after the enforcement of TRIPS Agreement where the agreement provides that a member shall comply with Article 1 through 12 and Article 19 of Paris Convention.⁶

Compulsory licensing under TRIPS is covered under two Articles. Article 30 of TRIPS Agreement maintains a limited exception for compulsory license. Further, TRIPS Agreement states that exception does not unreasonably prejudice the legitimate interests of the patent owner taking into account of the legitimate interest of the third party. However, Article 31 is more concentrating on compulsory licence, where it conveys that for providing other use without authorisation of right holder and modulated conditions for using compulsory licence.

National laws of various countries has adopted the principle of compulsory license, but failed to meet the demand of essential patented commodities or products. Developing countries identified compulsory license as an important sources to fulfill the objectives of public policy. Compulsory license was first introduced in England at the end of the 19 century. The introduction of compulsory licensing was due to the fear of

⁵ Para 5(b) of Doha Declaration on TRIPS Agreement and Public Health.

⁶ Article 2(1) TRIPS Agreement.

dominant market by foreign traders who might buy the patent for exploitation. Another concern was patentee without disclosing patent would impede the technological progress. There was also risk that patents might be used to prevent the adequate supply of patented product. United States had issued compulsory licence in more than hundred anti-trust cases. The Chinese patent law grants compulsory licence for patented products for public interest.

Compulsory licence has been with complex of issues with respect to technical and legal aspect as far as India is concerned. With all its technical and legal complexity, it acts as an important mechanism to meet the needs of the public. National Bureau of Economic Research (NBER) working paper, indicates that compulsory licensing is a strong and persistent positive effect on domestic invention.⁷ Blogger J. Matthew Buchanan,⁸ states that compulsory licensing provision under the new patent amendment is a direct threat to the integrity of the new patent provisions in India.

Compulsory license is permitted by the patent office only under certain contingencies specified in the Patent Act, 1970. Compulsory licence can be granted in relation to any of the right conferred by a patent including manufacturing, importation, and exportation of patent-protected product.⁹ This implementation of compulsory licence stabilizes economic growth, and harmonization of patent system.

II.I Grant of Compulsory License

Grant of patent system should not only benefit the owner, but also serve the public in all fields. There is always a danger that the patent holder will abuse monopoly rights granted to him. To prevent such abuse Indian Patent Act provides compulsory licence with conditions. The Compulsory licence is granted not only for non-working but also for other available circumstance. Any person interested in the production of patented products can approach the government to issue of compulsory licences on patented product on grounds specified with terms and conditions under sections 84 and 90 of the Patent Act, 1970, respectively. Allowing compulsory licensing, the patent holder must be given a chance to hear to object or any adverse decision against their interest under Section 87 of Patent Act, 1970. Both common law and statutory law contemplate right to hearing by the controller as being a principle of natural justice.

⁷ Discussion paper on Compulsory Licensing, 24 August 2010, accessed, NBER working paper (15598)—Compulsory Licensing: Evidence from the Trading with the Enemy Act, by Petra Moser and Alessandra Voena, December 2009.

⁸ Patent Attorney in the United States.

⁹ Article 28.1(b) of TRIPS Agreement, Patent protected products includes patents on products as such, as well as products directly obtained by patented process.

II.II Condition of Compulsory License

The first and foremost condition is that compulsory licence cannot be granted unless three years period has been lapsed from the date of patent. This position again endangers the respective field or sector becoming helpless for first three years on every new patent allowing the public to suffer without any solution. Further condition includes, payment of royalty or other remunerations to the patentee, licence granted is a non-exclusive licence and non-assignable. The term of licence is usually for the balance term of patent unless a shorter term is consistent with public interest and not available at a reasonable affordable price not worked to the fullest extent by the patent holder.

II.III Grounds of Compulsory License

Diverse ground are available for granting compulsory licensing such as refusal to licence, public interest, public health and nutrition, national emergency or situation of extreme urgency, anti-competitive practices, dependent patents, failure to exploit to insufficiency of working. Article 31 of TRIPS Agreement sets forth the possible grounds for granting compulsory licence and the Agreement also permits the WTO member to adopt other grounds such as non-working, public health or public interest. Originally, compulsory licence was adopted to force the patentee to work his invention, but presently, due to increase of population, their requirements and public emergency and other grounds are also considered nationally.

The essential proposition of a compulsory licence is that a new invention (medicine) product must be patented either product or process. Patent is territorial in nature and exception to it would provide under domestic patent law. However, the grounds conferred on compulsory licence differ from one country to another and differ with procedure for its application. One of the ministerial conference of WTO confirms right to compulsory licence under the following grounds other than what is envisaged in TRIPS. They are:

- (a) National emergency or situation of extreme urgency
- (b) Dependency of patents
- (c) Licenses to remedy anti-competitive practices
- (d) Lack of or insufficient working of the patent
- (e) Refusal to deal
- (f) Public interest
- (g) Public health

The US Supreme Court makes it amply clear that in the US apart from mere 'ownership' of patent system some additional exclusionary conduct is essential for a grant of compulsory licence. In the US, compulsory licences are provided under six categories.¹⁰ They are:

- (a) Mandatory compulsory licence for patents whose term was extended by GATT implementation;
- (b) Cases involving government use under 28 USC 1498;
- (c) Cases involving the Bay Dohl Act;
- (d) Cases involving merger reviews;
- (e) Cases involving non merger remedies to anti-competitive practices; and
- (f) Cases subsequent to the Supreme court opinion in eBay versus Merc Exchange.

The grounds for grant of compulsory licenses are determined by national laws. In India compulsory licence is allowed under the following grounds when the central government satisfied at any time after the sealing thereof to work the invention:

- (a) Circumstances of national emergency
- (b) Circumstances of extreme urgency
- (c) In case of public non-commercial use

The general principle for granting compulsory licenses 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 practicable¹¹ and the interest 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.¹²

II.IV Non-working of Patented Product at Domestic Regime

Another area for issuance of compulsory licence is non-working of patented product at the domestic regime. The grant can be claimed if the required demand is not met by the public. Compulsory licence is allowed on two grounds for non-working of patent product:

- (a) The invention is not worked in the territory of India.

¹⁰ Discussion Paper on compulsory licensing, 24 August 2010.

¹¹ Section 89(a) Patent Act, 1970

¹² Section 89(b) Patent Act, 1970

- (b) The reasonable requirements of the public is not being met.

The term working in the territory of India would mean either new invention manufactured in India or make available for local sale. Article 27(1) of TRIPS stipulate that patents shall be available ... whether products are imported or locally produced. So TRIPS clarifies that if the products are affordable at the market, the issue of patent cannot be differentiated whether manufactured within a country or imported from foreign country.

II.V Government Use

In case of government use of patent, the Patent Act, 1970, states that adequate remuneration in the circumstance of each case, taking into account the economic value of the use of patent. Patentee at R&D would have utilized financial input and other factors including the labour, etc.; therefore, while calculating the royalty, cost and labour must also be included benefiting both licensee and patentee provoking for future R&D. The compensation entitled by the patent owner must be of a proper measure where it should be that what the owner has lost, not what the taken has gained.¹³

II.VI Export of Patented Product

Compulsory licence is a mechanism to assist other countries with no manufacture capacity. Export of patented pharmaceutical product was restricted by TRIPS which was later waived in 2003. Original TRIPS Agreement allowed compulsory only for domestic use under Article 31(f)¹⁴ of TRIPS Agreement. To implement Para 6 of Doha Declaration, Article 31(f) was waived and allowed WTO members to issue compulsory licence for producing generic version drug for export to least developed countries (LDCs) and other developing countries which have insufficient manufacturing capacity in pharmaceutical sector.

The Patent (Amendment) Act, 2005, has inserted new Section 92-A for issuance of compulsory licensing for export of patented pharmaceutical products¹⁵ in exceptional circumstances. Earlier, general principle of Section 84 of Patent Act, 1970, was followed to grant licence. The Act provides that compulsory licensing is allowed to manufacture and export of patented

¹³ *Hughas Aircraft Company vs. The United States.*

¹⁴ Article 31(f) of TRIPS Agreement, such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use.

¹⁵ Pharmaceutical Product 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.

pharmaceutical products to any country having insufficient or no manufacturing capacity in the respective sector for the concerned product to address public interest.

III. Implementation of Compulsory License

Compulsory license has various complex issues in its implementation. The difficulties are lack of specific requirements in determining eligibility for compulsory licensing, risks of arbitrage and remuneration.

(a) Risk of Arbitrage

Arbitrage is also known as parallel trading. It is a problem that manifest when a buyer purchases products at below market price and subsequently exports to another market where they are priced high. In terms of economic theory, arbitrage essentially shifts surplus from the producers to the consumer. Arbitrage poses threat to innovation as this attempt to provide affordable products through differential prices reducing the revenue required for further research and development.

(b) Remuneration

With respect to grant of compulsory licence Indian Patent Law eventually specifies that royalty and other remuneration should be reasonable considering the nature of innovation expenditure incurred by the patentee during his research and other relevant factors.¹⁶ Further, the licence holder must work only with a reasonable profit. A patent owner can make an appeal with regard to remuneration which is subject to judicial review or other independent review by a distinct higher authority in that member.¹⁷

Compensation is an essential element of compulsory licence satisfying the due process clause.¹⁸ TRIPS has not defined remuneration concerning compulsory licence. TRIPS Agreement stipulates that grant of compulsory licensing must be with adequate remuneration. Neither the TRIPS nor the Patent Act, 1970, defines what amounts to adequate remuneration or the procedure for calculating the remuneration to be awarded to the patentee. The agreement simply states that remuneration shall be determined taking into account the economic value of the

¹⁶ Section 90(1) Patent Act, 1970.

¹⁷ Article 31(j) of TRIPS Agreement.

¹⁸ *Florida Prepaid Postsecondary Education Board vs. College Savings Bank*, Prescription Drugs: India Values Their Compulsory Licensing Provision—Should the United States Follow in India's Footsteps?, <http://gollath.ecnext.com>, accessed 08/01/2011.

authorization. But it is not defined what constitutes economic value or determined to calculate for the remuneration.

The licence holder must consider for royalty or adequate remuneration. If the reward is insufficient, the owner of the patent fails to recoup the investment on R&D and the inventor will not revamp further invention or development. The payment of royalty or remuneration must be consistent with the TRIPS Agreement. United Nation Development Program (UNDP), Human Development Report (HDR) 2001 specifies that royalty can be at a rate of 4 per cent. In most of the developing countries, royalty rate is less than 3 per cent.

In the US, grant of compulsory licence, is subject to liability for payment of compensation. Most of the dispute leading to litigation in the area of compulsory licenses has been on the matter of adequacy of the compensation package which has ranged from 0 to 10 per cent of sales.¹⁹

In India, the mode of payment of royalty is not specified under the Patent Act, 1970, but, simply specifies that the patentee must be paid an adequate remuneration with similar footings of TRIPS. Further, the Act fails to define what amounts to adequate remuneration and moreover states that if a dispute arise regarding remuneration it must be dealt with the High Court.

IV. Conclusion

Patent often affect the accessibility of new invention in all fields. The TRIPS Agreement and other respective conventions argue that there should be a balance to formulate the public policies of the nation. Compulsory license should be adopted to increase the access of patented product as specified in the ministerial conference of WTO, “the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provides flexibilities for this purpose. Arrangement of compulsory licence existing in Patent Act, 1970, should be activated to secure a balance between interest of the producers and users of the patented products. The act must consider a valuable method for calculation of remuneration to patent holder, further must clearly define the grounds for compulsory licence.

¹⁹ Nair, M. D., ‘Compulsory Licenses Imbroglio: Provisions under TRIPS and Their Interpretations’, *Journal of Intellectual Property Rights*, Vol. 9, September 2004, p. 417.