



COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN INDIA

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Abstract-- Patents give exclusive privileges for the holder of patents on their novel, creative and creations. Patents are usually permitted with belief that the holder of patent would carry the creation in the absence of unnecessary stoppage on the economic range to the entire length as far as possible. However, there are certain situations where the patent privileges may be subject to misuse by the holder of patent. To safeguard those misuses some provisions of compulsory license are granted under the law of patent i.e. The Indian Patent Act, 1970. This paper basically ends with providing means to enhance the provisions of compulsory licenses in India.

Key Words: Patent Act, misuse of patent, patent, Agreement on TRIPS, compulsory licensing.

INTRODUCTION

Basically, patents are the absolute privileges given to an individual that creates a novel and valuable process or product. Further, a patent grants an exclusive privilege for a period of 20 years to the owner of patent so as to restrict remaining peoples from misusing the creation¹. Moreover, the patents are particularly granted to the creators for their ability, exertion as well as assets to stimulate the novelty². The Government provides the patent provided that the creator has fully revealed the creation³. Unless there is existence of scheme⁴ of patent the creator will not be in a position to be cheered to reveal his creation and he may opt to maintain his creation as trade secret, which may result in apathy to the progress of fresh machinery⁵.

The study in the area of pharmaceuticals and medicines is costly, time absorbing and particularly unforeseeable in essence. Creator's pharmaceuticals associations hence make efforts to achieve their study patented so as to restrict market access of their opponent's narcotic drug associations. Further, there may be situations when the patent privileges are misused by the creators of patent⁶. The pharmaceuticals associations that are in possession of patent privileges may not cheapen the patented medicines in their own nation or may also not grant the medicines in requisite amount to accommodate the needs of the community and they may also raise the value of the medicine very huge. Medicines being the most important product, the misuse activities by the associations can greatly provoke the agony of the inmate, particularly the indigent peoples.

In an effort to restrain the misuse of patent privileges⁷, provisions of the concept of compulsory license are introduced in the laws of patent. The WTO i.e. World Trade Organization⁸ has explained the meaning of the concept of Compulsory Licensing as a process where the government grants other person to develop the patented commodity or to the patented method beyond the assent of the holder of the patent. So, the Compulsory Licensing⁹ is the main part on preservation of patent incorporated under the agreement of TRIPS¹⁰.

¹ Compulsory license under agreement on TRIPS, Gupta R.

² See Journal of Intellectual Property Rights. Compulsory Licensing under the TRIPS.

³ See Intellectual Property Rights in India: Significance of Patents.

⁴ See Journal of Intellectual Property Right, Volume 16.

⁵ See the case of Natco Pharma Ltd. v/s Bayer Corporation, 2012.

⁶ See Compulsory Licensing of Medicines and Pharmaceuticals by Chaturvedi.

⁷ See the effects of compulsory license on innovation and access to health care.

⁸ WTO is a global institution that deals with norms of trade among nations.

⁹ This concept was brought by U.K. in 1623 by its Statutes of Monopolies.

¹⁰ See Compulsory Licensing of TRIPS and Pharmaceuticals.



The Compulsory Licensing is basically an unintentional agreement betwixt an active purchaser and reluctant vendor levied or sanctioned by the legislation¹¹. It enables a third body to prepare, benefit or advertise a patented creation beyond the assent of the owner of patent. Basically, in India the concept of Compulsory Licensing and the authorization of patent privilege are guided by the Indian Patent Act, 1970.

INTERNATIONAL ORGANIZATION GUIDING COMPULSORY LICENSING¹²

A) Paris Convention

The Paris Convention on Protection of Industrial Property properly considers representative's privilege to provide compulsory license. The number of members of are 176 including India¹³. As per its Article 5A, representatives can provide licenses to restrain misuse of privileges of patent. Provided that:

- 1) One cannot administer for the compulsory license if there is deficiency to perform or inadequate working prior to termination of term of 4year from the date of registering of application for patent or 3 years from the date on which the patent was permitted have transpired¹⁴.
- 2) In case patentee shows his inability by valid logics, his license may be declined.
- 3) The license must be non-absolute and non-assignable.

B) Trade-Related Aspects Of Intellectual Property Rights¹⁵

ARTICLE 30: Representatives may give definite exclusions to absolute privilege granted by the patent but the condition is that such patent should not irrationally compete with profiteering of patent and should not irrationally affect valid interest of patent holder.

ARTICLE 31: The Trade Related Aspects of Intellectual Property Rights governed by the WTO comes into force on January, 1995. The agreement on TRIPS has established the rules of IP for the manufacturing schemes throughout the nation. Moreover, it has set up lowest guidelines/necessity for the safeguard of Intellectual Property which is to be accepted by all its representative nations. Further, agreement of TRIPS provides some adaptability which allows developed and minimum-developing nations to adopt the standards of TRIPS in such a way that allows them to seek their individual procedure like safeguard of public well-being and advancement of connection to drugs¹⁶.

There is no explicit mention of the concept "Compulsory Licensing" in the agreement of TRIPS but it is recognized in Article 31 of TRIPS. This concept is an element of TRIPS adaptability which desires to maintain a harmony betwixt popularizing approach to existent medicines and popularizing study and progress in fresh medicines¹⁷.

The essential necessity under Article 31 of TRIPS agreement for the compulsory licensing¹⁸ is as follows:

- 1) Authorizing on personal virtues: Every application for the authorization of compulsory license to be recognized on personal virtues. This is provided under Article 31(a).

¹¹ See the Journal of Technology and Law, 1993.

¹² See compulsory licensing: An emerging trend towards Indian-patent regime.

¹³ See Compulsory licensing- need or not?

¹⁴ See WIPO: Paris Convention for Protection of Industrial Property, 1883.

¹⁵ See WTO legal texts- summary of Uruguay Round.

¹⁶ See WIPO. TRIPS Agreement.

¹⁷ See TRIPS and Pharma patents.

¹⁸ See Instances of health-related compulsory licenses.



- 2) Earlier attempts is essential for acquiring compulsory license: The only requirement through which compulsory license might be granted is if the aspirant has formed earlier attempts to acquire willing license from the person granting patent on justified agreement. This provided under Article 31(b).
- 3) License in matter of semi-conductor machinery: Here, the license will be granted exclusively for non-profitable usage or to cure aggressive business activities. This is given under Article 31(c).
- 4) Non-absolute ground: The license will be provided only upon non-absolute grounds which are given under Article 31(d).
- 5) Non-transferrable: The license granted cannot be transferred further. This is provided in Article 31(e).
- 6) Potent usage for the domiciliary business: The license will be given exclusively for the purpose of potent usage in the domiciliary business¹⁹ of that nation which is providing the license. This is in Article 31(f).
- 7) Expiration of Compulsory License: If the demand has been made by the patentee to the efficient administrator for the expiration of license then he can expire his license as per Article 31(g).
- 8) Sufficient compensation to the patentee: After taking into consideration the financial worth of license given there shall be provides a sufficient compensation to the patentee. This is laid down under Article 31(h).
- 9) Judgment on the basis of legal analysis: The constitutional legitimacy of all the judgments is based on legal analysis in the nation that provides the license as given in Article 31(i) and Article 31(j).
- 10) Appropriate scrutiny in matters of contradictory activities: If it is seen that the patentee is involved into contradictory activities then the representative nations is not bound to administer the situations of “previous attempts of the claimant essential to achieve a willing license”. This is given under Article 31 (k).
- 11) Licensing of connected patent: Partner of a patent can administer for the permit of license in regard to other patent. This is provided under Article 31 (l).

C) Doha Declaration Of Public Health And Trips²⁰

The fourth clerical seminar²¹ of WTO took place in Doha, on 14th of November, 2001. In this seminar “Declaration on Public Health and Agreement on TRIPS”²² was accepted by the representatives of WTO²³.

The following things were considered and guaranteed by representatives of WTO, as per the Doha Declaration:

- a) The agreement on TRIPS must not restrain representatives from adopting means to safeguard well-being of community.
- b) Every representative has privilege to decide what comprises interstate necessity²⁴ or other situations of intense necessity²⁵.
- c) Every representative has privilege to provide licenses.

The main point to be noted is that the 6thPara of the Doha Declaration considered that the agreement of TRIPS narrowed the competent usage of licensing in those nations that does not possess requisite production ability in the field of pharmaceuticals. It was also given in Article 31(f) that the license will be

¹⁹ See World Trade Organization.

²⁰ This concept was adopted in Doha on 14th November, 2001.

²¹ See The Doha Round’s Public Health Legacy.

²² See Doha Declaration on Public health and TRIPS.

²³ See Canada’s Access to Medicines Regime,” American Journal of Law & Medicine”.

²⁴ See Population of India, Google.

²⁵ See India’s Population, Google.



given exclusively for the purpose of potent usage in the domiciliary business of that nation which is providing the license²⁶.

The WTO's General Council in 2003, accepted the judgment on fulfillment of 6thPara²⁷ of the Doha Declaration on Public Health and TRIPS, and this lastly concluded in the shape of Protocol to rectify the agreement of TRIPS in the year 2005²⁸. Finally, the 6thPara rectified Article 31(f) and permitted representative nations to grant licenses for transport of patented pharmaceuticals commodities to the nations with inadequate production abilities in this field.

PROVISIONS OF COMPULSORY LICENSE IN INDIA

Sections 80 to 92 given in Chapter XVI of Indian Patent Act, 1970 provides for the permit of license. Further there are also some rules contained under Rules 96-102 provided under Chapter XIII of Patent Rules, 2003²⁹ that talks about compulsory license³⁰.

i) Compulsory License under section-84

A license may be permitted to willing individual only after termination of period of 3years from the date of permit of patent on any one the below given criteria which are as follows:

- a) Creation that has obtained patent is not accessible to the community at a justified low-cost amount.
- b) Creation that has obtained patent is not processed in the Indian domain.
- c) A justified criterion of community with regard to the creation that has obtained patent has not contended.

ii) Compulsory license for trading of pharmaceuticals commodities as per section 92A³¹

This section permits production and trading of pharmaceuticals commodities³² to nations with deficient or no productions abilities for the said pharmaceuticals commodities to address the well-being issues of community³³. They will be given license on a condition that they permit a license to the aspirant (if commodity gets a patent in that nation) or if they permit admittance of those pharmaceuticals commodities that got patent from India (if the commodity does not get a patent in that nation).

Case: Natco v/s Bayer Case³⁴

On 9th of March,2012 the very first compulsory license of India was given by office of patent to the Natco Pharma limited, for the purpose of manufacturing generic form of Nexavar that was a patented commodity of the Bayer's Corporation and which is helpful in the cure of cancer of kidney and liver.

The matter was decided by the Controller wherein he was against the Bayer³⁵ on all the three parameters that were provided under section-84³⁶ of Indian Patent Act, 1970.

²⁶ See the Limitations of Compulsory Licensing. The Health Law Journal.

²⁷ See doi:http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

²⁸ See World Trade Organization. The Amendment of TRIPS Agreement.

²⁹ See Indian Patent Act, 1970 as amended in 2002 by Patents (Amendment) Act.

³⁰ See Manual of Patent Practice and Procedure.

³¹ See Natco Pharma Ltd. v/s Bayer Corporation.

³² See Indian Pharmaceutical Industry Report.

³³ See Gene Patents and Public Health.

³⁴ See Intellectual Property Appellate Board, Order No. 45/2013.

³⁵ See Economic Times, 4th March 2013.

³⁶ See Vishwanthan M. The government refused to revoke Novartis patent.



COMPULSORY LICENSE IN COMPLIANCE WITH TRIPS OR NOT?

To identify if India has abide by the TRIPS necessity for the compulsory license, we have made contrast between the provisions of compulsory license as per the agreement on TRIPS and the Patent Act, 1970.

Comparison

S.NO.	TRIPS necessity for compulsory licensing	Appropriate section in Patent Act,1970	India abide by TRIPS (Yes or No)
1	Authorizing on personal virtues. Under Article 31(a).	Section 84(6) (i), (ii) and (iii)	Yes
2	Earlier attempts are essential for acquiring compulsory license. Under Article 31(b).	Section 84 (6) (iv)	Yes
3	License in matter of semi-conductor machinery. Under Article 31(c).	Section 90 (1) (viii)	Yes
4	Non-absolute ground. Under Article 31(d).	Section 90 (1) (iv)	Yes
5	Non-transferrable. Under Article 31(e).	Section 90 (1) (v)	Yes
6	Potent usage for the domiciliary business. Under Article 31(f).	Section 90 (1) (vii)	Yes
7	Expiration of Compulsory License. Under Article 31(g).	Section 94	Yes
8	Sufficient compensation to the patentee. Under Article 31(h).	Section 90 (1) (i)	Yes
9	Judgment on the basis of legal analysis. Under Article 31(i) and (j).	Section 117A	Yes
10	Appropriate scrutiny in matters of contradictory activities. Under Article 31(k).	Section 84 (6) (iv) and Section 90 (1) (ix)	Yes
11	Licensing of connected patent. Under Article 31(l).	Section 91	Yes
12	Trading of patented pharmaceutical commodities.	Section 92A	Yes

From the above analogy it is clear that all the necessities for licensing as given in agreement on TRIPS in in consonance with the Patent Act, 1970. So, it can be wound up by saying that all the provisions of licensing under Patents Act, 1970 are completely in compliance with TRIPS.

CONCLUSION

So, the compulsory licensing is an efficient instrument to safeguard the misuse of privilege of patents. Representative nations are allowed to permit license as per agreement on TRIPS. From the above analysis it is clear that all the parts of compulsory license are in consonance of agreement on TRIPS. Till now, there is a single license which is given to India and that is also in consonance with already existent international trade norms. The important goal of compulsory license is to reform approach to patented drugs. Due to this there is a rise of clash in the domestic market which further results in lowering of value of medicines.



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Further, Agreement on TRIPS as well as Doha Declaration regarded compulsory licenses as an essential ingredient to grant advantage of well-being to the community without doing any kind of prejudice in respect of complexion, race, religion or nation. So, basically it grants adaptability as the necessity of each nation and each ailment varies.