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VOLUNTARY LICENSING: A NECESSARY ALTERNATIVE TO COMPULSORY LICENSING IN THE PHARMACEUTICAL INDUSTRY

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Introduction

The main objective of the grant of any patent is to incentivize innovation and give the inventor the monopoly subjected to a limited period. However, the main debate exists between the advocate of the public health interests and the economic benefits derived by the multi-national companies from that invention. The protection under TRIPS ensures that these public rights are not overridden by the private rights. To ensure the objective of the same, Governments use the tool of Compulsory Licensing to that allows the use of patented invention without the consent of the patentee. This mechanism basically tries to establish an equilibrium between the rights of the public while also making sure that the patentee is awarded a reasonable reward for the patent, safeguarding the private rights of the patentee. Rights obtained through compulsory licenses are generally regarded as equivalent to those granted directly by the patentee.[1] While it is contested that in the case of pharmaceutical products, it helps in the availability of affordable drugs in the developing countries while at the other hand a parallel debate exists that this kills the innovation and hampers the enthusiasm for further research and development.[2]

Compulsory Licensing Under TRIPS And In India

Article 7 of the TRIPS states that "*...to transfer 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".*[3] This provision elucidates not only the protection to the innovation but also to protect the economic and social benefits of the society. Article 8(1) provide freedom to the countries to adopt appropriate policies to protect the socio-economic interest in public health. Article 8(2) further puts that "*appropriate measures, may be needed to prevent the abuse of intellectual property rights by*

[1] TRIPS Agreement, Apr 15, 1994, Article 31 (h), 33 I.L.M. 1125 (1994).
[2] Cf lain M Cockburn, Intellectual Property Right and Pharmaceuticals: Challenges and Opportunities for Economic Research, Wipo's The Econs. Of Intell. Prop. 150, 160-161 (2009)
[3] Article 7, TRIPS (n 1).

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right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."[4] This provision basically provides a sword against the monopoly enjoyed by the patent holder.

The conditions pertaining to Compulsory Licensing provides the precondition of the attempt of the applicant to get a voluntary license from the patentee and such attempt from the applicant must have failed. In that case, Compulsory Licensing is used on the lines of the grounds mentioned in the TRIPS.[5] While the definition of Compulsory Licensing is absent from the TRIPS agreement, Article 31 provides 'on other use without the authorization of the right holder', specific conditions under which Compulsory License can be granted. These are basically 5 grounds under the TRIPS which include: -

i. *Refusal to deal*
ii. *emergency and extreme urgency,*
iii. *anti-competitive practices,*
iv. *non-commercial use,*
v. *dependent patents*

Many countries provide the explicit provision of Compulsory Licensing in their domestic legislations. To align with the TRIPS regime, India amended its patent law thrice in 1999, 2002 and 2005. Like the other developing nations, Compulsory Licensing emerged as the sword against the monopoly practices and prices by the patent holders. Section 83 provides for encouraging for the innovation and to ensure that inventions are worked in India on its fullest commercial scale. Section 84 provides the concept of Compulsory Licensing and gives the circumstances when they can be granted. These are: -

i. *After three years of grant of patent appicatioon to the controller of patents.*
ii. *The reasonable requirement of the public has not been met.*
iii. *That the patented invention is not available to the public at a reasonably affordable price.*
iv. *That the patented invention is not worked in Indian Territory.*

[4] Article 8(2), TRIPS (n 1).
[5] JH Reichman, Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, The Yale Law Journal, 46 (8) (2009).

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Shortcomings of Compulsory Licensing

Interpreting the TRIPS provision, compulsory licensing was initially viewed as something to be invoked only in extreme circumstances or in situations of dire need. Article 31 of TRIPS provides authorization under the extreme cases of national emergency, extreme urgency or the non-commercial use for the public.[6]

A major concern for the pharmaceutical companies is the looming problem of 'Parallel Imports' after the Compulsory License is granted in any country. The gray area created by the compulsory licensing in any country gives the opportunity to other players to take advantage by the difference in prices in various markets where the compulsory licensing regime did not intend to reach.

Another hurdle is of the pharmaceutical giants entering new markets of these developed and underdeveloped countries with their ambitions of reducing patent life and the looming uncertainty to patent protection and ever-present fear of enabling local generic manufacturing companies competing at the reduced prices under Compulsory Licensing without keeping the cost of production in consideration.[7] Compulsory Licensing mechanism in these countries is sometimes people driven.[8] As healthcare cost continue to rise, these countries are pressured up to reduce the prices of drugs which are very expensive and are outside the domain of the common people.[9] This likely starts as a practice where Compulsory Licensing is used as a tool to ensure essential medication to common masses. The one size fits all strategy of developing countries to lower down the prices of pharmaceutical drugs does more damage than the benefits of price reduction.

One of the biggest concerns against compulsory licensing are the international setbacks. One of them being the decrease in Foreign Direct Investment (FDI) for developing countries like India. For example, U.S. has been vocal about its disapproval of the *Bayer Corporation v. Natco Pharma Ltd* [10] decision, arguing that such rulings undermine patent rights and could

[6] Article 31, TRIPS (n 1).
[7] Cockburn (n 2).
[8] Kristina M. Lybecker, Elisabeth Fowler, Compulsory licensing in Canada and Thailand: comparing regimens to ensure legitimate use of the WTO rules, 37 J. Law Med. Ethics 222 (2009).
[9] Sara M. Ford, Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents,15(4) American University International Law Review 941, 953 (2000).
[10] *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013, 40 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.html.

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affect future investment by creating a regime perceived as less secure for patent rights of manufacturers.[11]

The Case of Voluntary Licensing over Compulsory Licensing

The biggest hurdle with the Compulsory Licensing is the prospective threat of trade retaliations[12] and of reduced investments in research and development. Even in India, grant of first compulsory licensing took the path of political rhetoric and resistance by various groups. In many developed and underdeveloped countries, the biggest problem with compulsory licensing is the lack of an existing pharmaceutical structure to implement the compulsory licensing. Even under the flexibility which TRIPS provides, if the developing country issues a compulsory license and it does not have the capability to manufacture such drugs, compulsory licensing does not provide any incentive in that case. The problem persists relating to lack of human capital, insufficient investments and lack of scientific expertise to manufacture the same. Even after the Doha Ministerial declaration to help developing countries to accommodate the manufacture and export of the generic drugs that don't have the capabilities to manufacture the same, the objective of the compulsory licensing has been far from fulfilled.

Voluntary licensing should get preference before compulsory licensing for both of the parties, i.e. pharmaceutical companies as well as the government. When faced with the prospect of a compulsory license, companies may agree to grant a voluntary license. Even if the system of issuing compulsory licenses were perfect, the system would rarely be used because the patent holder would rather get something for the use of the patent than the nominal royalty fee. Therefore, identifying that compulsory licenses are only meant to be a safeguard in case negotiations are stifled by the refusal of a patent holder to negotiate a voluntary license.

The Threat to Pharmaceutical Research Incentives

Large capital and investment are required by the pharmaceutical companies for the research and development of any medicine. Very less percentage of these medicines researched are marketed and put into for public use. The return on the investment on these medicines are expected to cover by prices of these medicines. Compulsory licensing in these cases lower

[11] Amiti Sen, *US Protests Patent Issuance to Natco to Sell Copied Versions of Nexaver*, The Economic Times March 27, 2012, available at http://articles.economictimes.indiatimes. com/2012-03-27/news/31245102 compulsory-licence-patent-owner-indian-patent-office. Last accessed 13 September 2024.
[12] Sahni, The Economic Times, 'US Threatens take India to WTO over Nexavar Generic', 5 July, 2012.

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down the prices by the mechanism of generic drugs, hence hindering the return on investment and profitability of the pharmaceutical companies.

Voluntary licensing enables the pharmaceutical giants to collaborate with the generic medicine manufacturers and governments of these developed and underdeveloped countries in a defined machinery of exchange of expertise and revenue for broader public health interests.

Voluntary Licensing as a Solution

Voluntary licensing enables the pharmaceutical giants to collaborate with the generic medicine manufacturers and governments of these developed and underdeveloped countries in a defined machinery of exchange of expertise and revenue for broader public health interests. Voluntary licensing was basically regarded as the alternative against the Compulsory Licensing but became as a response against the threat of Compulsory Licensing.[13]

Also, the preference of the Voluntary licensing over compulsory licensing could be highlighted by the fact that while voluntary licensing helps in preserving the incentives for innovation and the patent rights autonomy of the pharmaceutical companies while also avoiding the adversarial licensing by the intervention of the government. This approach of voluntary licensing helps these companies to negotiate on terms mutually beneficial to parties and collaborative environment helping the other parties with innovation and necessary technological exchange.

Gilead Model

Gilead Sciences, a pharmaceutical company, negotiated agreements with 11 companies for manufacturing of generic Hepatitis drugs. The agreement defines the territorial limitation of the production and distribution of these drugs. It reserves the 7% royalty on the same and provides guidelines for the selection of third-party distributers. This helped the company to maintain the reputation of the drugs, having its patent right autonomy and having made a model of price differential making available the drug at a cost accessible to people.

This is a working example of a model where this ensures the accessibility of medicine to a larger number of people but also giving the control to the patent holder, of the profitability and

[13] Tahir Amin, 'Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution To Providing Access To Affordable Medicines', Oxfam Gb At 3 (2007).

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the additional control over licensee on which countries he can export or enter into market.

The Bayer Case: A New Start or a Lost Cause

While one of the main objectives under TRIPS is the patent protection but the flexibility in TRIPS allows the government to revoke the patent rights in a manner for affordable price machinery.[14] An example of this can be seen in the case of *Bayer Corporation v. Natco Pharma Ltd*, which changed the Compulsory Licensing Paradigm in India. In 2011, Natco, a generic drug manufacturer company filed an application for a compulsory license for the cancer drug Nexavar before the Controller General of Patents under Section 84(1) of the Indian Patents Act, 1970. In 2012, the Controller granted the license to Natco, which Bayer subsequently appealed to the Intellectual Property Appellate Board (IPAB). Upon appeal being heard, Bayer requested a stay on the Controller's decision however, this request was denied by the IPAB, allowing Natco's compulsory license to remain in effect. IPAB's decision was in the light of public health benefits needs which comes under the Right to life under Article 21 of the Indian Constitution.

When we look into the essentials on which Bayer's Claim was rejected, we look into the provision of Section 84 of Patents Act of India. Court held that after Natco's request was rejected by Bayer as per Section 84(6)(iv), there was no obligation on the part of Natco to make further attempts to do so. Though this finding can be correct on facts, the problem was even though the content of the application by Natco was found to be harsh by Controller, IPAB ignored this contention altogether. This paves the way for the other players to use compulsory licensing as a threat while applying for it using as a bargaining tool to get their favourable terms.

Also when looking at whether the reasonable requirements of the public were met by Bayer, the approach by IPAB was heavily inspired by the public interest perspective.[15] The sole factor which IPAB analysed was whether the drug in question was available to the public at a reasonable price ignoring other relevant steps taken by Bayer.
Further on the contention of the manufacturing of the drug in India, IPAB dismissed the Bayer

[14]Clair Cassedy, Transcript of Bayer CEO Marjin Dekkers quote at the December 3, 2013, FT Event, regarding India compulsory license of Nexavar, Knowledge Ecology Int'l (Feb. **7,** 2014), available at http://keionline~org/node/1924. Last accessed 13 September 2024.
[15] *Bayer Corporation v. Natco Pharma Ltd.*, (n 10)

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plea about non feasibility of manufacturing in India while ignoring Article 27.1 of TRIPS which provides 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."*[16] While IPAB attempted to avoid monopoly of a manufacturer based solely on imports, the decision on the same is in contrast to the aforesaid provision of TRIPS.

Conclusion

While Compulsory Licensing aims at the accessibility of cheaper drugs to the pubic under the lens of public interest but it brings many drawbacks on the table too. In India, while the provision existed in the patent legislation since 1970, providing regulation and grant of compulsory licenses but was first used only in *Bayer Corporation v. Natco Pharma Ltd*. While the objectives were noble, it opened a pandora box about the flexible interpretations of the TRIPS such as working requirement under Section 84 and the expected policies ahead for the drug manufacturers.

The solution for the same comes in the form of Voluntary Licensing. It caters to the need of making accessible affordable drugs to the common masses while also maintaining the quality and reputation of the drugs, having its patent right autonomy and having made a model of price differential. The successful Gilead Model is a working example on the same. Voluntary Licensing provides most of the benefits of the Compulsory Licensing while avoiding the drawbacks and debates against Compulsory Licensing.

[16] Article 27 TRIPS (n 1).