COMPULSORY LICENSING IN INDIA: NATCO VS BAYER CASE, IMPACT IN INDIA

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ABSTRACT:

Patents provide monopoly rights to patent owners to manufacture, sell, and import the product resulting in overpricing of the patented products. Without patents, the inventors and innovators can neither be adequately compensated for their costs of research nor be encouraged or motivated for further research to develop new and improved products. Patent protection is therefore accepted as a necessary evil despite its conflict with the competitions laws and human rights law. The Natco vs Bayer case may be a point of interest case within the pharmaceutical industry in India, because it has had a critical affect on the industry and the individuals of India. The case included a debate over the obvious of the cancer medicate Nexavar, which was created by Bayer. Natco, a non specific sedate producer, challenged the obvious and looked for authorization to deliver and offer a bland adaptation of the sedate at a lower fetched. The administering in favor of Natco had far- reaching results for the Indian pharmaceutical industry, and it was a triumph for reasonable solutions and the get to of the masses to life-saving drugs.

Introduction:

Bayer corporation vs Natco pharma Ltd (2013) may be a point of interest case within the history of the long-standing debate over obligatory permitting within the pharmaceutical division of India. Compulsory licensing is considered to be the grant of licence to a third party for a patented drug by the government without the assent of the patentee. Bayer corporation is a global pharmaceutical company, it bargains with the making of Aspirin drugs. While Natco pharma is an Indian pharmaceutical company that bargains with the generation and manufacturing of cheap and reasonable drugs. The reason for the debate between the two companies was a drug named Nexavar "Sorafenib tosylate" which is utilized to treat kidney cancer. In this case, it has been talked about how Natco pharma filed an request for the allow of compulsory licence for the drug "Nexavar" of Bayer corporation before the Intellectual Property Appellate Board ('IPAB') and after a long run of debate at the conclusion, India's first compulsory licence was granted to Natco pharma. This article gives a case analysis of this landmark choice.

Meaning of Patent:

According to WIPO, a patent is an exclusive right given for an invention, which is generally a product or a process that offers a new method of doing something or an innovative technological solution for a problem[1]. For 20 years, a patentee will enjoy sole ownership of his invention, and during that time, he will be prohibited from allowing anybody else to utilise it in any way. However, under certain conditions, a third party may be granted a compulsory licence to use a patented product. The Indian Patents Act, 1970's chapter XVI introduces the idea of forced licencing.

Compulsory Licenses under the Patents Act:

Compulsory licences are permissions granted to a third party by the Controller General to manufacture, use, or market a certain product or employ a specific procedure that has been protected by a patent, without the need for the owner's consent. This idea is acknowledged on both a national and international scale, and it is specifically mentioned in both the TRIPS

[1] https://www.wipo.int/patents/en/

Agreement and the (Indian) Patent Act, 1970. Sections 84-92 outline the pre-requisite conditions that must be met before a compulsory licence is issued in someone's favour.

As per Section 84, any person, regardless of whether he is the holder of the license of that Patent, can make a request to the Controller for grant of compulsory license on expiry of three years, when any of the following conditions is fulfilled –

1. the reasonable requirements of the public with respect to the patented invention have not been satisfied
2. the patented invention is not available to the public at a reasonably affordable price
3. the patented invention is not worked in the territory of India

Additionally, pursuant to a notification from the Central Government, the Controller may issue obligatory licences "suo motu" under section 92 in situations of "public non-commercial use," "national emergency," or "extreme urgency."

The ultimate decision to award the compulsory licence rests with the Controller, who also takes into consideration other considerations such the nature of the invention, the applicant's ability to use the product for the benefit of the public, and the reasonability. Even if a third party receives a compulsory licence to use a patent, the patent holder retains ownership of the patent and is still entitled to compensation for copies of the products produced using the compulsory licence.

The potential misuse of exclusive patent rights may manifest through the failure to engage in utilization activities, such as abstaining from attempting to commercialize the invention in question. The fabrication of the patented novelty within India obstructs the progression of indigenous commerce and industry. The misapplication of patent rights encompasses the imposition of unreasonable terms upon the licensee, the imposition of restrictive conditions upon the use or sale of patented products beyond the expiration of said patents, price fixing, and the denial of a license by a patent holder to third parties seeking licit production of patented products within a given market.[2]

[2] https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

Changes in compulsory licensing due to TRIPS Agreement:

The TRIPS Agreement, a protocol conducted by the World Trade Organization (WTO) aiming to establish consistent standards for Intellectual Property (IP) protection among its members, obligated its signatory nations to address instances of patent non-fulfillment. The primary objectives of the TRIPS Agreement were to facilitate international competition and to establish a universal patent framework. Consequently, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) comprises a multitude of provisions that primarily focus on protecting and preserving essential aspects such as public order, morality, and health.

In addition, the TRIPS Agreement delineates the circumstances under which compulsory licensing is permissible, exemplified by prerequisites such as diligent pursuit of licensing from the patent proprietor, satisfactory remuneration to the patent proprietor, as well as employment of non-exclusive and non-transferable use. Of paramount significance is the stipulation in TRIPS that the provision of compulsory licenses must be extended solely for the purpose of fulfilling the needs of the domestic market of the member [2] who is granting said license.

The TRIPS Agreement does list a number of conditions for issuing compulsory licences, in Article 31. normally the person or company applying for a licence has to have tried, within a reasonable period of time, to negotiate a voluntary licence with the patent holder on reasonable commercial terms. Only if that fails can a compulsory licence be issued, and - even when a compulsory licence has been issued, the patent owner has to receive payment; the TRIPS Agreement says “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”, but it does not define “adequate remuneration” or “economic value”.

There’s more. Compulsory licensing must meet certain additional requirements: the scope and duration of the licence must be limited to the purpose for which it was granted, it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and it should be subject to legal review.[3]

[3] https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

India and TRIP agreement and its effect on compulsory licensing

Prior to India's adoption of the TRIPS Agreement, the country's patent regulations did not permit the issuance of product patents, resulting in the inability to introduce novel and inventive pharmaceuticals with patent shielding. Following India's access to the TRIP Agreement, its patent laws were revised to permit the inclusion of product patents. This measure additionally provided patent holders with increased adaptability in terms of drug availability, volume and pricing. The Indian Patent Laws were equipped with extensive compulsory licensing provisions to deter the abuse of patent rights in response to this outcome.

The TRIPS agreement requires its member countries to provide patent protection for a minimum of 20 years and to ensure that the rights of patent holders are protected. However, it also provides flexibility for countries to take measures to protect public health and to ensure access to essential medicines. The Doha Declaration, adopted by the WTO in 2001, reaffirmed this flexibility and recognized the right of member countries to issue compulsory licenses for public health purposes.

After India became a member of the WTO in 1995, the country had to amend its patent laws to comply with the TRIPS agreement. India amended its Patents Act in 2005 to comply with the TRIPS agreement, which included provisions for the granting of compulsory licenses. However, the amendment also included several conditions that must be met before a compulsory license could be granted. These conditions include efforts to obtain a voluntary license from the patent holder and evidence that the product is not available at an affordable price.

The effect of the TRIPS agreement on compulsory licensing in India has been significant. Although the agreement increased the protection of intellectual property rights, it also recognized the need to balance the rights of patent holders with the need to provide access to essential medicines. The flexibility provided by the TRIPS agreement and the Doha Declaration has allowed India to issue compulsory licenses for essential medicines, thereby increasing access to affordable medicines for the general public.

There are several provisions that remedy misuse of patents rights and provide legal framework to the Office of the Controller General of Patents, Designs and Trade Marks generally known as the “Indian Patent Office” to grant a compulsory license to a third party. For instance, under

Indian Patent Laws, a compulsory licensing can be granted after 3 years of getting a patent. Moreover, the Indian Patent Office might grant a compulsory licence only if the use of the patented product is not satisfying public requirements, or the patented product is not accessible to the public at a reasonable price, or the patentee has not worked the patented product in India.[4]

Indian patent law however requires that number of criteria should be taken into consideration when deciding whether a compulsory licence should be granted to a third party i.e., the applicant for the compulsory licence. Some of the criteria which the Indian Patent Office considers include for instance: if the third party has already approached the patent owner to obtain a licence, or whether the third party has capabilities to meet public interest by manufacturing the patented product, or the actual type of the invention and its benefits for the public.[5]

Requirements for obtaining a compulsory license:

Compulsory licensing under the Indian Patent Act is well codified and is in line with international agreements. The purpose behind granting a compulsory license is to maintain the working of patented inventions on a commercial scale in India so that the interest of any person working or developing an invention is not prejudiced.

Section 84 (1) of the Indian Patents Act, 1970, provides the objective behind compulsory licenses and requires that when granting the same, the general considerations enunciated in this section be focused upon. The Indian Patent Act imposes a duty on the patentee to work the patent in India. Under the Indian Patent Act, compulsory license can be granted after the expiration of a period of three years from the date on which the patent has been granted. The grounds include:

- The reasonable requirements of the public with respect to the patented invention have not been satisfied; or
- The patented invention is not available to the public at a reasonably affordable price; or
- Patented invention is not worked in the territory of India.

[4] The Patents Act, 1970 (Act 39 of 1970), s. 84 (1).
[5] The Patents Act, 1970 (Act 39 of 1970), s. 84 (6).

Under the Indian Patent Act, the reasonable requirements of the public are deemed not to have been satisfied where:

- The patentee refuses to grant a license or licenses on reasonable terms; and
  - a trade or industry is prejudiced; or
  - demand for the patented article has not been met to an adequate extent; or
  - a market for exportation of the patented article manufactured in India is not being supplied or developed; or
  - the establishment or development of commercial activities in India is prejudiced.
- The patentee imposes a condition on the patented invention;
- Non-working of the patent in the territory of India;
- Working of the patented invention in India on a commercial scale is prevented by the importation from abroad.

Section 146 (2) of the Indian Patent Act requires every patentee and licensee to provide information on the extent to which the patented invention has been worked on a commercial scale in India[6].

Relevant information is submitted by patentees and licensees with Form 27. It is required to be filed every calendar year, within three months of the end of each year.

The information includes the following:

- Whether the invention has been worked;
- If not worked, the reasons for non-working, and steps being taken to work the invention;
- If worked, quantum and value of the patented product;

[6] The Patents Act, 1970 (Act 39 of 1970), s. 146 (2).

- If manufactured in India;
- Whether imported from other countries, giving details of the countries concerned;
- Licenses and sub-licenses granted during the year;

Whether the public requirement has been met, at a reasonable price either partly, adequately or to the fullest extent.

Failure to supply such information creates a presumption of non-working and may contribute in grant of a compulsory license. It is also a punishable offence and invites a fine which may extent up to 10 lakh (13,361.84 USD). Knowingly furnishing false information is an offence punishable with imprisonment up to six months, a fine or both.

Under section 92(1) of Indian Patent Act, a compulsory license can be granted Suo moto by the Central Government in circumstances of:

- National emergency; or
- Extreme urgency; or
- In ease of public non-commercial use[7].

To enact the provision outlined in Paragraph 6 of the Doha Declaration, which acknowledges the potential obstacles faced by World Trade Organization (WTO) members lacking manufacturing capabilities in the pharmaceutical realm with respect to effectively utilizing the compulsory licensing mechanism provided for in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the Indian Patent Act underwent an amendment process to insert Section 92-A. This provision pertains to compulsory licensing for the manufacturing and exportation of patented pharmaceutical products to countries that are unable to meet their public health needs with sufficient manufacturing capacity. The act of exporting patented pharmaceutical products is deemed permissible predominantly in countries that have authorized compulsory licensing, and where said countries have provided notification or consent for the importation of such products from India.

[7] The Patents Act, 1970 (Act 39 of 1970), s. 92 (1).

Under Section 100 of the Indian Patent Act, compulsory license can be issued by the Government on a patented drug for use by the Government. The Bombay High Court in the case of Garware Wall Ropes Ltd. Vs. A.I. Chopra and Konkan Railway Corp. allowed third party agencies to use a patented invention on behalf of the Government.

Under section 102 of the Indian Patent Act, Government can obtain a pending or already granted patent for public use. In return the Government must pay the patentee royalties as mutually agreed upon between the parties.

Procedure for granting a compulsory license

Under section 87 of the Indian Patent Act, upon filing the application for grant of compulsory license, the Controller at the Indian Patent Office (Controller) shall analyze the prima facie case made by the applicant against the patentee. The Controller takes into consideration:

- The nature of the invention;
- The applicant's ability to work the invention;
- Whether the applicant made any efforts to reasonably obtain a license from the patentee;
- If such efforts have not been successful within a reasonable time period.

A notice will be issued to the applicant if the Controller is unsatisfied with the request and will provide a statement rejecting the compulsory license. The applicant may request a hearing with the Controller, within a month from the date of notice of rejection. At the conclusion of the hearing, the Controller will decide the matter.

If the applicant's petition is approved, the necessary clauses and conditions will be established, allowing the issuing of a mandatory licence. The Controller shall have sole discretion in determining the amount of royalties to be paid to the patent holder. The patent holder's investment in their invention, the applicant's ability to implement the invention practically, the price at which the patented product will be sold, and the particular terms of the licensing agreement will all be taken into consideration. After the Controller assesses the application and determines that a national emergency or exigent circumstance exists, the method described in Section 87 is made inapplicable.

Termination of compulsory license

A patentee or any other person possessing title or interest in the patent may apply to the Controller using Form 21 together with any evidence requesting to terminate the compulsory license granted under Section 84.[8]

Appeal/Review

An appeal of the Controller's decision to grant or deny a compulsory license can be made to the Appellate Board. The appeal can be held under:

- Sections 84 (1)-(5) Compulsory License;
- Section 85 Revocation for non-working of invention;
- Section 91 Licensing of related patents;
- Section 92 Special provisions for Compulsory License on notifications by Central Government; or
- Section 94 Termination of Compulsory License.

Bayer Corp. v. Natco Pharma:

On March 9, 2012, the Patent Office issued the first-ever compulsory licence in India to Natco Pharma for the generic manufacturing of Nexavar, a life-saving drug used to treat liver and kidney cancer produced by Bayer Corporation.

In accordance with Section 84(1) of the Indian Patents Act, 1970, Natco submitted an application for a compulsory licence for Nexavar with the Controller General of Patents in 2011. The March 9, 2012 decision ruled in favour of Natco because the licence was issued, and Bayer had filed an appeal with the IPAB. Bayer sought a stay of the Controller's judgement, but it was denied since IPAB's conclusion was consistent with the Controller's.

The Facts:

[8] Application for termination of compulsory licence under section 94

- "Sorafenib", an active pharmaceutical compound used for the treatment of liver and kidney cancer was patented by Bayer Corporation, Germany, in India (Patent No. IN 215758). Sorefenib is marketed worldwide under the brand name Nexavar.

- The Indian generic manufacturer CIPLA started producing and marketing the generic version of Sorafenib in 2008 under a brand name 'Soranib' and the description of 'Sorafenib Tablets 200mg'. Bayer filed a suit for infringement against CIPLA before the Indian courts (not the subject of this case summary).

- At the time of the suit, Bayer charged 280,438 INR (~ US $ 5280) per month compared to CIPLA's generic version marketed at 27,960 INR (~ US $ 525) for the same amount of tablets.

- During the ongoing dispute between CIPLA and Bayer, another generic manufacturer, Natco Pharma Limited, filed a request for compulsory license against Bayer's patent on Sorafenib before the Controller of Patents. Natco requested the compulsory license based on Section 84 (1) of the Indian Patent Act of 1970, as amended in 2005.

- Section 84 (1) of the Indian Patent Act as amended provides for compulsory license after the expiration of three years from the date of the grant of a patent on any of the following grounds: a) the reasonable requirements of the public with respect to the patented invention have not been satisfied, or b) the patented invention is not available to the public at a reasonably affordable price, or c) the patented invention is not worked in the territory of India.

- The Controller found that Natco Pharma was deserving of a compulsory license as Bayer had failed to meet the requirements of S. 84 of the Patents Act, 1970. The Controller drafted the terms and conditions of the compulsory license and awarded a 6% royalty from profits to Bayer.

- Bayer appealed the Controller's decision before the Indian Intellectual Property Appellate Board (IPAB).

  The issue of this case was whether compulsory licences be granted to a generic medicine producer while the same is already patented and used by a registered user. The issue had resulted in many big questions before the pharmaceutical sector as have been pointed out hereunder.

- Whether Bayer Corporation had failed to abide by the reasonable requirements of the public with regard to the drug?

- Whether Nexavar was made unavailable to the public at a reasonably affordable price, thereby making it accessible?

As we have understood previously, the concept of compulsory licence has been given a green signal under the Trade related aspects of Intellectual property rights agreement (TRIPS), which is an international agreement establishing a uniform series of rules and regulations concerning intellectual property rights. The grant of compulsory licence reflects proof of the exception that has been introduced under the TRIPS agreement. In accordance with the patent laws in India, the provisions of compulsory licensing range from Sections 84, 86, 89 to 93. This regulation has been given room to aid the government in improving access to the invention that is being enjoyed by the patent holder. The compulsory licence also helps in limiting the misuse of the monopoly rights that are attained by the patent holder upon being conferred with registration for his invention.

Arguments submitted by the petitioner:

Natco Pharma claimed that Bayer's arguments under Section 84 (b) of the Indian Patent Act, 1970 were invalid. This was due to the firm charging the public an unaffordable high price for the drug, thereby restricting access to it. Natco Pharma believes that if they are granted compulsory licencing, they will be able to address the issue of accessibility and affordability in terms of public need and welfare in terms of pharmaceuticals.

Arguments submitted by the respondent:

Bayer corporation claimed that the compulsory licensing trend in Section 83 of the 1970 Indian Patents Act by diminishing research and development. Their belief is twofold, as they consider this to be both contrary to the essence of business and several international agreements, including Article 27.1 of the TRIPS agreement in which India is a participant. The respondent also argued that if a compulsory license is granted, it would limit the research and development process.

Points of Significance Reasonable Requirements of the Public

The IPAB, like the Controller, found that the reasonable requirement of the public had not been met by the patentee. The IPAB then postulated that the reasonable requirements had not been met for the following reasons:

- if there is no working of the patented invention the reasonable requirement is not satisfied,
- if the price is not reasonably affordable the reasonable requirement is not satisfied,
- if the working of the patented invention is not on a commercial scale then the reasonable requirement is not satisfied

In essence the IPAB's ruling states that the reasonable requirement condition laid down in S. 84 (1) (a) is not met if the conditions in S. 84 (1) (b)-(c) are also not met. The IPAB found that the public could neither access nor afford the drug. The IPAB held that the failure to meet the demand on reasonable terms must logically mean that the quantity of the drug supplied was minimal and the price was too prohibitive for the general public.

Affordability:

- The issue of reasonable affordability as a sole factor was also addressed by this decision. The IPAB unequivocally stated that the issue of reasonable affordability would necessarily be adjudged on the basis of whether the general public is able to afford the drug.

- The IPAB agreed with the Controller that the price of the drug made it unavailable to the public at large and therefore the drug was not found to be reasonably affordable.

Working of the Patent

- While the IPAB did not make it clear whether the term 'working of the patent' meant manufactured in India or imported into India, it found that the patent was not being worked in India.

- The IPAB agreed that there could be certain situations in which a drug could only be imported and not manufactured in India and such import could completely satisfy the requirement of the drug being worked in India. However, IPAB held that such import must be on a commercial scale to an adequate extent and at a reasonably affordable price.

Therefore the IPAB held that the drug could not be said to be worked in India.

- Further, the IPAB rejected the argument advanced by the appellant that its Patient Assistance Program contributed to the working of the invention. This argument was rejected on the ground that philanthropic efforts did not contribute to working on a commercial scale

Public Interest:

- The IPAB held that the public interest was paramount and efforts made by the appellant to make the drug available to the public subsequent to the filing of the application seeking a compulsory license are not disallowed.

- The IPAB found that the words of S. 84 (6)1[9] are not a taboo to prevent the inventor to step down from his position and make the invention available to the public. The provisions of the Patents Act dictate that the patentee must provide the necessary technical information about the patented invention. The provisions favour public interest and not the interests of either the patentee of the compulsory license applicant.

- The IPAB held that patents are granted for the benefit of the public and therefore must be easily attainable and affordable by the public.

- Further, the IPAB noted that the patentee was allowed a gestation period of three years from the date of grant of the patent to work the patent in India.

Sale by CIPLA:

- The IPAB then considered the relevance of the sale of Nexavar made by an infringer.

- CIPLA had been engaged in the manufacture and sale of Nexavar without obtaining a license from the patentee. The patentee had filed a suit for infringement against CIPLA (see above). Although the Delhi High Court refused to grant an injunction, it directed CIPLA to maintain accounts of the sales from the infringing product. The appellant argued that both the appellant and its infringer together meet the reasonable requirements of the Indian public (S 84 (1)) and

[9] Section 84 (6) provides: In considering the application filed under this section, the Controller shall take into account,-
(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the me asures already taken by the patentee or any licensee to make full use of the invention;
(ii) the ability of the applicant to work the invention to the public advantage;

therefore the compulsory license cannot be granted upon this ground.

- The IPAB opined that the term 'patented invention' used in S 84 (1) of the Patents Act, 1970 must refer to:

the invention that must be made available to the public by the patentee;

the invention in respect of which reasonable requirements of the public must be satisfied by the patentee; and o the invention which the patentee must work in the territory of India.

(i) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(ii) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit: Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

- The IPAB held that 'patented invention' can only mean that which is made available to the public by the patentee or the patentee's licensee. If it were otherwise it would mean a monopoly is granted to a person who does not make an effort to ensure the invention reaches the public but instead shifts this obligation on a third party.

- The IPAB held that while CIPLA's presence in the market is relevant, the law is clear that the requirements and conditions to be satisfied for the grant of the compulsory license is something to be decided with respect to the patentee alone and not a party whose presence itself is litigious.

- The IPAB further stated that the patentee is expected to furnish technical knowledge and render assistance to licensees since the invention is the patentee's property. It was undisputed that Bayer had not shared any technical knowledge with CIPLA.

- The IPAB found that it is the patentee who should make sure that the invention

is worked adequately and commercially.

Judgement of the case:

Ratio Decidendi – "The court 'held'"

The final judgement of the controller of the patents was to grant a compulsory licence to Natco Pharma for the drug "Nexavar". The controller gave his judgement under Section 84 of the Patents Act of 1970 because Bayer wasn't able to meet any of the requirements of the section.

1. The first requirement given in Section 84 (1)(a) was not being fulfilled as the reasonable requirements of the public were not being fulfilled with regard to this drug.

2. The second requirement given in Section 84(1)(b) was the main issue as the price of the drug was unaffordable by the majority of the public and this is a big issue to address as in India the biggest problem is of affordability as only a very minor percentage of the population is actually privileged to afford these costly medicines and benefit from them while the majority of them cannot.

3. The third requirement given in Section 84(1)(b) that wasn't fulfilled was that the patented invention shall be worked in the territory of india.

Also, the controller rested heavy weight on Article 5(A)(2) of the Paris Convention to justify his reasoning i.e each country has the right to grant a compulsory licence to benefit the general public. There were also many requirements set by the controller which cannot be breached by Natco, for example, the monthly treatment price of the drug should not exceed the limit of Rs.8880/-. Bayer has to pay 7% of the medicines net sale etc.

Obiter dicta:

The court observed that there would always be a play of Audi Alteram Partem i.e both sides would be heard and the IPAB also stated that before filing for the compulsory licence both parties should make significant efforts and settle terms for a potential voluntary licence. The IPAB also made a remark when CIPLA was in the picture that the sales of the first party can only be shown and not of any other party.

Impact of compulsory licensing in India:

The notion of compulsory licensing presents undeniable advantages to the populace at large; nevertheless, there exist contrasting perspectives on the matter. The local customers are provided with access to the product at an affordable price through the authorized licensing of its patent to a third party. This process ascertains the quality of the recently created product before releasing it to third parties, while also motivating the patentee to construct highly effective merchandise. The concept of mandatory licensing has resulted in global unification, as individuals are permitted to assist each other in times of urgent need, in accordance with established regulations. The provision of employment opportunities to the indigenous population through engagement in the adjacent industrial sectors serves as a catalyst for overall progress and development. The aforementioned sectors possess the potential to ostensibly facilitate the advancement of the overall nation.

Industrialized nations hold a predominant share of compulsory licenses. By granting such licenses to underdeveloped nations, these nations' populace can gain accessibility to patented merchandise. Individuals espousing divergent viewpoints maintain that "compulsory licensing entails the government compelling an individual or entity with exclusive rights to permit the utilization of said rights by others on predetermined terms delineated by the government".[10] The issuance of a compulsory license constitutes an infringement upon the patent holder's exclusive rights. The process of uncovering novel knowledge requires numerous resources, including substantial exertion, keen intelligence, and significant investments of both temporal and monetary capital. Upon successfully achieving the discovery, proprietary rights are subject to transfer to a third party for a meagerly assessed payment at the end of a three-year term, as established by the government.[11]

The remuneration accorded to the inventor by way of royalties is disproportionate to both the expenses incurred during the product's development phase and the potential for economic gains that would have been derived from retaining exclusive rights.[12] This phenomenon has been observed to have a detrimental impact on individuals' drive to create, thus impeding youthful

[10] T. Jain, Compulsory licenses under trips and its obligations for member countries, ICFAI Journal of Intellectual Property Rights, vol. 8, 1 (2009).
[11] E. Durojaye, Compulsory licensing and access to medicines in post Doha Era: what hope for Africa? Journal of Intellectual Property Law, vol. 18, 2, 35 (2011).
[12] R. Gottschalk, Vital speeches of the day.

innovators from generating novel ideas.[13] Individuals who are granted a compulsory license are able to reap advantages from a particular product without having made any substantive contributions to its development, research or innovation. The consumption of counterfeit products that are not of comparable quality to genuine innovations poses a risk to consumers.[14]

Numerous multinational corporations may demonstrate a willingness to investigate, explore, and construct a remedy, subject to assurances that their respective patents are safeguarded, given the existence of diverse maladies in third-world nations that are uncommon elsewhere in the world. Multinational corporations selectively pursue initiatives that offer economic gain. As such, the creation of novel pharmaceuticals for a particular ailment can only transpire if these enterprises receive exclusive rights to their findings. Moreover, the potential for an enterprise to make investments in India and other countries that impose compulsory licensing regulations is significantly reduced.[15]

The economic advancement of emerging nations such as India significantly hinges upon foreign direct investment, whereby obligatory licensing measures instill trade barriers that lead to tensions with nations known for their patenting practices and dissuade potential investors from directing funds towards Indian markets.[16] The aforementioned phenomenon is known to impede the growth of the country's economy. Consequently, an inadequate policy towards intellectual property poses a challenge for nations seeking to maintain their competitiveness in the global marketplace.[17] Many youths with promising creative aptitude from diverse nations often experience a decline in their motivation to engage in innovative endeavors, leading them to seek opportunities elsewhere. Pharmaceutical corporations often assert that compulsory licensing is unnecessary in underdeveloped nations due to the availability of affordable products, occasionally even devoid of any profit margin.[18]

Pros of compulsory licenses:

- The first and foremost argument which is sought to strengthen the position of

[13] xv G. J. Arnold, International compulsory licensing: the rationales and the reality, PTC Research Foundation of the Franklin Pierce Law Center, IDEA: The Journal of Law and Technology (1993).
[14] xvi Lamb, Compulsory licensing: A necessary evil? Pharmacy Times, 57 (2007).
[15] R. C. Bird, developing nations and the compulsory license: maximizing access to essential medicines while minimizing investment side effects, Journal of Law, Medicine & Ethics, vol. 37, 2, 210 (2009).
[16] F. M. Abbott, Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration, Decision, Quaker United Nations Office, Geneva, 160 (2002).
[17] J. Kuanpoth, Proceed with caution on compulsory licensing, 1 (2011).
[18] xx Lamb, Compulsory licensing: a necessary evil?, Pharmacy Times, 57 (2007).

granting Compulsory Licenseit strengthens the government's negotiating position vis- a-vis the patent holders and thus manipulates them to lower their product's prices. If the producing companies are given an opportunity to negotiate the price of the product before granting the License, they would be willing to do the same so as to avoid the worst effect i.e. grant of Compulsory Licenses for those products[19]

- Since developing and under developed countries usually don't have their own domestic and technical infrastructure, granting patents in pharmaceuticals in such countries can be harmful as patents may result in non-availability of basic necessities to the population of such country and may also become an impediment in their economic growth.

- Since the developing countries have fewer patents to protect as compared to the developed countries, therefore such opposition of granting the licenses, by advanced countries, may arise the thoughts of "neocolonialism" as patent protection disproportionately favors advanced countries.

- Another strong argument in favour of granting Compulsory License is that the licenses must be granted in situations wherein if refused it might prevent utilization of another important invention which can be significant for technological advancement or economic growth[20]

- Apart from economic arguments, social justice grounds can also be used to support the grant of compulsory licensing to protect the public interest. Patent protection should be strongly recommended but not at the cost of human lives, so the strict adherence to patent protection cannot be supported without giving importance to the concept of public welfare. And thus the protection can be compromised by granting Compulsory Licenses if the public welfare requires so. Thus it can be said that compulsory licensing of pharmaceutical patents sometimes becomes inevitable to save the lives of a large number of population by ensuring accessibility of drugs at reasonable and affordable prices[21]

- The supporters of CL also argue that compulsory licensing plays a vital role in

[19] J. A. Yosick, "Compulsory patent licensing for efficient use of inventions," University of Illinois Law Review, 2001.
[20] G. J. Arnold, "International compulsory licensing: the rationales and the reality," PTC Research Foundation of the Franklin Pierce Law Center, IDEA: The Journal of Law and Technology, 1993.
[21] T. Jain, "Compulsory licenses under trips and its obligations for member countries," ICFAI Journal of Intellectual Property Rights, vol. 8, no. 1, pp. 47, Feb. 2009.

developing and fostering a local generic pharmaceutical industry. Further, it can be used to break up monopolies and cartels, which are some of the most prevalent abuses of patent rights[22]

Cons of compulsory licenses:

- A Compulsory License only grants the permission to produce the protected product and does not in any way guarantee transfer of technology or know-how. This means that the licensee might face difficulty or it might even be impossible for him to produce and sell the same quality product at a price lower than the price at which the originator was selling them. The application which is filed for granting Compulsory License, must contain the description as to how the product may be manufactured, however this need not be the most efficient process. At times, such processes are protected through 'know-how' or 'trade secrets' instead of patents, or even by a separate patent owned by another company[23]

- The patent holder, in order to secure his interest and enforce his rights, will probably oppose the grant of Compulsory License, and therefore the licensee and the rights holder will operate in an unfriendly environment, which might possibly include prolonged litigations and other such delays.[24]

- Another important point is that granting Compulsory Licenses might raise some serious concerns in under- developed and developing countries. There are many diseases which are unique and specific to the region of under-developed countries. Now the multinational pharmaceutical companies would want to invest they could be granted patent protection for their products instead of in countries where patent protection isn't ensured. It can be said that patent protection would provide an incentive to multinational companies to invest in the research to investigate and to find the cure of these diseases which could otherwise remain incurableas multinational pharmaceutical companies usually carry out investment on research and development after considering the potential financial gain[25]

- Repetitive grant of Compulsory licenses gives rise to not-friendly legal climate

[22] R. P. Rozek, "The effects of compulsory licensing on innovation and access to health care," Journal of World Intellectual Property, vol. 3, no. 6.
[23] M. Z. Abbas, Pros and Cons of Compulsory Licensing: An Analysis of Arguments, International Journal of Social Science and Humanity, Vol. 3, No. 3, May 2013, available at http://www.ijssh.org/papers/239-D00013.pdf
[24] Jenkins, Compulsory licensing: a major IP issue in international business today? pp. 371.
[25] Lamb, "Compulsory licensing: a necessary evil?" Pharmacy Times, pp. 57, 2007

which in turn discourages the patent owning firms to start any new ventures in such country.[26]

- Further, the grant or even the probability of granting the compulsory license may cause trade friction with the countries wherein the patented drugs are produced. Interestingly, actual grant of compulsory licensing is not required to cause this loss instead even the fear of granting such license has an unpleasant impact on the existing trade relations between two countries. Moreover, the economy of the developing countries depends a lot on the foreign direct investment and many local industries in such countries heavily depend on the foreign investment, and therefore the decision of a government to grant compulsory licenses may lead to the loss of foreign direct investment and thus might have a striking effect on the economy of the nation as a whole. The foreign multinational companies would thus want to invest in any other country where their work can be protected by the legislation thereof.[27]

- Furthermore, if a country cannot protect the intellectual property i.e. if a country has a weak intellectual property regime, it becomes less competitive, and therefore brain drain can be reasonably expected there. As a result of which the talented scientists and researchers leave the country in search of better opportunities elsewhere in the world where they can protect their work.[28]

- It is also argued, at times, that on humanitarian considerations the drug producing companies sell the medicines in the least developed countries at a price which is almost equal to their cost of production and therefore the granting of Compulsory Licenses must be refrained from as such licenses are neither effective nor warranted.

The situation thereafter:

BDR Pharmaceuticals v. Bristol-Myers Squibb

The following case illustrates licence sought for Sprycel® which is used in cancer treatment, On March 4, 2013 the Controller rejected BDR Pharmaceuticals' (BDR) application for a

[26] J. Kuanpoth, Proceed with caution on compulsory licensing, pp. 1-26, 2011
[27] R. Bird and D. R. Cahoy, "The Impact of compulsory licensing on foreign direct investment: a collectivebargaining approach", American Business Law Journal, vol. 45, no. 2, 2008, pp. 284
[28] Guglielmo Marconi, Patent disputes, available at http://sciencep613.blogspot.com/2007/10/patentdisputes.html

compulsory license for the cancer drug Sprycel®. The controller stated that BDR failed to make a prima facie case for the grant of compulsory license.

Specifically, the Controller found that BDR had made no credible attempt to procure a license from the patent holder and the applicant had not acquired the ability to work the invention to public advantage. Thus, the compulsory license was denied.

Lee Pharma v. AstraZeneca

The following case illustrates license sought for Saxagliptin® which is used in the treatment of Type-II Diabetes Mellitus, On June 29, 2015, Lee Pharma filed an application for compulsory license for patent covering Astra Zeneca's diabetes management drug Saxagliptin®. The application was rejected stating that no prima facie case had been made out on any of the three grounds under section 84 (1) of the Indian Patent Act.

Reasonable requirements of the public had not been satisfied: Lee Pharma failed to demonstrate reasonable requirements of the public with respect to Saxagliptin® and further failed to demonstrate the comparative requirements of the drug Saxagliptin® vis-à-vis other drugs.

The patented invention was not available to the public at a reasonably affordable price: It was held that all related drugs were in the same price range and that Saxagliptin® being sold at unaffordable price was not justified.

The patented invention had not been worked in the territory of India: Lee Pharma also failed to show the exact quantitative requirements of Saxagliptin® in India. Therefore, it could not be concluded whether manufacturing of the drug in India was necessary or not.

Many reasons were stated by the Controller emphasizing the failure of Lee Pharma to be as prima facie in the said CL application. Earlier in the year 2014, Lee Pharma requested the AstraZeneca for license of the patented drug 'Saxagliptin'. The AstraZeneca then replied in response to the letter and the clarifications for denying the license were provided with the details of the particular drug. Further, for not receiving the appropriate reply from the AstraZeneca, despite of the fact that AstraZeneca send the email reply to Lee and Lee Pharma was in fact that no reply had been received from AstraZeneca, the Lee Pharma sent many reminders to AstraZeneca and later approached the Patent Office seeking the grant of compulsory license. According to the Controller's decision in holding the application, there was

a 13 months difference in the filling of the application at the Patent office and the initial request for license which was made by Lee Pharma to AstraZeneca. The time limitation, as per the Section 84(4) of the Patents Act, 1970, which is of 6 month, had elapsed in the present case without any efforts being successful. This was apparently the foremost reason to deny the request of CL application made by Lee Pharma. Also, presence of equally efficacious DPP-4 inhibitors which were reasonably substituted for Saxagliptin in treating Type II Diabetes Mellitus was noted by the Controller. It was concluded that the assumption regarding the demand for Saxagliptin without accounting for these substitutes was impossible for Lee. This was thus the second reason for holding the application of Lee Pharma and denying their request for CL. Further, the Lee Pharma also failed to prima facie show that the availability of patented invention to the public was not at a reasonable affordable price and hence, no specific case was made in such respect. This conclusion was directed by the case of Bayer v. Union of India, in which there was a substantially high difference between the price quoted by the applicant and the respondent i.e. Rs. 2,84,000 and Rs. 8,800 respectively. In the discussed case, the price quoted by Lee Pharma was majorly cheaper than AstraZeneca's and thus the Controller was unable to find the availability of the patented product at an affordable price as per Section 84(1)(b) of the Patents Act, 1970. Lastly, as in Section 84(1)(c) of the Patents Act, the Lee Pharma again failed to prima facie show that the invention of the patent is not worked in the Indian territory. In this section, the Bayer CL case was cited by the Controller which held that local manufacturing is not entailed by the local working in all cases. The Controller said that the obligation of the patentee is only to furnish reasons which make it prohibitive to manufacture the product locally and that this requirement is applicable in those situations where the patentee has manufacturing capabilities in India. It was also held that if the data concerning AstraZeneca's local manufacturing capabilities provided by Lee Pharma is absent then it cannot be accepted that a primafacie case has been made out under this provision.

In what is widely being hailed as an extraordinary victory for the multinational pharmaceutical industry over the Indian government, the US-India Business Council (USIBC), in its submission to the United States Trade Representative (USTR), reports that the Indian government has “privately assured” the industry that it would not use compulsory licences (CLs) for commercial purposes. Since it came to power in 2014, it has been speculated that the NDA government is keen to accommodate objections of the USTR and the US based pharmaceutical industry regarding the use and implementation of a number of health safeguards in domestic laws on intellectual property rights designed to promote affordable access to

medicines in India. We now have confirmation that the government is willing to travel the extra mile in order to placate the US and that the Big Pharma's vicious campaign after the first CL was granted in India has been a success.

"…the level and frequency of engagement between the U.S. and Indian governments was encouraging and many have noted that they had not seen this level of engagement with the Government of India before". Aghi goes on to compliment Prime Minister Narendra Modi for "several public statements reaffirming his commitment to a strong and robust intellectual property regime" and also notes with approval that "(the) Government of India has denied several compulsory license applications". Particularly disturbing is his assertion that "the Government of India has privately reassured India would not use Compulsory Licenses for commercial purposes".

Attempts to regulate the prices of these patented medicines have yet to bear fruit. A 'Committee on Price Negotiation of Patented Drugs' was set up to recommend ways in which the prices of patented drugs could be controlled. The committee's report, submitted in 2013, suggested the ceiling prices of patented drugs be fixed by factoring in their prices in a select group of reference countries (a practice known as reference pricing), and the comparative per-capita GNP of India and the reference countries. No headway has been made since as the industry, especially the Organisation of Pharmaceutical Producers of India (OPPI) – representing drug MNCs in India – has opposed the formula suggested. Concerns have also been raised that reference pricing would push up costs enormously given that patented drugs are exorbitantly priced in all countries and have no relation to real manufacturing costs.

CONCLUSION:

Although patent encourages monopoly and overpricing, it is a necessary evil because without patent protection firms have no incentive to develop new products. Thus, patent protection is necessary to ensure innovation; the patent is therefore an imperfect but effective instrument to promote the development of new products. The pharmaceutical patent protection, however, works well only in high income countries with citizens having purchasing power to buy expensive patented pharmaceuticals. It does not work well in developing and least developed countries because of different factors, affordable access to medicines being the most important of them. Compulsory licensing is therefore yet another necessary evil. It is a violation of the rights of the patent holder. But this violation sometimes becomes necessary in order to avoid

misuse of monopoly right and to protect human right to health. It is noteworthy that the CL provisions in the Indian law have remained virtually unused and only one CL has been issued till date. In contrast, several low income countries – Zambia, Zimbabwe, Eritrea, Ghana, Mozambique – have issued CLs to promote the access to high-priced patented medicines. The only CL issued in India (to NATCO in 2012 for Sorafenib, an anti-cancer drug marketed by Bayer as Nexavar) indicates the power of a CL. NATCO's price for Sorafenib is 8,800 rupees for a month's treatment, in contrast to 2,80,000 rupees for Nexavar.

Although several patented drugs have started entering the Indian market, there have been few CL applications. Intuitively this would indicate a link between the new strategy of domestic Indian companies to 'collaborate' rather than to 'oppose' pharmaceutical MNCs. In large measure, this is related to the chilling effect of the government's overt manoeuvre directed at appeasing foreign drug companies and the USTR. As submissions to the USTR indicate, CL applications are being actively discouraged. To sum up, a compulsory license falls mid-way; neither full patent protection is granted, nor is it denied altogether.

Reference:

1. https://blog.ipleaders.in/bayer-corporation-vs-natco-pharma-ltd-a-case-analysis/#Obiter_dicta
2. https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/Bayer%20Corporation%20Vs.%20Union%20of%20India%20and%20Others%20IPAB%202013.pdf
3. https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india
4. https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/compulsory-licensing-india-and-changes-brought-it-trips-agreement-2021-10-12_en
5. https://www.zeusip.com/bayer-vs-natco.html
6. https://indiankanoon.org/doc/52483234/
7. https://patentblog.kluweriplaw.com/2021/08/16/compulsory-license-india/#:~:text=Under%20the%20Indian%20Patent%20Act%2C%20compulsory%20license%20can%20be%20granted,have%20not%20been%20satisfied%3B%20or
8. https://ipindia.gov.in/writereaddata/Portal/ev/rules/pr102.html
9. http://www.ijssh.org/papers/239-D00013.pdf
10. http://iaeme.com/MasterAdmin/Journal_uploads/IJIPR/VOLUME_8_ISSUE_1/IJIPR_08_01_001.pdf
11. https://thewire.in/health/india-assures-the-us-it-will-not-issue-compulsory- licences-on-medicines
12. https://glslawjournal.in/index.php/glslawjournal/article/view/67/79
13. https://glslawjournal.in/index.php/glslawjournal/article/view/67/79