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COMPULSORY LICENSING OF DRUGS: USES AND CHALLENGES

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Abstract

Molecules, which are byproducts of chemical reactions, were not patentable in India under the earlier patent regulations. This restriction, along with the restriction on mere admixtures resulting in aggregation of qualities in which the components do not exhibit any synergistic activity, severely limited the goods, which could be patented in India. Even if they had functional qualities, "actives" created through chemical synthesis were not as such patentable in India. In India, typical medicinal formulations in which the constituents act just as admixtures are likewise ineligible for patents. In these circumstances, just the process, or the way the product was made, was patentable.

The Indian patent regime lacked patent protection for products in pharmaceutical and agrochemical industries, this led to a significant development of the pharmaceuticals throughout the country as they soon became experts in reverse engineering of the product which was patentable everywhere in the world except India. With the coming of the new amendment in 2005 in regulation with signing the TRIPS agreement has put a stop on the same.

This was accompanied by introducing a new regime of compulsory licensing which gave the government right to grant license to another company to manufacture, which previously only resided with the patentee. This gave rise to a whole new set of problems. This paper mainly focuses on this new regime of compulsory licensing and its implications on the pharmaceutical industry. On one front it faces the opposition by pharmaceutical industry as it causes them huge losses whereas on the other hand the government remains adamant to grant the same on grounds of public morality to make the drug accessible to the poorest stratum.

Keywords - Compulsory Licensing, TRIPS, Product Patent, Section 3(d), Doha Declaration.

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Introduction

Patent is a right given by the government to an invention if it fulfils the basic criteria of novelty, non-obviousness and industrial use. It basically subjugates giving anyone a right to hold monopoly to regulate their market prices as the aforesaid invention cannot be replicated for the time period for which the patent is granted. Patent rights prevent the other party from selling, making and using the invention[2]. Patent as such is regarded as one of the most used and abused kinds of intellectual property[3]. It is specifically given as an incentive to reward innovators for their creation, but it cannot be overseen that it may be used by patent holder arbitrarily. The situation in case of patent of drugs differs to an extent that before any molecule could not be patented but only the process of procuring the ascertained new molecule could be. Thus, the Indian pharmaceuticals used to obtain patent for drugs that are already patented everywhere else in the world but not in India.

The position shifted completely with the signing of the TRIPS agreement which was formerly implemented in the year 2005. The Paris Convention contains provisions dealing with compulsory licenses[4], which were embodied in the TRIPS Agreement as well.[5]The TRIPS Agreement also lays set of detailed obligations in Article 31 that need to be complied with, if compulsory licenses to patent are granted[6]."

Now product patents have become legal and thus this practice was stopped but it also brought another provision for Compulsory Licensing to tackle monopoly of companies when the demand of a certain drug in the market is not met, or cheap medication is required due to national medical emergency or other reasons.

Compulsory licensing is a legal mechanism that allows a government to grant permission to third parties to manufacture, use or sell a patented product without the consent of the patent owner. This mechanism is intended to balance the interests of patent holders and the public by ensuring that essential goods and services are available at affordable prices and that innovation is not hindered.

The use of compulsory licensing has become increasingly important in the context of public health, as it allows governments to override patent protections on pharmaceuticals and other medical technologies in order to address health emergencies or provide access to life-saving treatments. However, the use of

[2] Gupta R, "Compulsory licensing under TRIPS: How far it addresses public health concerns in developing nations" 15 *JIPR* 357(2010).
[3] Amanpreet Kaur, Rekha Chaturvedi, "Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma" 20 *JIPR* 297 (2015).
[4] The Stockholm Act ,1967 (as amended in 1969) of the Paris Convention for the Protection Industrial Property, art. 5A.
[5] The TRIPS Agreement 1995, art. 2.1
[6] The TRIPS Agreement,1995, art. 31.

compulsory licensing is a complex issue with implications for both intellectual property law and public policy and requires careful consideration of the competing interests involved.

Methodology of pricing the medication

Now, whenever a new drug is introduced in the market it is subsequently priced by the pharmaceutical company exercising their monopoly right obtained through the grant of patent. The pricing, however, is affected through various factors. For example, a breakthrough drug in a particular field would be priced higher than another drug which is just a newer and effective version of the one already available to cure the disease. Companies take various factors into consideration while pricing the drug, as to get certain number of profits that can overcome the money spend on developing and researching for that drug. It essentially includes the cost incurred on the development of the drug, its manufacturing cost in an industry and the market value of the drug. Also consider various other factors like if the drug treats a general disease or is made for a rare disease. Another important factor at hand is the price of the competitive dug present in the market. Thus, companies try to extract the maximum price from the public to gain huge profits, thus the monopoly gained through patent can objectively lead to such high price d drugs that are not affordable by the poorer strata and in case of drugs for rare medicine not even by the middle classes depending on the nation's economy and distribution of wealth in the different categories. There are some drugs that are priced different in different countries according to the economy and buying capacity of the public in general. For instance, a 12.5 mg Sunitinib Malate capsule (used to treat renal cancer and GI tract cancer) costs INR 11,731 in India., INR 82,539 in Australia, INR 1,04,192 in New Zealand, and INR 92,035 in France[7].

The patent holders may yet abuse their patent right to generate profits by either non commercialization of the patented invention as to increase the benefit from their already marketed product present in the market. The reason being the newly made invention would yet again include investing large sums of money for production and manufacturing and lower benefits from the drugs in the market that are of the same nature. Another method it can devise is it can manufacture the product in wealthier countries and thus import it to the low- income based countries, making it inaccessible to a larger stratum of poorer generation. But in India the patentee must fill form no. 27 according to sec. 146(2) and rule 131(1) of the Indian Patent Act to provide information about the commercial usage of the patent within a time frame of 3 months at the end of the year[8].

[7] Government of India, Report: *Price Negotiation for Patented Drugs* (Ministry of Chemicals and Fertilizers, 2013).
[8] Nair G & Fernandez A, "Patent policies and provisions relating to pharmaceuticals in India" 19 *JIPR* 9 (2014).

TRIPS and introduction of compulsory licensing in the international scenario

The compulsory license, often referred to as a non-voluntary license, is a permit given by the government to a third party other than the patent holder that enables him to use or commercialize an invention without the patent holder's approval[9]. "The advantage of having such provisions involving the issuance of compulsory licenses in nation's statutes is that the threat posed by these provisions incites patent owners to give contractual licenses on fair conditions," claims Ladas[10]. When the TRIPS agreement was signed by the country, we came across a fairly new notion of compulsory Licensing, though the term is not explicitly used in the agreement but in certain Article 31, it clearly mentions that the government can pass on the right of the patented invention to either themselves or any organization allowed by the government without permission from the patent holder. The right was provided to keep a check on "use of invention on grounds of public morality"[11]. This right though can only be exercised in fulfilment of certain other conditions like applicant has supposedly already applied for the same; the patentee has not sufficiently commercialized the patent and other conditions. Compulsory licenses are typically non-exclusive and subject to payment of royalties to the patent holder[12].The article at the same time provides rights for the patentee so as not to completely denounce his rights. It has a provision for providing necessary remittance to the patentee *in lieu* of the licensing rights. But the TRIPS agreement had restricted the scope of compulsory Licensing only to the countries that were capable of manufacturing drugs[13] and have the necessary infrastructure, to devoid a major section of the population that live in the either developing and under developing nations of these rights. This was further corrected by Doha Declaration of November 2001 which allowed member nations to allocate compulsory Licensing for export to countries that establish that they are either unable or subpar at the production of drugs in their country.

It can be noted that after this provision came into being, the companies were threatened by governments granting compulsory license of their patent to other companies which would result in immense loss to them. Thus, many companies voluntarily started lowering the prices of their drugs in order to make it affordable to all and also granting licensed to other companies. Some notable examples can be Gilead that announced non-exclusive licensing contracts in September 2014 with seven generic drug producers in India to produce Sofosbuvir and the experimental Ledipasvir/Sofosbuvir single tablet for the purpose of distribution in 91

[9] Philibert Baranyanka, "The inability of compulsory licenses to address the problem of medicines and vaccines access in ldcs in the context of the covid-19 pandemic" 11 *WIPO-WTO COLLOQUIUM PAPERS* 40 (2020).
[10] Pericles Ladas S, Patents, trademarks and related rights: national and international protection 427 (Harvard University Press, vol1,1975)

[12] Carlos M. Correa, "Intellectual Property Rights and The Use of Compulsory Licenses: Options for Developing Countries", 5 *T.R.A.D.E.*8 (1999)

poor nations[14].7 A middle-income nation like Brazil has aggressively utilized compulsory licensing as a threat to reach an agreement to reduce costs for AIDS medications like Roche's proprietary Nelfinavir.The corporation agreed for sale at a 40% extra discount in exchange for Brazil not imposing a compulsory license.[15]

Indian government has also taken the initiative and gave the first compulsory license in the year 2012 to a drug named nexavar. [16]. Many other countries like China, Taiwan etc. have start to grant license for various drugs while numerous others remain restricted in their approach.

The United States of America makes an annual report on nations that have infringed trade practices or the countries which do not act in Favor of protection of IP rights of American companies These are identified under Section 391 of Trade Act of 1974[17]. In the aforementioned report, USA ascertained that India should alter its policies on compulsory licensing and regarding Sec 3(d) of the Patents Act and has been enumerated in the 'Priority Watch List'[18].

Compulsory licensing in Indian patents act

Compulsory licensing dates back to the Indian Patents and Designs Act, 1911, as enacted, contained compulsory licenses[19]. Back then, an interested person could seek either license or revocation of the patent, if the "reasonable requirements of the public with re a patented invention" were not satisfied.[20]then further changes were made to 1911 act in 1950 in line with the UK Patents Act, 1949[21] keeping in mind the remedies available to handle the misuse of monopoly rights by the patentee. The parliament followed many of the recommendations of ayyangar committee while passing the Patents Act in 1970 where they included "reasonable price' and "reasonable requirements" as alternative grounds for the grant of patent.

The TRIPS agreement was implemented in 2005 in India. Before signing this agreement, we had a very different regime in terms of categories of granting patent. Any molecule as such was not patentable and only the process for making was, hence, the Indian pharmaceutical industry flourished as it provided the world

[14] "Gilead announces generic licensing agreement to increase access to Hepatitis C treatments in developing countries", Gilead Sciences, Business Wire, Sep.15, 2014.
[15] Examples of health-related compulsory licenses, *available at*: http://www.cptech.org/ip/health/cl/recent-examples.html (Last visited on Oct. 14, 2023).
[16] *Bayer Corporation v Union of India,* (2014) Bombay HC.
[17] Froman M, "2015 Special 301 Report" (Office of The United States Trade Representative,2015
[18] Seth D & Das S, "DIPP defers decision on issuance of compulsory license for cancer drug Dasatinib", *The Economic Times*, Oct.16, 2014.
[19] The Indian Patents and Designs Act, 1911, ss. 22-25
[20] Ibid. s 22(1).
[21] The UK Patents Act, 1949, ss. 37-45.

with cheap and generic medicines due to no restriction on patent product. But we faced one problem that was no new product could be launched in India only when India became a member to the TRIPS agreement product patent became legal. India is a hub of pharmaceutical companies where it is 3rd in terms of producing Quantity of medication in the world. This unprecedented power could lead to abuse by the patent holders as discussed above. Thus, we have comprehensive sections which define and describe the regime of compulsory Licensing in India. These are-

- **Section 90** deals with the terms and conditions of compulsory license.
  It states that required remuneration should be paid to the patentee keeping in mind the cost that was incurred in the making and manufacturing of the drug. It also states that the drug should be supplied to the public at a reasonable price and the Licensee should commercialize the patent to its full potential. It also states that this right provided to the licensee is not to be re assigned to another. License is provided mainly for the commercial utilization of the product for the Indian market, but it can also be subjected to export. However, import of the same would only be allowed on special permission from the Central Government.
- **Section 84** specifies that in any of the following three circumstances, the patent controller may grant a compulsory license:
  a) The public's reasonable expectations regarding the patented innovation have not been met in any of the following situations.
  b) The drug is not sold at an affordable price for the public.
  c) The invention is not being worked on in India.
- **Section 92** offers a unique requirement for a license. The Controller of Patents can submit an application for a compulsory license in a situation involving a national emergency or situation requiring immediate action or at an instance of non-commercial public use.
- **Section 92A** relates to the requirement of an export license for patented medicinal items. According to this, a CL may only be given for the manufacture and export of medicinal products to underdeveloped nations. Depending on the situation, the Controller General may add additional terms and conditions. Pharmaceuticals with patents include medicines along with the substances required for the production of that medicine and the diagnostic tools.
- **Section 94** relates to the ending of compulsory license. It stipulates that if the conditions that led to the grant are no longer present and are not anticipated to change, the Controller may revoke the compulsory licence. The CL holder is permitted to protest such termination. Also, the CL holder's license may be revoked if he is unable to comply with the conditions for which the compulsory licence was issued.
- **Section 100** offers patents for use by the government. It provides that in exchange for payment to

the patentee, the government may purchase the patented invention for its own use. The patent holder must be informed by the government of the usage and scope of the invention. Nonetheless, the patentee may object to such use or the conditions of such use.

- **Section 102** stipulates that a patentable invention may be purchased by the government for public use. The patent holder receives some money in exchange for giving up all the rights to the innovation.

Three conditions for grant of compulsory license

There are three most important requirements that must be met in order to apply for such a compulsory license, these are-

1. The public's reasonable expectations have not been met,
2. The patented innovation is not easily accessible to the public at an affordable price,
3. The invention is not being developed in India.

- The public's reasonable expectations have not been met.

The court's ruling stance about what comprises "reasonable restrictions" is vague, though it may be persuaded with a subjective approach. It is essential that an applicant should concentrate on the significance of the patent to society. With the court's emphasis on public perspectives, a large number of patients should be able to obtain life-saving medications. This idea is further supported by key precedents like Novartis AG v. Union of India[22], which highlighted the value of public health and equal access to medications. The legal justification for this strategy is unclear, notwithstanding the possibility that this decision may encourage multinational pharmaceutical businesses to adopt differential pricing as recommended in this case.

Similar to a more recent case, Lee Pharma v. AstraZeneca[23], the applicant was denied compulsory license due to their inability to provide reasonable conditions, emphasising the importance of this criteria.

- The patented innovation is not easily accessible to the general public at a reasonable price.

No legal definition of "reasonable pricing" exists. As a result, it is standard practise to compare the cost of drug consumption to the income levels of the population depending on it. However, this comparison is frequently insufficient because patients with complex diseases frequently receive multiple prescriptions, and their expenses are not entirely covered by their medications.

In order to buy a monthly dose of Nexavar, according to Natco, the lowest-paid government worker would need to labour for three and a half years and earn INR 2,80,000. (a USD 5700)[24].

[22] (2013) 6 SCC 1

[23] Lee Pharma v. AstraZeneca AB, C.L.A No, 1of 2015 Patent Office, Jan. 19, 2016.

[24] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013, (Intellectual Property Appellate Board, Chennai) < http://www.ipab.tn.nic.in/045-2013.htm > (last visited on Apr. 6, 2023).

Bayer argued that in order for "reasonable price" to be reached, it must be viewed from both the public's and the Patentee's perspective. At the time that Bayer launched a lawsuit for patent infringement against CIPLA, the business was manufacturing a generic version of the medicine. The CoP, however, inclined that the word must be understood in light of the public's needs and came to the conclusion that Bayer's high pricing was not affordable for patients all across the nation. In Cipla Ltd. v. F Hoffmann-La Roche Ltd. & Anr[25]., the court gave public benefit priority while deciding whether there had been patent infringement.

- The invention is not being developed in India.

  The CoP made a connection between Sections 84(1)(c) and 83(b) of the revised Patent Act of 1970 regarding the third ground. S. 83 discusses the idea of an invention "functioning" after it has been granted an Indian patent. According to S. 83(b), patents are not granted only to grant importation monopolies for patented items. The requirement is that the patented innovation be manufactured in India as stated in the Act.

Problems in relation to compulsory licensing

- **Creation of Gray market**

  In several ways, the local availability of patented goods may result in the development of the gray market. It occurs when a company starts selling the drug for lesser than its listed price. This can occur when a company starts selling a drug to an altogether different nation for lesser prices than the original company in that country is offering, this market is referred to as the “Gray market”. Gray marketing might not be considered criminal in compared to black marketing, which promotes fake or illicit items[26]. But certainly, causes substantial Economic loss to a country. Gray marketing has a certain role in the infringement of Patent Rights. In case of compulsory Licensing, it occurs essentially when a company granted the compulsory license to sell the drug at affordable rated does so not only in the country where the right is granted but in the other countries as well. Whenever the right is assigned to make the generic version, other companies who do not have the license to do so also start manufacturing the same.

  One of the ways to tackle the same problem could be by keeping the prices low enough so that customers are not diverted towards gray markets. The batch of every medication should necessarily mention the country in which it is to be sold to or should mention only for export, either or both. This can also be curbed by making of certain symbols or watermarks that are difficult to copy and by voluntarily providing license to other companies to meet the demand in the market.

  Lastly the government can spread awareness in consumers that the product in gray market would not be as efficient and effective as the original one. For instance, in 2002, non-sterile tap water was used to make

[25] 2008 (37) PTC 71 (Del).

[26] Christensen K, “Gray Markets”, *Forbes India*, Apr.16, 2012, *available at* <https://www.forbesindia.com/article/rotman/gray-markets/32694/1> (last visited on Apr. 5, 2023).

counterfeit Procrit®, a medication intended to treat anaemia in cancer and AIDS patients, which led to infection in already frail[27]

- **No Definition of National Emergency**

  There is no defined boundary as to what can be categorized as national emergency and what cannot be. Different countries have different Social, economic and political situations, thus they cannot be put into one definition, as to what may constitute emergency for one might not be for other. Let's take an example that.

  A national emergency may be declared in a nation if 1% of the population is affected by a disease. In a country like India, where 1% of the population equates to **14,172,740** people, national emergency can be contemplated to be declared, but in Canada, where 1% of the population equates to **387,812** individuals it would not amount to national emergency[28],[29].

  In India, the swine flu outbreak in 2014–15 resulted in 2,123 fatalities.34, 656 people were reported to be affected as of April 6th, 2015.[30] This outbreak does not qualify as a national state of emergency in the country because the number of patients corresponds to a relatively small portion of the population and the drug is readily available to them.

- **Apprehensions of The Patent Holder**

  The patent holder has invested heavily in the idea and project to make the invention. It has incurred cost on research and development to make the innovation possible thus it is not just to put the company that has been granted license on the same pedestal as the patentee. There is a fair chance that when a company who is given the right to manufacturing and selling the product without investing into it, would create an apprehension in the mind of the innovator and thus would lead to a situation where innovation stops as there seems no incentive to work on a new drug. Thus, compulsory Licensing must be strictly regulated, and it can only be provided in cases where the patentee is unable to produce sufficient drugs that can meet the demand of the market.

  One can point out the positive position in this is the patentee gets royalty from the company without bearing the expenses of manufacturing the same.

- **Low Royalty**

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[27] Yadav D, "Spurious drugs/ counterfeit drugs- An overview", *Pharmatutor*, Ju. 15, 2015, available *at* <https://www.pharmatutor.org/articles/spurious-drugs-counterfeit-drugs-overview>
(Last visited on Apr. 5, 2023).

[28] Population of India, *available at*: https://www.worldometers.info/world-population/india-population (last visited on Apr. 3 ,2023).

[29] Population of Canada, *available at*: https://www.macrotrends.net/countries/CAN/canada/population (last visited on Apr. 3 ,2023).

[30] Charles Patrik Davis, "Swine Flu (Swine Influenza A [H1N1 and H3N2v] Virus)", *Medicine Net*, Apr.6, 2015, *available on* <https://www.medicinenet.com/swine_flu/article.htm> (last visited on Apr. 3 ,2023).

At time of an outbreak of disease, the product is needed in large quantities and at competitive costs so that everyone, regardless of their financial situation, may purchase it. In that instance, it is not possible to grant a very high royalty for a compulsory license, thus the cost should not increase. Yet, the patentee is still paid a royalty according to the contract.

The amount of royalty is determined by several factors, including the market worth of the product, the amount of product to be marketed, the percentage of clients, the length of the license, etc.

If marketing is done in large quantities, royalties are typically lower as even 1% of a great quantity is a huge amount of money, and it is also indicative of higher demand for the product. When disease burdens are modest in middle- and high-income countries, royalties can be greater; when disease burdens are large in low-income countries, royalties are significantly lower.

Compulsory licensing and Covid -19

Compulsory license can be granted when there is medical emergency. The idea of compulsory licensing was highlighted during the Covid pandemic where more and more people advocated that not only license be granted for making affordable version of the drug, but people also advocated that no patent be granted to any pharmaceutical whatsoever in case of drugs that cure covid to deal with the ever going pandemic and the impending deaths.

Granting compulsory License is justifiable if it serves to preserve the public interest, such as public health. Because to these factors, epidemic or pandemic ailments, such as COVID-19, can be deemed a national emergency to support the awarding of such licences and thereby address the demands of poor countries in terms of access to medications or vaccines.

It already appears that the 2005 Protocol[31] provision cannot be implemented in reference to the SARS-COV-19 pandemic, which is why many nations, including the United States, France, the BRICS, and the European Union, are in favour of suspending patents on new COVID-19 vaccines to enable developing nations to more affordably obtain the doses required to immunise their populations. Countries who desire to challenge or even suspend the current patent system have done so because they have seen the mechanism put in place by the 2005 Protocol has failed.

Furthermore, it was debated that doing so is not a solution as companies would lose incentive to work in direction of finding a cure and thus that would directly affect the population with no medication.

Even if these actions, such as suspending patents, do not, provide adequate solutions to the issue of patents and access to medicines in developing nations, they at least have the merit of demonstrating that the WTO's current system is not likely to address this issue and that additional steps must be taken to adopt mechanisms

that are likely to do so. There are various proposals, it only remains to analyse and adopt them.

Detailed discussion on some landmark judgements

- Novartis AG v. Union of India[32]

The facts of the case were that one if the biggest pharma companies in the 90's, Novartis filed for patent of a drug named *gilvec* used to treat Chronic Myeloid Leukaemia (CML) and Gastrointestinal Stromal Tumours (GIST). The aforementioned drug was already used patented in other 35 nations. Madras high court did not grant the patent mainly observing that the drug did not satisfy the conditions of novelty and non-obviousness as was anticipated through prior publication and that was further non- patentable under section 3(d) of the patents Act, 1970. Subsequently they filed an appeal to Supreme Court under article 136(SLP).

The issues were raised on what would constitute known material and defining "Efficacy" in accordance with section 3(d) of the Patent Act of 1970. Another important question was to determine was that whether the "Beta crystalline form of imatinib mesylate" that Novartis claims to have invented more effective than the imatinib mesylate from which it was derived.

The Supreme Court made it abundantly clear that in reference to medicine, "Efficacy" in section 3(d) only refers to "Therapeutic Efficacy" and that all other drug-related characteristics are irrelevant. Instead, the characteristics that directly relate to efficacy in reference to medicine are its therapeutic efficacy.

The Supreme Court compared the effectiveness of "Beta Crystalline form of Imatinib Mesylate" with concluding that none of these properties contribute to an increase in therapeutic efficacy in accordance with section-3(d) of the Patent Act, 1970.[33]

The decision was taken in view to stop the big pharmaceuticals to bag patent for such minor changes in the drug in wake of which the general public has to suffer the consequences of not being able to afford the necessary medicine due to the overprices drugs in the market as a result of the monopoly of the patented drug by the respective pharma company.

- NATCO v. Bayer Corporation

The facts of the case were that the active pharmaceutical ingredient "Sorafenib," which is used to treat liver and kidney cancer, was patented in India by the Bayer Corporation, a German company. It is advertised as Nexavar. In 2008, the Indian generic firm CIPLA began manufacturing and advertising its generic equivalent under the brand name "Soranib." Before the Indian courts, Bayer accused CIPLA of infringement of its patent rights.

During the ongoing legal battle between CIPLA and Bayer, Natco Pharma Limited filed a request for

[32] (2013) 6 SCC 1

[33] Mohammad Suleman Palwala, "A Study On: Novartis AG v. Union of India", *Mondaq* 17,2019) *available on;* <https://www.mondaq.com/india/patent/826478/a-study-on-novartis-ag-v-union-of-india> (last visited on Oct. 15, 2023).

compulsory licence against Bayer's patent on Sorafenib before the Controller of Patents. Bayer charged 280,438 INR (about US $ 5280) per month at the time of the lawsuit, while CIPLA's generic version was sold for 27,960 INR (about US $ 525) for the same number of tablets.

Another generic producer, Natco Pharma Ltd, submitted a request for a compulsory licence against Bayer's patent on sorafenib before the Controller of Patents during the ongoing litigation between CIPLA and Bayer. The Controller determined that Natco Pharma deserved a compulsory licence since Bayer had not complied with S. 84 of the Patents Act of 1970.The compulsory license's terms and conditions were written by the Controller, who also gave Bayer a 6% profit-sharing fee. The Controller's judgement was challenged by Bayer before the Indian Intellectual Property Appellate Board (IPAB).

The issues that were raised were mainly if the Bayer Corporation had failed to abide by the reasonable requirements of the public with regard to the drug and also that if Nexavar was made available to the public at a reasonably affordable price.

It was held by the court that the reasonable requirements of the public were not being met with regard to this medicine, hence the first criteria stated in Section 84 (1)(a) was not being met.

The second condition stated in Section 84(1)(b) was the main problem because the drug's price was out of reach for most of the population. This is a significant problem to address because affordability is India's biggest issue because only a very small portion of the population is privileged to afford these expensive medicines and benefit from them while the majority of people cannot.

The patented idea had to be used on Indian soil, which was the third criteria listed in Section 84(1)(b) that wasn't met. The controller also heavily relied on Article 5(A)(2) of the Paris Agreement, which states that each country has the power to issue a compulsory licence for the benefit of the public, to support his position.

Conclusion

The patent regime has changed to a greater extent after signing of TRIPS agreement. Earlier the Indian pharmaceuticals have made significant profits in the international market through reverse engineering of products that were protected by patent everywhere else but not in India. After being a member to TRIPS and honoring the international agreement product patents were made possible in India that led to a stop in this practice.

Through this the Concept of Compulsory Licensing was also introduced at around the same time for protection of health rights of people in general and that to stop the abuse of patent rights by the pharmaceutical industry. Pharmaceuticals companies after gaining patent had monopoly rights to decide the price and production of the product, they used to charge hefty price for their drug due to no competition, thus making the drug inaccessible to the poorer and in case of some rare drugs even to middle class.

Compulsory Licensing has worked to sufficiently threaten the companies to regulate prices on their own and

make it available to the major section of population but at the same time it has various drawbacks associated with it, which include emergence of gray market where the licensed companies sell drugs to even nations they are not allowed to. Another it, gives arbitrary power to the government to decide granting of license in case of national medical emergency, the definition for the same has not been propounded.

The use of compulsory licensing has raised concerns among patent holders and the pharmaceutical industry, who argue that it undermines the incentive to invest in research and development. They argue that without the ability to protect their intellectual property, they will be less likely to invest in the development of new drugs, which will ultimately harm patients.

It can be sufficiently concluded that the grant of compulsory licensing is a complex issue that requires a balance between the need to protect intellectual property and the need to ensure access to essential goods and services. While compulsory licensing may undermine the incentive to invest in research and development, it is a necessary tool to ensure access to life-saving drugs, particularly in cases where the patent holder is unwilling to license, or the price is prohibitively high. The use of compulsory licensing should be guided by the conditions set out in TRIPS, to ensure that it is used in a responsible and transparent manner.

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