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The Utilization of Compulsory Licensing by Government of India, Scrutinizing its Compliance with International Laws and Domestic Public Health Policies.

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ABSTRACT-

Patent is a Legal Identity of an Invention which is invented by an Inventor. That Invention comes under Intellectual Property Rights I.e. Patent Law 1970. Patents are Protected under Indian Patent Act 1970 came into force on April-20-1972. This Law Protects the rights of an inventors by providing them protection for 20 years and remedies if Patent holders rights are infringed. Patents are protected by Indian laws complying with International agreements and Treaties such as T.R.I.P.S., to protect the right of an inventor act has provisions under which an inventor can register his Invention and enjoy monopoly for next 20 years. But when it comes to social welfare its clearly mentioned in our constitution that India is a Socialist State. Under the Patent Law 1970 there is a provision of compulsory licensing. Which means government can anytime after 3 years of the issuance of Patent can grant compulsory licensing for the welfare of the society. we are discussing Compulsory licensing in this Paper, and in the world of Pharmaceuticals compulsory licensing is often used. From the perspective of a Pharma Company it's a loss-making deal because the money pharma companies have invested in R&D is in millions and some times its in billions. If compulsory license is issued then same Drug/ Medicine will be manufactured by other pharma companies. This will increase the supply of drug in the market and reduce the price. And Pharma companies may never be able to recover the principle amount they invested in R&D. In the case of Natco v Bayer, court ordered Natco to pay 6% of profit share as a royalty to Bayer. And with the perspective of Government and Society Compulsory Licensing is like a magic spell. A spell which can be used to turn laws 360 degree. As this provision will force Government to avail any drug at very low price. that will save the pocket of the society and they will be able to use that money somewhere else. Law on Patent Protects the Rights of the Patent holder and Article 38 of Indian Constitution protects the Rights of the society by promoting duty of state to maintain a socialist state.

KEYWORDS: - Patent, Socialist, Compulsory Licensing, Pharmaceuticals, Drug's, Constitution, Patent Protection,

1. INTRODUCTION-

Patent is the legal right given to the Inventor for the invention. he/she has made. It is a "right in rem" which means "to inventor against the world" he can claim his right over the invention if he is registered under the Patent Act 1970[11]. Section 2(1)(m) of the Indian Patent Act 1970,[22] defines Patent. Patent is given for any invention which qualifies to be novel and patentable there are many inventions people do which are not novel as patents are either not granted or if granted then it's not allowed for general public. Such as Patent of Car Engine, Phone, Technology, Medicines (Drugs) can be granted by the controller appointed by the government under the Indian Patent Act 1970. But Patent cannot be granted for anything which can cause harm and pose threat to the mankind. For example, weapon, guns, or any harmful thing which can poses threat to humans. Thus, patent on inventions which are contrary to the Section 3(b) of the Act can't be granted.

Patent is "right in rem" as it is against the world and a "negative right". That prohibit the world to use the Patent without the Permission or Prior permission of the Inventor(s). If it's found that Registered Patent/ Invention is being used by any another person then there are legal remedies provided for that too in the Act. "Right in rem" exist but at the same time exception of "right in rem" also do exist i.e. "Compulsory Licensing"[3]. In such situations, the government can license the patent to private or other State run/funded entities for the well-being of the society. It is mentioned under Article 38 of the Constitution of India[4]. It says that, it is the duty of State to promote "*welfare of the people by securing and protecting as effectively as*

[1] Indian Patents Act, 1970 (Act No. 39 of 1970).

[2] *Ibid.*

[3] Indian Patents Act, 1970 (Act No. 39 of 1970), Section 84.

[4] Constitution of India 1950 Article 38.

it may a social order in which justice, social, economic and political, shall inform all the institutions of the national life." In this context, for the welfare and wellbeing of the State/Society, the government use Compulsory licensing as a tool to use patented pharmaceutical drugs to be licensed to other private or State run/funded companies so they can reduce the cost of the drug - in the Case of *Bayer vs Natco*[5] Government of India issued the compulsory license for the German Companies drug and allowed the Natco to produce same drug at extremely low cost against 6%[6] royalty of total sales of drug.

Compulsory licensing is a boon for the nation as well as for the society. But society is not just about welfare, it's about economy, business, GDP, Jobs, Employment and Sustainable development too. society must be observed with the black and white view. If there are pros then there will be some cons and repercussion's too. If positive side of something exist then there are very high chances that there will be negative too. Except some rare blue diamonds in the world. where we are completely surrounded by intellectual properties such as Patents, should not be used by state with "mala fide" intention.

Patent in India under the section 53 of Indian Patent Act 1970[77] is issued for 20 years. Anyone who has the Patent has the right to commercially exploit the patent for next 20 years. In Pharmaceutical industry patents are issued for drugs- It can be "Product patent" or "Process patent". Pharmaceutical companies spend millions and sometime billions of dollars for the research and development of the drug, to achieve the accuracy the cure. There are multiple new chemical compositions are tested and created and that comes under the novelty. To recover the millions or billions Pharmaceutical industry have spent, they file a Patent over that drug and monopolize it for the next 20 years. They also control the price of the drug. In India Patented Drugs are any day 10 to 20 percent more expensive than normal Generic drugs. In-short Patented drugs are the new chemical compositions which can cure any existing decease for which we never had any or same category of the medicine.

Drug manufacturing companies contributed 1.72 percent of India's GDP i.e. 42Billion[8] USD we are the world's Pharmacy. There can be two observations that Industry is very small and compulsory licensing is must for the mass production of the drugs. Second and most sensible is that, India is a developing country where everything is emerging and compulsory licensing will create a gas chamber in India that might kill the Pharmaceutical Industries. And killing industry mean making a country paralyze. Which will ignite the chain reaction of the fall of industry and country itself.

History of Pharmaceutical Industry in India-

The first Indian Pharmaceutical company was established in 1901 and started operations in Calcutta (now Kolkata). There followed four distinct periods:

- **1911-1970**: Prior to 1970, the patent regime was founded on the Indian Patents and Design Act of 1911, which documented both product and process patents. During this time, foreign companies conquered the market, with only a few national companies.
- **1970-1995**: The Government's Patents Act of 1970[9] added fresh proposals and revisions to the 1911 Act. This new Patents Act recognized process patents but not product patents. Implying that the patenting regime was solely focused on manufacturing. It also enabled indigenous Pharmaceutical companies to reverse engineer drug manufacturing processes without having to pay royalties to the original patent holders. As a result, the number of patents awarded between 1970-1971 and 1980-1981 reduced by three-quarters. Furthermore, the 1979 Drug Price Control Order stopped Pharmaceutical corporations' overall revenues. This decade saw a significant increase in the number of domestic Pharmaceutical enterprises (from 2,000 in 1970 to 24,000 in 1995). Resulting in a thriving Generic Medication Industry. It also resulted in a significant outflow of multinational Pharmaceutical corporations.[10]
- **1995-2005**: As a number of Indian Pharmaceutical businesses entered the distribution market. The experience gained by focusing on Generic medicine manufacture allowed them to increase their capacities and gain a global reach. This period saw a surge in Pharmaceutical export growth. Spurred by India's economic liberalization in 1991. Which opened up the economy to privatization and globalization.
- **2005-2018**: The 2005[11]Patents (Amendment) Act replaced the process patenting system with product patents. This choked Indian Pharmaceutical businesses from making Generic versions of these Pharmaceuticals. While they were still protected by patents. Encouraging international Pharmaceutical companies to return to India. In this post-process patent paradigm. Indian Pharmaceutical businesses began investing more in research and development (R&D) to compete with their overseas counterparts. with some inventing their own novel compounds and others forming R&D joint ventures with foreign Pharmaceutical corporations.

Emergence of Compulsory Licensing in India

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[5] *Natco Pharma Ltd v Bayer Corporation*, Intellectual Property Appellate Board, Order No. 45/2012 (2012).

[6] *Ibid*. .

[7] *Supra* note 1.

[8] Annual report on Pharmaceuticals *available at* https://pharmaceuticals.gov.in/sites/default/files/English%20version%20of%20Annual %20Report%202023-24.pdf Last visited on 12-10-2024.

[9] *Supra* note 1.

[10] History of Patent medicine *available at* https://www.hagley.org/research/digital-exhibits/history-patent-medicine last visit 10-10-2024.

[11] The Patent Amendment Act 2005.

The public in the developed world first became aware of Indian Pharmaceutical producers when the business "Cipla" promised to deliver Generic versions of copyrighted HIV/AIDS drugs to South Africa around the turn of the time. At the time, Indian law only granted patents for industrial methods, not Pharmaceutical items. As a result, Indian companies had become masters in reverse engineering. Discovering new ways to create Pharmaceuticals. This competence became even more important worldwide when the World Trade Organization meeting in Doha[12] agreed in 2001 that, States might issue compulsory licenses for the manufacturing of Generic versions of proprietary medications if they could not otherwise protect public health. Furthermore, its authorized governments to buying such Generic s from foreign countries. After Independence, global companies controlled the Indian Pharmaceuticals sector. Prices were too expensive for the poor country, So the government implemented a number of measures. One of these was the Patent Act of 1970[13]. It protected techniques rather than products. Other efforts included establishing state-owned Pharmaceutical businesses and financing in higher education and research facilities. By 1982, Indian enterprises had gained almost 50% of the home market. Foreign companies increasingly lost interest in the Indian market, while local enterprises, notably private-sector firms, gained significantly from acquiring their Indian operations.

1.2 Contribution of Pharmaceutical Industry in Indian Economy-

India is the third largest Pharmaceutical producer by volume in the world, very famous and known for Generic medicines at very low-cost vaccines. In terms of manufacturing volume, the Indian Pharmaceutical sector ranks third in the world and is very important internationally. As one of the world's biggest providers of affordable vaccinations, India leads the globe in DPT, BCG, and measles vaccination supply. Ninety percent of the Who is demand for the measles vaccine and forty to seventy percent of the Who is demand for vaccinations against Bacillus Calmette-Guérin (BCG) and Pertussis (DPT) are satisfied by Indian producers, who also supply sixty percent of UNICEF's vaccine supplies.[14]

India is the country with the highest number of Pharmaceutical plants outside of the USA that are in compliance with USFDA regulations. There are 500 API producers globally. Accounting for around 8% of the API market. India holds a 20% global market share in the production of Generic medications with 60,000 distinct brands produced in 60 therapeutic categories. Making it the leading supplier of these drugs. One of the biggest medical stories is the availability of low-priced HIV medication from India. Indian medications are highly regarded globally for their affordability and superior-quality. Earning them the title of "pharmacy of the world". The industry has been expanding at a hearty leap. The Pharmaceutical industry's total yearly revenue in 2023–2024 was Rs. 4,17,345 Crore, an increase of 10% from 2022–2023. The sector's yearly turnover trend over the previous five years[15]

Financial Year	Turnover (in Crore)	Growth Rate %
2019-2020	2,89,998	12
2020-2021	3,28,054	13
2021-2022	3,44,125	05
2022-2023	3,79,450	10
2023-2024	4,17,345	10

Pharmaceuticals are one of the most important export-oriented industries; in 2023–24. Total Pharmaceutical exports were Rs. 2,19,438.60 Crore, while total Pharmaceutical imports were Rs. 58,440.37 crore.[16]

Pharmaceutical Industries are the backbone of Indian Medical System. As they contribute a lot in the Indian Economy and works for the well-being of the society by providing them the Medicines, Vaccines patients need. This is the industry which is one of the most supported industry in India. Government provide them monetary benefits/ loans and make new policies for the facilitation of the Pharmaceutical Industry. The approach of Government of India towards Pharmaceutical industry is very supportive as long as the acts of industry/ companies are working according to the laws and policies formulated by Government.[17]

Understanding the definition and meaning of Generic Drugs

Generic Drugs are of two type- "Branded Generic Drug" and "Generic Drug", when Drug becomes off Patent then it comes into the public domain that means anyone i.e. licensed Pharmaceutical companies can manufacture that drug, if a well-known company is manufacturing the off-Patent drug then

[12]Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2 (2001).

[13] *Supra* note 1.

[14] Ministry of chemicals and Fertilizers, Department of Pharmaceuticals, "Annual Report on Pharmaceutical" 2023- 24 *available at*https://pharmaceuticals.gov.in/sites/default/files/English%20version%20of%20Annual%20Report%202023-24.pdf last visit 10-10-2024.

[15] *Ibid*.

[16] *Supra* note 14 at 34 (Table 3.1).

[17] *Supra* note 14.

it's called Branded Generic drug which cost less than Patented drug. And if it's just Generic drug then there will be just name of salt mentioned on the medicine, and that will cost 80-90% cheaper than other medicines for same cure.

For example, for the fever the best and most researched medicine available is "PARACITAMOL" which is available for very less price but when same salt i.e. "PARACITAMOL" is sold with the brand name i.e. "DOLO-650" it costs way more than Generic medicine reason being DOLO-650 is not a Generic medicine, Generic medicines are best for the welfare of the people in India we produce world's most Generic medicines and consume less comparatively. Most of the medicines we manufacture we sell to foreign nations. There is a lack of knowledge among peoples and nexus of doctors too, who prescribes only Patented medicines instead of Generic medicines, Generic medicines are so boycotted by doctors that in the time of "Covid-19", medicine sold for fever was "DOLO-650" not "PARACITAMOL"[18]. Generic drugs have different concentrations. The prescribed limit for concentration is 80 % to 125% which means how strong is the drug if its 80% then the life of drug activity graph might be not spiked and drug might be for sensitive patients and if its more than 100% concentration then it will be considered as a strong drug which might dissolve into blood stream very quickly and may remain in body for many hours these kind of drugs are for less sensitive patients, but problems accurse when less concentrated drugs are given to less sensitive Patients. Who might not feel any effective of the medicine due to less "SALT CONSENTRATION"[19]. But if opposite happens that means highly concentrated medicine is given to very sensitive patient then it might make the condition of the Patient worse and there might be some side effects too, in our country India there are no law regulating these practices or malpractices.

Generic drug is same drug created for same purpose and same cure with same dosage form, strength quality etc. Generic drug works same as Patented drug and to ensure that (IMA) makes sure that drugs which is available in the market has same market name to maintain the "Bioequivalence Generic medicines are cheaper than Patented Medicines and they works same as Patented Medicine. Generic medicines are medicines with same quality and effectiveness but with very less price, they have same salt used in it and they work same"[20] Bioequivalence means, "*The biochemical similarity of two (or more) drugs that share the same active ingredient(s) and desired outcome(s) for patients*"

Understanding the definition and meaning of Patented Drug

A patent is an exclusive right granted for an invention. Patents benefit inventors by providing them with legal protection of their inventions. However, patents also benefit the society by providing public access to technical information about these inventions, and thus fast-tracking innovation. The first drug to receive a patent in the United States was "Dr. Lee's Windham Bilious Pills[21]", which was patented in year 1796. The UN Secretary General's Special Envoys on HIV/AIDS in the Asia Pacific and Africa. Originally operated together in 2005 to write to the Indian government stressing the value of Generic HIV medications[22]. From India in achieving the goals of universal access to treatment. The world, along with the UN Special Envoys, was intently observing India's move to reconcile its role as the primary provider of safe, effective, and reasonably priced Generic HIV drugs. With its obligation to meet the deadline set by the TRIPS Agreement for amending the Indian Patents Act, 1970. The original Indian Patents Act of 1970[23] removed product patent protection in the Pharmaceutical industry with the goal of guaranteeing public access to affordable medicines. This move was primarily motivated by a "1959 commission report[24]" chaired by "Jurist Rajagopala Ayyangar", which stated that laws "*must be designed, with special reference to the economic conditions of the country, the state of its scientific and technological advance, its future needs and other relevant factors, so as to minimize, if not eliminate, the abuses to which a system of patent monopoly is capable of being put.*"[25]

1.3 REMOVAL OF PRODUCT PATENT IN PHARMACEUTICAL INDUSTRY BY GOVERNMENT OF INDIA

The TRIPS Agreement required India to update its Patent laws to meet the minimum criteria for patent protection and patentability. In 2005, India changed its Patent Act to conform with TRIPS, removing several clauses that made it easier to produce and import low-cost Generic Pharmaceuticals.

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[18] Business Today, Medicine nexus Dolo scandal *available at* https://www.businesstoday.in/industry/pharma/story/dolo-650-makers-spent-rs-1000-cr-on-freebies-to-doctors-to- prescribe-drug-345033-2022-08-19.

[19] Pharm Easy Website, Medicine Concentration Dolo 650 *Available At Https://Www.Google.Com/Search?Q=Generci+Vs+Branded+Generic&Oq=Generci+Vs+Branded+Generic+&Gs_Lcrp=Egzjahjvbwuybggaeeuyotimcaeqixgngiaegiofmg0iahaagjecgiaegiofmhaiaxaagjecgledgiaegiofmgwibbaagbqyhwiygaqycggfeaaysqmygaqydqggeaaysqmygaqyiguycggheaaysqmygaqycggieaaysqmygaqydqgjeaaysqmygaqyigxsaqg1mji1ajbqnkgcalacaq&Sourceid=Chrome&Ie=UTF-8 Last Visited on 10-10-2024*

[20] Pfizer, Branded Vs Generic Drug *Available At* Https://Www.Google.Com/Search?Q=Generci+Vs+Branded+Generic &Oq=Generci+Vs+Branded+Generic+&Gs_Lcrp=Egzjahjvbwuybggaeeuyotimcaeqixgngiaegiofmg0iahaagjecgiaegiofmhaiaxaagjecgledgiaegiofmgwibbaagbqyhwiygaqycggfeaaysqmygaqydqggeaaysqmygaqyiguycggheaaysqmygaqycggieaaysqmygaqydqgjeaaysqmygaqyigxsaqg1mji1ajbqnkgcalacaq &Sourceid=Chrome&Ie=UTF-8 Last Visited on 10-10-2024.

[21] Connecticut History First American Patent *Available At* Https://Connecticuthistory.Org/First-American-Medicine- Patent-Today-In-History-April-30/ Last Visited on 10-10-2024.

[22] *Ibid.*

[23] *Supra* note 1

[24] Ayyangar Committee report 1959, *available at* https://ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-_Justice_N_R_Ayyangar_committee_report.pdf last visit 20-10-2024.

[25] *Supra* note 24

The modified Patent Act established product patents for Pharmaceuticals, requiring inventors to reveal all aspects of their innovations and granting them exclusive rights for 20 years. The study offers an outline of how the TRIPS Agreement[26] has affected the availability and affordability of Generic medications in India. The Indian government's participation in the Pharmaceutical sector is reviewed, including the regulatory framework, policies and programs aimed at boosting access to affordable medications, preserving public health, and balancing the interests of the Pharmaceutical industry.

1.4 LAWS RELATED TO DRUG MANUFACTURING IN INDIA

In India there are many laws which regulated the operation of drugs in all dimensions, some Laws regulated the manufacturing process and guidelines regarding the making process and some regulates quality and quantity of products.

Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940 regulates the distribution, Import and manufacturing of medicines and cosmetics in India. The main purpose of this act is to ensure that these products are safe, effective and meet the standards.[27]

Pharmacy Act, 1948

This Act regulates the Pharmacy profession stops malpractices and established the Pharmacy Council of India. The Pharmacy Council of India oversees the education on Pharmacy and every state has its own pharmacy council which regulated the operations and other activities for pharmacist enrollment.[28]

Essential Commodities Act, 1955

The Essential Commodities Act, 1955 regulates the production, supply, and control of all essential commodities, including drugs/ medicines.[29]

Indian Medical Council Act, 1956

This Act Regulates the medical profession and medical education in all over India. Only those with a recognized medical degree and registration with a state medical council are permitted to practice medicine in India. This law also prohibits medical Practitioners if they are found conducting malpractices.[30]

1.5 HOW FOREIGN NATIONS DEALS WITH COMPULSORY LICENSING:

Compulsory licensing can be termed as a license given by the government or an authorized agency in an intellectual property such as Patent. Once the License is given third party can without the prior or any consent of the original owner or inventor of that Intellectual Property can reproduce the good's which were patented earlier.

United Kingdom- Statutes of Monopolies 1624 In the United Kingdom was the Law, which monopolized the Patented works. The concept of monopoly was severely disapproved by the State. This Act Statutes of Monopolies used to focus on reducing the impact of Patent as many peoples were not able to access and reap the benefit of Patented product or Invention.[31]

The Statute of Monopolies of 1623 states that the United Kingdom is where compulsory licensing originated, as was previously mentioned. In the UK, compulsory licensing is now governed by the Patents Act of 1977. It states that a compulsory license application may be submitted three years following the patent's issuance, provided that the following criteria are met:

- cannot be fulfilled on a reasonable schedule.
- The establishment or growth of commercial activities is negatively impacted by the refusal.

Dependent patents are another feature of the Act. The owner of a dependent patent, or one that is dependent on prior patents, may request a compulsory license on a dependent patent in the event that a technical progression in a patented invention or product that is deemed significant for economic reasons occurs. But the prior patent holder prevents its use. Conversely, the original patent holder will receive cross-licensing on the subject matter.

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[26] [26]W.T.O.T.R.I.P.S Agreement, *available at* https://www.wto.org/english/docs_e/legal_e/27trips_01_e.htm#:~:text=The%20TRIPS%20Agreement%20is%20Annex,Morocco%20on%2015%20April%201994. Last visited on 20-10-2024.

[27] Drugs and Cosmetics Act, 1940 (Act 23 of 1940)

[28] Pharmacy Act, 1948 (Act no 08 of 1948)

[29] Essential Commodities Act, 1955

[30] Indian Medical Council Act, 1956 (Act no 102 of 1956).

[31] United Kingdom- Statutes of Monopolies 1624.

United States of America- 28 US Code, section 1498- There is no explicit clause pertaining to mandatory licensing in US legislation. Still, the government has developed several cures for medical crises and to make pharmaceutical items more accessible to the general public.[32] According to Section 202(c)(4) of the US Code The Bayh-Dole Act of 1980[33] "*grants the US government the right to practice any innovation anywhere in the world as long as it is used to promote and use government-funded technology*". This license is non-transferable, non-exclusive, and irrevocable. Furthermore, it stipulates that the proprietor of an invention created with government assistance may grant a license to any third party for the purpose of health and safety, in accordance with 35 US Code, Section 203(a)[34].

"Section 1498 of the 28 US Code" grants the government the authority to use or manufacture patented products without the consent of the owner or patentee. For the use and production of a patented innovation or product, the patentee may, however, request payment. Therefore, the US does not specifically recognize the idea of forced licensing nor does it have any provisions in place for it. Laws and regulations, however, have been put in place to control the cost of patented goods, particularly those pertaining to the pharmaceutical sector.

1.6 GOVERNMENT'S APPROACH TO COMPULSORY LICENSING

Government of India always tries to balance between social welfare and Economical needs, as Government will always priorities the society over any business. As life of an individual or society is more important than any other thing, whenever the Government have to choose between the society or any other thing then society will be first priority of the government.

Article 38 of Indian Constitution- "*Ensuring that justice, social, economic, and political, informs all institutions of national life"*[35] in DPSP its already mentioned that state is responsible for social welfare, socio economic justice etc. All though DPSP's[36] are non-justiciable we as a citizen can't claim them by filing a suit against the State bur state can take actions for the welfare and upliftment of the society. In the case of Patents and Pharmaceutical Industry Government of India operates in a different manner. The kind of Government we have is Socialist Government, it's also mentioned in our Preamble.[37]

Section 84 of Patent Act 1970- The Act's Section 84 addresses licenses that are required. Section states that following the expiration of three years from the date of patent grant, any interested party may apply to the Controller for the issuance of a compulsory license. The following grounds may be used to support an application for a compulsory license:[38]

- Requirements of the public are not satisfied with respect to patented inventions.
- The patented invention is not available at affordable prices to the public.
- The invention is not working in the country.

Bayer Healthcare LLC vs Natco Pharma Limited

The German Pharmaceutical business Bayer Corporation developed the medication "Nexavar" to treat kidney cancer. In 2008, India obtained patent protection for this medication. Following that, in 2010, an Indian Pharmaceutical business made contact with Bayer Corporation in order to request a voluntary license to produce the medication. They applied to the Controller for the issuance of a compulsory license, but their request was turned down. The Bayer Corporation approached the Intellectual Property Appellate Board (IPAB) in 2012 after being given a license that they felt was unfair. Similar to the Controller's choice, the board made one as well. As the patentee is using the rights granted to it, the board also stated that the patentee needs to make sure the drug is accessible to the general public. All three of the requirements listed in Section 84 were also met in this instance. This medication, which treats kidney and liver cancer, costs about Rs 2.8 lakh for a month's supply. Natco Pharma proposed to sell it for about Rs 9000, making this potentially life-saving medication easily affordable for everyone in society, not just the wealthy. The broader public gained from this choice. The Pharmaceutical corporations, however, criticized it, arguing that the license should never have been granted since they feared losing their rights to their copyrighted discoveries and products.[39]

Notwithstanding, Natco Pharma is honoring its agreement with the United Nations Development Program (UNDP)[40] by paying Bayer royalties at a quarterly rate equal to 6% of total sales. Three anti-cancer medications "trastuzumab", "ixabepilone", and "dasatinib" were suggested for mandatory licenses by the Indian Health Ministry in January 2013. Due to this, the governmentwill be able to provide these medications at a much-lower cost and make them available to those who were earlier unable to purchase them.

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[32] United States of America- 28 US Code.
[33] The Bayh-Dole Act of 1980.
[34] 35 US Code.
[35] Constitution of India, Article 38.
[36] *Ibid*.
[37] *Supra* note 35.
[38] *Supra* note 3.
[39] *Bayer Corporation Vs. Union of India and Others (Bayer v. Natco*), year *available at* https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020- 12/Bayer%20Corporation%20Vs.%20Union%20of%20India%20and%20Others%20IPAB%202013.pdf last visit 20-10-2024.
[40] UNDP *available at* https://www.undp.org/india/publications/five-years-product-patent-regime-indias-response last visit 20-10-2024

1.7 IMPORTANCE OF COMPULSORY LICENSING FOR SOCIAL WELFARE

Following are some of the main reasons why Patented works must be licensed compulsorily: Works that have been unjustly kept out of the public domain can now be accessed through compulsory licensing.[41]

- These works are accessible to the public, allowing for a variety of useful and instructive applications.
- This licensing scheme encompasses a variety of works, such as works by disabled people and works by orphans.
- When an unpublished work's author passes away before it is published, the work can still be made public, thanks to forced licensing.
- The primary aim of compulsory licensing is to guarantee public accessibility to the work, allowing everyone to utilize and reap its benefits for various purposes.
- Fair use of the material and abstaining from unethical behavior are crucial.

1.8 EFFECTS OF COMPULSORY LICENSING ON RIGHTS OF PATENT HOLDER

Compulsory license is used to manufacture patented medicine at low cost by licensed private pharmaceutical companies. When a patented drug is manufactured by many manufacturers then cost of production decreases and quantity increases. As result it becomes assessable to public in large due to the steps taken by government, government always tries to promote equal distribution of resources among the citizens and compulsory licensing is the best way to do that in health care sector, Government also runs many schemes such as *"JAN AUSHADHI KENDRA"*[42]

The Department of Pharmaceuticals and the Government of India announced a new initiative in 2008 to improve citizen wellbeing because India is an emerging country with a very low per capita income. This initiative, called "JAN AUSHADHI"[43] (a Hindi term meaning "Medicines for Peoples") is tasked with producing high-quality, unbranded medicines at very reasonable and cheap prices for the nation's needy population. In practice, however, "JAN AUSHADI KENDRA" always offers more discounts than the specified MRP, ensuring that no one is left behind. Since Generic medications are so pocket friendly and of outstanding quality, more people are choosing them these days. As of March 15, 2018, 3200 Jan Aushadhi Stores had opened in more than 33 States and Union Territories. However, there are still insufficient Jan Aushadhi Kendras available countrywide because there are more than 8 lakh retail pharmacy stores. According to the most recent data available as of June 30, 2024. There are 12616 Janaushadhi Kendras that are operational. The product basket includes 300 surgical instruments and 2047 medications. Pharma and Medical Bureau of India (PMBI), a society registered under the Society Registration Act, is in charge of carrying out the project. However, Jan Aushadhi Kendras are still needed in a lot of rural regions, but they are not available.[44]

Public health emergencies- In case of Public health emergencies such as Pandemic and Epidemic Government always allows Private drug manufacturers to enter into the patented drug market and manufacture the drug with the permission of government of India. The first compulsory license was given in year 2012, In the case of Bayer Healthcare LLC vs Natco Pharma Limited where the medicine price of German Company was way too high and Indian Company was able to manufacture and sell for 9000/ INR only, in the case of public health emergencies government allows compulsory licensing.

Patent holder profits- compulsory licensing is done only after three years from the date on which the patent has been granted. And there is always royalty money awarded to original patent holder or inventor company. Government's approach towards Patentee and Society are very positive, Government promotes both of them at the same time, despite knowing that the invention and manufacturing of Drugs cost billions of dollars, the Research and development is way too costly as result government take care of the rights of Patent holders, in the case of Bayer vs Natco, 6% of profit margin is given to German company i.e. Bayer Healthcare LLC . Because welfare of the state is only possible by facilitating businesses and government have to maintain the balance between Society and Business.[45]

1.9 CONTEMPORARY CHALLENGES FACED BY THE PHARMACEUTICAL INDUSTRYIES IN SECURING THEIR PATENT **RIGHTS**

Under Section 84 of Patent Act 1970, regarding compulsory licensing, there are many challenges which are faced by Government, Pharmaceutical companies and Citizens also.

Inadequate supply of Generic medicines which fails the Compulsory licensing of government

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[41] *Supra* note 4.
[42] Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals , PMBJP *available at* https://janaushadhi.gov.in/pmjy.aspx last visit 20-10-2024
[43] *Supra* note 42
[44] *Supra* note 42
[45] *Supra* note 39.

To Promote the Generic medicines government introduced Jan Aushadhi Kendra's nation-wide, in this policy government endorsed Generic medicines over patented medicines. But when people visit's Janaushadhi Kendra there are many medicines which are never available most of the time those medicines are the costliest one's. Which are always short on demand? This is nothing but the nexus between Pharmaceutical Companies and retailers who don't sell Generic medicines as they provide very less profit margin compared to Patented medicines, and in the race of monetary benefit Doctors prescribes Patented medicines only. Where they can prescribe Generic medicines. This nexus between retailers and Pharma companies is regulated by distributers who offers chunk of cash and other monetary benefits such as Family Trip, Cash, Gift etc. If retailer is able to sell Patented medicines up to the mark set by distributers. In this race of sale of medicines and earning profit public health and purchasing power parity is highly affected.[46]

The main purpose of compulsory licensing is to provide Generic low-cost high-quality medicines to the peoples. But when pharmaceutical industries enter and tries to temper the sale and supply chain of the medicines then the real problem accrues. It tries to collapse the rules and regulations made by government of India and makes the loophole to bypass the existing laws. When there will be no supply of goods then what retailers will sell? that's the mindset behind patented drug manufacturers retailers don't sell Generic medicines as a result only option public is left with is to buy Patented medicine.

When a person suffers from fever the main medicine required for cure is "Paracetamol" which costs 8 rupees only per strip is a Generic drug, and Dolo 650 which costs 33 rupees per strip which is a Branded Generic drug[47]. Here branded Generic drug costs more than 4 times of Generic drug both having same active ingredients used for same problem, most of the medical stores and Pharmacies sell Dolo 650 or any other Drug having Paracetamol salt in it but not original Paracetamol because there is very low margin in the sale of Generic medicines. This is the place where compulsory licensing fails that's the gap where the law should be formulated in India, in United States of America doctors suggests 70-80 percent Generic drugs rest 20-30 percent can be patented medicine, in USA law regulates the distribution of medicines but in India there is no such law exist which regulated the prescriptions of doctors.[48]

BIBLIOGRAPHY –

1. V.K. Ahuja Book on "Laws related to intellectual property rights" Lexis Nexus.
2. Patent Amendment Act 1970.
3. WTO article on Compulsory licensing of pharmaceuticals and TRIPS.
4. Trade related Intellectual Property Rights. TRIPS Agreement.
5. Bayer Corporation v. Natco Pharma Limited case law.
6. Kluwer Patent Blog, United States Article on Compulsory Licensing in United States.
7. Pharmaceuticals and Medical Devices Bureau of India (PMBI) article on Pradhan Mantri Jan Aushadhi Pariyojna (PMBJP), Ministry of Chemicals & Fertilizers Department of Pharmaceuticals.
8. The Constitution of India, Article 38.
9. National Library on Medicines, United States journal of global health on Compulsory licensing during Covid-19.
10. United Kingdom- Statutes of Monopolies 1624.
11. United States of America- 28 US Code, section 1498.
12. Bayh-Dole Act of 1980.
13. Department of pharmaceuticals, Ministry of Chemicals and Fertilizers, Annual Report 2023- 2024 on Pharmaceutical Industry in India.
14. Competition Act 2002.

[46] PMBJP Department of Pharmaceuticals *available at* https://janaushadhi.gov.in/pmjy last visited on 20-10-2024.
[47] Paracetamol drug price *available at* https://pharmeasy.in/online-medicine-order/dolo-650mg-strip-of-15-tablets- 44140 last visit 20-10-2024.
[48] *Supra* note 42.