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COMPULSORY LICENSING IN PHARMACEUTICALS: FROM BEING RELEVANT TO BEING NECESSARY

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ABSTRACT

India is a developing nation shouldering the responsibility of sustaining 17.5% of the world's population. According to Multidimensional Poverty Index, 2022 India ranks first in the world. Given the lack of resources with people and the prevalence of several complicated health conditions, the majority of people in India cannot afford the high prices of 'Cure Medicines'. Therefore, under Chapter XVI of the Indian Patents Act, of 1970, India provided for compulsory licensing keeping in view public health and morality. Compulsory licensing refers to a legal mechanism that allows a government to grant licenses for the production or use of a patented invention without the permission of the patent holder. It is an important tool that can be employed in certain circumstances to ensure access to essential products, particularly in the fields of healthcare, pharmaceuticals, and public health. Compulsory licensing is typically used when a patented invention, such as a medicine, is deemed to be of vital importance for public health, but the patent holder is unable or unwilling to supply the product in sufficient quantities or at affordable prices. By granting compulsory licenses, governments can authorize other manufacturers to produce the patented product or use the patented technology, thereby increasing its availability and affordability. The decision to grant a compulsory license is typically made by the government or a competent authority based on specific criteria and procedures outlined in national patent laws and international agreements. These criteria often include factors such as public health needs, the unavailability of the product, efforts to negotiate with the patent holder, and fair compensation to the patent holder. Compulsory licensing is recognized under international trade agreements, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO). A TRIP allows member countries to issue compulsory licenses under certain conditions, including cases of national emergencies, public non-commercial use, and anti-competitive practices. The use of compulsory licensing is a balancing act between the

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protection of intellectual property rights and the public interest. It aims to strike a balance by ensuring that essential products and technologies are accessible to those in need while providing reasonable compensation to patent holders for their innovations. It's worth noting that compulsory licensing should be implemented judiciously and by applicable laws and international obligations. It is generally considered a measure of last resort, to be used when other efforts to obtain the necessary products or technologies through voluntary means have failed or are deemed inadequate. Through this paper, the researcher aims to comprehensively analyze the importance of compulsory licensing in India and also aims at evaluating to what extent its application is deemed to be judicious and well-placed.

Keywords: Compulsory Licensing, TRIPS, Patent, Intellectual Property, Pharmaceuticals.

Introduction

A patent is a protection given to the inventor for a product or a process that provides, a new resourceful way of doing something, or offers way out to a problem. An invention which has Novelty, Inventive Step and Industrial use is the one eligible for patents right.[3] The Patents Act, 1970 is the ultimate legislation governing patent regime in India. The Office of the Controller General of Patents, Designs and Trade Marks or CGPDTM is the body responsible for the Indian Patent Act. Under this act patent right is granted for 20 years from the date of filing the application for patent. In case the application is filed under Patent Cooperative Treaty, then the patent is deemed to be allotted from international date of filling. A patentee has several benefits of attaining patent, namely Right to sue for infringement, Right to exclude others from manufacturing patented product, Right to grant license, Right to exploit patent for own material benefit and Right to surrender or transfer patent.

In 2005, India patent law underwent material change as it had to be brought under the umbrella provisions of Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. India brought complete compliance to TRIPS agreement by bringing in Patents (Amendment) Act, 2005. Prior to ratification of TRIPS, Indian Patent laws related to Pharmaceutical industries were more inward looking allowing cheaper imports of drugs and domestic production of generic medicines providing affordable medicines to masses. However, due to TRIPS India had to amend Patents Act, 1970 in order to comply with the minimum standard of patentability and protection of patents rights. India had to remove some provisions[4] which earlier provided for a way to protect Indian Pharmaceutical industry from cut throat competition and provided

[3] The Patent Act, 1970, India, Section 3 and 4 of Patent Act, 1970, available at: https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.html (last visited on June 12,2023)

[4] The Patent Act, 1970 (Act 39 of 1970) Section 3(d).

affordable medicines for masses. There was an introduction of 'Product Patents 'for pharmaceuticals, making it mandatory for inventors to disclose the full and complete details of the invention and enabling them to exclude others and fully exploiting their invention single handedly for 20 years.

Compulsory Licensing: International aspect

Compulsory licensing has international implications and is governed by international agreements, most notably the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement under the World Trade Organization (WTO). Here are some key international aspects of compulsory licensing:

- *TRIPS Agreement*: The TRIPS Agreement sets out minimum standards for intellectual property protection, including patents, and provides flexibility for member countries to issue compulsory licenses under specific conditions. It does not specifically mention words ' Compulsory Licensing' but does provide for 'other use without authorization of the right holder' in Article 31[5] Without the right holder's consent, the government or other parties it has granted authorization to may exploit a patent. Such permission is granted if specific requirements are met, including non-commercial use, non-exclusive usage, applicant has already made steps to seek license from patentee (although, this is not applicable in cases of national emergency or extreme urgency conditions), etc. Subparagraph (h) of Article 31[6] of the TRIPS Agreement additionally stipulates that the patent holder shall receive an adequate compensation that takes into consideration the economic worth of the patent. The most significant part of Article 31's subparagraph (f)[7] is the statement that the product is solely intended for the local market, which restricts the countries that can manufacture goods from receiving the advantages of a compulsory license. However, poor or least developed nations with little to no industrial capacity are the ones who experience health crises the most. TRIPS undoubtedly offered many advantages, but it also required modification, which was accomplished by the Doha Declaration in November 2001, which permitted the member country to issue a mandatory license to produce drugs for export to nations that proved they had no or very limited drug manufacturing capacity.[8]

[5] The Agreement on Trade-Related Aspects of Intellectual Property ,art.31
[6] Id.
[7] Id.
[8] Amanpreet Kaur and Rekha Chaturvedi, "Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma"20 Journal of Intellectual Property Rights, 279-287 (2015).

- *Doha Declaration on TRIPS and Public Health*: The Doha Declaration, which was adopted in 2001, underlined the TRIPS agreement's flexibility to safeguard public health and advance universal access to medications. One of the flexibilities listed in the Doha Declaration is "the right to grant compulsory licenses." A government organization or a court may issue a compelled license to use a patented invention in a particular way without the consent of the patent holder. This approach is acknowledged as a legal alternative or flexibility under the TRIPS Agreement, and some WTO members have taken advantage of it in the pharmaceutical sector. It typically appears in the majority of patent laws. To address anti-competitive behavior, mandatory licenses had to be given under the original TRIPS regulations, which restricted their use to domestic markets. It was made clear that TRIPS permits the use of mandatory licensing.[9] In order for nations to be able to take the necessary actions to safeguard the interests of public health, licensing is required to address public health emergencies.
- *Paragraph 6 System*: The TRIPS Agreement introduced the Paragraph 6 system, also known as the "compulsory licensing and export" provision. It allows countries with insufficient manufacturing capacities to import generic versions of patented medicines produced under compulsory licenses from other countries. This provision addresses the challenges faced by developing countries in accessing affordable medicines.[10]
- *Differential Treatment for Least Developed Countries (LDCs):* LDCs have additional flexibilities under TRIPS. They have an extended transition period until 2033 to implement patent protection for pharmaceutical products. During this period, they are not obliged to grant or enforce patents or provide exclusive marketing rights for pharmaceutical products, which allows them more flexibility in addressing public health needs.
- *Access to Medicines in Developing Countries*: Compulsory licensing is particularly relevant in developing countries, where access to affordable medicines is often limited. The international framework, including TRIPS, recognizes the need to strike a balance between intellectual property rights and public health, allowing countries to issue compulsory licenses to address public health challenges and promote access to medicines.
- *International Disputes*: Disputes related to compulsory licensing and its compliance with international agreements, including TRIPS, can be brought before the WTO's Dispute Settlement Body. This mechanism ensures that countries can seek resolution

[9] The Doha Declaration, 2001. Para 6.
[10] Id.

when concerns arise regarding the implementation of compulsory licensing provisions.

It's important to note that while international agreements provide guidelines and flexibility for compulsory licensing, the specific implementation of compulsory licensing provisions may vary among countries based on their national laws, regulations, and specific public health needs. Countries have the flexibility to tailor their compulsory licensing provisions within the framework provided by international agreements to address their unique circumstances.

Patenting in Pharmaceutical Industry in India

Known to be emerging '*Pharmacy of the World'* India's pharmaceutical industry is currently valued at USD 50 bn[11] with major chunk of exports of generic medicines being provided by India to entire world. Automation in the pharmaceutical industry has revolutionized the way that materials are handled, medications are distributed, and formulations are manufactured and packaged in various industries with little to no human involvement. Companies are constantly utilizing improvements in AI technology to develop new and improved medicines as well as to locate rapid access points for patients to care. Recently, patents have been granted for the use of machine learning, including the classification of digital images of cells that have been treated with various experimental compounds as well as the use of image processing and machine learning algorithms to test compounds against samples of diseased cells based on previously recorded historical data as a control. Convolutional Neural Network (CNN) usage is just one example of a recent advancement in diagnostic and research. Just before the 2005 amendment. The Indian pharmaceutical industry was significantly impacted by the lack of product patent protection in the pharmaceutical and agrochemical sectors, which resulted in the development of significant expertise in the reverse engineering of drugs that are patentable as products throughout the industrialized world but unprotected in India. But after introduction of amendments and product patenting, prices of many lifesaving medicines have skyrocketed making them completely inaccessible and unaffordable to masses. The main problem that is being faced by India currently is that pharmacy industries indulge in strategic improvements in medicines which actually have minimal contribution towards improvement of efficacy of drug but a happy gift to the inventors of renewed 20 years of patent rights.

Indian pharmaceutical firms have been accused of breaking intellectual property rights (IPR) rules, which has led to legal battles with international pharmaceutical firms. In one such instance, Roche, a Swiss pharmaceutical business, and Cipla, an Indian pharmaceutical

[11] bn- Billion

company, engaged in 2014. By creating a generic version of the cancer medication Tarceva, Cipla was charged by Roche with violating the terms of the drug's patent. The argument intensified, resulting in a legal struggle between the two businesses. The Delhi High Court found in Roche's favor in 2016 and confirmed that Cipla had in fact violated Roche's patent rights. As a result, Cipla was mandated to compensate Roche.[12] Patenting in the pharmaceutical industry in India is closely tied to the provisions of compulsory licensing, which allow the government to grant licenses to third parties to produce and sell patented pharmaceutical products without the consent of the patent holder.

Here is an overview of how compulsory licensing relates to patenting in the pharmaceutical industry in India:

Compulsory Licensing Provisions: The Patents Act, 1970, includes provisions for compulsory licensing in certain circumstances. Section 84 of the Act[13] outlines the grounds for granting compulsory licenses, which include:

- *Failure to work the invention in India*: If the patented invention is not being worked in India or if there is insufficient working of the invention in India, a compulsory license can be granted. This provision aims to prevent the abuse of patents that are not being utilized or exploited effectively in the country.
- *Reasonable requirements of the public*: If the demand for the patented product is not being met on reasonable terms or at a reasonable price, a compulsory license can be granted to address the public's needs. This provision ensures access to essential medicines and promotes public health interests.
- *National emergency or extreme urgency*: In cases of national emergency or circumstances of extreme urgency, such as public health crises, the government can authorize the use of a patented invention to meet urgent requirements. This provision allows for the production and supply of essential medicines during emergencies.
- *Compulsory License Application Process*: To obtain a compulsory license, an interested party needs to apply to the Controller of Patents by submitting a detailed application justifying the grounds for seeking the license. The Controller evaluates the application based on the specified criteria and may grant the compulsory license if the

[12] The Law Brigade Publisher*, Case Analysis: F. Hoffmann-La Roche Ltd. & Anr. v Cipla Ltd.*, June 16,2017, available at https://thelawbrigade.com/intellectual-property-rights/case-analysis-f-hoffmann-la-roche-ltd-anr-v-cipla-ltd /(last visited on 30 June 2023)
[13] The Patent Act, 1970 (Act 39 of 1970) S. 84 Compulsory licences.

grounds are satisfied.

- *Negotiations and Attempts to Obtain Voluntary License*: Before granting a compulsory license, the Patents Act requires the applicant to make efforts to obtain a voluntary license from the patent holder on reasonable terms and conditions. The applicant must provide evidence of such attempts in the application for a compulsory license.
- *Terms and Conditions of Compulsory License*: The terms and conditions of a compulsory license, including the scope, duration, and royalty payments, are determined by the Controller of Patents. The license is non-exclusive, and the licensee is typically required to meet the reasonable demands of the market and ensure the affordability and availability of the product.
- Public Interest Protections: The Patents Act includes safeguards to protect the interests of patent holders and to prevent the abuse of compulsory licensing provisions. These safeguards include provisions for reasonable compensation to the patent holder and the ability to revoke the compulsory license if the circumstances justifying it no longer exist.

There have been a few landmark cases related to compulsory licensing in the pharmaceutical industry in India. Here are a few notable examples:

Natco Pharma Ltd. v. Bayer Corporation:[14] This case involved Natco Pharma seeking a compulsory license for Bayer's patented cancer drug, Sorafenibtosylate (Nexavar). Natco argued that the drug was not reasonably affordable or available to the public. The Controller of Patents granted Natco a compulsory license, allowing them to manufacture and sell a generic version of the drug. This case was significant as it marked the first compulsory license issued in India under the amended provisions of the Patents Act.

BDR Pharmaceuticals vs. Bristol-Myers Squibb:[15] BDR Pharmaceuticals filed an application for a compulsory license for Bristol-Myers Squibb's patented cancer drug, Dasatinib (Sprycel). BDR Pharmaceuticals argued that the drug was not available to patients at an affordable price. The Controller of Patents rejected the application, stating that BDR Pharmaceuticals did not make sufficient efforts to obtain a voluntary license from Bristol-Myers Squibb. This case highlighted the importance of demonstrating efforts to obtain voluntary licenses before seeking compulsory licenses.

[14] Natco Pharma Ltd. v. Bayer Corporation Before the Indian Intellectual Property Appellate Board (IPAB) Decision Date: 04.03.2013
[15] BDR Pharmaceuticals vs. Bristol-Myers Squibb CS(COMM) 27/2020

Lee Pharma Ltd. v. AstraZeneca[16]: Lee Pharma applied for a compulsory license for AstraZeneca's patented diabetes drug, Saxagliptin. Lee Pharma argued that the drug was not being made available to the public at a reasonably affordable price. The Controller of Patents rejected the application, stating that Lee Pharma did not establish a prima facie case for granting a compulsory license. This case highlighted the importance of providing strong justifications and evidence to support a compulsory license application.

It's important to note that compulsory licensing is a complex and contentious issue, and the specific application and interpretation of the provisions can vary depending on the circumstances. The use of compulsory licensing in the pharmaceutical industry is aimed at balancing the protection of patent rights with public health interests and ensuring access to affordable medicines.

Compulsory Licensing- Gracious Messiah of masses

Compulsory licensing can play a significant role in helping poor people by improving access to essential medicines. Here are some ways in which compulsory licensing can benefit the poor:

- *Affordable Medicines*: Compulsory licensing allows for the production of generic versions of patented drugs, which are generally more affordable than their branded counterparts. This helps lower-income individuals and marginalized communities access life-saving medications that they may otherwise be unable to afford.
- *Increased Competition*: By introducing competition into the market, compulsory licensing can drive down prices of patented medicines. When multiple manufacturers produce generic versions of a drug, it creates a competitive environment that can lead to further price reductions, benefiting poor patients who rely on these medicines.
- *Expanded Availability*: Compulsory licensing can expand the availability of essential medicines, ensuring a more significant supply to meet the needs of the population. This is particularly relevant in developing countries where access to healthcare infrastructure and medicine distribution networks may be limited. Increased availability can save lives and improve the overall health outcomes of poor individuals.
- *Public Health Emergencies*: During public health emergencies or crises, such as outbreaks or pandemics, compulsory licensing can be invoked to address urgent needs. It allows for the rapid production and distribution of medicines, vaccines, or medical

[16] Lee Pharma Ltd. v. AstraZeneca C. L. A. No. 1 of 2015.

technologies required to combat the health crisis, ensuring that poor populations have access to critical healthcare interventions in a timely manner.

- *Health System Strengthening*: Compulsory licensing can contribute to the strengthening of healthcare systems, particularly in resource-constrained settings. By facilitating access to affordable medicines, it helps governments allocate their healthcare budgets more effectively, enabling them to provide a broader range of essential services and treatments to underserved populations.

It is important to note that while compulsory licensing can positively impact access to medicines for the poor, it should be implemented judiciously and in line with legal frameworks and international agreements. Balancing the interests of patent holders and the public interest is crucial to maintain innovation incentives while ensuring affordable access to necessary medications for disadvantaged populations.

Conclusion and Suggestions

On the one hand, creators make a substantial contribution to the development of novel, improved treatments for the benefit of society. In contrast, generic drug companies benefit society by offering less expensive versions of name-brand drugs, which drives down drug costs and makes it simpler for individuals to access affordable treatments. Society benefits most from new and improved drugs as well as prompt access to generic drugs when the interests of these two parties are balanced. However, if one of the parties wins out, society will suffer since there won't be enough access to either innovative or cost-effective treatments. The effective promotion and protection of both generic competition and pharmaceutical innovation are so imperative.

Suggestions:

- Strengthen Regulatory Frameworks: Governments should establish robust regulatory frameworks that clearly define the circumstances and criteria for granting compulsory licenses. This will ensure that the provision is used judiciously and in alignment with international agreements, such as the TRIPS Agreement.
- Prioritize Public Health Needs: When considering compulsory licensing, policymakers should prioritize public health needs, especially in cases where access to essential medicines is limited due to high prices or insufficient supply. Balancing patent rights with the urgent requirement for affordable and accessible medications should guide decision-making.
- Promote Collaboration and Voluntary Licensing: Encouraging voluntary licensing

agreements between patent holders and generic manufacturers can be an effective alternative to compulsory licensing. Governments can facilitate negotiations and incentivize voluntary licenses to promote innovation and access simultaneously.

- Ensure Fair Compensation: When granting compulsory licenses, mechanisms for fair compensation should be established to address the concerns of patent holders. Determining reasonable royalty rates or other forms of compensation can help maintain a balanced approach that supports innovation incentives while addressing public health needs.
- Continued Monitoring and Evaluation: It is crucial to monitor the impact and effectiveness of compulsory licensing provisions in the pharmaceutical sector. Regular evaluation of the outcomes, including access to medicines, innovation, and market dynamics, can inform policy adjustments and ensure that the provision remains relevant and necessary.

By adopting these suggestions, governments can navigate the complex landscape of compulsory licensing in pharmaceuticals, recognizing its importance in promoting public health while upholding intellectual property rights and fostering innovation.

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