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CRITICAL ANALYSIS OF COMPULSORY LICENSING IN PUBLIC HEALTH CARE SYSTEM

ABSTRACT

The COVID-19 pandemic has disrupted the most economies across the world. The cost of treatments has risen. Even in the developed nations of the world, the patients have struggled to pay for such expensive treatment of drugs and medicines. In this situation, the low-income countries are looking forward to leverage the system of compulsory licensing. Under the Trade-Related Aspect of Intellectual property Rights (TRIPS) of the World Trade Organization (WTO). However, these measures may also prove counterproductive. It discourages research during the time of the pandemic, makes developing nations more vulnerable to non-availability of critical drugs, and makes the provision available for abuse at the hands of developed economies with mature patents systems. This paper aims to critically study the provisions for compulsory licensing in public health care systems.

Keywords: compulsory license, health care, TRIPS, WTO, research, intellectual property

BACKGROUND

Compulsory licensing authorizes the use of patents to companies and individuals other than the owner of such patents. The term compulsory licensing is not used in TRIPS Agreement. It uses the phrase 'other than the authorized use'[1]. The agreement provides for various grounds and circumstances under which government can make use of such provision. Under A. 31of the TRIPS agreement, it is imperative for a person applying for a license to have tried negotiating with the owners of the patent for voluntary licensing. Even though it does agree, the authorities have to ensure 'adequate remuneration' or 'economic value' to the patentee for taking away one's compulsory licensing use rights to use of his intangible assets. It mentions certain grounds under which such licensing can be authorized. Such compulsory license can be used for national emergencies, other circumstances of urgency, government or public noncommercial use. This, however, is no justification for the provision of compulsory licensing. The compulsory licensing was primarily aimed at the supply of essential medicines in the domestic market. However, the 2017 amendment at the ministerial conference at Doha, allows for export to countries who lack infrastructure for manufacturing it themselves.

In India, the patent legislation has incorporated this provision under Sec 84 of the Indian Patent Act, 1970. A compulsory license can be granted after the expiration of 3 years from the issue of license. The reasons for which this can be done are- Reasonable requirements of the public with respect to patented drugs have not been satisfied or non-availability of essential drugs at a reasonable cost or if the patented invention is not worked in India.

NEED FOR COMPULSORY LICENSING

The need for compulsory licensing was felt at the background of the growing need for drugs in life-threatening diseases like HIV Aids, cancer, etc. It was an afford directed to aid low and middle-income economies to provide affordable drugs for people suffering from such diseases. The Agreement on Trade-Related Aspect of Intellectual Property rights (TRIPS) provides for authorized use of patented drugs for 'own use' by the government. The government use license

[1] Article 31 of the TRIPs Agreement.

allows both government entities as well a private entity to make use of the patented drug. This provision could further be used for both domestic and for exporting to other low and middle-income groups. The use of compulsory licensing is further supported by various treaties, legislations, etc. The UN High-Level Panel on Access to Medicines recommended the implementation of legislation and the use of compulsory licensing. the Lancet Commission on Essential Medicines Policies recommended that in case of voluntary licensing, the national patent legislation can provide for effective licensing of essential medicines. The need for the provision has been reaffirmed in the Doha Declaration of the WTO ensuring the right of member nations to provide essential drugs for public health care.

JUSTIFICATIONS FOR USE OF COMPULSORY LICENSING

1. **Avoid monopoly-** The patent system has aimed to protect the rights of the innovators and to encourage research and development. However, often it is seen that pharmaceutical companies dissuade competition from generic medicine and biosimilar medicine by simple reformulations of drugs. This allows them to have an absolute monopoly over the market.
2. **Preventing over the pricing of medicines**- The provision of compulsory licensing is an effective remedy to prevent overpricing of medicine. The Covid 19 pandemic provides a perfect ground for studying overpricing of medicines, out of the pocket expenditure. Even the patients in developed countries of Europe, USA have struggled with the cost of treatment. This has made the situation in low and middle-income countries difficult. The provision has been used in case of HIV treatment. The same can be done for the treatment of the coronavirus[2]. While there is no remedy for the treatment of the virus, the government of developed countries can issue a compulsory license for certain drugs used in the treatment.
3. **Import of foreign generic medicine as an alternative to overpricing**- It has been an issue not just for alternate production of generic medicines for the domestic market but also for imports from foreign countries. For example: On 24 March 2020 the Israeli government issued a compulsory license to import generic versions of lopinavir/ritonavir (AbbVie's Kaletra). This antiretroviral drug has been determined as a potential drug that could be a possible treatment for COVID-19 patients. Hence, Israel's government has

[2] https://www.ncbi.nlm.nih.gov/pmc/articompulsory licensing es/PMC7242884/

decided to issue a compulsory license. However, unlike Thailand and Brazil, Israel did not issue the license due to the drug's pricing. Instead, lt has been issued to get alternative generic medicine from India.

In March, lawmakers in Canada, Chile, and Ecuador set the legal foundation for the issuing of COVID-19-related forced licenses. The Canadian Patent Act was altered by the COVID-19 Emergency Response Act to allow for a faster process for obtaining a compulsory license on public health concerns. The legislation permits the government to grant necessary inventions a license and afterward negotiate remuneration. Chile's Chamber of Deputies (the lower house of the country's Congress) has enacted a resolution authorizing the use of obligatory licenses for COVID-19 prevention and treatment. The resolution affirms that the coronavirus pandemic is an adequate cause for granting COVID-19-related technologies compulsory licenses. Similarly, an Ecuadorian National Assembly Committee has passed a resolution demanding the Ecuadorian President and Minister of Health to employ compulsory licensing to give free or inexpensive access to COVID-19-related preventative, diagnostic, and treatment technologies. Other developing countries should take comparable legal and legislative actions to create a framework for employing compulsory licenses if they are required.

4. **Evergreening of patents**- Evergreening of patents is often referred to as abuse of the patents systems. Evergreening of patents is referred to the practice where the life of a patent is extended to another 20years by minor reformulations or slight iterations in the drug without necessarily increasing the efficacy of the drug. To prevent this, the patents regime in India proposed an amendment to the Indian Patents Act, 2003. Its intent is also reflected in the Novartis case.

Sec 3(d) of the Indian Patents Act, 1970 which says "the mere discovery of a new form of a known substance or mere discovery of any new property or new use for a known substance or of the mere

use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant'[3]

The provisions of the act aim to prevent the evergreening of patents. The Indian patent level in the pharmaceutical industry thus has led to a greater emphasis on the therapeutic efficacy of the drugs. The stand has been substantiated in the Novartis case[4]. The condition of increased efficacy of the drug in Sec 3(d) of the Indian Patents Act was in question. The Novartis contended that improvement in physical characteristics and product stability

Novartis had filed an application before the Chennai Patent Office, in relation to a drug called GLIVEC. This drug was only slightly different from the earlier drug used for Leukemia. The Patent Office rejected the application under Sec 3(d) of the Act. The Novartis prayed the court to decompulsory licensing are sec 3(d) violative of A.14 as it was based on arbitrary powers to the controller and to decompulsory licensing are sec 3(d) non-compliant with the TRIPS Agreement. The Court, however, rejected the application. It added that the aim of the patent system was to discourage exploitation in the patent system.

The judgment is further affirmed the following

- The patent systems aimed at preventing the evergreening of patents
- To provide easy access to life-saving drugs
- To fulfill the constitutional obligation of providing access to public health care for its citizens.

SUCCESS STORIES IN THE ISSUE OF A COMPULSORY LICENSE FOR THE TREATMENT OF CERTAIN DISEASE

Compulsory licensing has primarily been used for HIV/AIDS therapies, whether it results in an actual issuance or a lower negotiated drug price. Brazil, Ecuador, Ghana, Indonesia, Malaysia, Mozambique, Thailand, Rwanda, Zambia, and Zimbabwe all issued obligatory licenses for one or more antiretroviral medications in the 2000s, in response to the misery of their HIV-infected

[3] Indian Patents Act, 1970
[4] https://indiankanoon.org/doc/165776436/

residents who couldn't afford antiretroviral therapy. While most nations only provided licenses for a single patented medicine, Ghana and Zimbabwe issued blanket licenses covering all antiretroviral drugs.

Thailand and Brazil were two nations that had substantial progress in lowering antiretroviral medicine prices in the mid-2000s. Both countries provided free antiretroviral treatment to all residents living with HIV/AIDS, thus they were eager to find low-cost antiretroviral supplies. Both companies wanted to get efavirenz (marketed by Merck as Sustiva) and lopinavir/ritonavir (marketed by AbbVie, then Abbott Laboratories as Kaletra) for their patients. Merck proposed efavirenz for $500 per patient per year (PPPY) in initial price negotiations with Thailand, whereas Abbott offered lopinavir/ritonavir for $2200 PPPY. Due to the high prices, the Thai government rejected both of these offers and issued forced licenses for both medications in late 2006 and early 2007. The Thai government was able to acquire generic versions of antiretroviral medications from India at a far reduced cost, with generic efavirenz costing US$224 PPPY and generic lopinavir/ritonavir costing US$676 PPPY.

In 2007, Brazil, like Thailand, issued an efavirenz required license. Merck proposed efavirenz to Brazil at a price of US$760 PPPY at first. Brazil was able to import generic efavirenz at a cost of US$170 per patient/year after receiving a required license. Unlike Thailand, however, Brazil has not issued a mandatory license for lopinavir/ritonavir. Abbott Laboratories eventually reduced the price of lopinavir/ritonavir in Brazil from US$3241 PPPY to US$1380 PPPY for an earlier version and US$1518 for a heat-stable version in response to Brazil's repeated price discussions and serious threat of invoking a compulsory license. Notably, Abbott's lopinavir/ritonavir was still more than twice the price of the generic lopinavir/ritonavir that Thailand obtained through compulsory licensing and import from India.

THE THREAT OF COMPULSORY LICENSING TO THE PUBLIC HEALTH CARE SYSTEM

1. **Disincentive's investment in research and development:**
   Research and Development in the Public health care system during the covid-19 pandemic especially in the pharmaceutical sector is an extremely time-consuming, expensive, and

resource-intensive process. To top it all, it also involves a considerably high risk of failure. Compulsory licensing may cause trade friction between countries but not necessarily lead to loss. Most developing and underdeveloped countries are not so much concerned about the protection of IPRs and are not willing to spend on costly administrative mechanisms to enforce IPR. Moreover, the growth of developing countries heavily depends on foreign investments.

Whereas on the contrary, the developed countries are extremely concerned about the protection of IPR because their economic growth and progress highly depend on investment in R&D. In Italy, more than 600% increase was in pharmaceutical R&D after Italy approved the Drug patent act 1978. The limited executive right of the patent owner enables them to use the invention to recover the cost of R&D of the invention and for further research. compulsory licensing is action is the action of the government for the betterment of the society at large by interfering in the executive holders' rights according to the terms decided by to government.

Royalty is paid in order to compensate due to incentives to invest, innovate and create new works that may be diminished as a result of compulsory licensing. The amount set by the state cannot be considered for further research, as it is not even nearby potential financial benefit that the owner would have enjoyed on an executive basis. Accordingly, this is the reason behind compulsory licensing being opposed by many developed countries. It has been criticized that the U.S and many multinational pharmaceutical firms because of the government of the states reap the benefit of R&D of the owner of IPR without contributing a fair share to the cost incurred on R&D. It is criticized and further argued that 90% of the drugs in compulsory licensing used in the essential drugs list published by WTO are not protected by U.S patents, the consumer of counterfeit products is at risk due to the inferior quality which are unapproved generics that may contain harmful diseases and impurities. In developing countries, most of the research is funded and heavily depends on foreign investments. The government's decision to grant compulsory licensing may lead to the loss of foreign direct investments. A country may lose a potential source of financial source economic growth due to compulsory licensing. Due to weak IPRs and high requirement of

investment for R&D, it is nearly impossible to retain the country's human capital, their talented scientists, and research experts which leave the country in search of better opportunities elsewhere in the world. One argument against the compulsory licensing of pharmaceuticals is that company lowers prices to mere cost of production in the least developed countries on humanitarian considerations.

2. **Abused at the hands of high-income economies:**

   There are two aspects to this. Although the provision was aimed at low and middle-income countries. The high-income countries with a mature system of patents are more likely to exploit the provision. For a compulsory license to be granted there needs to exist a mature patent system. Many a time it has been seen that though the system is designed for low and middle-income countries, it is more used and abused by developed countries. The TRIPS Agreement doesn't grant worldwide access to patent networks. It is limited to the nation. Therefore, a patent issued for some countries in Africa says Rwanda will be used to provide generic medicine in that nation only and that issued in the USA will be used for generic supply in the USA. So, if Rwanda doesn't have the technological capacity for manufacturing a medicine, the flexibilities provided by the compulsory licenses remain an empty shell.[5] Although not extensively used the Doha declaration aims to provide a solution to this problem. It recognizes that low-income countries without the capabilities of manufacturing may be at a disadvantage, The provision of compulsory licensing does no good to these countries. Hence, it allows for the export of compulsory licenses.

COMPULSORY LICENSES IN INDIA

In India, we have lucrative generic industries, and where the consumers demand all kinds of products for health care which is growing rapidly, the interpretation of the law is done for the public good which leads to compulsory licensing. In 2012, the Indian patent office issued is very first compulsory licensing for a pharmaceutical drug named Nexawar, manufactured by Bayer for the treatment of both liver cancer and kidney cancer. The licensee was required to pay Bayer

[5]https://www.bmj.com/content/365/bmj.l2098

royalties at 6% of its net sales, this complies with the United Nations Development Programme's criteria (UNDP) negligible figure as to the Bayer original price. The IPO decision was heavily criticized by the pharmaceutical industry as it would disincentive to innovate and dissuade potential investors from participating in the inherently risky business of pharmaceutical innovation.

In some cases, involving the grant of compulsory licenses in the pharmaceutical industry were turned down by the controller for a variety of reasons, including failure to establish a prima facie case, failure to apply for a patent license before applying for a compulsory license, and failure to establish public use of the product sought to be used by the compulsory license. It is claimed that in patent law, simply having a patent registration is insufficient. The Court must consider the entire case, including the patentee's case as well as the defense's case.

In recent judgments, Indian courts have concluded that the competition act's provision against anti-competitive acts and the patent act's provision of compulsory licensing is not in exclusion of each other; rather, they must be interpreted together. The Controller could also look into whether a patentee had engaged in anti-competitive conduct. However, if CCI has finally concluded a patentee's conduct to be anti-competitive and its finding has reached definitive, the Controller will proceed on the same premise, and the patentee will be estopped from arguing otherwise, based on a principle similar to issue estoppel.[6]

The judicial perspective to the award of the compulsory license is that the provision is for the public good and cannot be abused to limit patent holders' rights. There must be a balance between your rights and using the product for the prosperity of others.

[6] Koninklijke Philips Electronics N.V. vs. Rajesh Bansal and Ors. (12.07.2018 – DELHC): MANU/DE/2436/2018

CONCLUSION

Compulsory licensing has been issued under the TRIPS Agreement for the low and middle-income countries. The usefulness and the need for such provision cannot be understated. Evergreening of patents through manipulative business strategies is also one of the key concerns justifying its use. However, over the years, the system has been abused by developed countries that have more mature patent systems. The poor technological capacities, research, and development don't allow lower-income countries to make the best use of the system essentially designed for them. Solutions such as the Doha Declaration for the export of compulsory licenses provide some relief for low-income countries. This is needed to ensure that research and development are not discouraged at the same time the system doesn't fall prey to the manipulative tactics of the pharma companies.