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Compulsory Licensing in India & world

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A method that would allow the state to use the innovation without the previous approval from the inventor or the patent right holder is referred to as obligatory licencing. This kind of licencing may be described as a mechanism that would enable the state to utilise the invention. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement has rules for the patenting of pharmaceuticals. Additionally, the agreement contains specific measures for a method of compulsory licencing, which is designed to prevent the probable misuse of patent rights. There has been a significant disparity between the profits made and the availability of drugs to people all across the globe, especially in India. Since the landmark judgement in Bayer v Natco, the Indian patent system has undergone a significant transformation. It was clear that the judicial approach defended the public interest and guaranteed that pharmaceutical firms do not abuse their position. It has always been a difficult task to provide patent protection for drugs, especially essential treatments. In addition, the following rulings on the aforementioned subject matter have contributed to the uncertainty over the position of mandatory licencing requirements in India. The battle that has always existed between profit-driven pharmaceutical companies and welfare-oriented governments, each of which is attempting to provide more affordable access to essential medicines, has often captured the attention of people all over the globe.

Keywords: *compulsory licensing, patent, IPR, TRIPS.*

INTRODUCTION

In spite of the fact that it is illegal under both human rights law and competition law, patent protection is widely acknowledged around the globe as a necessary evil that must be endured in order to encourage innovation. However, there is always the possibility that circumstances could occur in which this exclusive right to profit from the production will fail to pass the test of being in the public interest and would need to be violated in order to safeguard human rights. In the event that an epidemic breaks out, a patent on a medicine that may save lives could be weakened, which would be to the prejudice of the person who has the patent. "A licence to utilise a patent that is provided by a state authority to a government agency, a firm, or another person without the approval of the patent holder" is an example of what is known as "Compulsory Licencing."[1] The idea that "necessity is the mother of innovation" should thus serve as the philosophical foundation for mandatory licencing originates from an oft-quoted proverb. It's possible that such circumstances will lead to the inevitable dilution of a patent.[2] Therefore, the legal framework has the flexibility to invalidate the patent if this becomes necessary. When dealing with a public health emergency, when admittance to proprietary pharmaceuticals turns to be pricey and the patent has to be weakened to create conventional duplicates of the essential medications, this flexibility is especially vital for third world nations.

RATIONALE OF COMPULSORY LICENSING

In terms of the concern for the preservation of intellectual property rights, when the preceding statement is taken into consideration, the nations may be classified into two groups, whose actions are completely distinct from one another based on the concerns of each group. A typical perception is that developing as well as underdeveloped nations are not especially worried about the security of intellectual property rights (IPRs) and that these countries are also reluctant to burn through cash on the improvement of a costly administrative component to authorize the security of IPRs. This nonchalant attitude toward the preservation of intellectual property rights might be attributed to a variety of factors.[3]

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[1] Richard Reik, 'Compulsory Licensing of Patients' (1946) 5 TAER 813- 832
[2] *Ibid*
[3] P J Federico, 'Compulsory Licensing in Other Countries' (1948) 2 Law and Contemporary Problems 295, 319

To begin,[4] when developing and impoverished nations legalise piracy, they are able to guarantee that essential products and services may be obtained by their inhabitants at costs that are within their means.[5] Second, the local businesses that create counterfeit products employ thousands of people, which helps to lower the number of people who are unemployed. Thirdly,[6] in order for countries of the third world to make progress in the fields of science and technology, they need maximal access to the intellectual property held by nations that have already achieved success. Fourthly,[7] inhabitants of technologically sophisticated countries own ownership rights to more than 80 percent of the patents that are issued in emerging and impoverished nations. As a consequence of this, the legislatures of underdeveloped countries are not prepared to invest large sums of money in the development of efficient administrative mechanisms to protect the intellectual property rights of residents of advanced states.[8]

In contrast, developed nations place a high priority on safeguarding their intellectual property rights. This is due to the fact that the rate at which these nations advance technologically and expand their economies is directly proportional to the amount of money they pour into innovative work. Their patent framework surrenders impetuses to increase their technical advancement, raise their efficiency, and further develop their worldwide exchange position by reinforcing their economy. These goals may be accomplished via the improvement of their economy.[9] For example, in the 10 years that followed Italy's passage of medication patent legislation in 1978, the country's pharmaceutical research and development industry saw growth of more than 600 percent.[10] The owner of the patent should be granted a limited exclusive right to allow them to utilise the innovation in order to recoup the financial investment they made in developing the idea and provide an incentive for more creative research. Investing in research is likely to come to a halt if there is anything that might compromise the patent holder's entitlement to an exclusive monopoly on their invention.[11] Developed nations are

[4] *Ibid*
[5] *Ibid*
[6] *Ibid*
[7] *Ibid*
[8] Richard Reik (n 1)
[9] P J Federico (n 3)
[10] 'Compulsory Licensing of Pharmaceutical Patents' (2010) 45(39) E&PW 8, 9
[11] *Ibid*

worried about the security of intellectual property rights (IPRs), furthermore, they are against any obstruction in the selective privileges of the patentee of the development. This is because the advancement of developed nations is primarily the result of extensive inventive research.

"A compulsory licence is an action taken by a government that forces an exclusive holder of a right to permit the use of that right to other individuals on the conditions determined by the government," according to one definition of the word.[12]

The patent holder, on the other hand,[13] receives a royalty payment from the government as compensation for the use of their invention by the government without their permission. Because of this, obligatory licencing violates the exclusive rights of the inventor who was granted the patent for the innovation.[14] Because of forced licencing, there is a possibility that the incentive to develop and generate new works may be reduced. Because it takes time and resources to bring new ideas to market, there has to be an incentive for people to come up with them.[15] The number of royalties that are determined by the state when it grants a mandatory licence can't be viewed as a motivation for additional exploration since it is not the slightest bit tantamount to the potential monetary advantage that the patent proprietor would have delighted in if they had enjoyed exclusive ownership of the patent. Therefore, many industrialised nations hold the view that compulsory licencing should be avoided. The United States of America and other foreign multinational corporations criticise the countries that implement compulsory licencing provisions. This is done due to the fact that the licensee receives the rewards of others' examinations without contributing their reasonable portion to the costs that are brought about by innovative work.

In addition, opponents of compulsory licencing contend that more than ninety percent of the pharmaceuticals featured on the Essential Drugs List published by the World Health Organization are not covered by patents issued by the United States. In addition, forced licencing may give rise to safety issues; people who purchase counterfeit goods are putting

[12] Frank I Schechter, 'Would Compulsory Licensing of Patents Be Unconstitutional? (1936) 3 Virginia Law Review 22, 287-314
[13] *Ibid*
[14] Compulsory Licensing (n 10)
[15] *Ibid*

themselves in danger since authorised generics of lower quality may include a number of potentially hazardous contaminants.[16] In addition, the nations of the third world are home to a number of illnesses that are found nowhere else on the globe. If patent protection were to be ensured in these countries, it would give a motivating force to multinationals to put resources into the exploration to research these sicknesses, which would somehow keep on being serious.[17] Global pharmaceutical organizations make an investment in research and development work later considering the potential financial gain. The lack of confidence around patent protection might put an end to the quest for novel treatments, which are desperately needed in third-world nations.[18] If there is not a legislative environment that is conducive to business, patent holding companies may be dissuaded from beginning any new initiatives in a nation that utilises compulsory licencing requirements.[19]

In addition to this, the use of forced licences may result in economic friction with the nations that are responsible for the production of patented pharmaceuticals. It is not required for there to be an actual instance of forced licencing for this misfortune to happen; in specific cases, even the danger of mandatory licencing may have a detrimental impact on commercial ties between nations.[20] In addition, the expansion of domestic industries in nations still on the path to economic development is significantly reliant on investments made by parties located outside the nation. If a government decides to issue obligatory licences, this might result in a reduction in the amount of foreign direct investment received by the country. Pharmaceutical corporations could look into conducting their clinical tests in a separate location in order to shield their medicines from the threat of being required to get licences.[21] Because of this, the issuing of obligatory licences might result in a government missing out on a potential source of economic development.[22] In addition, when a nation's intellectual property laws are lax, the country's

[16] Charitini Stavropoulou & Tommaso Valletti, 'Compulsory Licensing and Access to Drugs' (2015) 1 The European Journal of Health Economics 16, 83-94
[17] *Ibid*
[18] *Ibid*
[19] *Ibid*
[20] James J McRae & Ors, 'Compulsory Licensing of Drug Patents: Three Comments' (1984) 1 Canadian Public Policy/Analyse de Politiques 10, 74–87
[21] *Ibid*
[22] Charitini Stavropoulou (n 16)

overall business climate deteriorates, making it less competitive and inevitably leading to a loss of talent.[23] Capable researchers and analysts leave the country on a mission of better possibilities somewhere else in the globe since it becomes practically hard for such countries to keep their human capital.[24]

One more compelling reason to oppose compulsory licencing of pharmaceuticals is that, out of consideration for the well-being of the people living in the world's least developed nations, pharmaceutical companies typically offer price reductions on their life-saving goods that go as far as bringing them down to the level of their production costs.[25] Therefore, industrialised nations are of the view that compulsory licencing is neither an efficient nor a required cost control mechanism.[26]

This doesn't suggest that there are no reasons in favour of licence being mandatory. Some examples are as follows:

To begin, licenses, especially on drugs, are adverse to developing as well as underdeveloped nations on the grounds that these countries miss the mark on their own homegrown and specialized framework. Patents have the potential to turn into a snag to the financial development of such countries and to the accessibility of necessities to the populations of such nations.[27] Patents for pharmaceuticals are particularly problematic.[28] When attempting to negotiate a fair price for the required medication that is satisfactory to both the patent proprietor and the public authority, the use of the threat of a non-voluntary licence might be beneficial.

Second, the opposition of developing countries to compulsory licencing by developed countries may evoke thoughts of "neo-colonialism."[29] This is due to the fact that patent insurance

[23] James J McRae (n 20)
[24] Arvind Subramanian, 'Compulsory Licensing in Patent Legislation: Superfluous and Misleading' (1990) 34 E&PW 1880-81
[25] *Ibid*
[26] James J McRae (n 20)
[27] *Ibid*
[28] Colleen Chien, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?' (2003) 3 BTLJ 853-907
[29] *Ibid*

lopsidedly helps developed nations, as developing nations have a significantly smaller number of patents to protect.

Thirdly, necessary licensing of drug licenses once in a while becomes unavoidable to save the lives of the general population by guaranteeing openness of medications at reasonable costs; it very well may be utilized to separate syndications and cartels, the two of which are instances of maltreatments of patent rights.[30] In addition, this type of licencing can be used to save lives.

Fourthly, there are situations when deadlocks between the inventor of an improvement and the original patentee create a delay in the development of an essential piece of technology. As an example, "holdup difficulties" arose in the situations of both the Wright Brothers and Marconi. Similarly, the wide Edison lamp patent stifled innovation in the realm of incandescent lighting, which resulted in slower overall advancement. It is possible to break these impasses by the use of an efficient technique known as obligatory licencing, which applies pressure on the original patentee in order to get them to come to terms with the improver. As a result, it has the potential to contribute to the acceleration of technological advancement.[31]

Fifthly, in order to cope with the problems caused by "patent suppression", it is unavoidable to resort to forced licencing. The governments of developing nations have the potential to exert pressure on the patent holders to use the patent to the greatest extent possible for the nation's benefit if they implement an efficient process of compulsory licencing.

Sixthly, compulsory licencing may be required in circumstances when the rejection of a licence might prohibit the exploitation of an additional major innovation that may be significant for the improvement of technical capabilities or for the expansion of the economy.

Seventhly, defenders of necessary licencing contend that it doesn't deter research and development work on the grounds that the costs brought about by research are recuperated from deals of licensed items in cutting-edge conditions of the world that have tough patent assurance. In other words, the proponents of compulsory licencing are correct that it does not discourage research and development.

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[30] Arvind Subramanian (n 24)
[31] *Ibid*

A local generic pharmaceutical sector is believed to benefit greatly from compulsory licencing, which is considered to play an important part in the company's growth and development. Last but not least, in addition to economic justifications, the use of forced licencing to safeguard the public interest might be upheld on civil rights grounds; thorough adherence to patent assurance can scarcely be encouraged when it comes at the expense of human lives.[32]

The ability of sovereign governments to award a compulsory licence has been successfully accepted on an international level, despite the fact that compulsory licencing has drawn criticism and has a number of disadvantages. Because a patent is a privilege that the state bestows upon the holder of the patent, the government of the state has the authority to restrict the scope of that privilege in specific circumstances.[33] This is the fundamental justification for the implementation of mandatory licencing. After the onset of pandemics like HIV/AIDS, the question of access to critical pharmaceuticals arose as a major worldwide concern, which is what brought the notion to the forefront of public attention. A comprehensive examination of the conundrum posed by the rights of patent holders vs those of patients is warranted.

HEALTH CARE AND ACCESS TO MEDICINES AS A HUMAN RIGHT

Not just in the nations of the third world, but also in those of the industrialised world, the availability of public health care has been a significant source of worry. The significance of leading a healthy life is recognised in global settlements and conventions as well as in the constitutions and the local legislation of a number of governments. The right to health is one of the human rights that has been recognised as such by a number of international agreements.[34]

According to the Universal Declaration of Human Rights (hereinafter referred to as UDHR), which was embraced by the United Nations in 1948, "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family," which includes the right to food, attire, lodging, and clinical consideration. In 1966, the right to health was reaffirmed as key basic liberty in Article 12 of the International Covenant on Economic, Social,

[32] Adi Gillat, 'Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry' (2003) 4 Food and Drug Law Journal 711- 740
[33] *Ibid*
[34] *Ibid*

and Cultural Rights (hence referred to as the ICESCR).[35] In the Convention on the Rights of the Child, the Convention on the Elimination of all Forms of Discrimination against Women (hereafter CEDAW), and the International Convention on the Elimination of All Forms of Racial Discrimination, the right to health care has been further defined (hereinafter ICERD).

In a similar vein, the right to health as crucial common liberty has been remembered for the constitutions of no less than 135 distinct states on the public level.[36] For instance, the constitutions of Thailand, South Africa, and Brazil all have sections that guarantee citizens the right to get medical treatment. Access to essential medicines is given a lot of significance under global regulation as a commitment of states to safeguard the fundamental human right to health.[37] Despite the fact that only five countries have explicitly recognised access to essential medicines as a prerequisite to the right to health, international law accords this obligation with a great deal of weight.[38]

THE RELATIONSHIP BETWEEN TRIPS AND THE HUMAN RIGHT TO HEALTH

A stringent legal system for the protection of intellectual property rights was created as part of the TRIPS Agreement, which is perhaps of the most complete accord on intellectual property rights. IPR assurance is especially more significant in the drug business to empower the drug business to recover its speculation and improvement costs and to give an impetus to additional development and examination.[39] For this reason, IPR protection is especially more significant in the drug business. The process of developing new compounds that are effective is an expensive one that requires a significant investment in research and development. Because of this, patents are often regarded as the industry's primary source of revenue.[40]

During the twenty years that the TRIPS Agreement was in effect, patents in all areas of technology, including medicines, were given legal protection. Furthermore, despite the fact that WTO Agreements are planned to energize deregulation, patent insurance under TRIPS has

[35] International Covenant on Economic, Social, and Cultural Rights, (adopted 16 December 1966, entered into force 3 January 1976, General Assembly Resolution 2200A (XXI)) 993 UNTS 3 (ICESCR) art 12
[36] *Ibid*
[37] S Srinivasan, The Compulsory Licence for Nexavar: A Landmark Order (2012) 14 E&PW 10-13
[38] Adi Gillat (n 32)
[39] S Srinivasan (n 37)
[40] *Ibid*

exchange prohibitive impacts. Besides the fact that it raises the cost of imported licensed prescriptions, it likewise diminishes how many exchanges stream involving these products. Prior to the implementation of TRIPS, local legislation in over fifty nations excluded medicines from the scope of patent protection. Prior to the implementation of TRIPS, patent protection was not afforded to pharmaceutical items in even a significant number of the industrialised nations of the globe. As an example, "Germany until 1968, Switzerland until 1977, Italy until 1978, Norway, Portugal, and Spain until 1992, and Finland until 1995."[41] In order to comply with TRIPS, all governments were required to safeguard drugs with patents. However, taking into account the challenges faced by poor and underdeveloped countries, a longer grace period was granted to these nations before they had to comply with the new standards.[42]

In spite of this, states in the creating scene are stood up to with a conundrum between the protection of pharmaceutical patents on the one hand and access to medications on the other. The rising cost of medications because of the restraining infrastructure conceded to patent holders is a frequent worry among developing nations that are contemplating strengthening their protection of intellectual property rights (IPRs).[43] When the TRIPS Agreement was finalised, the issues that third world nations confront, particularly those that are the result of the emergence of diseases what's more, pandemics, were not expected, and the worry for general wellbeing was not given the prominence that it deserved.[44] The World Health Organization (WHO) and the World Intellectual Property Organization (WIPO) discussed the connection between admittance to meds and the TRIPS Agreement toward the end of the 1990s in order to find solutions to the problems that are being experienced by the developing world. This discussion was prompted by the outbreak of the HIV/AIDS pandemic, which was particularly severe in Africa. At the international level, the concern for general health as a political need emerged interestingly.[45]

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[41] Aditi Bagchi, 'Compulsory Licensing and the Duty of Good Faith in TRIPS' (2003) 5 SLR 1529-55
[42] *Ibid*
[43] *Ibid*
[44] Monirul Azam, *The experiences of TRIPS - Compliant Patent Law Reform in Brazil, China, India, and South Africa* (Open Book Publishers 2016) 89-148
[45] *Ibid*

According to a report by the United Nations Sub-Commission on Human Rights from the year 2001,[46] "there are obvious inconsistencies between the intellectual property rights framework reflected in the TRIPS Agreement, on the one hand, and international human rights legislation, on the other side." The World Intellectual Property Organization (WIPO) also notes that "conflicts may exist" between the Doha Declaration of 2001 and the WTO General Council's Waiver Decision of 2003. Both of these documents were produced as a direct aftereffect of the endeavours of the agents of underdeveloped nations who spoke out during the 2001 WTO ministerial conference. [47]

Therefore,[48] modifications were made to the TRIPS requirements in order to allow greater flexibility to the less developed nations and to raise the safeguards that nations might utilise while still staying compliant with the TRIPS duties in order to improve the quality of general medical services. Notwithstanding, whether the progressions were significant or corrective and how much the underdeveloped nations have had the option to utilize the adaptabilities is an easily proven wrong issue, and this discussion is past the extent of this work. Regardless of whether the progressions were significant or corrective, it is hazy how much the underdeveloped nations have had the option to utilize the adaptabilities. The effect on human rights is contingent on how the protections given by the TRIPS Agreement are actually used in practice by developing nations.[49]

CONCLUSION

Even while patents foster monopolies and excessive pricing, they are a necessary evil. Without the protection that patents provide, businesses would have no reason to produce innovative new items. Therefore, patent security is expected to ensure advancement; in this manner, the patent is a defective yet valuable apparatus to animate the creation of new things. Patent assurance for drugs, then again, is only effective in nations with high per capita incomes and populations that have the financial means to purchase costly patented drugs. It does not work

[46] Aditi Bagchi (n 41)
[47] World Trade Organisation, Doha Declarations [2013] Doha Development Agenda 23-26
[48] *Ibid*
[49] *Ibid*

very well in developing what's more, least created nations because of different variables, the most significant of which is reasonable admittance to medicines. Developing countries also have a hard time keeping their populations healthy.[50]

Therefore, mandatory licencing is another undesirable but unavoidable practice. Practice an infringement on the rights of the person who has the patent on the invention. However, this infringement might on occasion become essential in order to prevent the improper exploitation of monopoly rights and to safeguard the right of humans to health.[51] At the international level, mandatory licencing is one of the topics that has been subjected to the most in-depth discussion. There is widespread worry among the representatives of poor nations and non-governmental groups that strong patent legislation would make it more difficult to get necessary medications.[52] On the other hand, there are those who argue that if intellectual property rights aren't protected, it will make it more difficult for people to get access to medical care. This is due to the fact that the monopoly that is granted to pharmaceutical companies by means of patent protection enables these businesses to recoup the expenses of research and development work and money for extra innovative work projects. Because pharmaceutical companies are hesitant to launch new goods in nations that do not have patent protection, the failure to secure intellectual property rights has a negative impact on patients' ability to get important medications.[53] To summarise, a forced licence is a compromise solution that offers neither complete patent protection nor a complete lack of protection at all.

[50] Aditi Bagchi (n 41)
[51] Monirul Azam (n 44)
[52] Ganapati Mudur, 'Indian Health Groups Welcome Country's First Compulsory Licence' (2012) 7849 BMJ 6
[53] *Ibid*