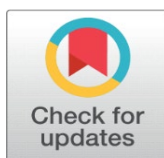
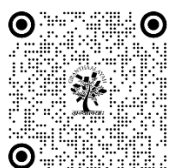


RIGHT TO HEALTHCARE: A DOCTRINAL STUDY OF COMPULSORY LICENSING OF MEDICINES IN INDIA

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ABSTRACT

In today's world, each one relies on one or more pills to survive and extend their life amid new diseases. Though the advancement of science and technology certainly resulted in numerous changes in society; it has not come up with a panacea to cure the most challenging survival issue which is to combat poverty and disparity. Pharmaceutical companies are like a demi-god and they decide who should live and who not. Patent for R&D to encourage and incentivize creators has, on the other hand, posed a threat to the public in accessing and affording the patented products, especially in the case of medicine and health. The disparity among world nations and the application of one general rule to overcome the situation concerning access the medicine is not a proper solution. However compulsory licensing issued to balance the disadvantages caused by issuing patents has to be analyzed concerning its working. Hence this article would throw light on the use of the compulsory license by the government with special reference to accessing medicines. To analyze the same this paper would extensively discuss the Conceptual viewpoint of compulsory licensing, the phase of the patent in public health, use of the compulsory license by the government with special reference to accessing medicines.

Keywords: Compulsory Licensing, Government Use, Access to Medicines, Research and Development

1. INTRODUCTION

Human creativity is god's gift. All are imbued with various creativity and skills which are to be distinguished and honored. Property resulting from one's intellect is termed to be intellectual property (IP). A world without IP is a world of zero. Recognition of IP and rewarding the same is done by the international community through drafting intellectual property rights (IPR). However, property in any form is subject to theft, and for intellectual property, it is much easy due to technological advancement to duplicate or reverse engineer the IP without being entangled in midst of infringement provisions. The strongest form of IP protection is required for technological development leading to societal development. However stronger protection for IP causes the birth of monopolistic rights leading the public to suffer for access. Especially in the case of accessing pharmaceutical products fixation on high prices due to monopoly restricts all tiers of people from accessing the same equally. Hence to lower the impact of monopoly created by exclusive rights given by IPR an exception in name of compulsory licensing was enshrined as a blessing in international convention later the same decorated the national legislation according to their economic and social status. Prodigies of IPR feel that the usage of compulsory licensing (CL) would undermine the interest of the creator but few others say that the application of compulsory licensing does not create a huge impact on research and development. However, it is very much essential to

balance the rights of IP owners and the interest of the public to access IP. Value to property raises with demand and use by the public. Non-accessibility and non-affordability situations create a vacuum in need for the creation of any intellectual property. Therefore, the trio's interest that is creators, the public, and new researchers should be balanced and addressed in case of grievances through the drafting and application of new laws. This paper would throw light on the conceptual viewpoint of compulsory licensing, the phase of the patent in public health, and the use of the compulsory license by the government with special reference to accessing medicines.

2. COMPULSORY LICENSING AND ITS EVOLUTION

The evolution of compulsory licensing can be better understood only with the evolution of IPR, especially patents. In the 7th century Byzantine Empire was the first one to grant one year of monopolistic rights to cook which was later lifted to reduce the impact of monopoly. However, the need for silk production instigated the governments to issue monopolistic rights and seven years of protection was given to traders introducing new technology for the fastest production of silks. Hence it can be traced that creators of technology were honored with incentives and a limited period to exploit their inventions. Along with positive rights to use and exploit one's property the owner of IPR has certain negative rights. Negative rights are like stopping others from exploiting IP without authorization. In general owner of IP has been flooded with more rights.¹ Philosophers have advocated for incentivizing creativity through rights. John Locke identified that 'ideas' are common to all but the labor exerted to 'express' the same has to be honored by incentivizing the same. Locke propounded labor theory that realized the importance of labor. Jeremy Bentham propounded utilitarian theory.² Jeremy Bentham stressed the importance of benefiting a large public by saying "Greatest Good for the Greatest Number". His principles were based on the maximization of happiness for people. This theory especially provides support for accessing the property for the public good.³ Kantian and Hegel advocated that property is an extension of personality theory. The paternal right over creativity doesn't transfer or change with the transfer or change of ownership. According to reward theory, the creator of IP is rewarded in form of incentives and royalty.

Justification of intellectual creativity as one's property can be evolved from analyzing the above theories and practice. IP is an exclusive right given to the owner that prevents others from accessing and exploiting the same. The international community's intention to make the IP available to the public and safeguard the interest of the creator by providing strong IP rights has required them to have a balanced approach. Creativity is encouraged for the development of society. At the same time, creativity has to be made accessible to the public then only it shall lead to development. But there is always a tug of war between the accessibility to the public and the creators' interest.

Crown of Britain in the early 12th century issued a letter of the patent to foreigners who came up with new technologies. Through this letter crown expected foreigners to share and teach their technology to natives of British. This facilitated downpour of technology in Britain with skill development for Britain natives. Later the monarchs extended the issuing of the patent to all kinds of new findings. This resulted in an eruption of the problem as one way of protecting the creator without any restriction gave exclusive rights for an unlimited period of protection. Small incremental findings facilitated creators to extend their patent rights which barred the public from accessing the new creations. On the whole, Patent was misused by creators. The very objective with which the patent was given to encourage innovators and thereby enhance technological development was shattered. Strengthening the IP rights for owners without having a check on monopoly was a disaster.⁴ Hence In 1623 Statute of monopoly was brought to address the issues created by monopolistic rights. Later based on the statute of monopoly British Patent Act 1852 was enacted. As India was colonies of the British, Indian laws related to patent was an extract of the British Patent Law that came in the year 1856.⁵

After two world wars, the economy of the international community was shattered. The only way to survival was understood to be interdependence and doing any activity that could ensure the same. Realist and their theories spoke of

¹ Lopez, R. S. (2011). *Silk industry in the Byzantine empire*.

² John Locke: The classical perspective. (2005). In *The Labour Theory of Value* (pp. 48-64). Routledge. <http://dx.doi.org/10.4324/9780203022221-11>

³ Bentham, J., & Mill, J. S. (2003). *The Classical utilitarians*. Hackett Publishing.

⁴ Kukimoto, A. (1970). *On the history of British patent law*.

⁵ Dulken, S. V. (1999). *British patents of invention, 1617-1977: A guide for researchers*. British Library Board.

selfishness and war proved survival of the fittest but liberalist explained that at all times the view of realism would not work for survival. Liberalist identified that in the era of globalization only interdependence would pave way for survival with development. Hence war is not the solution for development on the other hand war results in disruption and disharmony among the international community.⁶ The impact of globalization was harmonizing the trade laws internationally. Especially the IP laws are a modern law that needs a separate forum to address the issues relating to trade aspects of intellectual property. Many international conventions like the Paris conventions for protecting patents, the Madrid protocol for protecting Trademark, Berne Convention for protecting copyright, and many other international agreements existed to protect various kinds of IPR separately. However, the establishment of the WTO (World Trade Organization) and the evolution of Trade-related Aspects of Intellectual Property Rights (TRIPs) expanded the provision for protecting various IP types under one roof.⁷

In 1995 TRIPs came into existence and insisted its members make changes in their TRIPs provisions must be incorporated into national IP laws. In case there is no specific provision for any form of IP in national legislation it was thereby insisted to come up with a sui generis form of protection. As in India, there was no separate protection for plant varieties till it became a member of the TRIPs agreement. Later separate legislation was brought by India in protecting plant varieties to comply with TRIPs provision.

TRIPs facilitated protection for creators and TRIPs' flexibilities facilitated the public to access IP by reducing the impact of exclusive rights provided to the creator. Too much of anything is good for nothing. Similarly, excessive rights and restrictions hamper development. Creator's interest and public interest are like two eyes. Both should be balanced to have technological and societal development. Hence TRIPs Flexibility stands as a barrier to exclusive privileges granted to creators. Compulsory licensing is one among the flexibility used under special circumstances to help the public by accessing and affording the IP that remains non-affordable and non-accessible due to exclusive rights granted to the creators. In case of accessing and affording pharmaceutical products, there has been always a debate as to the steps taken by the government in balancing the interest of the creator and the public. The next topic would introduce the role of the patent in public health and its impact on accessing and affording medicines.⁸

3. NEED OF PATENT IN HEALTH SECTOR

A patent is a legal right that is granted to a creator as a part of honoring his inventions. Creativity to be termed as invention should prove to be either a novel process or product, developed by imaginative methods and not readily apparent to a qualified practitioner and capable of industrial use. In the case of patenting inventions all inventions even though satisfying the criteria for being an invention are not patentable. TRIPs provide a set of restrictions on inventions that cannot be patented. Those innovations that influence public order or morals, such as protecting plants, animals including humans, or plant life or public health to avoid major prejudice against the environment, are among those that cannot be copyrighted. TRIPs members may also exclude therapeutic, diagnostic, and surgical procedures for treating people and animals, animals and plants other than microbes, and fundamentally biological processes for the creation of plants and animals other than microbiological and non-biological processes.⁹

Research and development in the public-health sector is a transforming concept with the motive of addressing the severity of diseases among the people, further the R&D methodology should ensure a safe and effective platform in the era of patent culture. An individual's health condition is determined based on the intellectual and knowledge-based output of an inventor. In the evolving era of the patent phase in the health sector, the research and development should comparatively favor the accessibility and affordability of health care, rather than veiling the medical sources to open access.¹⁰ "High-quality healthcare" is the agenda of the day in most of the health sectors and its implementing agencies

⁶ Introduction. (n.d.). In *The International Economy Since 1945* (pp. 1–12). Taylor & Francis. Retrieved April 10, 2022, from http://dx.doi.org/10.4324/9780203438398_chapter_1

⁷ Taubman, A. (2020). 'Trade-Related' after all? In *Across Intellectual Property* (pp. 129–143). Cambridge University Press. <http://dx.doi.org/10.1017/9781108750066.013>

⁸ Geiger, C., & Desautnettes, L. The revitalisation of the object and purpose of the TRIPs Agreement: The plain packaging decision and the awakening of the TRIPs flexibility clauses. *SSRN Electronic Journal*. <https://doi.org/10.2139/ssrn.3556585>

⁹ Martínez, J., Patents and public health, Volume - 5, 2019/01/01, Finance, Markets and Valuation

¹⁰ Nuffield Council on Bioethics (2002), "The Ethics of Patenting DNA: A Discussion Paper". London: Nuffield Council on Bioethics, www.nuffieldbioethics.org.

nevertheless it cannot be claimed without proper interference of R&D (research and development) in the medical industry. Prof. Dr. Sarmansingh, the Director of AIIMS Bhopal addressed that, "In India, there is the only negligible percent of investment in the R&D industry compared with the GDP of pioneering countries like Korea, Japan, and the USA."

Whenever health is considered to be a subject matter, it should always top the preferential list owing to its capability of saving lives, in this context whenever a patent is filed for registration it takes a minimum of six years or above to get the approval, this portrays a delayed research and development process in our society. Secondly, health and access to medicine are not only limited to human society but also extend to all living organisms including animals and plants.¹¹ Hence technological development should ensure flexible patent laws for veterinary and agricultural research around the globe. "Voluntariness" is a diminishing area in today's research and development. For example, we have invented the diagnostic technologies for AIDS, Tuberculosis, etc to fetch the result in just a matter of a few minutes, but the lack of voluntariness of partner who further develops such medical technology to the general public. TRIPS Agreement which emphasizes the compulsory licensing concept should be implemented in its full strength rather for name's sake.

Many countries' investments in the health care industry remain low than their investment in the electronics and computing industry, this advocates the lack of involvement in many governmental agencies to be medically aware. Most of the compulsory licensing of drugs deal with a person's immune system and lifesaving medicines, as we already discussed the life of an individual should only be monitored and regulated by the health care industry rather than in determining who should be alive according to the whims and fancies of medical corporate. IPR grants protection for such inventions, when it comes to the livelihood of people which is the most basic need of a person to survive, the industry-leading protocols will be considered secondary by the governments. In the evolving society, when everything is subjected to transformation, the pattern and variants of diseases get drastic transformation. Hence the research and development industry should be a compendium for producing health care solutions that substantiate an individual's right in accessing medicine.¹²

Transfer of technology in the health sector is the appropriate way through which we approach the medical analysis and render proper medical treatment. Technology changes every day with the orientation to new diseases and advancements in modern technology. Gone are the days when a process patent like diagnosing disease with chemical compounds are administered, the current technology in such circumstances has become more intellectual and intelligent. In the contemporary IPR era, even a machine's intelligence in diagnosing and treating a disease serves more effectively than the former.

Article 1 of the 1997 UNESCO declaration conveys that " As the symbolic sense of human ancestry, the human genome underpins the fundamental unit of all members of human families".¹³ Hence an individual's heritage and recognition should be a matter of concern in providing proper treatments with the existing technology. Of late, the trending technological transfer in the healthcare system is telehealth. Instead of approaching a medical expert physically, the physicians are readily available on our doorstep in virtual mode. Hence virtual analysis and diagnosis techniques should be claimed with proper intellectual rights. Salsa's view of incorporating the latest technology in public health paves way for new developments which are comparatively more efficient than the existing patient to doctor relationship. Legally analyzing the ownership of such latest technology, by considering the Paris convention and TRIPS Agreement for compulsory licensing they should be open to every inventor without any barrier. Another area of great dilemma in IPR is the artificial health care system. Intelligence as said, is created artificially nevertheless the matter of discussion is, who processes the original patent rights, whether the machine or the man who developed the machine. Global IP laws advocate those intellectual rights are guaranteed for humans alone because the machines itself is the brainchild of the human being.

Generally speaking, patent rights are to encourage and promote inventors' intellectualness but they should not be directly applied to the healthcare technology and its process. Our Indian Constitution itself is subjected to some reasonable restrictions; only the adaptability of IPR in the medical business can fulfill the demands of today's health problems. The efficient requirements in Patent Act Section 3 (d) state that the mere discovery of a novel form of a known

¹¹ Love, James (1999) Health care and IP: compulsory licensing. Compulsory licensing of patents and other intellectual property. <http://www.cptech.org/ip/health/cl>

¹² Gaikis, Gunars (1992) Pharmaceutical patents in Canada. An update on compulsory licensing. Patent World, 42, 19-25.

¹³ Polacheck, S. W. (2007). Earning Over the Lifecycle: The Mincer earnings function and its application. Bonn. UNESCO. (2015).

substance that does not lead to an improvement in the known effectiveness is not patentable." Hence many new forms of drugs that are involved in creating a drastic change in the health sector and the most needed technology in producing such medicines and health services should be considered for open access to serve the public, accompanied by feasible patent laws.¹⁴

Every day the pharmacy industry witnesses new evolutions in their research and development and the process of treating a disease gets updated. Millions of investments are being done in the pharmaceutical industry for new technological developments and all their intellectual asset are subject to protection from being pirated. With the legal eyes of IPR, there are following steps that must be ensured for a patent to have both societal concern and efficiency in its specialization. The initial step is the invention stage by the inventor, here the prime motto of the inventor should be in serving all the sections of society with medical aids rather than concerned only with patent registration. The second step is the development stage, here all the research and development of the study should be finalized and the result should be fetched in a positive connotation. Subsequently, in the next incremental innovation, the process or product that has been invented is put forth for further development by the peer inventors without compromising the regulations of compulsory licensing laid down by the TRIPS Agreement.¹⁵

Our point of discussion in this paper primarily relies on the accessibility of medicines, hence in the next stage; product differentiation will be a crucial one. Here the medicines and health services are clinically tested and new drugs which were invented are scrutinized to whether they are easily accessible and whether the differentiation in public access is regulated accordingly. In the last stage of our research, safety monitoring of the trial is ensured to check all the patent laws are properly followed and if any infringements have been done, they are rectified legally.¹⁶ Kelham Scott, who is a pioneer in the pharmaceutical industry, relates the pharmacy sector to "Laws of diminishing returns", where the voluntariness of all the corporate should be for curing the societal disease, but not to grow commercially with the only intent of making money.

Patent laws should not only safeguard one's intellectual property, rather they should positively catalyze the process of patenting, either product patent or process patent. In the growing demand for medical needs by the society, when an investor takes less time in research and development but when the patent recognition and registration takes the lengthiest duration, the ultimate motto of the invention will not be to serve the public at right time and in a speedy manner. As the legal maxim goes as follows, "Justice delayed is the Justice denied", the same can be modified as delayed access is a denied access with regards to the public healthcare system, fortunately, which stands as a valid statement. Hence the R&D in the pharmacy industry should inculcate the sense of public access and its health care system in its full strength by abiding by the IP laws. To overcome the impact of patents on public health, compulsory licensing has been issued. The upcoming paragraphs would discuss the role of CL and the use of the same by the government with special reference to accessing medicines.¹⁷

4. UTILIZATION OF COMPULSORY LICENSE TO ACCESS MEDICINES

Paris convention was the first international convention to address the issue of non- affordability and non-accessibility of the patented products through compulsory licensing as mentioned in Article 5. Each contracting state in the international community would enact legislation to avoid abuses that may arise as a result of the monopoly created by a patent giving exclusive rights under specified conditions. In the event that the patent owner refuses to provide the

¹⁴ Cohn, Michael (1990) Compulsory licensing in Israel under pharmaceutical patents – a political issue? Patent World, 27, 22-27

¹⁵ Heinz Klug, 'Access to Essential Medicines – Promoting Human Rights over Free Trade and Intellectual Property Claims', in Keith Maskus and Jerome Reichman (eds.), International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime. (2005), 481–92, 492.

¹⁶ World Health Organization, 'Influenza A (H1N1)', www.who.int/csr/disease/swineflu/en/index.html at 18 June 2009; and Médecins Sans Frontières, 'Generics and Access to Influenza Treatment', (7 May 2009), www.msfaccess.org/main/access-patents/generics-and-access-to-influenza-treatment/.

¹⁷ World Health Organization, 'Member States' Comments and Inputs to the IGWG 2 Conference Paper' (A/PHI/IGWG/2/Conf.Paper1/Rev.1) (Geneva, World Health Organization, January 2008), www.who.int/phi/submissions/submissions_confpaper/en/index.html.

license, the forced license is issued by a governmental authority in the state involved. Compulsory licensing may be given in the event that the patented innovation fails to function or functions insufficiently. The same can be granted only after three years have passed after the patent was awarded or and it can be refused if the patentee provides a good basis for doing so. In some situations, a patent may be forfeited to prevent further misuse; but, in the case of compulsory licensing, this is insufficient to prevent abuse. In the instance of patent forfeiture, the action for forfeiture may be brought only after two years have passed since the first obligatory license was granted.

Following the protection given by Paris Convention, TRIPs allow using of compulsory licensing in a very restrictive manner. Other uses without the right holder's permission are included in Article 31 of the TRIPs agreement. Under certain unusual situations, a member's law may allow the government or third parties authorized by the government to make patented items without the permission of the right holder, according to Article 31. The legality of such usage will be determined on its own merits. The intended user should have attempted to seek authorization from the right holder but failed to do so within an acceptable time frame. The proposed user apply to the government citing that he had requested the right holder and his denial has made him approach the government. The most important thing reasonable opportunity has to be provided to the right holder and proposed user. In case the proposed user proves that there is a public necessity that is not being fulfilled by the right holder compulsory licensing will be issued. On another hand, if the right holder proves that there is no immediate necessity to the public as cited by the proposed user compulsory licensing will be denied. If more than one person proposes issuing compulsory licensing then the person who might best work the invention would be issued with compulsory licensing. In the event of great national urgency, or in situations of public non-commercial usage, a member may waive this provision. The scope and duration of such use must be confined to the reason for which it was given and shall be non-exclusive and non-assignable. Finally, Article 31(f) underscores that any such use must be primarily for the supply of the Member allowing such use's domestic market. In addition, Article 31 (h) stresses providing sufficient recompense to the right holder in each situation, taking into consideration the economic worth of the authorisation. The two provisions on issuing compulsory licensing created a problem in using the same. The most affected country was the one that lacked manufacturing capacity and the one that cannot afford to pay the cost of medicines. After becoming members of TRIPs the countries like India which was acting as the pharmacy world by producing generic drugs and supplying the same to least developed nations was having trouble doing the same due to the inclusion of a product patent regime and insisting to issue compulsory licensing only to satisfy the domestic requirements of the concerned nations. The anti-retroviral drugs which were supplied from India to South African countries faced the issue due to Article 31 of TRIPs. To overcome the lacuna created by Article 31 f and to address the issue of the same the Doha declaration concerning public health was convened. However, the WTO established the Doha Declaration for the developing nations that were prohibited by TRIPs to provide simple access to medications for critical ailments. The Doha Declaration's paragraph 6 decision, as offered by poor nations, was found to be a remedy to TRIPs restrictive rules. The important point in paragraph 6 states that member countries may Permit third-party manufacture and export of patented pharmaceuticals to nations with insufficient manufacturing capability. By invoking paragraph 6, the General Council has exempted the responsibilities set down in Article 31 (f) and (h) of the TRIPs agreement regarding pharmaceuticals, specifying certain conditions for exporting and importing nations. Paragraph 6 also puts a specific condition to export drugs by importing and exporting nations. The conditions specify that exporting countries should export such drugs by giving notification to the Council for TRIPs. After getting confirmation that compulsory licensing has been issued in the territory where such importation is required notification must be made comprising of the following conditions. The product names and expected quantities should be specified in the notice. The notification should have a declaration attached that the country which is to import pharmaceutical items because the pharmaceutical sector lacks or has insufficient manufacturing capacity for the products. The content of paragraph 6 was incorporated in TRIPs as Article 31 bis. Although Article 31 bis were drafted to overcome the hurdles imposed by Article 31 of TRIPs Due to the lengthy procedure, it was unable to remedy the issue of simple access to inexpensive drugs. Till recent times Article 31 bis have not been ratified by all members of TRIPs. The case study of Rwanda and Canada was the best example of working of Article 31 bis. The system of administration created by Article 31 bis was not easy as there was much administrative burden that delayed the accessibility of the drugs. The actual problem was mentioning the number of drugs to be imported. Though there was no restriction for quantity through one application. However sudden requirements apart from the quantity mentioned in the application there is difficulty in getting the license again and

again. It is a cumbersome procedure and condition mentioned in the annex and appendices of the waiver of Article 31 bis of TRIPs. But these cumbersome procedures were favorable for the pharmaceutical industry.¹⁸

Many countries have incorporated compulsory licensing provisions regarding public health after complying with TRIPs. However, analysis of the government's use of CL shows that it is used as the last choice in the rarest situations. Even if it is to be used, the administrative procedures to be followed for implementing compulsory licensing cause a burden for the country that tends to import or export pharmaceutical products. Although compulsory licensing is tended to be used during an emergency the administrative procedure delays the process of implementing the same and thereby delays accessing the pharmaceutical products. There are many cases where countries have used compulsory licensing in a very noteworthy way.

Brazilian case was an ever-to-be best case study to show how compulsory license was used as a tool that made pharmaceutical companies allow discounts on their pharmaceutical products. After complying with TRIPs Brazil made changes to its national legislation and it started issuing patents with a condition that any pharmaceutical industry that holds a patent for any pharmaceutical product should make that product for a minimum of three years. In three years if the Pharmaceutical Company faces difficulty in supplying the same to the public and satisfying the public need, the pharmaceutical company can take the help of local drug manufacturers and fulfill the same. This made the U.S.A initiate a proceeding against Brazil's patent laws and behavior and insisted WTO's Dispute Settlement Board in taking action against Brazil. USA initiated this case against Brazil as many as the USA remained a hub for many Pharmaceutical Giants. Political pressure and WTO's DSB asked the USA to withdraw the case against Brazil and this, in turn, encouraged Brazil to use compulsory licensing in full swing. Threat and fear of issuing compulsory licenses made pharmaceutical giants like Roche and Merck give issue medicines at discount.¹⁹

The best Scenario that brought the USA to the limelight of acting like a Chameleon was during the spread of Anthrax. Though many medicines would cure or reduce the impact of Anthrax Bayer's patented Cipro was in demand due to hype created by Media. Canada was the richest company to issue compulsory licensing. Though Canada had manufacturing capacity it issued compulsory licensing on the ground of national emergency to secure public health. The USA also wanted to follow in Canada's footsteps in piling up Bayer's patented Ciproflaxin to recover from the Anthrax attack. Political pressure to handle the threat of national emergency George W. Bush (American President) established flexibility through executive order 13323, which allowed the HHS (Health and Human Services) Secretary to issue compulsory licenses during public health urgencies incorporating national defense. At the same time, the Secretary of the Department of HHS proceeded with price negotiation with Bayer for Cipro. Confused by USA's action Bayer accepted to donate drugs for free. Everyone believed that Bayer was very generous in donating the medicine; however, the real intent of Bayer was to divert the USA from issuing compulsory licensing. This showed that compulsory licensing had been used as a law in the paper without enforceability in a few developed nations.²⁰

Thailand was very active from 2006 to 2010 in issuing compulsory licensing. The reason for issuing many compulsory licensing to revamp its public health care system which was an election agenda to convince people that was depressed due to the economic crisis. It was a part of pro-poor policies to uplift the people from economic depression. Ruling parties succeeded in 2001 using the election agenda to reform health care. They announced the idea of Universal Health Coverage as the main campaign theme. Therefore, the aim behind issuing an enormous number of Compulsory licenses was to overcome the issues of poverty, health, and WTO TRIPs Flexibilities. While the Thai Ministry of Public Health (MoPH) was dissatisfied with price negotiations it decided to implement compulsory licensing on the advice of Thailand's people who said "It is useless to negotiate with the pharmaceutical company unless you start to announce that you want to go compulsory licensing. Then they start to talk to you." As a result, Thailand has effectively implemented TRIPs flexibilities.²¹

¹⁸ Bartelt, S. (2005). Compulsory licences pursuant to trips article 31 in the light of the Doha Declaration on the Trips Agreement and public health. *The Journal of World Intellectual Property*, 6(2), 283–310.

¹⁹ Curzel, R. *TRIPS and access to medicines: Pharmaceutical patents and the experience of Brazil*. Kluwer Law International B.V.

²⁰ Charatan F. (2001). Bayer cuts price of ciprofloxacin after Bush threatens to buy generics. *BMJ (Clinical research ed.)*, 323(7320), 1023. <https://doi.org/10.1136/bmj.323.7320.1023>

²¹ Yamabhai, I., Mohara, A., Tantivess, S., Chaisiri, K., & Teerawattananon, Y. (2011). Government use licenses in Thailand: an assessment of the health and economic impacts. *Globalization and health*, 7, 28. <https://doi.org/10.1186/1744-8603-7-28>

Diseases were classified based on their severity and transmission in order to issue CL. The disease that easily spread, kills rapidly and involves an infectious acute disease that required immediate attention fell under the First category that should be issued with compulsory licensing under the head of national emergency. The second Category of diseases involved those diseases which are infectious and chronic and capable of transmission however it would take many years for a disease to progress into a life-threatening disease. The third category involved diseases resulting from lifestyle like cancer and heart disease which involved major complications but which does not require immediate attention like the diseases categorized under the first category. Korea had a problem in seeking medicine for the rarest form of the disease called Chronic Myeloid Leukaemia (CLM). Novartis drug Glivec was the medicine that was used in treating Chronic Myeloid Leukaemia. The problem, in this case, was Novartis fixed high prices for the drugs which were about 37 percent of the average income earned by the citizen of Korea. Korean people requested for reduction in price as they were not able to afford and it was not accessible to them. Korea went for price negotiation. However, Novartis wanted its drug Glivec to be added to NHIS (National Health Insurance Scheme) scheme so that insurance could pay the amount for the treatment of people. Korea said only 70 percent of treatment expenses would be covered by the state insurance scheme and the remaining has to be paid with one's own money. Novartis was not ready for a reduction of price as it said the price was fixed and standard and a reduction of price would pave way for the other countries to initiate price negotiations. Hence Novartis accepted to provide drugs for free to treat the patients with rarest diseases like Chronic Myeloid Leukaemia. Though Korea could have applied a compulsory licensing provision, Korean price negotiation created pressure and threat to be issued with compulsory licensing instigated Novartis to give drugs for free.

In the case of India, the transition from only process to product patent regime saw many changes. The application for availing product patenting and complying with TRIPs procedures created pressure on India and its generic drug industry. Generic drug industries of India supplied pharmaceutical products to least developed countries without entangled in any infringement provisions. However, Article 31 of TRIPs restricted to issue of compulsory licensing only in special circumstances of national emergency and urgent situations and only for domestic purposes. But Article 31 bis came as a panacea to the above problem. However, the application of compulsory licensing is not that easy as the pharmaceutical industry was very cautious in avoiding the same. Besides the caution taken by pharmaceutical companies, India had applied compulsory licensing in the Novartis case. Aftermath complying with TRIPs and during the transition period, India developed a provision called the Mailbox provision. Through mailbox provision, the pharmaceutical industry could apply for product patents and start marketing and selling their product in India. Novartis was one such company that marketed the medicine called Glivec and it has obtained a process patent in India. Novartis was generously donating the drug to India to convince India to give the product a patent after amending Indian patent Act to include patenting the product. However, the reverse happened as thought by Novartis. Controller of the patent in India after the 2005 amendment while evaluating the mailbox application rejected Novartis's application, that the patented medicine was a slight alteration of known substance. Novartis was maddened and decided on the controller of the patent to appeal. However, the then health minister warned that it had not used its compulsory licensing yet and Novartis should not force the Indian government to take such action. However, Madras High Court upheld the decision of the Controller of Patent. This shows how the Indian government acted tactfully to avail the drugs of Novartis thereby paving way for the development of generic industries.²² In Natco Vs Bayer compulsory licensing was used perfectly to match the criteria to issue compulsory licensing. Natco was ready to give away the same drugs at around 9000 Rs which Bayer gave away for Two lakh Eighty Thousand rupees. It was issued based on non-accessibility by the public.²³

5. CONCLUSION

Governments of the international community have used compulsory licensing as a tool to reduce the price of pharmaceutical products and in some cases allowed for accessing the pharmaceutical products for free. Pharmaceutical companies mostly invest in diseases that will earn profits in return. However, the diseases that affect a very rare number of people are not considered for research and development too. Incentives are a must for investing in rare diseases. Above all the issuing compulsory licensing discourages investors from investing in the research and development in

²² Gabbie, R., & Kohler, J. C. (2014). "To patent or not to patent? the case of Novartis' cancer drug Glivec in India". *Globalization and health*, 10, 3. <https://doi.org/10.1186/1744-8603-10-3>

²³ Raju, K. D. (2016). The first compulsory licencing case in India under the TRIPS agreement: An analysis of Bayer versus Natco Pharma Ltd. *Journal of Development Policy*.

developing new medicines. The choice of issuing compulsory licensing by Europe in today's Covid-19 scenario has proved compulsory licensing is a tool that is effective in balancing the interest of the public and the creator's interest. This occurrence is very rare. Since compulsory licensing can be used as a double-edged sword that can cut the interest of the pharmaceutical industry by lowering the price and bringing loss to them and this would lead to discouraging them and retaliating by not investing in research and development thereby impacting the public to access medicines for new variants of the disease. Hence it is always better for Governments to use compulsory licenses with caution as IP laws strive only for balancing the interest between the public and creator.

CONFLICT OF INTERESTS

None.

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