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ACCESS TO AFFORDABLE MEDICINE- WHETHER COMPULSORY LICENSING AN APPROPRIATE MECHANISM

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Abstract

Pharmaceuticals are an inalienable requirement of the public health. India before the implementation of TRIPs was a major distributor of generic drugs. In the Indian market, manufacturers were free to manufacture generic drugs using different manners or processes. However, the patents in the field of pharmaceuticals are not regulated before TRIPs. The introduction of product patents in the field of pharmaceuticals granted global protection of intellectual property rights to drug manufacturers. Necessary amendments were introduced in the Indian Patent Act to grant protection to pharmaceuticals backlashing the generic drug industry of India. While implementing intellectual property rights protection TRIPs failed to consider the needs of LDCs with the least drug manufacturing capacity. It is essential to consider that the protection of pharmaceuticals under patent has led to monopoly resulting in the non-accessibility of affordable drugs in LDCs. Despite the protection of pharmaceutical patents has led to the infringement of health care needs of low low-income population. In order to remedy the situation, the importance of Compulsory licensing was depicted in the DOHA Declaration. Compulsory licensing was implemented to prevent monopolistic rights of patent holders. However, the ambiguities in the insertion of compulsory licensing in the Indian Patent Act failed the essential outcome of accessible medicines. Even after 20 years, the compulsory license was granted only once. Therefore, this paper will focus on all such issues related to compulsory licensing of pharmaceuticals in India.

Keywords: *Pharmaceutical Patent, Right to Health, Compulsory Licensing, Grant of Patent,*

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INTRODUCTION

Article 21[1] of the Indian Constitution guarantees every person and citizen of India the right to life and the right to personal liberty. Further, Article 47[2] of the Indian Constitution declares that it is the duty and obligation of the state to improve public health. In addition, Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) adopted by India asserts that nations have to facilitate the right to health. Thus, the Indian government operates under the premise that medicines are critical to the healthcare needs of India's population and must be both available and affordable. Indeed, this paradigm is the foundational basis for India's vision for the right to health under Article 21 of the Indian Constitution. Thus, Indian policymakers strive to meet India's constitutional obligations for the right to health while promoting its innovation ecosystem and safeguarding the legitimate business interests of MNCs.

In 1856, India made its first initiative to grant patents to inventors. Under British Rule, India enacted the First major legislation in 1911. India was a British colony till 1947, and most of the patents granted during the period were to foreigners. During the time of independence, India's Pharmaceutical sector was dominated by MNCs. The post-independence laws were framed for the development of the indigenous pharmaceutical industry in India with the recommendations made by the Tek Chand Committee and Ayyangar Committee. In 1953 the Patent Bill recommended by the Tek Chand Committee modelling the Patent Act 1949 of the United Kingdom lapsed. The patenting of Medicines and Food was introduced under the Patent Bill 1965 by the Ayyangar Committee. In 1972, after repeated expert reports and deliberations in Parliament, the India Patents Act of 1970 came into force.

The 1970 Act underwent three major amendments to formulate the Indian legislation following the Trade-Related Aspects of Intellectual Property Rights (TRIPS) introduced in the Uruguay Round of General Agreement on Trade and Tariffs (GATT). The Patent Act 1999 introduced the product patent to medicines in India Trip's member country. India as a developing country availed ten years of transition period. During this period any application for pharmaceuticals will be processed under the mailbox system. However, the EMR system nullified the exemption of transition period granted by the TRIPS. India was forced to implement EMR and mail – box system after US Complaint for non-implementation.

[1] INDIA CONST, art 21.
[2] Ibid.

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By the 20th century the pharmaceutical industry in India had taken its form as allopathic medicines, the patent granted to medicines aimed to further development of the pharmaceutical sector. For the production and development of new drugs, the R&D efforts play a major role. Hence the pharmaceutical industry met with incredible R&D expenditure. Providing exclusive rights to the inventor as to making and selling of pharmaceuticals grants incentives to the inventor which further can be invested in the R&D. implementation of TRIPS, helped the pharmaceutical industries to develop new drugs by the brand name thereby reserving its exclusive use by patenting it.

While this shift led to the development of the pharmaceutical industry, it led to the downfall of the Indian generic drug export market. The medicines being an inevitable element of public health, many countries including India made arrangements for patenting them. Till 1999 India granted only process patents to the pharmaceuticals thereby the end product was not patented and the process of manufacturing them was granted protection. Hence many manufacturers who used different ways to manufacture similar medicines were not held liable as they used non-infringing processes. This mechanism allowed Indian companies to manufacture Generic medicines in India using non-infringing methods. This fostered pharmaceutical availability at affordable prices not only in India but also in the other country market.

India is a welfare nation to protect the inalienable rights of every person and citizen of India including the right to health. India adopted ICESCR where it obliged the duty to facilitate the right to health under article 12 of ICESCR. The constitution of India obliges the Indian government to provide accessible and affordable medicines to the Indian population under Article 47 of the Indian Constitution. Thus, even when promoting the development and innovation of the country, the Indian constitution constantly imposes a duty on the Indian government to strive for the protection of public health as a superior goal. However, the legal framework of TRIPS provides a monopoly to the patent holders in raising the drug prices beyond the capacity of poor sections especially in a developing country like India have infringed the accessibility of affordable medicine restricting the right to life. As declared by Minister Indira Gandhi at the World Health Assembly, Geneva, in May 1982, India's policy on Patents has been the "idea of a better world is one in which medical discoveries will be free from patent and there will be no profiteering from life and death", can lead to a better framework were medicines are accessible to all sections of society irrespective of their earning

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capacity.[3]

The Doha Declaration on the TRIPS Agreement made arrangements to formulate a solution for the hazards faced by economically disadvantaged countries concerning the non-accessibility of affordable medicines to the low-income population. It reassured the importance of the issuance of compulsory licenses when patentable medicines are not accessible to the public. Doha Declaration has further issued circumstances that constitute a national emergency or urgent circumstances which grant the countries the right to take away exclusive rights granted to the patent owners of pharmaceuticals and the criteria to decide this was left to the discretion of the exporting nation.

Even though India implemented the declaration by the 2005 amendment which inserted Section 84 of the Indian Patent Act, 1970 however compulsory licensing has several loopholes that act as a hurdle to attain the real object of the declaration.

THE CONCEPT OF COMPULSORY LICENSING

The grant of the patent provides exclusive rights to the inventor for a certain period of time. Even though the law permits exclusive rights, it also takes precaution that exclusive right granted will not lead to monopoly. Hence it provides certain restrictions so that the rights granted cannot be abused. This indeed protects the rights of the patentee and promotes fair competition in the market. Thus, compulsory licensing is the mechanism that provides arrangements to revoke the patent granted when the invention is not accessible to the public to restrict monopoly. The concept of compulsory licensing first evolved in France. Under the French Patent Law 1791, if the patent holder fails to work on a patent within 2 years the patent will be revoked. This arrangement is said to be the origin of the compulsory licensing mechanism.

However, the same mechanism was in practice in the United Kingdom, when the granted patent was held void if the grants were prejudicial or inconvenient to the King's subjects. The power to restrict monopoly was first vested in the Board of Trade in 1883. By 1919 it was transferred through different authorities including the Judicial Committee of the Privy Council, the Court,

[3] Chander Udhay Singh, Indian Patent Act of 1970 has fettered the transfer of technology to India: Govt, India Today, www.indiatoday.in/magazine/economy/story/19840615-indian-patent-act-of-1970-has-fettered-the-transfer-of-technology-to-india-government-803049-1984-06-14.

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and finally to the Comptroller. Further, the patent law expanded its scope to include food and medicines. Under the Statute of Monopolies Act the compulsory licensing mechanism was framed as to restrict the monopoly.

In India, the post-colonial period patent laws followed the UK Patent Act model being a British Colony. Before the Patent Act of 1970, most of the patents were granted to foreigners, who were reluctant to work on their inventions in India. As with any other underdeveloped country, India's population was also facing non-accessibility to medicine. Thus, the Ayyangar committee implemented the compulsory licensing mechanism with the major reason being the non-working of the invention in the Indian market.

The provisions of compulsory licensing were first given by the Patent Act 1970. The Compulsory license provisions were substantiated by the Licences of Rights. The compulsory license Chapter XVI consists of Sections 82-94. However, once India became a party to the TRIPS Agreement, the sections related to Licences of Rights were removed. Currently, Sections 82 to 94 address compulsory licensing under the Patent Amendment Act of 2000. In India as per Section 84(1) of the Patent Act, compulsory licensing can only be granted after the expiry of 3 years when an application is made to the controller.

COMPULSORY LICENSING IN THE FIELD OF PHARMACEUTICALS

Domain for patent has been multidimensional as Article 27 of TRIPs guarantees a patent for any invention, whether product or process in all fields of technology. Therefore, Pharmaceutical manufacturers developing medicines which are inventive and capable to cure diseases can apply for grant of patent for their inventions. The inventions include new medicines as well as processes or methods of manufacturing them. The pharmaceutical manufacturing company is concerned about the formula of new medicine as well as the method of their preparation. When this information is disclosed in the market can often lead to the production of generic medicine, leading to a loss of revenue. As a result, the patenting of these medicines as well as the process guarantees them protection from infringement.

Article 19(1)(g)[4] of the Indian constitution guarantees freedom of trade, thus pharmaceutical

[4] Supra no1.

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manufacturers use the patent as a safety measure to establish their trade even outside India. Guaranteed rights to the patentee improve protection from infringement thereby flourishing their trade. The grant of exclusive rights provides significant revenue which is deviated to the research and development (R&D) of the medicines. Indeed, the protection of rights promotes further development with a significant improvement of revenue. According to Robinson,

"Patent privilege differs from an odious monopoly in that it does not deprive the public of an existing right but rather prevents only the exercise for the limited time of the new direction marked out by the inventor".[5]

Granting protection only for a particular period, after which the invention is open to the public is an effective mechanism to prevent infringement. However, in India, the protection period continues to 20 years which in turn restricts the low-income Indian population regarding pharmaceutical accessibility at affordable prices. At this point, the 2 major provisions of the Indian constitution granting freedom of trade under Art 19 and the right to life under Article 21 conflict with each other. As a result in certain situations including national emergencies, the compulsory licensing of medicines was granted immediately after the granting of the patent.

TRIPS AGREEMENT AND COMPULSORY LICENSING

To counter abuses of patent rights, TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) was adopted by WTO in 1994. The Agreement gave the provision to protect intellectual property balancing the availability of inventions to the public. TRIPS doesn't use the term 'compulsory license' as such. However, according to Article 31[6] of the TRIPS Agreement, a patent can be used by the government or third parties authorized by the government, without the authorization of the right holder.

Article 13 allows member countries to implement limitations with regard to special cases, that do not conflict with the normal exploitation of work. Article 30 of the TRIPs agreement allows members to provide limitations to the exclusive rights conferred by the patent.

Article 21[7] of the TRIPS agreement balances the rights of the patentee as well as the availability

[5] Robert A. Choate and William H. Francis, Patent Law, Trade Secrets- Copyrights-Trademarks, (West publishing Co. Second Edition 76, 1981).
[6] Agreement on Trade Related aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement] Article 31.
[7] ibid.

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of the patent. It provides provisions as to the availability of patents to all without any discrimination as to the place of invention, field of technology, or whether the products are imported or locally produced. [8] Further Article 31, provides certain conditions as to the use of the patented invention without the authorization of the patent holder by the government as well as by a third party after the application of voluntary licensing made to the patentee. Article 40[9] substantiates this provision by granting the right to the member countries to implement their legislation with licensing practices and conditions when exclusive rights are granted to harm the competition and trade.

EFFECTS OF DOHA DECLARATION ON COMPULSORY LICENSING

Doha Declaration on the TRIPs Agreement and Public Health was adopted to implement the TRIPs agreement by recognizing the power of the member countries to take measures to protect public health. The major implementation of the declaration is regarding the flexibility of TRIPs for the access to medicines.

The declaration has granted the right to determine what constitutes a national emergency to the member state. In such a situation the member states have been granted the right to grant compulsory licensing and freedom to determine grounds for granting compulsory licensing.

Even though TRIPS provided a lot of benefits there was a need for amendment in TRIPS which was fulfilled by the Doha Declaration in November 2001 which allowed the member country to issue compulsory licenses to produce drugs for export to the countries having fewer or no manufacturing capacity of drugs.

"*Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of member governments*"[10]

[8]Indian Patent Act, 1970, Act of Parliament, 1970 (India), Chap XVI, sec 31.
[9] supra no7.
[10] The United Nations Secretary-General's High-Level "Panel on Access To Medicines" (Sept 2016), p.27 Recommendation 2.6.1 (b). In addition, recommendation 2.6.1 (c) urges the revision and adoption of the Doha Declaration paragraph 6 decision. https://www.politico.eu/wp-content/uploads/2016/09/HLP-Report-FINALSept-2016.pdf (last visited on March 12, 2025)

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Section 92[11] of the patent, the act provides for the circumstances which allow central government to make the declaration as to the granting of compulsory licensing. These circumstances include:

a) National emergency
b) Extreme urgency
c) Public non-commercial use.

In the above-mentioned circumstances, the provision of granting compulsory licensing after 3 years, is not applicable.[12] In such circumstances, the patent application can be made immediately after the grant of the patent.[13] When an application is filed by any person controller shall grant a compulsory license with the terms and conditions to make the patented invention available to the public at the lowest price. While granting the compulsory license the Controller should be aware of his role to balance the rights of the patentee and to make it available to the public at a reasonable rate. However, granting of compulsory licensing is possible only after the Central Government makes the notification in the Official Gazette.

The provisions have been implemented to allow the Government to take urgent steps at times of public health crisis, including HIV, AIDS, Tuberculosis, Malaria, and other epidemics.

Section 100 provides patents for government use. It states that the government can acquire the patented invention for its use in return for some compensation to the patentee. The government is required to notify the patentee about the use and extent of use of the invention. The patentee however can challenge such a use or the terms of such use. Section 102 states that the government can acquire the patented invention for public purposes. The patent holder loses all the rights to the invention and gets some compensation in return. The patent holder cannot challenge the acquisition but can ask for more compensation.

LEGAL SCENARIO IN INDIA

In December 2010 when Natco approached Bayer to grant the voluntary license to manufacture Nexavar whereas Bayer turned it down. The drug is used in the treatment of Renal Cell Carcinoma (RCC) and Hepato Cellular Carcinoma (HCC). The drug was priced at INR 2.8 lakh for a monthly therapy by Bayer which was claimed to be sold at INR 8800 for a monthly

[11] Supra note9.
[12] Indian Patent Act, 1970, Act of Parliament, 1970 (India), Chap XVI, sec. 84.

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therapy by Natco. Then in 2011, Natco applied to the Controller for the grant of compulsory license under Section 84, stating that the patented invention was not available to the public at a reasonably affordable price. The compulsory license was granted, which allowed a royalty of 6% which was later raised to 7% on the appeal of Bayer. Even after three years of the compulsory license, Bayer has not amended the price of the drug. It is selling the drug at the same price. This could lead to the revocation of Bayer's patent under Section 85, as it is found that the public requirements of the drug have still not been satisfied. Section 85 says that if a single patient is away from access to the drug, the public requirements cannot be said to be satisfied.[14]

The application for the grant of a compulsory license for Dasatinib was filed by BDR in march 2013. Dasatinib is sold by Bristol-Myers Squibb. It is used in the treatment of chronic myeloid leukemia. In India, a month's therapy of this drug costs about INR 1 lakh. BDR Pharmaceutical claimed to sell the drug at INR 8,100 for a month of therapy. However, the application was rejected by the Patent Office because the prima facie case has not been made out by BDR Pharma under Section 84, to obtain a voluntary license for the drug from the patent holder. Later in 2014, the Health Ministry planned to compulsory license Dasatinib under Section 92. But, the Department of Industrial Policy and Promotion (DIPP) turned it down stating that the use of Section 92 is impermissible as no national emergency or national urgency situation is prevailing in the country.[15]

THE NEED TO REFORME COMPULSORY LICENSES

Finally, after discussing India's implementation of TRIPs flexibility to allow accessibility of affordable drugs, it can be argued that Indian initiatives to provide affordable medicines are suffering various loopholes.

"*The TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.* "[16]

The DOHA declaration under paragraph 6 provided wit the effective tool of compulsory license, obligating the member states to use the compulsory license to promote public health

[14] *Bayer corporation v. Natco Pharma Limited*, 2014(60) PTC 277(BOM).
[15] *Bristol-Myer Squibb Company & Ors vs Mr. J D Josh*, I.A.No.15720/2009.
[16] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)DEC/1,41 ILM 746,2002 Para 6.

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balancing the protection of patent's rights. However, the Compulsory licensing mechanism faced drawbacks, which are depicted as follows:

1. **Long-term legal battle**

Section 84 provides the conditions for granting compulsory licensing. As per the provisions of the Indian Patent Act, it can be depicted that a compulsory license minimum of 4-year period is required. Compulsory licensing can be granted only after the expiry of three years from the granting of the patent. Further, it requires the efforts of the applicant to get voluntary licensing within a reasonable period of 3 months. Further, every application for compulsory license shall be decided within one year. This can be further depicted from the records given below:

SL No.	Name Of Applicant	Year Of Filing Application	Date of Granting Application
1.	Natco	2001	09/03/2012
2.	BDR Pharmaceutical International	2001	29/10/2013
3.	Lee pharma	2002	19/01/2006

The above data depicts a serious concern over the time required to grant patent protection in India. The Nato is the one and only company to which compulsory licensing was granted. The time period to obtain compulsory licensing shows about 11 years of legal battle. Similarly BDR Pharmaceutical International and Lee Pharma battled for compulsory licensing for unfortunately could not secure the same, this trend shows the difficulty of obtaining compulsory licensing and the waiting period required for the same.

2. **The definition of national emergency**

Section 92 allows to grant compulsory licensing in the circumstances of National emergency or in the circumstance of extreme urgency or in the case of public non-commercial use. However, the definition of National emergency are extreme urgency has not been yet defined. The TRIPs agreement put forward the strategy of National emergency undefined to allow flexibility to its member countries to define the situation according to their public policy. The DOHA Declaration has depicted the need to define the scenario of a national emergency according to the needs of each member State to protect public health. National emergency have

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been defined by various UK The United Kingdom's Civil Contingency Act 2004 defines an emergency as "An event or situation threatens damage to human welfare only if it involves, causes or may cause loss of human life, human illness or injury, homelessness, damage to property, disruption of supply of money, food, water, energy or fuel, disruption of system of communication, disruption of facilities for transport, or disruption of services relating to health."[17]

As the definition is vague, it causes a huge confusion concerning the application of this provision. This profession has been incorporated under the Doha declaration to grant compulsory licensing to protect public health. As the circumstances of granting the compulsory licensing is not defined it fails the objective of DOHA declaration.

3. Trends during pandemics

The scenario of the HIV crisis in South Africa in 1990, shows the picture hoe the TRIPs agreement could affect an LDC in the non-accessibility of pharmaceuticals. The South African government's implementation of the Medicines and Related Substances Act 1997 shows the efforts made by the government to protect its country from health crises. This initiative was made as the government cannot afford high-cost ANTI-HIV drugs from the US. The government introduced Parallel importation of drugs as well as licensing for manufacturing of the drugs. This appealed to various MNCs.

COVID-19, still a serious threat affected the public health systems of various countries since December 31, 2019. Declaring COVID as a pandemic from 11th March, led to huge international concern over the matter. The Pandemic has taken over 1.5 million of life by November 2020. The limited manufacturing of vaccines and non-availability of vaccines oxygen cylinders and other drugs related to the treatment of covid faced by various developed as well as developing countries. The trends of patent applications filed during the pandemic as per the report of WIPO 'Exploring COVID-19 Vaccine Patents'[18] is given below:

[17] National Emergency Definition, Duhaime's Law Dictionary, http://www.duhaime.org/LegalDictionary/N/NationalEmerge ncy.aspx (Last visited on 19 March, 2025)
[18] Exploring COVID-19 Vaccine Patents, WIPO, https://www.wipo.int/en/web/patent-analytics/exploring-covid-19-vaccine-patents, (Last visited on March 20, 2025)

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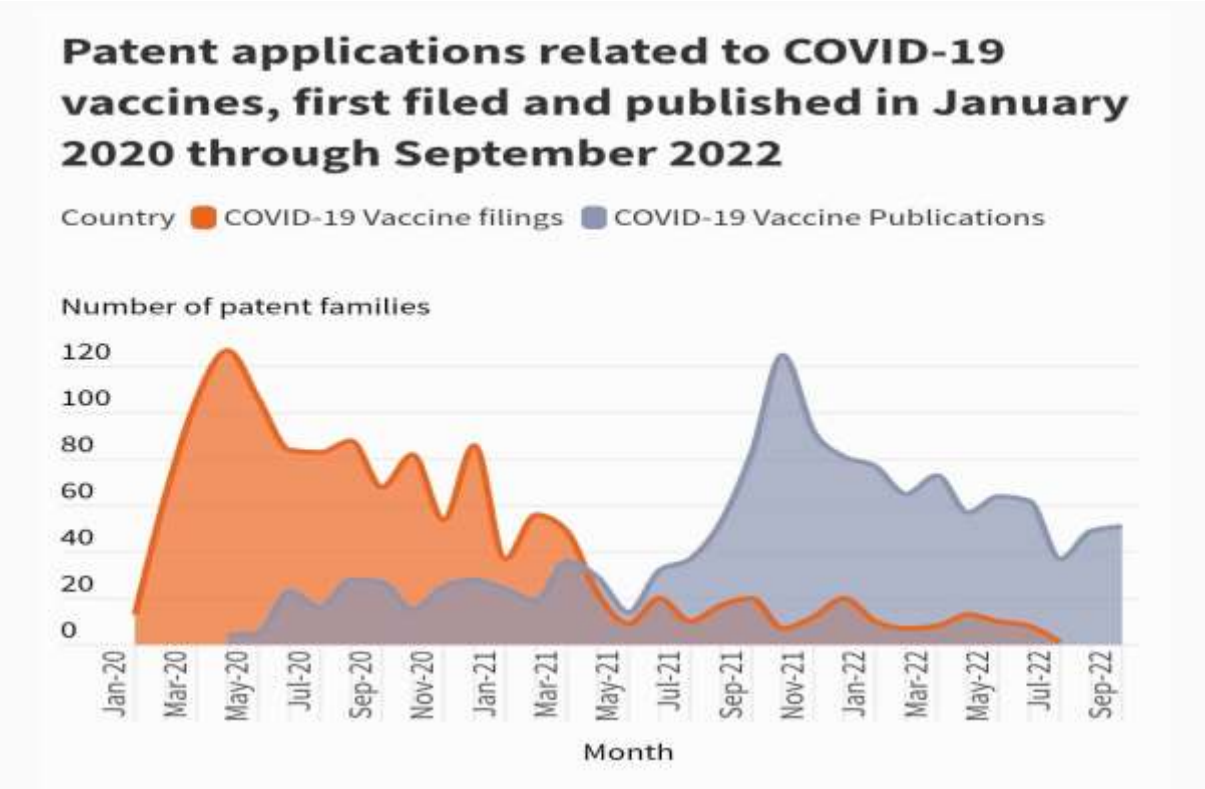

The above data clearly shows the patent application filed for COVID-19 drugs and therapeutic peaked from March to May 2020. The declaration of COVID-19 as a pandemic on 11 March shows the need for the vaccines in the month of March. Still, about 120 applications have been filed during that period of urgency. This shows the need for a stricter definition of national emergency so that the member states could make major steps at the time of the pandemic including compulsory licensing. The urgent situations of the pandemic were used by various MNCs to protect their profit by patenting the drugs. The MNCs are using the patent as a strong tool to protect their profit, not their intellectual property rights. The US asked their MNCs to reduce their price in their territory during the outbreak of Antrax. However, no initiatives were taken by the US to reduce the cost outside their territory in order to make them affordable for the developing and least developed countries. In this scenario India has made a drastic approach to wave the intellectual property patents. India and South Africa on 2nd October 2020, made a joint proposal for waiver of patent on the therapeutics and drugs concerning COVID-19 pandemic. Two years of battle have ended as WTO adopted the Ministerial decision on TRIPs agreement for the Partial waiver of intellectual property rights on COVID-19 vaccine on June 2022. However the same was opposed by developed nations including Australia, Brazil, Canada, EU, Switzerland, Japan, Norway, UK and US. This shows the egotistical strategy of the developed nations to enhance their national income by allowing their MNCs to marketize the health care needs of LDCs.

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CONCLUSION

"One should not forget that the patents represent an interventionist instrument, ultimately for the sake of community welfare. Thus intervention to restrict some of the effects of patents may be required, when the community welfare is no longer served."

Michael Kern

TRIPS and the Doha Declaration considered compulsory licenses as a life-saving weapon to meet the cry of LDCs. The main aim of compulsory licensing is to improve access of the public to patented expensive medicines. It also helps the development of the generic pharmaceutical industry in developing countries like India. In low-income countries. It plays a significant role by allowing the government to import affordable medicines from any part of the world. But if a country goes on a spree to grant compulsory licenses as a regular measure for abuse of IPRs and anti-competitive practices then it may shrink the foreign direct investment of a country. This arrangement can lead to low investment in R&D. This may restrict the formation of new drugs as well as processes.

Even though compulsory licensing is an effective initiative to implement the TRIPs Agreement, it cannot be the most appropriate mechanism. An appropriate definition for national emergency still remains a question to be considered. This criticism itself restricts the major outcome. Declaration of national emergency being a question prohibits appropriate steps during urgent situations like the COVID-19 pandemic. The government has to take appropriate steps to enlist the "essential medicines" according to the Indian scenario. The drug which is restricted to the major portion of the Indian population should be enlisted. The definition which includes an exhaustive list of these drugs should be framed. The government can also use the provision to acquire the patented invention for its use in return for some compensation to the patentee can also aid in providing affordable drugs.