 DOI: *https://doij.org/10.10000/IJLMH.113047*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 5 | Issue 3

2022

Analysing the Role of Intellectual Property Rights in the Development of Vaccines

M.S. SUDHIKSHA[1]

ABSTRACT

The Pharmaceutical industry located in multiples parts of the world characterize themselves as one of the riskiest businesses. In spite of the same, the industry constantly strives towards innovative medical substances and ground breaking treatments to eradicate global illnesses. Vaccines are pivotal pharmaceutical commodities, formulated to eliminate acute infectious diseases and create "herd immunity" with the vision of securing a wholesome community. Few instances of success in vaccination includes – immunization against yellow fever and small pox. The recent debate for and against the temporary waive of vaccinations in light of COVID 19 necessitates an in-depth study into the Intellectual Property Law governing pharmaceutical products especially vaccinations. Furthermore, through this paper, the researcher sheds light up on domestic statutes and international treaties governing vaccines and IPR. Lastly, the repercussions of waiver of intellectual rights of pharmaceutical companies shall be highlighted throughout the paper.

Keywords: *eradication, developing countries, patent, pharmaceutical industry, vaccine.*

I. INTRODUCTION

Judicialization of the right to health has increased the possibility of high-standard medical goods and services across the world. The concept has become wider to include free vaccination and other such facilities in line with the COVID 19 scenario. Implementation of this right to every nook and corner of the world is the real challenge as it will require appropriate funding, response from citizens, and cooperation with the local government. This right must take into consideration the requirements of third world countries wherein the majority of the population is below the poverty line and cannot afford medical care. This concept also ensures that vaccination is administered to individuals regardless of social position, their religious, ethnic, and gender identity. On top of that, the laws must work to protect the right to health of citizens by taking preventive measures to counter the spread of illnesses that prolong the pandemic.

II. EVOLUTION AND HISTORY OF VACCINES AND VACCINE LAW

The first law that introduced and mandated vaccines was the compulsory vaccination act in

[1] Author is a student at School of Law, Christ (Deemed to be University), India.

 [ISSN 2581-5369]

1892 to battle against smallpox. In the early 20th century to battle Cholera and typhoid compulsory immunization was imposed through the Government of India Act which was entirely under the control of the Britishers. During this period, the law was coercive and in favor of the interests of the colonial rulers. The vaccination process mainly began so that the Indian soldiers could continue to fight on behalf of Britain in international wars. Post-Independence, the National Immunization Programme had been launched to increase the state welfare and boost the economy under the Prime Minister's 20-point program. In 1974, the World Health Organization launched the Expanded Immunization Programme to facilitate self-sufficiency in the production of vaccines amongst developing nations and increase coverage. In the initial years of the 21st century, various new public policies such as the National Health Policy and National Population Policy of India were crucial in preventing measles, smallpox, and other detrimental diseases. Despite efforts and stringent laws, few citizens continue to suffer from diseases due to the state's minimal efforts to engage the citizens and lack of awareness programs.

III. NATIONAL VACCINE POLICY BOOK ANALYSIS

The National vaccine policy book provides a framework of guidelines within which vaccine programs must be implemented in India. This policy book addresses all the processes, assessment, coverage, financing, formulation, surveillance, and waste disposal management involving vaccine production and dissemination. The policy places significance upon conducting safe and secure clinical trials of vaccines. Clinical trials are one of the most important methods through which the quality of vaccines may be assessed. Another globally certified method to assess the quality of medical goods is to ensure that the products are in adherence to Goods Manufacturing Practices (laid down by WHO). By adhering to GMP, the production facility is defining, documenting, carrying out tests, distributing, and performing other tasks in line with medical and legal ethics. Furthermore, the policy also lays importance on scientific research and development in line with constitutional values, the national budget, and ensuring the indigenous and local resources are not exploited whilst developing products. This document has further been critical in the formulation of strategies to tackle widespread diseases and monitor the effects that stem out from the introduction of a vaccine in society. In addition, the document mentions that the state must work closely with Private as well as public bodies and agencies such as the National Disaster Management Agency to counter a widespread panic and outbreak situation. The National Vaccine Policy book also acknowledges that the Vaccine-Preventable Diseases surveillance is not actively functional in our nation. However, such surveillance is required to detect and deploy medical interventions to safeguard

 [ISSN 2581-5369]

the health and well-being of vulnerable groups of society.

IV. INTELLECTUAL PROPERTY RIGHTS

The battle between the global accessibility of vaccines and the intellectual rights of production companies has been incessant. Various Research and Development private corporations are against giving up their formulas to manufacturers since it is in violation of their intellectual rights. However, countries like South Africa and India had laid down before the court that it is necessary to waiver the intellectual protection in order to increase the accessibility of vaccination to more citizens and to end the prolonged pandemic. The legal provision put forth by WTO- clearly mentions that patent and other protections may be waivered in case of global urgency and for collective benefit. Furthermore, the World Trade Organization also mentioned that in order to grapple with and battle the legal inefficiencies prevalent in underdeveloped and developing nations, countries with manufacturing potential must aid those incapables of producing vaccines.

Vaccine inventions which is inclusive of goods, methods, formulations, or enhancements that fit the criteria of novelty and mass utility are patentable.

A patent holder has the sole right to create, construct, and to use the invention, as well as sell it to others. Patent rights secure a vaccine's ingredients, formulation, manufacturing process, and means of delivery. A patent application claiming the ingredients that are combined to generate the vaccine, such as immunogenic response-invoking substances and any active ingredients, can be used to protect the content of the vaccine. The example listed above is just one instance of vaccine elements and characteristics that may be safeguarded by patents. This proprietary right is valid for a specific period of time. Many countries have signed to implement a patent term of 20 years from the date of the application filed as a result of the Paris treaty. The time for making an application is a factor in patents that generates a lot of trepidation among inventors. This is particularly necessary for vaccines, since they are typically manufactured in a competitive market structure.

In the wake of COVID 19, unequal access to vaccines between the developed and the developing countries, questioned if Intellectual property rights were the reason behind this wide disparity. Post studies undertaken by European Parliament, it was disclosed in their report that since June 30, 2021, 23.4 percent of the population had at least a single dosage of varied COVID-19 vaccine, while only 0.9 percent of persons in low-income nations received the same. With the view of increasing accessibility, the proposition of temporary waiver of intellectual rights in connection with COVID 19 vaccine was put forth before the World Trade

 [ISSN 2581-5369]

Organization. Over and above that, the proposal suggested removal of restraints and barriers in trade of vaccination across borders.

The major concern regarding wavering Intellectual Rights regarding vaccination is the devastation of technology which required toil, skills and financial resources of the inventor. One of the main reasons for securing vaccines is economic in nature: vaccines are costly to produce, and acquiring certain level of exclusivity to the holder of Intellectual right for a vaccine for a period of time might help offset some of the infrastructure costs. This economic incentive has additional ramifications in that at least a part of the proceeds may be guaranteed to the vaccine owner based on exclusive IP rights or reinvested in future innovation and technology. Furthermore, another rationale to adopt IP rights that protect a vaccine would be, to assert authority over its use, dissemination, public opinion of the vaccine's effectiveness and quality, and the stakes in the market. The efficiency of a vaccine's effort to reduce the frequency of people infected within a group is determined or rather influenced by societal approval of the vaccination. Unregulated trade and unlawful distribution of vaccines by counterfeited brands may lead to cases involving medical negligence in the form of unprofessional administration as well as mislabelled vaccines that results in adverse consequences.

Therefore, safeguarding the IP law governing vaccines and its numerous features and facets, have been held to be crucial to a vaccine's collective efficiency success.

TRIPS which stand for Trade Related Aspects of Intellectual Property Rights was framed post colonialism and neo-colonialism of developing nations in order to guarantee security and stability in the social and economic domain nationally and internationally. Prior to existence of TRIPS which has been ratified by almost 2/3rd of the countries globally, Paris Convention on the Protection of Intellectual Property existed. The above-mentioned convention was an undisclosed failure as it lacked in established guidelines in regard to patent, non-provision of period of protection of property rights as well as no objective for guarantee of exclusive rights to the inventors or creators. Countries across the globe were obligated to ratify the TRIPS Agreement, in order to set up a uniform regulatory system that assured intellectual property rights regardless of borders.

One of the most effective and pertinent provisions secured under the TRIPS agreement was parallel pricing. Parallel imports enable a developing country to benefit from the prevalent practice of differential pricing with regard to drugs across different regions of the world. For example, if a bundle of copyrighted medicine costs $250.00 in Europe but $275.00 in Nigeria, a corporation or the Nigerian government themself can take the step to import the

pharmaceutical commodity from Europe and sell it at a cheaper price without such local patent holder's permission. Parallel imports assist countries to gain socio-economic and medical benefits from patented drugs at the least market price globally.

Article 66 of the agreement being discussed, explicitly covers the application of IP rights in Least - developed countries. Because of "their economic, financial, and administrative constraints, as well as their need for flexibility to develop a sustainable theoretical underpinning," the article specifically excludes LDCs from many of the TRIPs obligations. It is not a permanent exemption, but rather a 10-year period beginning on the date the state becomes a signatory, with the opportunity of a further grace period on petition. TRIPs contain provisions regarding application of compulsory licensing in situations of "national emergency or severe urgency,". When such an emergency arises invention as mentioned in the provisions are required to be used for the welfare of the public which might not necessarily meet the commercial interests.

A country may declare specific subject matter non-patentable in accordance to article 27.2 in attempt to preserve public health equity and patient's safety. Vaccines as well as other medications are examples of such pharmaceutical drugs that may be suspended from protection under Intellectual property law if a particular nation deems fit. In relation to vaccines, in most instances, the rights of the patent holders is usually diminished and restricted to few liberties. That is the holder (could be an individual pharmaceutical company or a biotechnology developer) may not solely reap the benefits such as royalty that arises out of the vaccines. They will further not have the option to transfer their rights as they desire and shall be subject to constant interventions from the state as vaccines usually concern the public wellbeing at large.

It's however, crucial to have a conversation about vaccines in particular, because vaccines have qualities and consequences that distinguish them from other pharmaceutical commodities. Vaccines differ from other products since vaccine formulation which includes certain vaccinations that require competent expertise, distribution which necessitates much more sophisticated cold-storage transit, and administration can all be complex (injection of vaccines requires skilled and experts that are knowledgeable in the same).Because of these difficulties, statutes and laws of intellectual property in the context of pharmaceutical products may not necessarily apply to vaccines as well. A study conducted by WHO underlined the differences between both pharmaceuticals and vaccines, pointing out that vaccines have had much niche markets. It was also stated that the government sector is more involved in vaccine production, pricing, and marketing of the same. Additionally, vaccines as biological products are more

 [ISSN 2581-5369]

complicated and expensive to yield and that the clinical trials that are conducted are exorbitant in nature. With respect to Intellectual rights, copying a vaccine is also much more challenging. Lastly, the report claimed that "Regardless of the 1.5 percent share of worldwide pharmaceutical turnover in dollars that vaccines have, they constitute far more than 1.5 percent of the capability to cope with leading causes of death worldwide, as they have multiplier effects". Wavering of patent rights over vaccines may lead to counterfeiting as well as trafficking of pharmaceutical products in the black market. Companies such as Pfizer and Moderna place stringent guidelines and rarely disclose knowledge pertaining to their innovation to preserve technical data and prevent misuse of advance technologies. Lastly, it is expected that with time and increase competitiveness in the market, the accessibility and availability of vaccination, especially the covid-19 one, will be enhanced.

V. CONCLUSION

The rational behind the principle of wavering intellectual property rights over vaccines was to augment the accessibility of the same at a reasonable price. Through the paper, the researcher has been able to conclude that waiver of vaccines does not necessarily reduce the price of the vaccine. However, it does reduce the incentive and determination of pharmaceutical companies to formulate novel immunization products and methods. The alternate method to increase availability in developing and least developed countries would be to remove trade barriers, adopt differential or parallel pricing and manufacture vaccines locally. International diplomacy and relations must take a multi-lateral approach wherein developed countries contribute towards specialized technology and incur vaccine production expenses.

*****

 [ISSN 2581-5369]

VI. BIBLIOGRAPHY

1. WHO, "Intellectual Property Rights and Vaccines in Developing Countries" WHO /IVB/04.21, 2004 at 4
2. Mahoney RT, Maynard JE (1999) The introduction of new vaccines into developing countries. Vaccine 17:646–652
3. Fedson DS (2005) Preparing for pandemic vaccination: an international policy agenda for vaccine development. J Public Health Policy 26:4–29; and Barrett CL et al (2005) If smallpox strikes Portland., http://www.scientificamerican.com/article.cfm?chanID =sa006&colID=1&articleID=000 BBC08- CEA3- 1213-8EA383414B7FFE9F
4. Article 66(1) of TRIPs
5. TRIPS Council Agreements on Extension for LDCs on Pharmaceutical Patents. Bridges 6(25): 3 July 2002, http://www.ictsd.org/ weekly/02-07-03/story1.htm
6. Centers for Disease Control and Prevention. *Adult Immunization Schedule.* 2009. http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm.
7. Lynn Lazaro, *Patemt Waiver For Covid-19 Vaccines – Necessary Or Reckless?*, (accessed on Jan. 03, 2022), https://www.mondaq.com/india/patent/1071814/patent-waiver-for-covid-19-vaccines-necessary-or-reckless
8. Rytis Satkauskas, Vaccine sovereignty and international law, (accessed on Feb, 04, 2022), https://www.leidenlawblog.nl/articles/vaccine-sovereignty-and-international-law
9. Kitch, E. W. THE VACCINE DILEMMA. *Issues in Science and Technology*, *2*(2), 108–121. (1986). http://www.jstor.org/stable/43308964
10. National Vaccine Policy, Ministry of Health & Family Welfare, https://main.mohfw.gov.in/sites/default/files/108481119000.pdf.

*****