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Transfer of Technology with context to Healthcare Sectors & Concurrent Hindrances

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ABSTRACT

Intellectual property rights (IPR) are described as rights to concepts, discoveries, and artistic endeavors on the basis of which the society is prepared to grant the status of ownership. Patents and other intellectual property rights (IPR) grant certain exclusive protections to the innovators or developers of that product, allowing them to profit commercially from their creative endeavors or repute. There are many different forms of patent protection, including patents, copyright, trademarks, and so on, and each has its own advantages and disadvantages. A patent is a formal acknowledgment of an innovation that meets the requirements of worldwide originality, non-obviousness, and industrial application. Improved identification, planning, marketing, and rendering of inventions and ideas are all made possible by intellectual property rights (IPR). Based on its area of specialisation, each industry should have its own intellectual property rules, management styles, strategies, and so on. The pharmaceutical business now has a developing intellectual property rights strategy that will require a more focused and strategic approach in the coming age.

Keywords: *Intellectual property rights, Vaccinations, Medications*

I. INTRODUCTION

Intellectual property (IP) refers to any unique product of the human mind, including works of art, literature, technology, and science. Intellectual property may be divided into two categories: artistic creations and literary creations. When we talk about intellectual property rights (IPR), we're talking about the legal rights that are granted to the innovator or artist in order to safeguard his product or production for a specific length of time. Inventors/creators or their assignees are granted an exclusive right to fully exploit their inventions/creations for a specified length of time under the terms of these legal rights. It is widely acknowledged that intellectual property (IP) plays an important role in the modern industry. Also conclusively

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proven is that the intellectual work connected with the invention should be given proper consideration in order for it to result in a public benefit for the general population. There has been a significant increase in the expenses of research and development, which has resulted in a significant increase in the amount of money necessary to bring a new technology to market.[2] So because stakes for tech-innovators have become extremely high, it has become necessary to protect their knowledge from unauthorised use, at least for a time, in order to ensure a reasonable return on their investment in research and innovation while also generating adequate profits for their ongoing investment in research and innovation.[3] Intellectual property rights (IPR) are a powerful instrument for protecting the investments, time, money, and effort made by the creator of an IP, because they provide the creator an exclusive right to use his creation for a specific period of time. As a result, intellectual property rights (IPR) contribute to the economic growth of a nation by fostering competitive spirit, as well as industrial progress and economic prosperity. This article provides an outline of intellectual property rights, with a particular emphasis on medicines.

II. A BRIEF HISTORY

The laws and administrative procedures governing intellectual property are rooted in European tradition. Patents were first granted in the fourteenth century, and the practise continues today. In comparison to other European countries, the UK was technologically advanced in a number of fields, and it was well-known for luring skilled craftsmen from around the world on favourable terms. The first copyright laws were enacted in Italy. The intellectual property system was born in Venice, where the majority of legal thought on the subject took place; laws and systems were adopted for the first time worldwide here, and other countries soon followed suit.[4] The Patent Act of India has been in effect for more than 150 years. One of the first acts passed was the 1856 Act, "*which was modelled on the British patent system and established a 14-year patent period, which was followed by a series of subsequent acts and modifications*".[5]

III. STATEMENT OF PROBLEM

The problem statement for this paper is the issue of knowledge transfer of vaccines and medications to create larger supply and generic medication to make medicine affordable, with

[2] New Delhi: Department of Science and Technology (DST), Government of India; 2002. Anonymous. Research and development statistics.
[3] New Delhi: Department of Scientific and Industrial Research, Government of India; 2002. Anonymous. Research and development in industry: An overview.
[4] Bainbridge DI. New York: Longman; 2002. Intellectual property.
[5] Singh R. Vol. 1. New Delhi: Universal Law Publishing Co. Pvt. Ltd; 2004. Law relating to intellectual property.

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specific reference to covid-19 vaccine and medicines.

IV. REVIEW OF LITERATURE

1. ***Intellectual Property Rights and Access to Medicines: International Trade Issues, EveryCRSReport (2009)***

This paper examines the link between intellectual property rights (IPR) rules in international and U.S. trade policy and the availability of drugs. Additionally, it discusses variety of issues faced between trade policy and the public health.

2. ***Chandra Nath Saha and Sanjib Bhattacharya, Intellectual property rights: An overview and implications in pharmaceutical industry (2011)***

This paper discusses the role of Intellectual Property in the pharmaceutical industry specifically in the modern economy. It discusses how the research and development of medication is not driven by various illnesses that the world faces but it is actually driven by market needs.

3. ***Handbook on Intellectual Property Rights and Technology Transfer, Indian Institute of Medical Research (2017)***

The handbook has been put together under the leadership of Professor Seyed Hasnain. The booklet of FAQs on Intellectual Property Rights represent an attempt in the aim of raising knowledge of IP protection prior to publication of a piece of work.

4. ***Brink Lindsey, Why intellectual property and pandemics don't mix (2021)***

This article focuses on the debate going around the waiver of patents for covid-19 vaccinations and medications. It talks about how a simple waiver is not enough and the need of the hour is technology transfer.

V. MANAGEMENT OF INTELLECTUAL PROPERTY IN PHARMACEUTICAL INDUSTRIES

In more ways than any other technical field, medicines and pharmaceuticals fit the definition of globalisation and the necessity for a robust intellectual property system the most effectively. Understanding that the expense of bringing in a new drug into the market can range anywhere from $ 300 million to $1 billion, as well as the dangers associated with the building process, no company wants to take the chance of its intellectual property becoming public property without receiving adequate returns. The creation, acquisition, protection, and management of intellectual property (IP) must be considered a business activity in the same way that generating resources and finances is. The knowledge revolution, which we will undoubtedly witness, will

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need the establishment of a distinct position for intellectual property and treatment in the entire decision-making process.[6]

While modern science drives competitiveness in the international pharmaceutical business rather than production know-how, the success of an organisation is heavily reliant on its research and development efforts. Therefore, investments in research and development in the pharmaceutical business are extremely high as a percentage of overall sales; some estimates imply that they might account for as much as 15 percent of total sales. One of the most challenging problems in this business is the handling of creative risks while simultaneously attempting to acquire a competitive edge over competitors companies. The level of risk in drug discovery and development is associated with a significant financial cost, with the advancement of prospective medications that fail to satisfy the strict safety requirements being stopped, often after many years of work.

It takes around 8-10 years from the date of the compound's initial synthesization for a medication to reach the market after clearing development obstacles. "*As product patents become the primary means of protecting intellectual property, pharmaceutical companies will be forced to divert their attention of research and development away from the development of new method for producing known drugs and toward the creation of a new drug molecule and new chemical entity to compete in the marketplace (NCE)*". While many illnesses of limited duration had been effectively treated throughout the 1980s, the research and development focus turned to long-term (chronic) disorders during the 1990s. It is necessary to verify that the criteria of various regulatory agencies are met while searching for a worldwide market when seeking for one.[7]

The number of papers that must be given to regulatory agencies has nearly quadrupled in the previous 10 years, according to some estimates. In addition, the time it takes for regulatory agencies to approve a new medicine has increased significantly. This results in a reduction in the length of patent protection available, resulting in the necessity to expend additional work in order to generate sufficient revenues. Especially in the case of medications created via the use of biotechnology, such as those involving the use of genes, the situation may be more serious. In the near future, it is expected that the industrialised world will begin lobbying for increased protection for pharmaceuticals. It is also likely that many governments may exert increasing amounts of price control in order to achieve public objectives. On the one hand, this

[6] Angell M. "The Pharmaceutical Industry.To Whom Is It Accountable?" *N Engl J Med.* 2000;342:1902–4.
[7] Lexchin J. "Intellectual property rights and the Canadian pharmaceutical marketplace: Where do we go from here?" *Int J Health Serv.* 2005;35:237–56.

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would highlight the need for lower medication research, manufacturing, and marketing costs, while on the other, it would demand planning for lower profit margins in order to recoup expenses over a longer period of time. As a result, it should come as no surprise that the pharmaceutical business must navigate a maze of competing regulations.[8] There have been several techniques developed over the last 10 to 15 years for cost reduction and competitive advantage in international commerce. Research and development activities are outsourced, research and development partnerships are formed, strategic alliances are formed, and other activities are outsourced as well.[9]

VI. Overview of local production of drugs in low- and middle-income countries

For most of the 1970s, pharmaceutical manufacturing was dominated by high-income nations, notably the United States and Japan, as well as Germany and other European countries. "Argentina, Brazil, Egypt, India, Mexico, and the Republic of Korea" were among the developing nations whose production was supplied by a couple of more established economies, accounting for two-thirds of total (developing country) output. A 1992 study and an update of that study in 2004 found that the north–south dispersion of production capability and share of world markets had remained relatively unchanged: according to the World Health Organization's "World Medicines Situation Report", pharmaceutical production is dominated in high–income countries. In 1985, these nations contributed for 89.1 percent of total world pharmaceutical output (measured in dollars), a percentage that rose to 90.5 percent in 1990 and 92.9 percent in 1999, according to the World Pharmaceutical Organization. The five countries that are home to major multinational pharmaceutical corporations – "the United States, the United Kingdom, France, Germany, and Japan" – accounted for 67 percent of pharmaceutical production (measured in dollars) in 1999, with Switzerland and Italy coming in second and third, respectively, and Japan coming in third.

In accordance with a classification defined by Ballance et al., ten countries were identified as having a "advanced industry" with "substantial research," with none of them being a poor nation. The report also identified 16 nations with "innovative competence" - that is, countries in which "at least one novel molecular entity was identified and sold by these countries between 1961 and 1990." Six of them are low- or middle-income nations: "Argentina, China, India,

[8] Chandra Nath Saha and Sanjib Bhattacharya, Intellectual property rights: An overview and implications in pharmaceutical industry, 2011 Apr-Jun; 2(2): 88–93.
[9] Mrudula BS, Durgadevi NK, Madhavi BR, Tejeswi B, Durga PV. Intellectual property rights pinpoint at IPR spotlights coveted R and D. Drug Inv Today. 2009;2:197–201.

Mexico, the Russian Federation, and the former state union of Serbia and Montenegro". The remaining countries are: The pharmaceutical manufacturing potential of an additional 97 nations was not fully used, with 84 countries producing just completed goods from imported active ingredients and 13 countries producing both active ingredients and finished medicines. From this group of 13, nine were low- or middle-income countries: "Bolivia, Brazil, Bulgaria, Cuba, Egypt, Indonesia, Poland, Romania, and Turkey". Bolivia was the lowest-income country. It was also determined that an additional 42 nations did not have any pharmaceutical sector at all, with the majority of these countries being developing nations.

In summary, the majority of low- and middle-income nations either do not have a pharmaceutical sector at all or are only capable of carrying out the relatively recent steps of formulation and packaging technology. A limited number of nations generate a diverse range of APIs, and an even fewer number of countries invest significantly in research and development.[10]

Nonetheless, as compared to the scenario in the 1970s or 1990s, the last few years have seen the emergence of some noteworthy new trends in local manufacturing that are worth noting. First and foremost, numerous nations who do not already have significant API production capacity are interested in creating it, realising that this value-added stage of the manufacturing process may be crucial in enabling businesses to compete on a global scale. Examples include the development of a "API Park" by the government of Bangladesh to promote the country's local industry, which is now focused on the formulation and packaging of imported active pharmaceutical ingredients (APIs). Tunisia, South Africa, Argentina, and Brazil have all expressed an interest in increasing their API manufacturing capacity, according to industry sources. Second, several of the larger generics companies are becoming into international corporations with manufacturing facilities in a variety of locations.

For example, the Indian pharmaceutical company Ranbaxy has manufacturing facilities in "China, Ireland, India, Malaysia, Nigeria, Viet Nam, and the United States", among other countries. In addition, the more sophisticated generics firms are devoting increasing and significant portions of their income to research and development for new formulations, new drug delivery methods, and new chemical entities. Lastly, Northern multinationals are acquiring or entering into joint ventures with Southern multinationals. In recent times, for example, "*Japan's Daiichi-Sankyo acquired India's Ranbaxy, United States-based generics*

[10] Ramesh Shankar, Handbook on IPR & Technology Transfer to step up awareness among scientists, 30th October 2017, http://www.pharmabiz.com/NewsDetails.aspx?aid=105125&sid=1

giant Mylan acquired India's Matrix Laboratories, and United Kingdom-based GlaxoSmithKline (GSK) acquired a 19 percent ownership stake in South Africa's Aspen Pharmaceuticals". As a result, in certain situations, "local producers" may be global corporations with advanced technological capabilities that conduct substantial amounts of research in addition to manufacturing.[11]

VII. RESEARCH & DEVELOPMENT FOR DEVELOPING COUNTRY DISEASES

While patents may serve as a reward for invention, others argue that the economic assumption underlying patents is only valid in cases where marketplaces give adequate monetary incentives for a financial return made in the invention. In certain cases, poor nations may be unable to give an adequate profit margin to pharmaceutical companies for remedies for illnesses that disproportionately impact their populace. It is acknowledged in the World Health Organization's "Global Strategy and Plan of Action for Public Health, Innovation, and Intellectual Property" that intellectual property rights (IPRs) serve a vital reward feature, but it also states that "this reward by itself does not fulfil the need for the new product development to battle illnesses where the prospective spending market is comparatively tiny or uncertain."[12]

According to a categorization system employed by the World Health Organization, there are three major categories of illnesses that differ in the amount of business incentives they provide for research and development.

"*Type I diseases (also known as chronic diseases), such as cancer, kidney disease, and heart disease*", are common in developed countries and are becoming more common in developing countries. Type II diseases (also known as acute diseases) are widespread in both developed and developing countries. In order to invest in cures for certain disorders, pharmaceutical firms have a significant monetary benefit to do so.

Type II illnesses are common in underdeveloped nations. Type I diseases are rare. Pharmaceutical firms may be enticed to spend in such illnesses if there is a huge requirement for development in high-income nations, as has been demonstrated in the case of HIV/AIDS research in high-income countries. In the case of other Type II illnesses, "*such as malaria and tuberculosis, high-income countries have little demand for medicines, and as a result, market-based incentives*" are insufficient to encourage pharmaceutical firms to engage in research and

[11] WHO, Pharmaceutical Production and Related Technology Transfer, https://apps.who.int/iris/bitstream/handle/10665/44713/9789241502351_eng.pdf;jsessionid=05254BEE8E496D3659B49BF234D549CB?sequence=1

[12] (WHA61.21.6)

development.

Infections classified as Type III illnesses, such as dengue infection and African sleeping disease, are those for which there is little need in affluent countries. These illnesses (which are also referred to as "neglected tropical diseases") are primarily seen in poor parts of developing countries. Pharmaceutical firms have limited financial motivation to invest in research and development for certain disorders, but they may be motivated by social considerations instead.[13]

According to a widely quoted figure, fewer than ten percent of worldwide spending on health research and development are focused toward the primary health problems that affect 90 percent of the worldwide people (the so-called "10/90 gap" in health research and development).[14]

A number of experts have suggested that low rates of research and development investment in "developing country illnesses" may be one of the factors influencing health problems in disadvantaged countries. For example, several neglected tropical illnesses are more frequent in poorer countries because of poverty-related factors such as contaminated drinking water, inadequate sanitation, and a lack of basic health-care facilities.[15]

Several of the pharmacological requirements of both developed and poor countries are becoming increasingly similar. Example: As a result of economic growth and development in developing nations, many Type I diseases, which are traditionally associated with high-income countries ("age" diseases), are now accounting for an increasing percentage of the disease burden in these countries as well. "*It is estimated by the World Health Organization that 80 percent of the burden of chronic illnesses is concentrated in poor and middle-income nations*."[16] Increased outbreaks of infectious illnesses such as the H5N1 "avian influenza" and H1N1 "swine influenza," as well as developing resistance to extremely infectious diseases such as TB, may spur research and development for illnesses that impact people of all ages and socioeconomic backgrounds.

VIII. DRUG PRICING

Pharmaceutical patents are only one of the numerous factors that might influence the pricing of pharmaceutical products. Additionally, economic growth, fees, customs, the effectiveness

[13] WHO, "Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights", Innovation and Public Health, 2006, p. 16.
[14] Ricki Lewis, Fighting the 10/90 Gap, Medecins San Frontiers (MSF), May 13, 2002.
[15] Phillip Stevens, "Diseases of Poverty and the 10/90 Gap, International Policy Network", November 2004.
[16] WHO, Preventing Chronic Disease: A Global Investment: WHO Global Report, 2005.

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of global production and supply networks, government procurement strategies, public healthcare policies, as well as price policies made by the government and business are all considered. The impact of these factors on medication pricing is also possible, but they are outside the focus of this article.

It is possible that patents will boost the price of a medical product by postponing the introduction of generic rivals into the marketplace. Patents are time-limited monopolies on the distribution of a medical product. Despite the fact that the time-limited, exclusive privilege may serve a reward feature, some campaigners are critical of the pricing for patented drugs, claiming that patents allow right holders to charge rates that are significantly greater than the marginal costs of research and development and manufacturing.

Generic medications, which are generally described as duplicates of patented treatments, mostly of medicines whose copyrights have expired,[17] have the potential to decrease the cost of drugs in the world market in a variety of ways, including through increasing competition. In most cases, generic versions do not need to duplicate the research and clinical studies done by major brand pharmaceutical firms in order to get regulatory clearance; instead, they just need to establish that their product is "bioequivalent" to the patented, brand name drug. In the United States, "*the Drug Price Competition and Patent Restoration Act of 1984 (also known as the Hatch-Waxman Act of 1984), among other provisions, allows the Food and Drug Administration (FDA) to grant marketing authorization for generic drugs based on bioequivalence data instead of more expensive clinical data*". Without this requirement, generic producers are allowed to join the market more rapidly once patents have lapsed and to sell the medications at cheaper prices than they would otherwise.

Generic medicines, by serving as market rivals, also serve to push innovator pharmaceutical firms to decrease the pricing of their branded drugs, which benefits consumers. Furthermore, the introduction of generic medications into a market may spur the development of additional medicines by innovator firms, resulting in an increase in the supply of drugs.[18]

IX. ACCESS TO ESSENTIAL MEDICINES

Since its inception thirty years ago, the field of public health has seen significant transformation. It has been more than three decades since HIV/AIDS first emerged infected people throughout the world, and there has been a marked increase in the tolerance to medicines

[17] World Trade Organization (WTO) glossary.
[18] GAO, U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification, GAO-07-1198, September 2007, p. 7.

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for malaria, TB, and a wide range of germs in the meanwhile. HIV/AIDS is a global pandemic that unfairly targets impoverished nations, despite the fact that it is a global pandemic. In addition, the developing world has been affected by a wide range of infectious and deadly illnesses.

The results of public health are influenced by a wide range of social, financial, and political factors, many of which are interconnected, one of which is accessibility to medications.

Specifically, according to the United Nations Millennium Development Goals, availability to drugs is characterized as "having medications constantly accessible and cheap at public or private healthcare facilities or medication shops that are within one hour's travel from people's homes."[19]

Many public health advocates emphasise the need of "important medicines" when addressing access to medications. A number of experts suggest that, given the financial restrictions that national governments confront when it comes to delivering health care, countries should rationalise their health policy decisions, which include the distribution of medications. Important medications, according to the World Health Organization, are those that meet the most urgent health-care requirements of the community. They are chosen with careful consideration given to their significance to public health, proof of safety and effectiveness, and comparative cost-effectiveness. It is planned that necessary medications be made accessible at all periods in acceptable quantities, in the right dose forms, with consistent quality and enough data, and at a price that the person and the public can pay, in the setting of functional health-care systems. The notion of necessary medications is meant to be flexible and open to a wide range of conditions; nonetheless, the determination of which drugs are considered necessary continues to be an issue of national responsibility.[20]

Pharmaceutical medication prices, especially for low nations and communities, can be a substantial obstacle to the access of critical and other medicines in these areas. In most areas of the globe, health services are provided through a combination of public and private health-care providers and facilities. In many poor nations (and, in certain circumstances, rich ones such as the United States), customers carry a significant portion of their health-care expenditures on their own shoulders. While other countries, such as Thailand, Japan, Turkey, and France, have larger publicly-funded drug marketplaces, this has resulted in a reduction in the costs that individuals must bear. Higher-priced medications, on the other hand, may put a

[19] United Nations, Delivering on the Global Partnership for Achieving the Millennium Development Goals, MDG Task Force Report, 2008, p. 35.
[20] WHO, http://www.who.int/topics/essential_medicines/en/, accessed September 30, 2021.

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crimp in the government's capacity to offer public health care in circumstances when the state is financing a bigger percentage of health care costs than usual.

There is a great deal of disagreement over the degree to which patent protection interferes with the availability of vital drugs. The ambiguity is exacerbated by various interpretations of what constitutes "important medications" and "access to medicines," respectively. For example, when it comes to measuring access to critical drugs, there are frequently no agreed-upon units of analysis. Having kept an Essential Medications List (EML) since 1977, the World Health Organization (WHO) is now assisting country governments in selecting medicines to fulfil their public health requirements and in developing national lists.[21] Despite the fact that the WHO EML is frequently utilised as a foundation for research, some global health advocates are concerned that the EML may not be broad enough. It is their contention that the EML may omit critical medications due to economic considerations. They argue that patents increase the cost of medications and that the EML contains just a small number of drugs that are currently protected by patent. In contrast, the EML points out that price is not a cause to automatically remove a medication from consideration and that a variety of factors are taken into consideration throughout the decision-making process.

Many experts also assert, however, that the percentage of prescribed drugs covered by patents is in "constant flux," owing to the fact that existing patents will lapse, new patents will be requested for new medicines, new medicines will be added to the World Health Organization's "Model Essential Medicines List", and other medications will be eliminated from the EML.

X. QUANTIFYING ESSENTIAL MEDICINES UNDER PATENTS

Despite the limits of the data, various research has attempted to estimate the number of critical medications that are protected by patent. As per a report released in 2004, 1.4 percent of critical medications were patented in 2003, according to the National Institutes of Health. An analysis of data from 65 low- and middle-income nations using statistical regression methods measured the rate with which "essential drugs," as defined by the World Health Organization's 13th Model Essential Medicines List (EML), were copyrighted and evaluated the data. The analysis found that 17 essential medications might be susceptible to patent protection in 2003, out of the 349 items included in the WHO Essential Medicines List. Whilst total incidence rate of patents for critical medications may be small, the study found that patents for antiretroviral medicines (ARVs) for HIV/AIDS therapy were much more common than for other types of

[21] WHO, WHO Model List of Essential Medicines, 15th List, March 2007, http://www.who.int/medicines/publications/essentialmedicines/en/.

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drugs. Furthermore, because HIV/AIDS treatment frequently involves the use of combination therapy (the administration of many medicines at the same time), a patent on a single medicine may restrict access to "totally generic based therapy."[22]

According to the result of the research, innovators were far more likely to file patent applications for patentable medications in bigger, established markets than in underdeveloped nations, where innovators may not have enough monetary incentives to pay the expenses of filing patent applications. China, South Africa, and Mexico were among the nations where patenting was found to be more frequent than in other big middle-income countries, according to the research. Pharmaceutical firms may also decide not to pursue patents in low-income nations for a variety of reasons, including societal motives to expand access to medications in these areas or worries about their reputation. Furthermore, if the developing nation did not recognise patents, pharmaceutical corporations might not have the choice to file a patent application. According to the findings of the survey, both perceptions of health programs and attitudes of pharmaceutical corporations are exaggerated: According to the authors, "Patents could not be the cause of essential drugs being unavailable in'many' developing nations since they do not exist 98.6 percent of the time; similarly, patents could be a 'global' requirement of the pharmaceutical industry because manufacturers forego them 69 percent of the time."[23]

XI. INTELLECTUAL PROPERTY AND COVID-19

In a statement released on April 25, 2021, Bill Gates, stated that "sharing vaccine formulae for COVID-19 with developing nations will not help minimize the global pandemic emergency since many of these nations did not have the capacity of producing COVID-19 vaccines effectively." The Bill and Melinda Gates Foundation, of which he serves as co-chair, released an official statement a few days later, stating that they favor a "limited copyright waiver for COVID-19 vaccinations during the pandemic." Since the beginning of the COVID-19 pandemic, the Gates Foundation has been actively engaged in vaccine research and development.

During the first year of the pandemic, "*India and South Africa made a proposal to the World Trade Organization (WTO) on 2nd October 2020, requesting IPR waivers on many products for COVID-19, including prescription medications, vaccines, protective clothing, ventilators, and diagnostic devices*". The WTO approved the proposal on 3 October 2020. The World Trade Organization (WTO) is the final authority on global trade regulations, covering *"intellectual*

[22] Amir Attaran, "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries," Health Affairs, vol. 23, no. 3 (May/June 2004).
[23] Ibid., p. 159.

property rights (IPR), and the facilitator of international trade agreements for 164 member nations, including India. Globally, intellectual property rights (IPR) are controlled by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)", which, according to the plan, would have to be granted as an exemption. According to the plan, these exemptions should stay in place until "the most of the world's population has gained antibodies" and until "widespread immunisation is in place throughout the globe."

This was also adopted by the World Health Organization's director general, Tedros Adhanom Ghebreyesus, who had stated that it would "ease global and intellectual property arrangements on COVID-19 vaccines, treatments and tests in order to make the methods available to all who require them at an affordable price." The plan has received the backing of health care advocates.

The momentum has just begun to swing in support of the plan as of May 2021, according to the latest available data. Aside from the differences between Bill Gates and his foundation, the United States government has also shown support for a waiver of the requirement.

The United States Trade Representative stated on May 5, 2021, that the administration "endorses the waiver of those restrictions for COVID-19 vaccinations" in the "interest of eliminating this pandemic." Pfizer, Johnson & Johnson, Merck, Novavax, and Moderna are among the COVID-19 vaccine manufacturers based in the United States, which also includes Johnson & Johnson and Merck. Within a day, many additional nations, including France, Russia, and New Zealand, signaled that they would accept an exemption.

Any exemption granted by the WTO would also have to be approved by a majority of its member countries. An exemption would be discussed, according to the European Commission. Germany, the home of BioNTech, the company that developed the vaccine now being marketed by Pfizer, said it was against an exemption since "the IP protection is a driver of ideas and must stay so."

The Government of India, on the other hand, has chosen a different approach within the country: When the government was called before India's Supreme Court in May 2021, the court inquired as to whether the administration planned to give any obligatory licences to firms that produce medications such as remdesivir, which are used in the treating of COVID-19. According to reports, the administration told the court that it was "actually participating itself with organizations worldwide at a diplomatic standard to come up with a solution," and that any exercise of lawful authority under the Patents Act 1970[24] read with the TRIPS Agreement

[24] The Patents Act, 1970 (39 of 1970) [19th September, 1970].

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and Doha Declaration, or in any other way, would be "counter-productive at this step." This "would have grave, serious, and unplanned negative repercussions" in the nation's efforts to compete on the worldwide scale utilising all of its funds, benevolence, and good offices through diplomacy and other routes if the government used its authority to waive patents on COVID-19 goods, according to the government.

The scarcity of COVID-19 vaccines is a global problem, and because India is a significant manufacturer, the country's shortfall has a direct influence on global supply. The World Health Organization's (WHO) COVAX laboratory for poor and middle-income nations is scheduled to provide COVID-19 vaccinations to 64 countries over the next two months. However, the WHO stated in March 2021 that nations relying on the AstraZeneca vaccine developed by the Serum Institute of India (SII), which is marketed in India as Covishield, would encounter disruptions "due to the higher consumption for COVID-19 vaccines in India," resulting in a postponement in the vaccine's availability.

Similarly, the manufacture and distribution of the Johnson & Johnson and Novavax vaccinations have been put on hold, as well. "*According to the Launch and Scale Speedometer of the Duke Global Health Innovation Center in the United States, several nations in the developed countries had put advance orders, but the corporations were unable to fulfil them*".

XII. IMPACT ON JAPAN AND JAPAN'S POSITION

In Japan, where vaccination rates are low, it would be preferable if a relaxation of patent rights on the COVID-19 vaccines resulted in an increase in the availability of vaccinations. The suggested interim exemption of the TRIPS agreement, on the other hand, is largely designed to aid developing nations with restricted access, and as a result, the effect on Japan, which has completed purchase agreements to meet the majority of its needs, will be minimal. Japanese officials must instead decide what measures to take in relation to the United States' policy shift. Japan has reaffirmed its objection to the suggested waiver.[25]

As Japan prepares to commercialise the production of Japanese vaccines now in production, the government will be faced with a tough choice between the necessity to obtain research subsidies and the likelihood of receiving a concession of the development incentives.[26] Even if the exemption of the TRIPS agreement is only applied to vaccines developed in the United States, vaccine manufacturers in other nations, including Japan, are predicted to be adversely

[25] Kremer, M (2000), "Creating markets for new vaccines: Part I: Rationale", Innovation Policy and the Economy, Vol. 1, pp. 35-72.
[26] Castillo, J C, A Ahuja, S Athey et al. (2021), "Market design to accelerate COVID-19 vaccine supply", Science 371(6534): 1107-1109.

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affected by it because, as a general rule, it would be beneficial for manufacturers if prices remained high across the platform. "*When price war happens in an oligopoly industry, like the industry for COVID-19 vaccines, where the number of vaccine makers is restricted, a price drop by one manufacturer will drive other manufacturers to drop their prices in response*."[27]

Given the fact that vaccination initiatives are subject to externalities, they are particularly vulnerable to the challenge of supply scarcity. Using advance market commitments (AMCs) to encourage investment in vaccine research has been successful in the past in delivering pneumococcal vaccine to underdeveloped nations, and it is being used in current outbreak to great effect.[28] Immediately following the United States' policy shift, the Japanese government announced on May 13th a governmental purchase plan for locally manufactured COVID-19 vaccines under the AMC method. In order to be prepared for future pandemics, it is critical to provide support for the development of local vaccinations in the United States. The other hand, until the COVID-19 epidemic is contained around the world, the chances for normalisation of Japan's economy, which is increasingly internationalised in all areas, remain dismal. Essentially, the country finds itself trapped between the necessity to vaccinate the people rapidly in order to allow for a quicker return to normalcy and the need to provide incentives for the development of domestic vaccine capacity in order to prepare for future pandemics.

A fast fix would be to increase both manufacturing capacity and export capability inside the G7 member countries themselves. Castillo and colleagues (2021) maintain that further investment is required to expand vaccine supply capacity due to the overwhelming worldwide advantages of vaccinations in comparison to their costs. Following bilateral talks, Japan began supplying AstraZeneca vaccines made in Japan to 15 poor countries, as well as Asian nations with high rates of infection like as Indonesia and Malaysia, under the COVAX Facility (COVID-19 Vaccine Global Access Facility). International trade would speed the worldwide roll-out of Covid-19 vaccines, if manufacturing and export capacity were increased within G7 nations. However, severe export controls would prevent the international trading system from accelerating the worldwide roll-out.

XIII. DEFINITION OF TECHNOLOGY TRANSFER

In the past, the phrase "technology transfer" had a reputation for being difficult to define

[27] AKANE OKUTSU and KIRAN SHARMA, Vaccine patent waiver: COVID stopper or innovation killer?, 14th May 2021, https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer

[28] Kremer, M, J D Levin and C M and Snyder (2020), "Designing advance market commitments for new vaccines", NBER Working Paper 28168.

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properly. In a broad sense, technology transfer is defined by the World Intellectual Property Organization (WIPO) as "a series of processes for sharing ideas, knowledge, technology, and skills with another individual or institution (for example, a company, a university, or a governmental body), as well as for acquiring by the other of such concepts, expertise, innovations, and skill sets".[29] Following the study's primary objective, the scope of efforts evaluated was confined to those with the expressly stated goal of transferring technology or taking other actions to improve the ability of local drug manufacturers to produce their products. Direct transfer of "software" (e.g., information, data, know-how) and "hardware" (e.g., machinery) necessary for manufacturing, as well as education and training programmes especially focused at medication or vaccine manufacture, were all considered for inclusion in the research study. "*Researchers eliminated from the study any research and development (R&D) activities that did not result in end-product manufacturing (e.g., clinical trials, university-to-private sector licencing), as well as general education and training that was not directly related to manufacturing (e.g. scholarships for higher education in the life sciences)*". Despite the fact that these sorts of activities may undoubtedly be viewed as diverse ways of increasing absorptive capacity for transfer of technology for domestic producers, they were eliminated in order to maintain the focus on the efforts that are most directly important for production. Finally, voluntary licences that did not include a knowledge transfer component for the purpose of manufacturing were evaluated in a distinct category.

XIV. WHAT DOES PATENT WAIVER MEAN WITHOUT TECH-TRANSFER?

In the absence of technology transfer, surrendering copyrights "is equivalent to declaring, 'From tomorrow, we will make space travel free,'" according to Gopakumar Nair, an authority on intellectual property and a former drug company administrator.

"The decision to forgo patents at the world scale is a wise one. Indian firms would be capable of stepping in and produce additional COVID-19 vaccines, according to the report "The Indian Pharmaceutical Alliance (IPA), which comprises of 24 prominent drug-makers, was founded by Sudarshan Jain and is headed by him as secretary general. According to him, the second step should be to secure the transfer of technology, because the first step is useless without it.

For decades, India's generic medicines sector has reverse-engineered pharmaceuticals in order to market cheaper, bulk produced generic equivalents. The development of vaccines, particularly those based on the more recent mRNA technology, requires a greater level of

[29] Adapted from UNITAID Strategy 2010–2012 (60).

technological expertise, according to Nair, which is why knowledge transfer will be critical.

Despite this, drug companies may be reluctant to cooperate with WTO exemptions, regardless if they are granted. Experts predict that once exemptions are granted, vaccine manufacturing will require well over a year to alleviate the existing shortfall.

The most efficient method, according to Jain, is for copyright owners voluntarily to give unilateral licences to other firms. He also noted that recent pronouncements have created an atmosphere in which patent owning corporations would be forced to acknowledge this as a genuine and urgent issue.[30]

According to a report published in May 2021 by the research and trading firm Sanford Bernstein, there are further reasons why individuals opposed to patent exemptions believe they will not be instantly advantageous to them. According to them, if the waiver does not include technology transfer, it would take longer for Indian manufacturers to build the technology needed from the ground up, particularly in the case of mRNA vaccines such as those from Pfizer and Moderna, which are now under development. Another reason they claim is that the current production capability in India is already being used, with just a small amount of capacity remaining idle.

Foreign drug firms and their industry groups have not yet embraced the exemption, nor are they confident that it would resolve any of the existing supply shortages. As a result, they argue, a waiver may cause disruption in current supply chains for raw materials and produced vaccines, as well as a less-than-optimal use of scarce resources during an especially important period. For example, "*a statement from the Pharmaceutical Research and Manufacturers of America (PhRMA) stated that patent exemptions would not solve the problem of restricted availability of raw materials or provide alternatives for actually distributing the numerous vaccines that would be produced as a result of the patent exemptions*". According to the "International Federation of Pharmaceutical Manufacturers and Associations", trade restrictions and supply-chain limitations are a more concerning problem than patents.

The British Medical Journal published a report on May 10, 2021, in which it stated that companies interested in manufacturing COVID-19 vaccines and governments interested in seeing this happen must make certain that raw materials are available, infrastructural development and machinery are available, high rates of quality assurance is retained, and a

[30] Latha Jishnu, Coronavirus vaccines: Tech transfer is the new mantra, 5th July 2021, https://www.downtoearth.org.in/blog/africa/coronavirus-vaccines-tech-transfer-is-the-new-mantra-77773

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large enough and skilled workforce is available.[31]

To summarise, "the patent is still the most significant barrier," according to Davinder Gill, an authority on vaccines and former vice president for global biotherapeutics at Pfizer. "The patent remains the most significant barrier," he said. "Comparing India to other nations in the peninsula and supposing that the same exemption was granted to other nations, India would be the one who performs the best, according to the data. Medicines and vaccines may be manufactured in India due to the country's capability and expertise." It may take much longer without technology transfer, but Indian firms will be able to create vaccines, according to him. "However, the patent is still the crucial barrier that poses the risk and prevents companies from entering the market," he added.

XV. GIVING LICENSES TO INDIAN COMPANIES

As an example of voluntary licencing currently occurring with some efficiency in current pandemic, the AstraZeneca Covishield vaccine, the Johnson & Johnson vaccine, and the Russian Sputnik-V vaccine are all examples of vaccines that have received voluntary licences. All of these firms have granted voluntary licences to a small number of businesses across the world.

If the exemption itself does not imply that businesses may immediately begin making COVID-19 vaccines, then why has there been such a strong backlash from large pharmaceutical corporations against the waiver itself? It is believed by some experts to be done in order to safeguard their long-held and inflexible stances on intellectual property, out of concern that they may be forced to give even more in the future.[32]

Despite the fact that patent owning corporations could licence their vaccine and receive royalties, and that too on a big scale, they have no reason or motivation to do so. Similarly, if a drug or vaccine is sold at a lower price in India than it is in the United States, the lower price in India will be regarded as a 'reference-price,' and the supplier will be required to explain why the same product is marketed at a lower price in India but at a higher price in the United States. "Pharmaceutical corporations are not compelled to lower their prices in developing countries for a variety of reasons. They don't want to be viewed as just walking away from a difficult

[31] Ito, B and T Yamagata (2007), "Who develops innovations in medicine for the poor? trends in patent applications related to medicines for HIV/AIDS, Tuberculosis, Malaria, and neglected diseases", The Developing Economies 45(2): 141-171.

[32] Banri Ito, Impacts of the vaccine intellectual property rights waiver on global supply, 8th August 2021, https://voxeu.org/article/impacts-vaccine-intellectual-property-rights-waiver-global-supply

issue."[33]

XVI. CONCLUSION & SUGGESTIONS

A growing number of public health advocates believe that the general public should have a bigger say in the development of pharmacological treatments for illnesses. Some argue that the United States' trade policy initiatives to meet public health requirements should go beyond patenting and forced licencing and include other measures. The "World Health Organization's Global Strategy on Public Health, Innovation, and Intellectual Property (WHO Global Strategy)" asks for the investigation of a variety of incentive systems. Besides patents, additional mechanisms for encouraging the private sector to do research and development focused on meeting the public health requirements of developing nations include advance market pledges, patent pools, and innovation rewards. However, while such systems may help to steer pharmaceutical research and development toward fulfilling the requirements of poor nations, they may also require governments to shoulder a higher part of the risks involved with research and development.[34]

What India can do

In the face of a global pandemic, authorities must use all of their powers, laws, and diplomatic skills, as well as rethink how patents work, according to Leena Menghaney, global intellectual property rights advisor for Médecins Sans Frontières' Access Campaign, "*We need to rethink how patents work*" she added.

"*Serum Institute and Bharat Biotech, the two Indian businesses tasked with supplying vaccines to India, have clearly failed to keep up with the pace of the market. As a result, this duopoly should be prohibited from continuing to exist* " she explained. What is the point of delegating all of our authority to pharmaceutical corporations to determine whether people in India and across the globe can pay or have access to COVID-19 medications and vaccines, and whether or not to provide licences for other companies to manufacture them?

When it comes to pharmaceutical patents, the Indian government has the authority to issue compulsory licences, which can compel a patent-holding pharma business to mandatorily provide a production licence to another company, which might be followed by knowledge transfer. Her company's Covaxin, which was created in collaboration with the Indian Council

[33] Centre for global development, Would Exempting COVID-19 Vaccines from Intellectual Property Rights Improve Global Access and Equity?, https://www.cgdev.org/debate/would-exempting-covid-19-vaccines-intellectual-property-rights-improve-global-access

[34] Carsten Fink, "Intellectual Property and Public Health: An Overview of the Debate with a Focus on U.S. Policy, Center for Global Development", Working Paper Number 146, June 2008, pp. 22-23.

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of Medical Research, has been licenced to three companies: "Indian Immunologicals Ltd, Bharat Immunologicals and Biologicals Corporation Limited, and the Haffkine Institute", according to her. It is necessary to carry out this type of license and technology transfer for all of the other vaccinations as well, she added.[35]

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[35] Anoo Bhuyan, Patent waver for Covid vaccine without tech transfer won't speed up supply, 18th May 2021, business-standard.com/article/current-affairs/patent-waver-for-covid-vaccine-without-tech-transfer-won-t-speed-up-supply-121051800392_1.html

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