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Patent Law in Pharmaceutical Industry and Doha Declaration-A study1 Pharmaceutical Patents

Authored By- Koyel Roy

In 2005, India started allowing pharmaceutical items to be patented, in accordance with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In this era, where ideas and inventions are valued highly, knowledge is a critical aspect in propelling development. Inventors not only have a lot of possibilities to show off their ideas and creative work, but they also have a lot of chances to make money. People, for example, pay more for an iPhone than is actually required to manufacture it. This is because a significant portion of the buyer's money goes to reward inventors and innovators for the iPhone's development.

India produces the most generic pharmaceuticals in the world. One of the greatest medical success stories is India's ability to provide affordable HIV therapy. India is one of the world's leading suppliers of low-cost vaccinations. Indian medicines are preferred over the world due to their inexpensive cost and great quality. As a result, the country has earned the title of "World Pharmacy." The pharmaceutical industry currently accounts for 1.72 percent of the country's GDP. The Indian pharmaceutical industry is a significant part of the country's international commerce, offering investors numerous outlets and opportunities.

As attorney Dr Peter Feldschreiber argues, drug research and development (R&D) "is a high-risk investment for the pharmaceutical business." The pharmaceutical patent system was designed and is used to help corporations secure their investment and recover costs associated with discovering, producing, and marketing new pharmaceuticals, thereby encouraging future drug research and development.Pharma companies apply for a patent as soon as a medicine and its innovative mechanism of action are discovered. The corporation then has a 20-year patent on the product, but R&D can take up to 15 years, so the patent could be close to expiring by the time the

[1] KOYEL ROY ASSISTANT PROFESSOR , AMITY LAW SCHOOL, AMITY UNIVERSITY, KOLKATA

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product is approved and available on the market.When the 20-year exclusivity period expires, generic competitors will be able to enter the market and compete on price with the branded drug. Companies frequently aim to extend the exclusivity term for a drug by seeking supplementary patents in order to safeguard their investment.

Feldschreiber emphasizes that these exclusivity extensions are lawful and "not loopholes in patent law," a point echoed by Graham Dutfield, a professor of International Governance at the University of Leeds School of Law, who says: "These...are valid practices, which the law allows."

One of the so-called "intellect-driven" industries is the pharmaceutical industry.The expense of pharmaceutical testing is high, and the results are unpredictably unpredictable. The outcomes of the study could lead to the development of a valuable new product or procedure. Pharmaceutical businesses must protect their inventions from illicit commercial use by gaining the right to a patent on the protected product or technique in this highly competitive sector.Pharmaceutical patents in India can be classified into one of the following categories:

- Patents on drug compounds.
- Patents on Technology
- Patents on formulations or compositions.
- Patents on biotechnology
- Patents on polymorphs.
- Patents on Synergistic Combinations
- Patents on processes.
- When a pharmaceutical company develops a therapy for a specific condition, it is first marketed under a brand name so that doctors may refer patients to it.A medicine is protected by a patent, which means it can only be manufactured, marketed, and profited from by the pharmaceutical company that holds the patent.
- A drug's patent typically lasts 7 to 12 years after it has been granted. Before undertaking clinical trials to establish the efficacy of a treatment, companies seek for patents. Other companies will be able to manufacture and sell the drug once the patent expires. Generic medications are drugs that have progressed to this point in their development.

Background Of Pharmaceutical Patent In India

The evolution of India's pharmaceutical industry can be divided into four stages. The first stage is the time prior to 1970, when foreign corporations controlled the Indian market with minimal domestic participation. The time between 1970 and 1990 is the second stage. Several homegrown enterprises began operations during this time. During this time, the Indian Patent Act of 1970 was enacted. During this time, export activities were launched. The third stage lasted from 1990 until 2010. During this time, India's liberalization led to the establishment of foreign operations by Indian companies. In 2005, the Patents Act was changed, resulting in the introduction of product patents in India. During this time, India became a major producer of generic drugs.

Sick people in India and around the world rely on Indian pharmaceutical companies to conduct research and develop affordable generic versions of second-line AIDS medications and other innovative treatments. India has a long history of fighting for public health protection over intellectual property; during the Uruguay Round of WTO negotiations, it led developing countries' opposition to the TRIPS agreement, and it also played a key role in the 2001 WTO ministerial conference in Doha, which resulted in the adoption of the Doha Declaration on TRIPS and Public Health. Unlike other developing countries, it has also waited the maximum amount of time allowed by TRIPS before issuing patents on pharmaceutical items.India must continue to establish policies that promote access to medicines in the post-2005 TRIPS setting, not only out of obligation to its own people, but also as a lifeline for patients in other developing nations.

Regulatory Framework Of Indian Pharmaceutical Industry Before The Trips Agreement

The focus of India's intellectual property regime, which it has had to adopt since taking commitments under the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, has remained on the country's ability to provide mechanisms that ensure that its citizens have access to medicines at affordable prices. India has a unique position among developing countries since it has a robust generic pharmaceutical industry that has been able to supply medicines at some of the lowest rates in the world. The Patent Act of 1970, which India passed, is largely responsible for this progress.[2]

[2]Piya Bhowmick, Dissertation on the Product Patenting in Respect of Medicine and Drugs: The Legal Scenario in India

This procedure was aided by two essential provisions.

- The first was the establishment of a process patent regime for chemicals, and
- The second was the reduction in the length of life patents awarded to pharmaceutical companies.

The stated goals of the Patent Act of 1970 were to promote the growth of an indigenous Indian pharmaceutical industry and to ensure that the Indian public had access to low-cost pharmaceuticals. The Act repealed British Colonial-era intellectual property rules and put an end to India's acceptance of Western-style "product" patent protection for pharmaceuticals, agricultural products, and atomic energy. Manufacturing "process" patents were ignored in favour of product-specific patents, allowing "Indian Companies" to reverse engineer or replicate foreign patented medications without paying a licence price. This allowed India's domestic sector to develop significant capabilities and lawfully provide a vast number of cheaper "copycat" generic copies at a fraction of the cost of the drug in the westas long as they used a production procedure that wasn't the same as the patent owner's Process patents were protected for seven years instead of the customary fifteen years required to develop and test new medications under the Act.

TRIPS Agreement And India's Pharmaceutical Patent System

India was one of the first countries to join the General Agreement on Tariffs and Trade (GATT) (GATT). However, it is clear that GATT favoured wealthy countries over underdeveloped countries. During the Uruguay Round negotiations, some developing countries, particularly Brazil and India, proposed that GATT have no business dealing with intellectual property issues, which should be discussed at the World Intellectual Property Organization (WIPO), the United Nations Educational, Scientific, and Cultural Organization (UNESCO), and the United Nations Conference on Trade and Development (UNCTAD). Despite the fact that countries at different degrees of development should have their own freedom to decide whether to award patent rights to certain items, India elected to join the nascent World Trade Organization during the negotiations (WTO).The TRIPS Agreement entered into force on January 1, 1995, requiring India, as a WTO member, to give up some of its long-held positions in the intellectual property field in order to comply with the TRIPS Agreement's rules. India was granted a 5-year transition periodFootnote3 and an additional 5-year time to update patent rules on pharmaceutical patent protection as a developing country. Footnote4 The influence of the TRIPS Agreement on India's pharmaceutical patent system is described in the following analysis, which is based on revisions to the Indian

Patent Law of 1999, 2002, and 2005.

The Impact Of Theworld Trade Organization On Patenting In Pharmaceutical Industries

The World Trade Organization (WTO) has ushered in a significant paradigm shift in global trade. "One of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry," according to the agreement on Trade-Related Aspects ofIntellectual Property Rights (TRIPS), which was negotiated during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade (GATT). On April 15, 1994, India signed the GATT, making compliance with the GATT's standards, including the TRIPS agreement, mandatory.As a result, India must adhere to the TRIPS Agreement's basic standards for patents and the pharmaceutical industry. Patent availability for both pharmaceutical items and process discoveries must now be included in India's patent legislation. Patents are to be granted for a period of 20 years of invention of the pharmaceutical product or the process.

To comply with the TRIPS Agreement, Indian legislation will require mandatory licence provisions to be restricted and conditional, and the government will award such licenses only on the merits of each case after allowing the patent holder an opportunity to be heard. Furthermore, in the case of process patents, there will be no distinction between imported and domestic products, and the party who infringes will bear the burden of proof.

Types Of Pharmaceutical Patents Available To The Inventors

There are four types of pharmaceutical patents available in India for the inventors. These are as follows: -

1. **Product Patent: -**

A product patent grants the original inventor(s) exclusive rights to a tangible product that they have made. No other manufacturer can create/manufacture/develop/provide the same product using the same or any other process if these rights are in existence. Violations of this guideline may result in patent infringement. Most developed countries, including the United States, the United Kingdom, France, Germany, and Canada, provide inventors with a product patent regime. Similarly, the product patent regime is followed by the majority of nations that have signed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

The main advantage of a product patent system is that it provides the innovator with a higher level of protection. The disadvantage, however, is that there are fewer competitors in such a system. This raises the likelihood of monopoly, which can be a big issue in developing countries where a large portion of the population struggles to meet basic needs.

2. **Process Patents: -**

A process patent is a type of patent that provides protection to inventors for a specific method of making or manufacturing a product. Most emerging countries, such as India and Argentina, provide its innovators and creators with a process patent regime. To put it another way, a process patent grants protection to a specific manufacturing process rather than the product itself. The identical product can be made using a different process or by simply changing the method's parameters.

The main advantage of a process patent regime is that it gives the government authority over the monopolies of powerful multinational corporations, allowing it to protect the interests of the poor. However, there is a risk that such a regime may deter pharmaceutical businesses from investing their hard-earned money in a low-profit-margin environment. Compulsory licensing is a prevalent practice in patent regimes where the government can compel corporations to produce particular products in the public interest.

3. **Product-By-Process-Patents: -**

A product-by-process patent defines a product as a product's manufacturing procedure. When a product cannot be characterized or distinguished from the prior art without referring to the manufacturing process, this patent is frequently issued.

Despite the fact that product-by-process claims are limited and defined by the process, patentability is determined by the product itself rather than the method of manufacture. Even though the prior product is created by a different process, the claim will be unpatentable if the product in the product-by-process claim is the same or obvious.

4. **Formulation Patent**: -

The pharmaceutical dosage form of the drug, also known as composition, is protected under formulation protection. However, the terms 'composition' and 'composition of matter' must not be confused. It's possible that it'll take on the shape of a drug formulation or a pharmacological class. It can also be a generic formulation that can be used for a variety of medications with varied effects. Slow-release technology, transdermal patches, and other methods are among them. Additionally, when conducting a complete patent search, it is critical to evaluate the type of patent. It aids in the narrowing of search results.

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How Is Pharmaceutical Patenting Affecting Public Health Access? -

Various viewpoints exist on the impact on the Indian pharmaceutical industry and access to critical medicines both within and beyond the country. India is ranked fourth in terms of pharmaceutical manufacturing volume due to its high number of enterprises. While pharmaceutical prescription patents are a vital tool in the discovery process, those unfamiliar with the patent system as a whole may find it confusing.

Drug companies regularly misuse patent monopolies, as well as unreasonably high prices for patented drugs. The introduction of product patents has impeded drug accessibility. A large number of generic medicines, including vaccines, are patented in India, making it difficult for the pharmaceutical industry to develop life-saving drugs.

Exorbitant drug prices make it difficult for ordinary people to obtain medication, which contradicts the government's professed purpose of protecting citizens' health. There is an unmistakable medical-care emergency with insufficiency in terms of healthcare and the affordability, availability, and accessibility of pharmaceuticals, especially in a country like India, where a large proportion of the population lives below the poverty line and healthcare prices are exorbitant. For India's administration, this is a huge challenge. As a result, they've adopted a variety of initiatives to safeguard the situation, including mandatory licensing (in the event of voluntary licence refusal) and parallel trade policies as alternatives to supporting developing nation governments in making important medicines more accessible to their citizens. Compulsory licensing brings competition to the market, which lowers consumer prices of the patent goods/articles. It provides as an organizational framework for the numerous pro-health components included in patent laws, first and foremost. Second, it presents the issue of competing claims between patentees and customers.

Solution And Suggestion To The Problem Of Pharmaceutical Patent Affecting The Public Health Access: -

The Indian Patent Act, which was passed in 1970, protects generic medication manufacturers in India. The act has put millions of people's health rights in jeopardy.

Previously, only the most privileged and rich members of society had access to life-saving drugs, but now they are available to all of our society's most vulnerable and needy individuals. Under Indian patent law, the interests of patentees and the demands of the general public are

intertwined. TRIP's adaptability has been carefully matched with its severe intellectual property constraints.

Despite the fact that Novartis' claim was denied by the Indian judicial system, Indian generic businesses went ahead and sold Glivec for a fraction of the original price.This has made it simpler for the impoverished in our country to access life-saving pharmaceuticals at a lesser cost.

Despite TRIPS' provisions to protect ordinary people's health, it has not been as effective in boosting public health in developing and least developed nations as it should be. TRIPS should be modified to require patent holders to sell pharmaceuticals at a lower price to the impoverished in developing countries.

Benefits Of Patent In Pharmaceutical Industry: -

Rapid technological advancements have resulted in the introduction of new and improved pharmaceuticals into the market in the globalized era. Many developments in the pharmaceutical industry have resulted in the launch of blockbuster pharmaceuticals, saving the lives of millions of people. The majority of the profits from these commercially successful pharmaceuticals are used to fund R&D and the development of new drugs.

Pharmaceuticals are one of the industries where innovation has a significant impact on drug manufacturers' bottom lines, thus these companies are putting more emphasis on R&D to stay competitive and win market share. The pharmaceutical industry's success is defined by innovation, yet the risk connected with the launch of new treatments might jeopardize its existence in the marketplace. Furthermore, innovation aids pharma companies in differentiating themselves from generic manufacturing firms to research-based firms. The majority of pharma companies use innovation to drive growth and provide significant returns on investment.The cost of developing and launching a new drug on the market is substantial, and its success or failure is greatly dependent on the industry's need for innovation. Because the stakes in the sector are so high, pharma companies must devote a considerable portion of their profits to research and development.

Future Of Pharmaceutical Industry

Instead of producing life-saving treatments, pharmaceutical corporations are focusing on drugs that increase sales volume and market share, hence increasing profits.Pharma companies have a finite amount of time to sell their products as drug discovery becomes more time intensive and expensive. As a result, the industry's patents on commercially proven drugs are about to expire.

The corporation will be unable to fund its R&D efforts if patent protection is not extended. Additionally, extending the patent product lifespan can allow corporations to devote more resources to research and development and the development of new treatments. Extended patent protection, on the other hand, means that these drugs will be more expensive for a longer time.

The generic players do not invest in innovation, preferring to gain market share by tweaking current pharmaceuticals and obtaining patents in order to increase revenue. The patent period for these products should be lowered to stimulate innovation, but the patent duration for life-saving drugs should be extended.

Pharma businesses must limit their patent portfolio in the absence of effective patent protection, resulting in market share erosion. Indian pharma companies must focus on developing new treatments and preserving their intellectual property in order to compete with global pharma corporations. It is critical to safeguard intellectual property in order to commercialize it in the near future. Because patents are so important to pharmaceutical businesses, they should concentrate on maintaining and expanding their patent portfolio.

Pharma businesses have had to deal with a slew of challenges in recent decades, including lack of efficacy and pre-grant resistance from third parties. As a result, when the validity of a patent is questioned, patents can help. Indian firms can also create copyrighted medications through licence agreements with foreign firms or profit from generic drugs. The pharmaceutical industry's expansion could be hindered by high research and development costs and a weaker product patent regime.

Current Drug-Patent System Is Bad Medicine

The paper, released by Tufts University economist Jeo DiMasi, is an update of his earlier research, the most current of which estimated that the cost of creating a medication in 2001 was $802 million dollars.A new study revealed that the cost of producing a new treatment is now 2.6 billion dollars, causing a minor stir in the media.

Many health care experts and campaigners questioned the study's methodology after seeing the 2.6-billion-dollar figure, which will surely be used to justify high medication pricing. The Tufts Centre for the Study of Drug Development, which DiMasi directs, receives support from the pharmaceutical industry, which adds to the issue. The study also makes use of industry-supplied confidential data.Furthermore, the study itself is not yet public; DiMasi merely issued a set of slides that summarized the study's principal findings. It's also worth noting that the $2.6 billion

figure only applies to drugs that involve new chemical compounds and did not rely on any outside funding in the development process, such as research from the National Institutes of Health (NIH); this category of drugs accounts for less than a sixth of all new drugs approved each year.

Whether or whether the study's concerns are correct, $2.6 billion is not a figure that the pharmaceutical business should be proud of. It means that the expense of producing a new drug has climbed at a rate about 8% higher than the overall inflation rate.This rapid rise in expenses is exactly what economists would predict from a sector that is government-protected from competition. The system of government-granted patent monopolies gives corporations little incentive to manage costs and avoid waste, just as the former system of cost-plus contracts in the military sector led to exorbitant rates for weapons acquired by the Defense Department. As a result, it's not unexpected that large pharmaceutical businesses are seeing rapid cost hikes.

The existing system of drug research has a slew of issues, with bloated development costs being the least of them. Patent monopolies make it impossible to afford drugs that would be reasonably inexpensive in a free market. For example, state governments and insurers are grappling with Gilead Sciences' $84,000 price tag for Sovaldi, the company's new hepatitis C medicine.

Generic manufacturers in India, on the other hand, may commercially offer the medicine for $1,000 each treatment. If we were talking about $1,000 instead of $84,000, we wouldn't see news pieces, hand-wringing columns, or editorials questioning whether the government and insurance should be made to pick up the price. Some other treatments' patent-protected pricing is even more outrageous, with many new cancer drugs selling for hundreds of thousands of dollars.

In addition to causing access issues, high patent prices provide pharma corporations with a strong incentive to misrepresent the safety and effectiveness of their products in order to increase sales. And they behave in exactly the way that economic theory predicts. It's rare that a month goes by without a fresh story about a firm hiding or misrepresenting study findings to boost sales.

Doha Declaration On The Trips Agreement And Public Health

At the WTO's Fourth Ministerial Conference in Doha, Qatar, on November 14, 2001, member nations unanimously approved the Declaration on the TRIPS Agreement and Public Health.Its goal is to allay fears that the TRIPS Agreement may make it harder for patients in developing nations to receive certain drugs.

Patent rights are granted to inventors in order to encourage research and development. This includes developing new medications. The TRIPS Agreement, which has been in effect since 1995, also recognizes governments' authority to take a variety of steps to qualify or limit intellectual property rights, including for public health reasons.Some members and public interest groups, however, questioned whether the TRIPS Agreement's flexibility was sufficient to ensure that it benefited public health, particularly in terms of promoting inexpensive access to existing medications while simultaneously encouraging research and development of new ones. Some of the doubts that arouse in the declaration. Some of them are: -

- Different perspectives were stated on the nature and breadth of the TRIPS Agreement's flexibility, such as compulsory licensing or parallel imports.
- It was questioned whether the WTO and its members would interpret this flexibility in a wide, pro-public-health manner.
- There was some concern about whether governments would be able to fully utilize this flexibility without fear of being pressured by trading partners or industry.

Effect Of Changes In The Patent Act On Pharmaceutical Industry

Following the amendments to the India Patent Act, the need to strike a balance between patent protection and sustaining competition among pharmaceutical businesses arose. The new product patent policy, which has been in effect in India since 2005, may result in a monopolistic position. Prior to the introduction of the notion of product patenting, generic companies posed a significant threat to major corporations. The generic drug businesses created the drugs at a low cost, forcing the big companies to sell their products at a low cost in order to stay in business.However, with the introduction of the notion of product patenting, the situation has altered. In such a case, competition law will play a critical role in preventing market monopolization. The 2002 Competition Act aims to avoid monopolies in any industry. In the pharmaceutical industry, three types of competition

difficulties might occur. Mergers and acquisitions, collusion, and the abuse of a dominant market position are all examples. These factors have the potential to drive up the cost of medicines to the point where poor patients will be unable to afford them.As a result, maintaining a balance between intellectual property protection and competition between enterprises is critical for the welfare of society.[3]

Problems That The Drug Patent Poses For Developing Countries

In the recent decade, patents and intellectual property limitations have become more difficult for developing countries. The discovery and influx of low-cost generic medications that developing countries require to treat HIV, tuberculosis, and other infectious diseases is at the Centre of the storm.The generic pharmaceutical business is critical to the availability of low-cost medications. The market is especially vital in southern Africa, where there is a high prevalence of HIV and a paucity of funding for health care and medicines.

Tensions have arisen between huge multinational pharmaceutical companies and the emergence of the generic medicine business. Patents are used by these companies to safeguard their products' intellectual property. Patents last for 20 years from the date of registration, according to legislation such as the World Trade Organization's agreement on Trade-Related Aspects of Intellectual Property (TRIPS). This allows manufacturers to provide pharmaceuticals exclusively for that time period, allowing them to recuperate research and development costs.However, it also gives drug makers the power to control medicine costs. As a result, many treatments are beyond of reach for the poor, particularly in developing countries. There are various many challenges which the developing countries face.[4]

The Indian Generic Drug Market: -[5]

India is a major supplier of generic drugs to underdeveloped countries. It supplies 20% of the global market for generic medications and purchases more than 80% of the world's anti-retroviral drugs each year. It has donated a significant number of critical pharmaceuticals to international charity and non-profit organizations like Medecins Sans Frontières, PEPFAR, UNICEF, and the Global Fund.

[3]Pramit Bhattacharya, https://blog.ipleaders.in/patent-law-india-pharmaceutical-industry/, visited on 2/05/22 at 8:49am
[4]Erica Penfold, https://theconversation.com/explainer-the-problem-drug-patents-pose-for-developing-countries-45667, visited on 2/05/22 at 6:48pm
[5]IBID

A lack of patent obstacles aided India's generic medication manufacturing skills, which have lowered the cost of certain medicines.However, global patent rules enacted in the recent decade, including one in India in 2005, prevent the generic business from producing some pharmaceuticals.

As a result, India has given some patents to US-made TB, HIV, and hepatitis C medicines, preventing Indian manufacturers from copying them. India, on the other hand, has not been constrained by patent laws. Its patent office has turned down patent applications from prominent pharmaceutical companies like Novartis and Gilead, which make cancer and hepatitis C treatments, respectively. This means that Indian companies are permitted to make lower-cost generic versions of the same products.In addition to the patent issue, India's ability to create generics could be impeded if it completes an fourteen-year-in-the-making free trade agreement with the European Union.

A data exclusivity provision is being negotiated, which will allow pharmaceutical companies in European Union member countries to keep clinical test data demonstrating a new drug's safety and efficacy for up to five years before it can be commercialized. It would imply that generic pharmaceutical businesses would have to generate their own data before marketing off-patent pharmaceuticals.If the clause is allowed, it might stifle India's generic business and affect the pharmaceutical industries in Southern Africa by preventing generic versions of these pharmaceuticals from being imported.[6]

The FUTURE OF GENERICS: -

Patent laws and drug exclusivity agreements are a major challenge for the global HIV and AIDS movement. South Africa and the Treatment Action Campaign fought a long but successful battle to gain access to more affordable medicines. It used constitutional litigation to gain access to cheaper generic anti-retrovirals.

Because of high HIV rates and medicine shortages, other southern African nations such as Malawi and Zambia rely significantly on low-cost treatment and generics.Because the future of generic drug manufacture is in jeopardy, developing countries must investigate other options for southern Africa.

To prevent generic businesses from losing money, pharmaceutical companies have long offered "reduced price offers" on anti-retrovirals to developing countries. These offers are tailored to specific products available in each country. There is a lack of transparency in terms of which countries are offered specific prices.Extensive research and development of new medicines and

[6]Erica Penfold, https://theconversation.com/explainer-the-problem-drug-patents-pose-for-developing-countries-45667, visited on 2/05/22 at 6:48pm

vaccines is becoming increasingly necessary. This would allow more businesses to enter the market, ensuring that pricing remain competitive.

Compulsory License For Exploiting The Pharmaceutical Patent

An inventor is awarded the essential protection for a set period of time after acquiring a pharmaceutical patent. During this time, an inventor has the right to use the invention in whichever way he sees fit.However, in some circumstances, if the competent authority provides others a compulsory licence to exploit the patent without the approval of the patent owner, an inventor is required to allow others the right to use the innovation. Thus, the patent is used by requiring the patent owner to enable others to exploit the innovation under the terms of a judgement issued by the state's competent authority for fair compensation.

Compulsory licenses for others to exploit a pharmaceutical patent are one type of exploitation that occurs against the patent owner's wishes and constitutes a restriction on medication protection. Though it is one of an inventor's rights to exploit his or her idea, it is also an obligation to utilize the pharmaceutical invention to meet the state's health needs. If an inventor fails to fulfil this requirement, the state has the authority to give forced licenses if certain conditions are met.

Pharmaceutical Patent Abuse: -

Our pharmaceutical industry in the United States is predicated on a balance between innovation and access. Brand pharmaceutical companies are rewarded for inventing and developing new treatments and cures that improve the quality of life for everyone. In return for the innovation, current law provides brand pharmaceutical companies with 12 years of guaranteed market exclusivity (monopoly) for biologics and 20 years for each patent. There is also extra monopoly time to incentivize pediatric drug development and orphan drugs. During the period of patent and marketing exclusivity, brand drugs are priced and sold free from competition. Once the exclusivity period expires and the drug is no longer patentable, generic manufacturers and the emerging biosimilars market are given the option to produce the identical medicine. When there is more competition on the market, the price of medicine drops dramatically, and patients benefit from having cheaper, FDA-approved drugs. Prescription medicine costs have been shown to drop by more than 60% in the first year after generics hit the market.However, we're seeing more and more evidence of how the patent system is being used to skew the scales and delay patient access much beyond what Congress intended. According to a recent assessment from I-MAK, the top 12 brand

pharmaceuticals on the market last year were covered by a total of 848 patents (71 per drug), allowing for a 38-year period without generic competition. Here are a few excerpts from the report:

- Humira, the world's best-selling brand medicine, is used to treat arthritis and other chronic diseases. Since 2002, 132 patents have been on the market, blocking competition for up to 39 years.
- The FDA authorized Revlimid, one of the most often prescribed cancer therapies, in 2005. The patent tangle consists of 96 patents that might provide 40 years of exclusivity.
- Due to the 49 patents issued, diabetes patients who rely on the insulin medication Lantus may not see a generic option for another 37 years.

Patent and Vaccines for Treatment of Covid-19: -

Several vaccinations to tackle the global coronavirus (COVID-19) disease have been created at a rapid pace in a spectacular accomplishment of science and technology. It is an example of what can be accomplished for humanity with adequate financing and investment in research and technology, as well as intellectual property regulations that encourage innovation. Patents contribute to this incentive. Patents are an important aspect of a healthy innovation ecosystem because they provide an incentive for businesses to invest in socially beneficial innovation. Patents are essential for incentivizing innovation, which includes the development of novel vaccinations.A patent specification's vital information enables for the public sharing of knowledge, allowing others to learn from current inventions and build on them to generate new and potentially life-saving advancements.[7]

There have been amazing research and innovation efforts to combat the SARS-COV-2 virus and linked sickness since the commencement of the COVID-19 epidemic. This patent landscape analysis combines results with clinical trial data for relevant candidate vaccines and medications, and gives early observations on the patenting activities in the field of COVID-19 vaccines and therapies.[8]

Vaccines against the coronavirus illness of 2019 (COVID-19) are currently the best option for combating the pandemic. The global fight against the severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) should be viewed as a global conflict in which no country, particularly low-income ones, can be left behind. With the emergence of new varieties, this last element may actually enhance the virus's unrestrained reproduction. The waiver of patent rights for COVID-19 vaccines is one possible approach to limit this problem.For the duration of the

[7]Kelli Larson, https://www.inderscience.com/info/inarticle.php?artid=118734, visited on 3/05/22 at 9:10am
[8]World Intellectual Property Organization (WIPO),https://www.wipo.int/publications/en/details.jsp?id=4589, visited on 3/05/22 at 10:01am

pandemic, until global herd immunity is achieved, India and South Africa asked the World Trade Organization (WTO) to allow all countries to choose not to grant or enforce patents and other intellectual property (IP) related to COVID-19 drugs, vaccines, diagnostics, and other technologies.The US administration indicated its willingness to liberalize intellectual property for COVID-19 vaccinations on May 5, 2021.

Although this is an intriguing topic, its viability is exceptionally difficult and complicated. As a result, there are differing viewpoints among academics and clinicians on the true use of patent liberalization. It has been proposed that an exception be granted to the World Trade Organization's founding accords, specifically the Agreement on Trade Related Aspects of Intellectual Property Rights. This request would be predicated on the notion that vaccines against the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) could be deemed a "common good" during a pandemic, analogous to water or air.The aforementioned concepts should be considered in the Roman category of "res communes omnium," meaning not appropriable and prohibited from legal trade, according to the Economic Theory of the Commons, which is backed by Elinor Ostrom, recipient of the Nobel Prize in Economics in 2009.

In practice, the suspension of patent rights would limit the business models available to legal COVID-19 vaccine producers. The direct donation of vaccines from high-income countries, the reduction of production line costs, the shortening of patent protections, and a series of preferential patent waivers to countries that manufacture a large percentage of the world's vaccines are all possible strategies to encourage the waiver of patent protections (e.g., India).Solidarity among several governments or other organizations is one of the other viable alternatives. The programme for COVID-19 Vaccines Global Access, for example, follows this concept (COVAX). The World Health Organization, the Global Alliance for Vaccines and Immunization (GAVI), and the Coalition for Epidemic Preparedness Innovations (CEPI) all endorse the latter (WHO).[9]

[9]Front Med (Lausanne), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8599977/, visited on 3/05/22 at 10:12am