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Patent Protection and Access to Healthcare: A Socio- Legal Perspective

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Abstract

It is true that advances in pharmaceutical technology have significantly contributed to improvements in human health conditions. Despite this, major health crises such as high mortality rates, particularly those related to HIV/AIDS, Malaria, Tuberculosis, and Avian Influenza continue to create major problems in many regions of the world. This has consequently been a key problem brought up in a great number of international conferences that have been addressing the concerns of patents in pharmaceutical innovations and access to healthcare that is both fair and cheap.

A pharmaceutical patent is the right given to a pharmaceutical firm to create a new drug exclusively for a term of twenty (20) years. This right is granted in exchange for the pharmaceutical company paying royalties. This, in turn, results in the dilemma of such medicines having prohibitively high prices and being difficult to access, particularly in developing nations. This study evaluates the rationale for the grant of pharmaceutical patents. It highlights the public health crises that are posed by such protection. It considers whether invention is truly accomplished by the grant of pharmaceutical patent. Finally, it examines the legal framework for pharmaceutical patent, particularly the TRIPS Agreement, in relation to the balance between the public health right and patents.

Because of this, the research aims to reduce the scope of protection afforded to pharmaceutical patents, promotes the most effective utilisation of the flexibilities afforded by the TRIPS Agreement, and provides recommendations concerning additional methods that

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Volume 11 Issue 1, 2023
pp: 2616 - 2629

can be utilised for the purpose of reducing the severity of public health crises and achieving innovation.

Keywords: patent protection, pharmaceutical industry, access to healthcare, legal framework

Introduction

To shed light on the significance of intellectual property (IP) protection in the evolution of healthcare, this study conducts a review of the research that is currently accessible. There have been two main lines of inquiry into how India's new intellectual property (IP) regime may affect the country's healthcare system and the medical industry. The literature that is relevant to the context of India has followed these strands and settles out following:

1. Product advancements in the pharmaceutical industry;
2. Advancements in manufacturing processes within the pharmaceutical business;
3. Novel medication delivery methods, bio-enhancers, and dosage formulations that boost bio-availability and efficacy;
4. Product developments in the fields of medical apparatus and instruments;
5. Developments in methods for the provision of healthcare services; and
6. Innovations in public policy that will increase access to medical care.

Because businesses and governments innovate strategically for a wide range of reasons, it is not always easy to trace all the developments to the shift in the IP system. However, for the purpose of this review, we will be focusing on two distinct "innovative responses" that have the potential to influence healthcare access and advancement. This is because these "innovative responses" may be, at least in part, a reaction to the changes that have been made to the IP regime:

a. Examining studies that capture the significance of intellectual property for changes in fields like R&D, tech licensing/collaboration, patents, and other forms of innovation at the company level.

b. In the healthcare industry, institutional and policy innovations that aim to improve access to healthcare are being developed. For the sake of this article, all policy experiments in this area are "innovative," even though these may not be considered "new" on a worldwide scale.

Objective of the Study

- To explain why protecting intellectual property (IP) is so crucial to the development of modern healthcare.
- To analyze the TRIPS Agreement and other legal provisions pertaining to pharmaceutical patents in light of the balance between the public health right and patent protection.
- To propose supplementary approaches that can be implemented to mitigate public health emergencies and encourage innovation.

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

Review of Literature

The researchers who worked on this paper have examined a variety of written works, such as books, papers, and journals, to determine whether or not there is a gap in the existing literature and to concentrate their attention on any grey areas that may have been overlooked.

- **Kenneth C. Shadlen, Samira Guennif, Alenka Guzmin, and N. Lalitha (2013)** are the editors of the book **"Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries."** Lalitha sheds light on the very starting time period of Pharmaceutical Industries, which is 1970 until the present, and analyses the different significant and extreme changes that the industry has undergone since that time. The research includes a comparative investigation of nine different developing countries located all over the world, with the goal of discussing the availability and accessibility of a selection of essential medicines in each of these nations. When discussing such rights and their implications, the book also sheds light on the function of economic policy as a leading factor, which is one of the many factors discussed in the book.
- The article **"TRIPS, pharmaceutical patents and health care for the poor in India,"** which was written by **Shubhra Khanna (2016)** and published in the Indian Law Institute's Law Review 71, discusses the challenges that are being faced by developing countries like India in the modern era. Some of these challenges include the dependence of the economy on pharmaceuticals, while simultaneously keeping in mind the Terms of TRIPS. Another challenge is determining whether it is truly possible to cater to the needs of the local people while maintaining a balance with international. The emphasis on health right in India in relation to the existing patent system has been the primary emphasis of the research presented in this paper.
- The article **"Public Health Safeguard under the Provision of TRIPS: India's Legal Response,"** written by Mr. Ashutosh kr. Srivastava, continues to describe how drug patenting is working as a negative right and how, at certain times, the price of certain essential lifesaving drugs has gone up too high, thereby making it difficult for an individual to gain access to appropriate healthcare facilities. On the one hand, the author seeks to negotiate between the granting of patent rights in order to promote inventions that are better for mankind, and on the other hand, the interests of those who are financially disadvantaged and in need.
- In the article **"Academic Patents and Access to Medicines in Developing Countries,"** written by Bhaven N. Sampat (2009), the author discusses how a lack of accessibility to certain lifesaving drugs is becoming a nightmare for the poor and the needy, particularly in developing countries where there is not that much security available regarding the availability of adequate medical care. Furthermore, the essay underlines that the patent rights have posed a difficulty for the easy availability of medications in developing countries, which has resulted in the poor suffering as a result.

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

Methodology

This research, which takes an analytical approach to the issues of pharmaceutical patents and access to affordable healthcare, has doctrinal implications. Primary and secondary sources will be used to explain the topic at hand. The international treaties and existing legal framework at the national level are the primary sources. Secondary sources include textbook on pharmaceutical patent and public health, journals, articles, reports, declarations, and internet sources.

Hypothesis

Although not all breakthroughs can be traced back to shifts in the IP regime, we contend that it is more accurate to see health care access and innovation as symbiotic rather than antithetical. This view is supported by the fact that there is a correlation between innovation and access to health care. We investigate this link by discussing the innovations that have been implemented in health policy and the pharmaceutical business in India to strike a compromise between the competing priorities of health care innovation and affordability.

Evolving Pace of Patent in India

In India, the history of patent law can be traced back to 1911, which was the year when the Indian Patents and Designs Act was passed into law. The existing Patents Act, 1970 came into effect in the year 1972, and it was intended to update and consolidate the patent legislation that was in place in India before to its passage. The Patents Act from 1970 was changed once again by the Patents (Amendment) Act from 2005. As a result of this legislation, product patent protection was extended to cover all areas of technology, including food, pharmaceuticals, chemicals, and microorganisms. Due to the amendment, the provisions pertaining to Exclusive Marketing Rights (EMRs) have been eliminated, and a clause for the issuance of a compulsory licence has been introduced. Furthermore, post-grant and pre-grant opposition provisions have become operational.

In India, a patent may be granted for an invention that is related to either a product or a method, if it is novel, involves an inventive step, and has the potential for industrial application. On the other hand, it can't belong to the class of ideas that can't be protected by a patent, as those categories are defined in sections 3 and 4 of the (Indian) Patents Act, which was passed in 1970. An application for a patent can be submitted in India by the true and first inventor or his assignee in either an individual or joint capacity.

Pharmaceutical Patents as an Innovation

Pharmaceutical products and processes are products of inventive activity that result from the efforts of the inventor or the inventor's company in the search for solutions or cures for certain debilitating diseases that are afflicting the society. These diseases are a threat to the society because they cause a lot of suffering. Examples of classic medications are those designed to cure or manage illnesses such as HIV/AIDS, cancer, tuberculosis, hepatitis, and

The Ciência & Engenharia - Science & Engineering Journal
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Volume 11 Issue 1, 2023
pp: 2616 - 2629

most recently, Ebola. What are the different steps that go into the manufacture of drugs? In order for a medication to be approved for use by patients, it must first be subjected to stringent testing and have its cost-effectiveness evaluated. There are just a handful of new medications introduced every year. These medications that make it to market after years of research and development and incur billions of dollars in expenditures (Ingrid Torjesen, 2015).

The drive of inventing of medicine begins in the research laboratory with researchers undertaking simple research to understand the process behind an infection or ailment to identify treatments, often on a cellular or molecular level. There may be as many as 10,000 compounds under consideration, but this number may be narrowed down to just 10 to 20 that have the potential to interfere with the progression of the disease. These compounds will need to undergo both pre-clinical and clinical testing in order to establish whether or not they are safe for use (S. Kraljevic , 2004). If a clinical testing application is approved, the pharmacology and safety of a proposed medicine will initially be evaluated in a phase one to three trial with a small group of healthy volunteers who are regularly monitored and assessed. Despite the exhaustive testing that has been done, it is estimated that roughly 10% of drugs will still be unsuccessful at this stage. The process of developing new drugs is very much the same everywhere in the world. In most nations, a submission for marketing authorization is submitted to the national regulatory body for pharmaceuticals that are successful in making it to market. Information regarding the chemical composition and manufacturing method, pharmacology and toxicity of the molecule, human pharmacokinetics, and recommended labelling are included in the submission. The information was gathered both preclinical and clinically. However, given that clinical tests are still being conducted and that regulatory agencies may require phase 4 tests for post-marketing and safety monitoring (pharmacovigilance), this might not be the end of the story(V. Suvarna, 2010).

In the pharmaceutical industry, protecting intellectual property and encouraging new ideas are two sides of the same coin. Patent protections ensure that drug companies will enjoy the revenues that arise from their investments in the productive research conducted by the pharmaceutical sector (O. Gurgula, 2020). This research can entail investments of billions of dollars. The goal of a country's patent system should be to "give essential incentives to innovative labour and its corresponding investment cost by assuring that the inventor obtains specific economic advantages from his or her work for a specified length of time, often 20 years." (E. Mansfield, 1986). Because of the patent system's requirement for a comprehensive explanation of the invention being patented, the capacity to change and develop a chemical is one of the most valuable instruments in therapeutic research (Benjamin N Roin, 2009). The World Intellectual Property Organization (WIPO) requires "key information about the substance that is to be patented." (J.L. Tidwell and L.A. Liotta, 2012). Abraham Lincoln once stated, "The patent system added gasoline to the fire of creativity." For an invention to be granted a patent, it must be described in "sufficiently complete, clear, succinct, and accurate" language such that "any person competent in the art to which the invention belongs" may

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

replicate it and utilise it. (E. Rosenburg *et. al.,* 2013). With a patent, the creator has the exclusive right to produce, use, and sell the patented product. Since this is the case, patents can be extremely valuable to their owners in the extremely improbable event that they cover economically viable innovations.

As the architects of a French patent law put it in 1791, "it would be a violation of the rights of mankind in their very nature if an industrial innovation were not recognised as the property of its inventor." This was probably because patents are highly prized by their holders, both for their own benefit and because of the social value associated with innovations. Strong patent protection is often cited as a key factor propelling technical progress, and this connection between patents and innovation has been recognised for some time. The first rights comparable to patents were issued about 500 B.C. in the Greek colony of Sybaris. From their general patent legislation of 1474: "We have among us individuals of great talent, apt to develop and discover inventive machines; and in view of the majesty and virtue of our City, more such people come to us every day from other regions." More individuals would put their minds to work, discover, and create things of great value and service to our commonwealth if provisions were established for the works and devices found by such persons, so that others who may see them could not build them and steal the inventor's honour away.

The assumption that patents "promote" development could find its way into the wording of laws and constitutions. To "advance the Progress of Science and useful Arts, by guaranteeing for limited Times to, Inventors the exclusive Right to their individual... discoveries," Congress is granted authority under the United States Constitution (Rebecca S. Eisenberg, 1989). The inclusion of this clause in the Constitution indicates the framers' confidence in the importance of scientific advancement to the fledgling nation and their conviction that the progress of research is intimately tied to patents. While the United States Constitution was drafted with the notion that scientific progress was intimately tied to patent law, the present international patent policy is more complex. The Federal Circuit was established in 1982 as a national "patent court," and subsequent legislation and judicial judgments helped increase patent value in the early 1980s. Both local and international law are influenced by the idea that stricter patent regulations encourage innovation. Inventors' "natural rights in their inventions" are not what the patent monopoly was intended to protect.

Trips

The Trade-Related Intellectual Property Rights (TRIPS) is one of the agreements agreed among the WTO members for the protection and enforcement of IPR. Members who became the member of WTO in 1994 have agreed the minimum level of protection of IPR in compliance with TRIPS Agreement. Underlying objective of the TRIPS was to ensure the global protection of IPR with minimum uniformity. TRIPS, often criticised to be prejudiced towards the developed nations. The governments of industrialised countries, especially the United States, listened sympathetically to industry groups (lobbyists) that complained about

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

the infringement of their intellectual property. Some countries had a problem with "counterfeiting," "pirating," "stealing," and "infringing," which hurt those countries and the countries that export intellectual property (Hedi Nasheri, 2005).

Another viewpoint is that TRIPS is the logical and practical persistence of efforts made after World War II to provide a workable framework for the global economy. The dispute here is that the passage of GATT and the WTO treaties was an important step toward enacting TRIPS. The GATT was the predecessor to the treaty that established the World Trade Organization, which contains the TRIPS Agreement. Dickinson Law School alum and intellectual property expert Matthew Kramer argues that TRIPS is a milestone in a global endeavour that has taken more than fifty years to achieve. He also describes it as a step in a process that has involved multiple nations (Rawat Singh and Karishma, 2021). "The push for stable and reliable global trading organizations, as well as the advent of the irreducible worldwide economy, has demanded the implementation of stringent protections for intellectual property. Therefore, the primary focus of this contemporary theory is on the concept that robust patent protection is necessary for the maintenance of a stable international economy, but not necessarily for the reason that it fosters innovation (Matthew Kramer, 2000). The following is an explanation of the philosophical foundations of the TRIPS Agreement provided by Adrian Often, Director of the Intellectual Property and Investment Division of the World Trade Organization. The TRIPS Agreement was negotiated due to the belief that inadequate standards of protection and ineffective enforcement of intellectual property rights were frequently unfairly depriving the holders of such rights of the benefits of their creativity and inventiveness and, as a result, prejudicing the legitimate commercial interests of their respective countries. Due to concerns over weak IP protection and enforcement, the TRIPS Agreement was drafted (Nadia Natasha Seeratan, 2017). It was generally agreed upon that a significant intellectual property agreement was a prerequisite for the continued upkeep and improvement of the multilateral trading system as a whole. Each of the several descriptions of TRIPS contains, most likely, some kernel of truth.

Factors Considered in the decision to allow a Pharmaceutical Patent

Awarding a patent for a pharmaceutical product has one overarching purpose to allow the pharmaceutical business that created the product to recoup its development expenditures and turn a profit. This surplus can be put toward developing novel therapies including gene and cell therapy, nanomedicines, and treatments that employ novel delivery methods, as well as covering the expenses of pharmaceuticals that were ultimately proven to be useless during testing. By the time a medicine has gone through all of the required testing and been awarded a licence, usually the first half of its patent life has already elapsed. It is estimated that for every 25,000 compounds developed in laboratories, only 25 are tested on people, only 5 make it to market, and only one earns back the money invested in developing the chemical (Ingrid Torjesen**,** 2015**).**

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

The Effect of the Product Patent Regime on the availability of Drugs and their Prices

The Right to Health as a Human Privilege

Many international treaties and national constitutions provide citizens the fundamental right to health care. However, just because this right is codified in certain documents does not mean it is universally enjoyed in the same way. The current international framework for protecting intellectual property rights, notably patent rights, significantly restricts the exercise of this freedom. The cost of medical treatment is directly affected by patent rights. Because of this, it's important that basic medication costs aren't too costly for low-income people to pay for them. Therefore, the right to health includes the availability of life-sustaining medications. Further, states must implement policies "to regulate the distribution of healthcare products including pharmaceuticals." This, it has been proposed, necessitates linking the costs of vital pharmaceuticals to the costs of similar treatments supplied by pharmaceutical firms. It is the responsibility of governments to respect, preserve, and fulfil the right to health and has ramifications for the design, implementation, interpretation, and enforcement of their national patent laws. State obligations to ensure the right to health necessitate that legislators consider the potential effects of any changes to national patent laws on that right. States must be aware of the potential effects of such legislative initiatives on the right to health if they are to fulfil it successfully. According to the World Health Organization's Action Programme on Essential Pharmaceuticals, "providing essential drugs, as from time to time specified by the WHO Action Programme on Essential Drugs," is one of the fundamental tasks of nations in respect to the right to health. A fundamental responsibility is one from which there can be no waiver (LM Forman, 2019).

Pharmaceutical Businesses and the Constitutional Right to Health

"While only states are parties to the Covenant and are therefore ultimately accountable for compliance with it, all members of society, individuals included, have responsibilities regarding the realisation of the right to health," says the Covenant. "These include health professionals, families, local communities, intergovernmental and non-governmental organisations, civil society organisations, and the private business sector." According to the accompanying declaration, the Committee on Economic, Social and Cultural Rights (CESCR) believed that corporations (and other members of society) had obligations in upholding people's right to physical and mental health. However, the right to health is not elaborated upon in the CESCR in terms of the obligations of business actors. Fortunately, this void has been closed by the introduction of the Hunt Guidelines and the Ruggie Guiding Principles. In the 1970s, talks on the United Nations Code of Conduct on Transnational Corporations were the first attempt to develop regulations to control the actions of corporate entities at the worldwide level (the Code). Under the aegis of the United Nations Centre for Transnational Corporations, the Code was negotiated (UNCTC). Negotiations on the Code may be directly linked back to intervention by corporate entities. Then, in the late 1990s, there was another movement to establish standards with the aim of imposing binding human

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

rights duties on corporate actors. With its Working Group on the Working Methods and Activities of Transnational Corporations, the United Nations Sub-Commission on the Promotion and Protection of Human Rights launched a second effort in 1998. As time went on, the Working Group completed a paper that was accepted by the Sub-Commission i.e. Guiding Principles on Business and Human Rights is the official name for this paper.

In 2005, the Commission for Human Rights created a unique mandate for a single expert on this subject. For this reason, the Commission demanded that the UN Secretary-General name the expert as a "Special Representative on the topic of human rights and multinational companies and other business entities." Secretary-General of the United Nations at the time, Kofi Annan, named John Ruggie as the Special Representative in July 2005. Ruggie said that he was motivated by "principled pragmatism" in his work. As such, in his interim report from 2006, Ruggie made the following observations: "For the UN Secretary-Special General's Representative, his job is mostly about using data to make decisions. But because it requires evaluating complex, ever-changing contexts, it will also contain normative judgments. The Special Representative's unwavering dedication to the ideal of improving the promotion and protection of human rights is the basis for his or her judgments." In June 2011, the United Nations Human Rights Council approved a report including Ruggie's Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect, and Remedy" Framework. In March 2011, Ruggie presented his final report to the United Nations Human Rights Council.

The Impact of Pharmaceutical Patents on the Public Health

i. The Increasingly Exorbitant Cost of Medications: Some developing countries have voiced significant concerns over the past two decades that the implementation of strong patent regimes may "affect their efforts to improve public health," given that "one of the primary goals of the patent system is to reward innovation by allowing innovators to charge higher price" for protected products. It has been contended that the cost of such items and the price at which they may be sold would be inversely related if the patent system worked as intended, which would serve to promote innovation.
ii. Accessibility Obstacles: There is no competition when a particular pharmaceutical company sets a higher price on its drugs. As a result, some have speculated that the worldwide intellectual property system is experiencing a crisis of public credibility, such as the potential impact of patents on people's ability to obtain necessary medications. In developed countries, this has caused the cost of medicine to be out of reach for the poor. An Increase in the Number of Deaths There will be no access to such urgently needed drug once prices of essential drugs become too high and unaffordable by poorer people and countries. As a result, death will invariably result. For instance, 5.7 million people lost their lives to HIV/AIDS, malaria, and tuberculosis in 2001 and “caused debilitating illness in many millions more”(Aanuoluwapo Babalola, 2018).

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

The Hunt Guiding Principles: The Essential Pillars:

Ruggie's Guiding Principles are predicated on three tenets:

a. The duty of states to respect, protect, and fulfil human rights;
b. The duty of corporate actors to comply with all applicable laws and respect human rights; and
c. The necessity of providing appropriate and effective remedies to those whose rights have been breached.

The requirement for corporations to respect human rights is summed up by the Guiding Principles, which declare that "this means that they should avoid infringing on the human rights of others and should repair the adverse human rights consequences with which they are linked." It also mandates that businesses take steps to remedy any harm to human rights that they may inadvertently create or exacerbate as a result of their activities. While the Norms sought to impose on corporate actors the duty to respect, preserve, and fulfil human rights, Ruggie's Guiding Principles separate themselves by recognising the requirement to respect as the basic responsibility of business actors. Thus, although corporate actors also have a duty to defend human rights, under international human rights law, states continue to play the main role as obligation bearers. While not legally binding in and of themselves, the Guiding Principles have been acknowledged by the UN Human Rights Council as providing a valuable basis for future legal developments in this field. The Guiding Principles don't mandate any new responsibilities on governments or businesses, but they do provide light on why the rules and regulations already in place make sense. Efforts have been made to define the obligations of pharmaceutical businesses in respect to the right to health, going above and beyond the Guiding Principles, which deal with the duty of corporate actors in relation to human rights in general. The United Nations appointed Paul Hunt as its Special Rapporteur on the right to the best possible health from 2002 to 2008. In 2008, he presented his findings to the UN General Assembly. Included in Hunt's report is a set of 47 recommendations called Human Rights Guidelines for Pharmaceutical Firms in Relation to Access to Medicines. These recommendations outline the responsibilities of pharmaceutical firms in relation to the right to health. Since Hunt believed that simply pressuring pharmaceutical companies to comply with their right-to health obligation would be fruitless, she set out to clarify and explain the human rights duties of pharmaceutical firms with regard to access to pharmaceuticals. In the months leading up to Hunt's 2008 presentation of the Guidelines, interested parties were given the chance to provide input on a draught version commencing in September 2007. The drought was meant to facilitate the needs of pharmaceutical companies and those who monitor the effectiveness with which those companies ensure that patients have access to necessary medications. Draft changes were prepared in response to comments from a wide range of interested parties (including governments, pharmaceutical companies, nongovernmental organisations, and academics) and were presented to the United Nations General Assembly in 2008. There are 47 suggestions in the Hunt Guidelines for how drug corporations should respond to patients' requests for medications protected under the right to health. An organization's duties are laid out, including "transparency, management,

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

monitoring and accountability, pricing, and ethical marketing," and activities like "lobbying for more protection in intellectual property laws," "patenting trivial modifications to existing medicines," "inappropriate drug promotion," and "excessive pricing" are outlawed. As was previously stated, while the Guiding Principles recognise that businesses have a duty to protect fundamental human rights, the Hunt Guidelines go beyond. Guidelines for Pharmaceutical Companies consider the right-to-health framework, which is based on the dignity and well-being of individuals and communities, as well as globally recognised standards, and go beyond the corporate responsibility to ensure that their products are safe, effective, and distributed in an ethical manner. We believe it is necessary to look beyond the duty to respect human rights and at additional duties that come with conducting business in the pharmaceutical sector because of the unique role it plays in people's lives, health, and prosperity. Attempting to go beyond the baseline responsibility of corporate actors to respect human rights in the Guiding Principles, Hunt created a situation in which the obligations of states to respect, protect, and fulfil the right to health overlapped with the obligations of pharmaceutical corporations to respect the right to health. Suerie Moon makes a compelling case for the distinction between regulations primarily related to the obligation to respect and those that may pertain to additional responsibilities. Moon provides three situations in which this distinction is useful.

An Examination of the Various Provisions Contained Within the Hunting Guidelines

Some of the aspects of the Hunt Guidelines will be analysed below to determine whether ones fall inside the purview of pharmaceutical firms' basic obligation to protect human rights (in accordance with the Guiding Principles) and which do not. This study will not look at all of the regulations in the Hunt Guidelines; rather, it will look at the provisions in the Guidelines that deal with making affordable medications more widely available. Responsibility of pharmaceutical patent holders to safeguard public health Hunting Regulations 1–5: General Principles Pharmaceutical Companies Should Follow to Safeguard Patients' Right to Health. (JY Lee , 2019)

Because of: First, pharmaceutical companies should "adopt a human rights policy statement which expressly recognises human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects, and activities of the company," as stated in the Hunt Principles. Human rights, particularly the right to the highest possible degree of health, must be included into all aspects of a pharmaceutical company's operations in accordance with Principle. Second, Companies in the pharmaceutical industry "must always comply with the national legislation of the State where it works. Third, any applicable laws of the State where it is domiciled," according to the third principle. Fourth, guideline states that the pharmaceutical industry "shall not engage in any conduct that will or may encourage a State to act in a manner that is inconsistent with its obligations emanating from national and international human rights law, including the right to the highest attainable level of health." The first four Guidelines are largely aligned with the Guiding Principles' call for the pharmaceutical industry to respect human rights

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

(especially the right to health). For Hunt, as he explains in his commentary on Guidelines 3 and 4, "it is axiomatic that they must be obeyed, at all times, by all pharmaceutical businesses, in accordance with simple principles of corporate good governance." The right to the best possible health is protected by a wide range of laws on both the national and international (and even regional) levels, as shown above.

Point 5 of the Guidelines states: Pharmaceutical companies should prioritise the needs of vulnerable people, comprising youngsters, the aged, and the economically disadvantaged, when developing and executing guidelines, programmes, policies, projects, and events that stands upon availability of medications. The document goes on to argue that "the very poorest in all marketplaces" require special consideration. Hunt notes in his explanation of Standard 5 that “equal opportunity and non-discrimination are among the most essential elements of global rights of human, including the right to the best achievable levels of health.” Therefore, Hunt claims, "the right to the greatest feasible quality of health has a special focus with disadvantaged persons, groups, and communities, including children, the elderly, and those living in poverty." According to Hunt, “all the other Guidelines must be read and used in light of Guideline 5, making it the most crucial”. Companies in the pharmaceutical industry have a basic obligation to protect the human right to health, and that obligation is reflected in this Guideline.

The Adoption of International Patent Laws by the Indian Legal System

If you're looking for a country that has a national patent law that incorporates human rights as a model, look no further than India. Therefore, other countries can learn from its example. The Indian legal system fosters public interest in the invention; the public interest in preventing or redressing an infringement of the patent; or the public interest in preventing or redressing an infringement". Section 84 of Indian patent set out the unique process for the grant of a compulsory licence premised on any ground”:

a. the failure of the patented invention to fulfil the rational necessities of the general community regarding the creation that was patented; or
b. The ineffectiveness of the invention that was patented technology available to the general public at a price that is affordable to the general public; or
c. Since the patented innovation is useless within Indian Territory.

"Provisions like these are allowed by art.31 of the TRIPS Agreement (which deals with the award of compulsory licences) and the Doha Declaration on the TRIPS Agreement and Public Health. Therefore, given that pharmaceutical firms are obligated, as a matter of principle, to uphold the right to health by abiding by national legislation (Guideline 3) and by allowing nations to make advantage of the TRIPS Agreement's flexibilities. It is worth noting that in 2014, Gilead Sciences chose to provide seven Indian generic medication manufacturers voluntary licences to produce generic versions of its blockbuster hepatitis C treatment, Solvadi. The voluntary licence allows Indian pharmaceutical firms to sell their product in 91

The Ciência & Engenharia - Science & Engineering Journal
ISSN: 0103-944X
Volume 11 Issue 1, 2023
pp: 2616 - 2629

low-income nations, which are home to 54 percent of the world's total hepatitis C patient population.

Conclusion & Suggestions

As has been mentioned previously, the pharmaceutical industry invests a significant amount of money into the research and development of new drugs, and as a result, these industries require exclusive protection in order to recoup the expenses that they have incurred. Inventors will only be encouraged to engage in additional innovation once they have recouped the expenses that they have incurred as a result of their previous inventions. However, in granting exclusive protection and subsequently allowing the pharmaceutical companies to fix the prices for their products, there results, limited access to affordable medicines. This has been a problem in battling the public health crises in our present world. The protection of pharmaceutical patent rights must therefore be balanced with the protection of public health demands. Pharmaceutical products are made to protect the health of the people and should therefore serve its purpose without overbearing prices. It is recommended that in preventing overbearing prices of drugs, government should set price control regulations on drugs. This will ensure access to affordable drugs in the country. This duty is placed on the Ministry of Health. Also, the government should have the right to reduce any rising prices as it deems fit in the interest of the public. It could be recalled in Article 8 of TRIPS that government should take necessary actions in ensuring access to drugs in the interest of the public. Furthermore, internationally, it is recommended that in balancing public health and patent rights, in cases of epidemics of emergency nature, national governments could adequately reimburse the pharmaceutical company for its innovative activities without giving out a patent which will limit the availability of the drugs needed to meet the emergency. It is therefore recommended that what constitutes "adequate remuneration" should be fixed reasonably by the global public of conditions to avoid overburdened remuneration, which will still amount to unaffordable prices of medicines. However, the issue of "adequate" remuneration in the TRIPS Agreement for compulsory licence should not serve as an impediment in the use of the flexibility. It is recommended that the "evergreening" technique, which is used by pharmaceutical industries to get patent protection over a long period of time based on infinitesimal improvements made by the inventor, should be prevented, and patents should only be granted for new products and processes. This is an important issue. It is possible to draw the conclusion that while ensuring that an inventor of pharmaceutical products and processes is rewarded by the grant of patent protection to recoup his efforts, it is also necessary to ensure that measures necessary for the protection of the public for whom the drugs are made are ensured. This responsibility of ensuring access to affordable medicines is therefore primarily placed on national governments, which have the duty to regulate their Intellectual Property and health laws, provide pharmacological research, and so on.

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