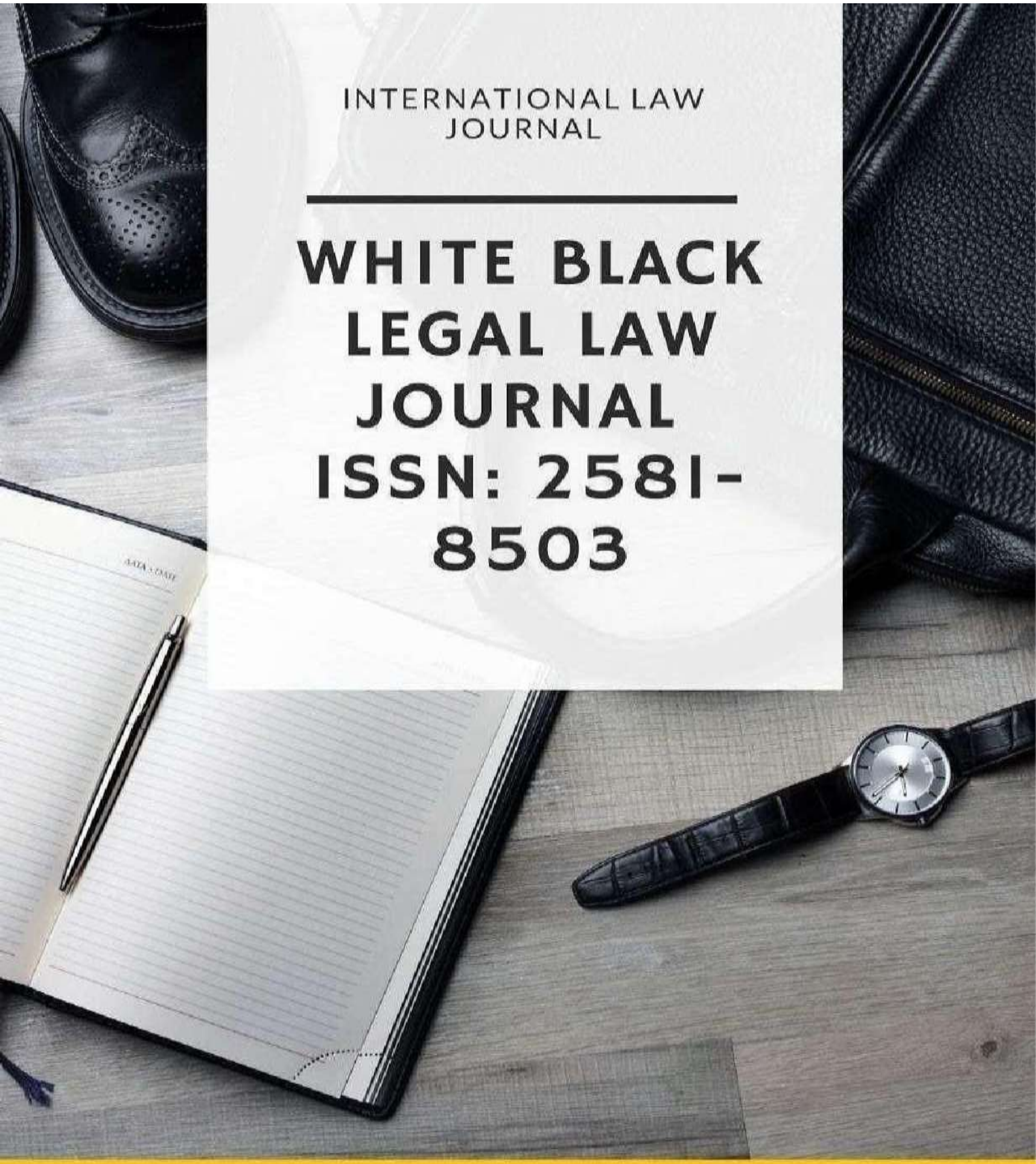

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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

PHARMACEUTICAL PATENTING AND PROBLEM OF PUBLIC HEALTH ACCESS

AUTHORED BY - DHANYA.B

Abstract

This research paper delves into the intricate relationship between pharmaceutical patenting and its profound implications on public health access. The pharmaceutical industry plays a pivotal role in the development of life-saving drugs and innovative therapies, making patent protection a vital mechanism to incentivize innovation and investment. However, the exclusive rights granted by patents can also create barriers to accessibility, particularly in the context of essential medications and treatments. This study explores the multifaceted dimensions of pharmaceutical patenting, examining the trade-offs between stimulating innovation and ensuring equitable access to medicines. This study investigates the historical evolution of patent systems, the legal framework, and the economic dynamics that underpin pharmaceutical innovation. It also critically assesses the impact of pharmaceutical patents on healthcare systems, both in high-income countries and resource-constrained regions. In addressing the public health access problem, focus is to analyse various policy mechanisms and initiatives aimed at striking a balance between innovation and access. This includes compulsory licensing, patent pools, differential pricing, and technology transfer agreements. This also considers the implications of international agreements such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its flexibilities, which influence the patent landscape for pharmaceuticals on a global scale. The findings and insights drawn from this research aim to inform policymakers, healthcare professionals, and stakeholders about the complexities surrounding pharmaceutical patenting and its impact on public health access. As we strive to balance the interests of innovation and affordability, this research paper offers a valuable resource for guiding future strategies and decisions in addressing the urgent global health access challenge.

Introduction

In the intricate fabric of global healthcare, the interplay between pharmaceutical patenting and the imperative of public health access constitutes a crucial and intricate juncture deserving careful examination. The pharmaceutical industry, a dynamic interface of innovation, commerce, and public health, exerts unparalleled influence over the health of individuals and communities worldwide. Central to this complex web is the matter of patenting, a vital mechanism designed to incentivize and regulate the development of new drugs, propelling medical science into uncharted territories. Originally conceived as a legal mechanism to encourage innovation by providing exclusive rights to inventors, pharmaceutical patenting has long been a foundational element of the industry's economic model. Yet, the unintended consequences of this system have given rise to a formidable challenge – the stark incongruity between profit-driven innovation and the urgent global need for affordable, equitable access to life-saving medications. This research paper delves into the intricate dimensions of the pharmaceutical patenting landscape, exploring its impact on public health access with a particular emphasis on the ethical dilemmas and complex issues that arise. Standing at the intersection of medical progress and systemic obstacles to accessibility, it is crucial to scrutinize the delicate balance between encouraging innovation and ensuring that scientific advancements are accessible to all segments of society. The evolution of pharmaceutical patenting has been characterized by an ongoing tension between promoting innovation and safeguarding public interest. Policymakers globally seek a delicate equilibrium, complicated by the nuances of international trade agreements, intellectual property rights, and the proprietary nature of pharmaceutical research and development. In this context, the paper aims to unravel the layers of this complex issue, shedding light on the historical trajectory, current challenges, and potential future directions of pharmaceutical patenting concerning public health. Moreover, the paper aims to critically evaluate the impact of pharmaceutical patenting on global health disparities, examining case studies that illustrate the real-world consequences of access barriers created by patents. By comparing the profit motives of pharmaceutical corporations with the moral obligation to ensure affordable and widespread access to essential medications, this research seeks to contribute to a nuanced comprehension of a pivotal issue in contemporary healthcare debates. In navigating the intersection of pharmaceutical patenting and public health access, this research aims not only to highlight challenges but also to explore potential solutions and policy frameworks that could reconcile the dual imperatives of innovation and accessibility. By fostering a comprehensive understanding of the intricate dynamics at play, this paper

strives to contribute to the ongoing discourse on pharmaceutical patenting, steering it towards a future where groundbreaking medical advancements can be harnessed for the collective well-being of humanity.

Literature Review

Prior research has comprehensively addressed the maintenance of balance between pharmaceuticals and public health, as well as the issues of access to affordable medicines. This section reviews some literature works in order to lay the groundwork for the study. While writing on "Globalisation, intellectual property rights, and pharmaceuticals: meeting the challenges to addressing public health gaps in the new international environment," KENNETH C. SHADLEN acknowledged that globalisation and the resulting harmonisation of national policies in intellectual property rights reveal a stark gap among countries in terms of their capabilities in accessing healthcare services. It was also agreed that, while effective healthcare is dependent on a variety of factors, the availability of essential medicines is absolutely critical. Treatment is impossible if drugs are not available. On the one hand, the harmonisation of policy for the grant of pharmaceutical patents causes disparities in countries' ability to access adequate healthcare. These attributes are related to their ability to invest in research and development. On the other hand, it was claimed that the high cost of Research & Development, combined with the ease of reverse engineering, makes originator firms extremely reliant on patents as a mechanism to ward off competition and thus appropriate the rent derived from innovation. The effects of the movement towards international patent harmonisation on developing countries have been hotly debated. There has been contention that the TRIPS Agreement provides advantages to developed nations over developing and least developed nations, who lack robust intellectual property laws, sufficient funding, and the necessary technology to foster innovation. It was claimed that a nation's level of innovation and access to medications is influenced by how much of its GDP it invests in research and development. For a set of sixteen countries (the United States, Canada, Japan, Germany, France, United Kingdom, Mexico, Korea, India, Australia, Denmark, Finland, Netherlands, Norway, Spain, and Greece), Guzman and Gomez (2008) estimate national pharmaceutical R&D efforts. This is done by calculating R&D expenditure as a percentage of value added in the sector over the period of 1980-2005. The output of the sector and its R&D expenses are more than 25% of each other in many developed nations. This ratio has gone up in the majority over time. Granted, there have been increases in certain developing nations as well, but even the most developed developing

nations—where R&D spending is rising—remain far from the OECD average. For instance, R&D spending in India, the developing nation with arguably the most developed pharmaceutical industry, accounts for about 6% of the value added in the industry. Both developed and developing nations must contribute to the availability of reasonably priced, high-quality medications in order to address these pressing issues. Shadlen says that this can be accomplished by appropriately incorporating the flexibilities found in the TRIPS Agreement as well as by elaborating on and incorporating some of the grounds that the Agreement leaves up to the states to define [3].

Statement of Research Problem

The world has an overwhelming amount of people living with various diseases; it is estimated that around 71 million people have chronic Hepatitis C infection [1].15 In addition, an estimated 36.7 million people were living with HIV/AIDS in 2016[2]. In the year, 2018, it was anticipated that there would be approximately 1 million seven hundred and thirty-five thousand three hundred and fifty new cases of cancer. Cancer death rates are predicted to have been around 33.1% between 2008 and 2014.17 In addition, without access to medications, around 399,000 people die each year as a result of Hepatitis C infection.18 These figures demonstrate the large number of people in desperate need of drugs to treat or manage their varied health issues. One challenge in providing therapy to those suffering from various ailments is the high cost of drugs set by pharmaceutical corporations. This is a major issue for developing and least developed countries who lack financing and hence are unable to purchase necessary pharmaceuticals despite severe health requirements in their countries. This public health issue, combined with high drug prices, has hampered access to important pharmaceutical items. Some factors that exacerbate the problem of drug access in developing countries, are a lack of infrastructure, technical know-how, and funding for medical research into the treatment of life-threatening diseases, as well as some other domestic factors that inhibit research. As a result, these issues motivate people to investigate the necessity for striking a balance between resolving health crises and safeguarding the creativity that goes into funding remedies for such crises. Some observers, including the author, are concerned that it will widen the gap between developed and developing countries by increasing the cost of technologically intensive goods. Others, on the other hand, argue that universally stronger intellectual property rights (IPRS) can yield widespread benefit by creating new incentive structures for the creation and diffusion of knowledge and

technology (Maskus 2004; Arora et al. 2005; Falvey and Foster 2005; Maskus et al. 2005).

Methodology

A doctrinal research methodology is used in this work. This will be accomplished through the presentation of materials derived from primary and secondary sources. International treaties are primary sources. Secondary sources include journals, and other publications on pharmaceutical patents and public health articles, reports, and internet websites.

Outline on Patents

Intellectual property rights protect works of human creativity. Since intellectual property is the most significant component of both the business process and the commerce industry, business today primarily depends on it. Intellectual property holds great value for a company. This can therefore result in more productive development for traders, manufacturers, and business owners. Therefore, the ownership of knowledge that people possess over the creations of their minds is known as intellectual property. Many of these categories usually give the creator exclusive rights to use their work for a certain amount of time, and they also usually come with financial rewards and recognition. A patent serves the function of granting exclusive rights to inventions, which are typically goods or procedures that present a novel approach to a problem or a technical solution. The technical specifications of the invention must be made public in the patent application. In essence, a patent is a kind of intellectual property that the owner or company owns. Innovations that are original and exclusive to the inventor or to the group of inventors are eligible for patent protection. A patent holder may use this "exclusive right" to recover development costs. To recover an investment, it aids in the development of patented technology. The agreement between the patent holder and the public is the fundamental component of any granted patent. In exchange for disclosing the invention to the public, the patent holder is given the sole right to use it. Eventually, the invention enters the public domain, and the underlying technical details are made accessible for anyone to comprehend. This keeps the innovation alive and disseminates information to the general public. The Venetian Statute of 1474 had an impact on how the European patent system developed later. In exchange for disclosing the nature of the invention to the Venetian General Welfare Board, it offered inventors of "new and ingenious device(s)" exclusive privileges of 10-year terms. This was a monopoly reward for

innovation meant to promote the creation of new tools and the dissemination of knowledge for "utility and benefit." Reform was sparked by public dissatisfaction with trade restrictions brought about by the 16th-century system that gave the UK monopolies on new inventions. A "true and first inventor" ought to be awarded a monopoly patent, according to the 1623 Statute of Monopolies that resulted [4]. Furthermore, Section 6 stipulated a term of up to 14 years for grants. The patentee's right to exploit as compensation and inspiration to innovate is explained by incentive theory. This is easily understood in light of the high development, testing, and regulatory costs associated with contemporary pharmaceutical innovation. A crucial aspect of any patent system is guaranteeing that innovation is accessible to the general public. Nonetheless, it is imperative to successfully enable public access to the medications that arise from this breakthrough. This goal is very important since states must have access to basic medications in order to fulfil their fundamental responsibility to protect people's health.

Pharmaceutical patenting

A person who is currently registered, approved, authorised under the Act to administer medication or medications in the course of professional practise is known as a drug practitioner. A number of terms are used under Pharmacy Regulation 2015 in Section 2(h) of the Act. The pharmaceutical industry is a sector where advancements impact very small pharmaceutical manufacturers. WHO focuses on research and development of a replacement medication and incurs significant costs in doing so, especially in situations where there is no guarantee or confirmation that the product under study will withstand modified testing protocols and can be commercially successful if released onto the market. The TRIPs Agreement requires the member states to protect biomechanical innovations in any way and permits them to forbid the patentability of plants and animals. India has long been a leader in this area, having modified its drug laws to take into account the needs of its own population, emphasise the importance of basic needs more than anything else, and progress in step with that progress. Given that the majority of Indians live below the poverty line and that the majority of medical expenses must be covered out of pocket, it is evident that the country is facing a serious health emergency due to a lack of access to affordable, high-quality healthcare and medication. Section 3(d) of the Indian patent regulation grants restrictiveness. "The understanding finds some kind of harmony between its command and the Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS) [5]"

by protecting access to medication for the underprivileged. Without a doubt, since TRIPS was implemented, this has been a significant change. One particular issue that comes up today has to do with India's drug patent system. Indian drug companies and the Indian market are important suppliers of low-value pharmaceutical products, such as nonexclusive drugs that are essential for overall health. India is a party to the Doha Declaration on TRIPS and Public Health, 2001, which has had global implications for prescription drug admission over the past millennium. Its turn of events is largely due to a drug industry that is trade oriented and increasingly aware of society at large. Since the global movement for drug admittance began in India, it has been a regional leader. The Indian business gave the mission a spine by demonstrating how an elective drug industry could be made. According to recent rulings pertaining to Indian patent law, such as the Supreme Court's Novartis ruling, India continues to prioritise public health when determining whether to grant licences for pharmaceutical products. Therefore, traditional rivalry is constrained by the drug patent framework. As a result, prices go up and access to medications is restricted in agricultural countries.

The Right to Health

The relationship between intellectual property rights and pharmaceuticals is fundamental to human rights. The International Covenant on Economic, Social, and Cultural Rights (ICESCR) was ratified by the UN General Assembly in 1966 and went into effect in 1976. It recognises the importance of encouraging innovation and granting access to it. ICESCR (Australia signed and ratified it in 1975 and 1972, respectively; the US signed it in 1977 but did not ratify it) [6] acknowledges that every person has the right to profit from their moral and material creations as inventors [Article 15(1)(c)], a right that is combined with their right to enjoy the advantages of science [ICESCR Article 15(1)(b)].

The right to health "is not confined to the right to health care," according to General Comment No. 14 of the CESCR, and it encompasses a wide range of socioeconomic factors like housing, work health and safety, and a healthy diet. Conflicts emerge when the rights to health and intellectual property rights (IPR) collide, and when safeguarding the rights of scientists to their creations is weighed against the rights of people to access science and their own health. Rich nations have a duty to assist less developed nations in achieving the fundamental health standards, which include having access to necessary medications. This is a significant matter for public health as well. Basic medications are unavailable to nearly 2 billion people [7]. Using criteria centred on medicine

affordability and financial support for vulnerable groups, Perehudoff et al. conducted a cross-national analysis of national medicines policies across 71 countries between 1990 and 2016. They discovered that good governance, measures to pool user contributions, and international cooperation were either non-existent or weak [8]. There could be major repercussions for people's right to health if IPR increased drug prices to the point where they became unaffordable. Inadequate health standards can have an adverse effect on other human rights, including decreased productivity and adverse economic outcomes [9]. A number of scholars have argued that access to life-saving medication should be included in a broad interpretation of the right to life, which is arguably the most fundamental human right, if refusing such treatment would otherwise deprive life [10]. The Universal Declaration of Human Rights (UDHR) guarantees the right to a living standard sufficient for one's health and well-being, which includes access to essential social services and medical treatment.

What is the impact of pharmaceutical patenting on public health access issues?

Drug companies routinely abuse the licencing system's restraints and charge absurdly high prices for prescription medications that are protected. The receptiveness of medications has decreased with the presentation of thing patents. Considering all of this, the development of novel medications necessitates significant efforts and extensive research [11], along with costly clinical foundations and reliable support systems. One of the driving forces behind the engineers' vital interests in that exploration of new medications is the selective right that comes with a patent. India is protecting countless non-exclusive solutions, such as vaccinations, which makes it challenging for the industry to produce life-saving drugs. The Indian government has launched numerous campaigns to protect the current situation. Mandatory permits and equal exchange strategies are two examples of elective measures that can assist state-run administrations in nonindustrial countries in improving the rationality of basic prescriptions for their residents. Buyer costs are reduced by mandatory authorising since it creates competition in the market for long-term gain. Overvaluing the drugs prevents ordinary people from getting access to them and undermines the government's duty to protect the health of its citizens. In India, in particular, where a sizable portion of the population lives below the poverty line (BPL) and medical costs are high, it is evident that there is a basic consideration crisis with inadequate medical services. If healthcare costs are exorbitant, the high cost of drugs prevents ordinary people

from accessing them. It causes a serious medical emergency and draws attention to India's inadequate healthcare system as well as the scarcity, unavailability, and difficulty in obtaining medications. The Indian government, which has taken a number of steps to address the issue, including mandatory licencing and parallel trade policies, faces a significant challenge. By lowering costs through competition in the market for the patented good, these alternate methods assist governments in developing nations in providing their citizens with more affordable access to essential medicines. The fairness, accessibility, and transparency of the medication framework rewards those who advance by granting patent syndication. A patent has many benefits, chief among them being the limited ability to use the patent, which yields a high benefit. A different thought is that the patent system might need to be changed. Licences for minor improvements will be accepted and discussed in relation to patent insurance. This will lessen the incentive to invest in consistent progress focused on improvements. Instead, by ensuring that money allocated to neglected medications is used for research and development that the public needs. Original drug companies have strong financial incentives to push the boundaries of the assurance framework in the drug industry. These companies view a patent as just one more tool at their disposal to fulfil their duty to maximise returns to investors. We can hope to see the original area working to extend the assurance security of its protected advancement assets in the best way it can, whether through innovation advancement, development in the use of lawful systems, or both. Evergreening patents is an irrational way to abuse patents by improving the pharmaceutical industry. It essentially entails making a minor alteration and then securing a patent ideal for a further twenty years in order to obstruct nonexclusive competitors who are seeking to provide safe and effective medications to the majority at reasonable prices. The agreements outlined in the Novartis case and the related provisions of Section 3(d) of the Patent Act, if accepted or become a template for another creative world, may help enable companies to invest entirely in development rather than attempting to obtain licencing through incremental changes. The Novartis decision will assist underprivileged people worldwide in having better access to affordable medications, regardless of what it means for the growth of pharmaceutical companies in the future. India boasts a sizable number of pharmaceutical companies and a convoluted patent system in relation to production volume. Nevertheless, the structure of these patents can be unclear, which makes it challenging for companies to provide life-saving drugs. Given the high cost of healthcare and the large number of impoverished people in the nation, the government must address the urgent problem of insufficient drug availability, affordability, and access. Citizens are being able to afford basic medications more

easily through the implementation of initiatives like equal exchange approaches and compulsory licencing. Article 21 of the Constitution guarantees the right to life, and it also includes the right to health, where it is crucial to have access to medical care. Pharmaceutical patents are crucial to maintaining health and guaranteeing access to medications.

Solutions

It may seem impossible to strike a balance between the right to health and pharmaceutical patents. Since the right to health is a fundamental right that is essential to all other human rights, it is really necessary to weigh it against minor and unimportant trade norms. One of the most vital rights is the right to health. It is still necessary for the law to give innovators some way to safeguard the profitable ventures that will support their livelihoods. The interests of innovators and the general public need to be balanced. With a few notable exceptions, I believe that the pharmaceutical industry has been far too avaricious in its pursuit of stronger patent protection at any costs. it is stressed in TRIPS article 7 that there needs to be a balance between technological knowledge producers and consumers. In compliance with Article 38 of the Constitution, various steps are taken to safeguard public health and nutrition while taking social and economic welfare into consideration. Researchers have spent time, energy, and expertise attempting to conceptualise potential solutions. Furthermore, PPPs and NGOs have worked with big pharmaceutical companies to carry out best practises. These organisations are making significant progress towards improving access to healthcare. The following part discusses several current strategies for resolving the conflict between pharmaceutical patents and patient access to care. I want to first discuss the solution that has garnered attention on a global scale: the flexibility of compulsory licencing under TRIPS. Legislative remedies, alternatives to mandatory licencing, and the Generic Competition alternative are some of the options. The secret is to apply them correctly. One of the most significant agreements signed by significant nations is the TRIPS Agreement, which became operative in India in 2005. Prior to the TRIPS agreement, India did not grant product patents for pharmaceuticals. During that period, India's generic drug industry flourished despite the stringent patent regimes in developed nations. As a result, under this system, drug accessibility in India was not an issue. In the same way, South Korea offered extremely low prices on medications that were highly costly in other nations. It is critical that medications be affordable for developing countries. Thus, laws should be crafted so as not to obstruct drug regulation, in order to guarantee that compulsory licencing is neither oppressive nor overly liberal, which would encourage drug abuse.

These solutions have been well-framed, but they haven't succeeded in making any major changes in this area. This is the reason that a lot of organisations and academics have worked very hard to find solutions that satisfy all parties. I'll start by outlining the industry-contested solution, which is price reductions for developing nations. If done right, these steps could greatly increase access to medications. Some of the potential solutions that can be proposed are good corporate citizenship, health impact funds, and price reduction. These solutions can be provided by offering a delicate balance. Prescription drug costs are a topic of frequent discussion among pharmaceutical companies, patients, advocacy groups, prescribers, payers, and policymakers. The availability of competing products influences prescription drug costs, but it's not the only factor. The federal government granted the innovator company patent rights and/or exclusive marketing rights, which prevent rival companies' products—generics and biosimilars, for example—from being readily available. By granting such exclusivity, the goal is to promote innovation and the development of new, safer, and more effective prescription medications. By fostering harmony between the patent owner and regulator, most drug prices can be lowered in this way.

Conclusion

To sum up, the complex relationship between pharmaceutical patenting and the issue of public health access highlights a pivotal moment in the history of global healthcare. Although patents are crucial tools for encouraging innovation and the creation of novel medications, the monopolies that arise from them frequently impose obstacles on accessibility. This paradox shows up as prohibitively high drug costs and limited access, which disproportionately impact vulnerable groups and obstruct the achievement of the right to health. It takes a multifaceted strategy that includes creative financing mechanisms, international cooperation, and policy changes to strike a delicate balance between encouraging innovation and guaranteeing equitable access. The need is to create a pharmaceutical environment that puts public health and innovation first, which will solve the moral and practical issues raised by the patent-centric paradigm that is currently in place. To create a more equitable and long-lasting healthcare system that benefits all, we must work together to balance the demands of universal health access with the goals of pharmaceutical innovation. In the context of India, the challenge of balancing the significant demand for affordable medication with the needs of the local pharmaceutical industry underscores the crucial role of government intervention. It is imperative for the government to proactively ensure accessible healthcare for all, implementing robust insurance

plans that extend coverage to the most economically disadvantaged. Moreover, strategic investments in research and development at the university level can lead to the creation of economically viable drugs. The government should also encourage the public sector to undertake essential research initiatives. Striking a delicate balance between using protective regulations to incentivize pharmaceutical companies to develop new medicines for currently untreatable diseases and ensuring that patients can avail themselves of these medications without causing financial strain is paramount. Achieving such equilibrium requires a comprehensive approach, where the government plays a pivotal role in fostering innovation, affordability, and accessibility in the healthcare sector. This multifaceted strategy is essential not only for the welfare of individual patients but also for the overall economic health of the nation.

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