PHARMACEUTICAL PATENTS, TRIPS, AND THE RIGHT TO HEALTH: RECONCILING INNOVATION WITH EQUITY

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ABSTRACT

The conflict between the drug patents and the right to health has perhaps been the most controversial matter of the contemporary intellectual property rights (IPR) regime. Patents are intended to promote innovation by giving pharmaceutical companies the sole rights of use; however, this protection is frequently accompanied by the practices of monopoly and over-inflated drug prices. Access to "extremely high-priced" basic medicines is, therefore, drastically limited, particularly in underdeveloped and developing countries, which is a direct violation of the right to health, the most basic human right. The corporations are trapped in the abovementioned crisis, so international agencies like the Doha Declaration (2001) and the TRIPS agreement of the World Trade Organization put forward new provisions, for example, compulsory licensing that could help overcome it. According to them, the local authorities are allowed not only to procure a generic drug of a relatively low price but also to produce the medicines patented and necessary for dealing with the public health crisis, even in the absence of patent rights holders' consent during a public health emergency. It claims that the existing intellectual property rights regime finds it difficult to strike the right balance between the two key aims of the system, one being to reward through patent protection, the other being the universal human right to health. To tackle such problems, the health sector may be required to implement and pursue reformation policies that would mostly dedicate themselves to public health and, thereby, ensure that medicines are easy to obtain under normal conditions as well as in the case of major health crises like a pandemic. Without these changes, a large portion of medical innovation will not be easily accessible for a significant part of the global population.

Keywords: Pharmaceutical patents, Intellectual property law, public health

1. Introduction

The conflict between the drug patents and the right to health has perhaps been the most controversial matter of the contemporary intellectual property rights (IPR) regime. Intellectual property law, particularly patent rights, was designed to encourage innovation by providing innovators with a time-limited monopoly over their inventions[1]. This entitlement is especially important in the pharmaceutical sector because drug development and discovery are risky and costly activities[2]. Patents enable further research into new treatments by enabling companies to make a profit and recoup the investment, with greater knowledge of public health as well as medicine. But the same mechanism which promotes innovation is restricting access, particularly for low- and middle-income countries, where the average citizen cannot afford basic drugs[3]. International discussion is sparked by the tension between protecting the international right to health and spurring innovation. The right to health is a global cornerstone of international law, as it is contained in treaties such as the Universal Declaration of Human Rights (1948) and the International Covenant on Economic, Social, and Cultural Rights[4]. The right to the medicines that an individual requires is the core component of this right, for without access to affordable health care, the right to health is an empty promise. Such existing patent legislation, nonetheless, significantly supports pharmaceutical firms to the detriment of their monopoly and overpricing practices. This disproportionately manifests itself in public emergencies with severe health consequences, such as pandemics and epidemics, where a growing need for fair accessibility to medicines and vaccines contradicts the financial interest of patent proprietors.

The World Trade Organization's 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) elevated the patent rights to a new level by requiring member governments to provide minimum standards of IP enforcement[5]. Whilst this provided a uniform legal basis for the pharmaceutical companies to conduct their business worldwide, it also raised concerns regarding the capability of the developing nations to provide cheap health care to their citizens. Cognizant of these issues, the 2001 Doha Declaration on the TRIPS Agreement and

[1] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries* 23–24 (2000)
[2] Frederick M. Abbott & Jerome H. Reichman, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions, 10 J. Int'l Econ. L. 921, 926–27 (2007)
[3] Ellen F. M. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power* 45–48 (2009)
[4] Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. Doc. A/810, at 71 (Dec. 10, 1948)
[5] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27–34, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299

Public Health urged the member states not to be hindered from implementing public health programs. The declaration emphasized the legality of flexibilities like compulsory licensing and parallel imports, through which governments can permit the manufacture or importation of generics without patent owners' authorization. For this reason, the present work critically examines the extent to which the present IPR regime strikes a balance between the twin imperatives of encouraging innovation as well as the protection of the inalienable right to health. This article tries to criticize the strengths and weaknesses of the existing system of pharmaceutical patents, compulsory licensing. Lastly, the article promotes transforming the global patent system into a health-based system that not only advances science but also ensures fair access to life-saving medicines worldwide.

Research problem

The research problem concerns the contentious discussion about whether pharmaceutical patents should be temporarily waived during global health crises. On one hand, patent protection under the IPR framework is meant to encourage innovation and investment in drug development. On the other hand, it could limit the access to affordable medicines that are necessary in a situation of urgent public health needs. The most important question is to what extent such a temporary waiver of pharmaceutical patents can be a means to guarantee fair access to healthcare without compromising the drive for innovation and investment in the pharmaceutical sector.

Research Objective

Essentially, the research wants to find out, by close examination, whether or not the pharmaceutical patents pose a problem to the right to health, especially, when considering the TRIPS Agreement and the Doha Declaration. The study is intended to assess if the existing global regime of intellectual property is able to strike a fair balance between providing motivation for innovation and ensuring that medicines remain affordable to all especially in under developed countries and compulsory licensing play as a reconciliatory mechanism between innovation and public health.

Research Method

This study employs a doctrinal method and is largely dependent on the examination of laws,

international agreements, court rulings, and academic publications. It actively questions these legal instruments such as the TRIPS Agreement, the Doha Declaration (2001), and various case laws like Natco Pharma Ltd. v. Bayer Corporation (2012). Besides, this research deciphers the laws and court opinions to fathom the interaction of patent law with the right to health, assess the prevailing legal frameworks, and suggest changes to create an equitable balance between innovation and access.

Research Questions:

This paper is guided by the following research questions:

1. To what extent does the present pharmaceutical patent regime ensure fair access to essential medicines in developing countries?

2. How effective are TRIPS flexibilities such as compulsory licensing and parallel importation in achieving the objectives of public health?

3. What legal, regulatory, and policy reforms are needed to balance innovation with equitable access to medicines?

Literature review

Reichman (2009) conducted a deep and critical examination of the modifications of compulsory licensing under the TRIPS regime and came to the point that only a small number of political and procedural factors have limited the use of such scenarios to ensure access to medicines, although from a legal perspective, it still gives developing countries the right to issue such licenses during a health emergency. Similarly, the Congressional Research Service (2022) report on the WTO COVID-19 TRIPS waiver suggests that the 2022 five-year vaccine patent waiver is only a part of the story. Issues such as bureaucratic delays, limited scope, and lack of technology transfer still exist, making it challenging to distribute vaccines in an equitable manner.

Individually, these pieces of research demonstrate the strong legal position of issuing waivers, which, however, is insufficient as this remains the main problem of accessibility. They point to the need for stronger global mechanisms that would allow the practical implementation of IPR waivers in times of crises. My research paper is focused on this problem. It examines how

existing TRIPS flexibilities such as compulsory licensing and a pandemic-related patent waiver could be developed in a way that would both preserve pharmaceutical innovation and ensure universal access to essential medicines.

2. Pharmaceutical Patents and the right to public health

The global intellectual property regime in its current form, particularly with the TRIPS Agreement, was designed to be a system where pharmaceutical patents have a significant bearing on how readily available and affordable drugs in different parts of the world, and, once unraveled through interconnected perspectives such as monopoly pricing, no immediate competition, evergreening, underutilization of TRIPS flexibilities and neglect of low-profit diseases that primarily affect the poor, it causes mind-boggling complexities[6]. The crux of the issue is with patent laws, per se - patent law confers the patent holder patent rights for twenty years, thus pharmaceutical companies can have a monopoly on the manufacture and distribution of the drugs that they have developed[7]. The company is said to resort to high pricing to recover the cost of R&D, yet in reality, monopoly pricing leads to the pricing of the necessary medicines that are unaffordable to many of the world's population, especially the low- and middle-income countries, where healthcare is mostly paid for out of pocket and the public health system is already under great pressure[8]. In the absence of the disciplining effect of competition, these prices are kept at an artificially high level because generics that could have brought the same drugs to the market at a fraction of the cost are not allowed to enter legally until the patent expires[9]. Hence, the lack of immediate competition is not only a temporary nuisance but also a structural characteristic of the patent regime that provides pharmaceutical companies with the opportunity to extract what economists refer to as "monopoly rents" by capitalizing on their exclusivity rights over vital products.

The problem is made even worse by such a common practice as "evergreening" when the companies try to stay monopolists longer by applying additional patents on minor changes like the formulation, dosage, delivery, or combining with other drugs without at all being real therapeutic efficacy innovations but gaining exclusivity period extension, thus slowing down

[6] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27–34, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[7] Id. art. 33.
[8] World Health Organization, Pricing of Essential Medicines (2019), https://www.who.int/medicines/access/fair_pricing/en/ .
[9] Frederick M. Abbott, The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference, 5 J. World Intell. Prop. 15, 22–25 (2002).

the entry of generics and the continuation of high drug prices; this conduct, while allowed by the broad patentability standards in some jurisdictions, is detrimental to the spirit of the patent system because it is rewarded for tinkering rather than for groundbreaking innovations, and the silence on this issue continues to be at the expense of voiced criticism for enabling corporate profits to be put far above the public health agenda[10]. Basically, the TRIPS Agreement is such that it has the going-ways for in favour of patent owners and it cleverly provides certain flexibilities to states when it comes to the protection of public health with compulsory licensing being foremost among them that makes it possible for the government to authorize the production of a patented drug without the consent of the patent holder when the case is a health emergency or is for free use and parallel imports being that which allows a country to import a patented product from another country where it is sold at a cheaper price thus making price arbitrage available across markets[11]. Nevertheless, on the ground, these instruments are in a deplorably little use situation by the confluence of political, economic and institutional causes since developing countries are subject to great pressures from developed nations and powerful trade blocs each time they attempt to access these flexibilities, for example, threats of sanctions, trade privileges withdrawal, or being included in bad actor lists such as the United States Special 301 Report that makes governments hesitant to assert their full rights under international law[12].

Besides that, even in cases where the political will is present, technical and legal incompetence, inefficient bureaucracy, and worries about the retaliation of large pharmaceutical corporations usually make it very hard for developing countries to use compulsory licensing or parallel importation effectively and promptly, thereby leaving millions of patients without access to affordable basic treatments. Such underutilization of the TRIPS flexibility leads to maintaining a global system that determines medicine access by the commercial strategies of the patent holders rather than by public health imperatives, and it is precisely in such a milieu that the disregard of low-profit diseases surfaces as yet another conspicuous deficiency since the pharmaceutical industry mired by the profit motive, most likely will channel its research and development efforts towards the therapeutic arena of lifestyle diseases and chronic conditions common to high-income populations besides the treatments that can be marketed in the long

[10] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[11] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, 4–6, WT/MIN(01)/DEC/2 (Nov. 14, 2001), 41 I.L.M. 755 (2002).
[12] Office of the U.S. Trade Representative, 2023 Special 301 Report 5–7 (2023).

term, while health problems that impact the underprivileged are not given adequate attention[13]. Moreover, the production of "10/90 gap" has been brought about by the said relationship, being the gap where less than 10 per cent of all biomedical research funds globally go to diseases that tally up more than 90 per cent of the global disease burden, exposing how morally wrong the system is that patent incentives are not aligned with the health needs of the most vulnerable in the world[14].

The combining of monopoly pricing with the non-existence of immediate competition is a situation of structural injustice in global health, where the practice of evergreening and the under-performance of TRIPS flexibilities strengthen the outcome that essential medicines stay unaffordable for millions, while innovation gets diverted from diseases that most require it and the supposed mutually beneficial balance between pharmaceutical innovation and public health tilts clearly towards private corporate interests. Conversely, the argument from the current system's supporters that if there were no patents and companies would not be able to get the exclusivity period prices, then there would hardly be any motivation for drug development, and much of it would be forfeited, inherently misses the point that a large chunk of early-stage research is publicly funded through universities, research institutions, and government grants, and the high prices of patented medicines scarcely reflect the actual R&D costs but are more indicative of what the market can bear; furthermore, when companies seek patents on incremental changes for evergreening rather than for groundbreaking therapeutic advances, the claim that patents are the condition for innovation loses much of its appeal. In fact, such a conflict was clearly demonstrated in the case of the COVID-19 pandemic, when the need for quick, fair and cheap access to vaccines and treatments was at odds with the principles of intellectual property rights, while the haggling over patent waivers at the WTO was signaling that the underuse of TRIPS flexibilities is not just a theoretical challenge but a cause of death for billions of people, especially those in the Global South[15]. At the end of the day, the connection of monopoly pricing, absence of immediate competition, evergreening strategies, underutilization of TRIPS flexibilities, and neglect of low-profit diseases is a symptom of a much larger global health governance crisis - one that requires the intellectual property system to be recalibrated to better fit with the principles of equity, justice, and the right to health for

[13] Patrice Trouiller et al., Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure, 359 Lancet 2188, 2189–90 (2002).
[14] Global Forum for Health Research, the 10/90 Report on Health Research 2000 17–18 (2000).
[15] Council for Trade-Related Aspects of Intellectual Property Rights, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

all; if reforms such as more rigorous patentability criteria to stop evergreening, increased utilization of TRIPS flexibilities by low-income countries, international investment for neglected diseases, and alternative research innovation models that uncouple from monopoly pricing were not undertaken, then the current situation would continue to favor profits over people and thus perpetuate the inequalities in access to medicines and counteract global public health efforts.

3. TRIPS Agreement and Public Health Mechanisms

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), finalized in 1994 as a part of the World Trade Organization (WTO) system, has been setting up the first comprehensive global system for the protection of intellectual property rights[16]. Regarding drugs, it required every member country of the WTO to recognize both product and process patents for no less than twenty years, as laid down in Article 27, therefore establishing a standard for patent protection that is uniform across various jurisdictions[17]. This was a huge change for many developing countries that had, in the past, excluded medicines from patentability to make it easier to produce generics locally. At the same time, by granting patent holders the sole right to produce, distribute, and sell pharmaceuticals according to Article 28, TRIPS not only improved the monopoly power of multinational pharmaceutical companies but also enabled them to set prices that were beyond the reach of poor populations[18]. The logic of the deal was to stimulate innovation, but in the very first moment, its corollary was to limit access to affordable medicines mainly in low- and middle-income countries experiencing public health crises like HIV/AIDS, tuberculosis, and malaria.

The TRIPS flexibilities that are closest to public health issues are the most significant ones, namely, compulsory licensing and parallel importation. Article 31 setting out the scope for compulsory licensing is the most important feature of TRIPS, where governments are empowered to authorize patent use without the right holder's consent, provided a set of conditions, such as proper remuneration and the possibility of judicial review, are met[19]. The TRIPS agreement did not establish a specific list of grounds for or against the setting of

[16] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[17] Id. arts. 27, 33.
[18] Id. art. 28; Frederick M. Abbott, The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference, 5 J. World Intell. Prop. 15, 21–25 (2002).
[19] Id. art. 31; World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001), 41 I.L.M. 755 (2002).

compulsory licenses, leaving member states entirely at their discretion to decide the issues of public interest that necessitate the use of such a measure. Importation of products under exhaustion, the legal basis in Article 6, allows countries to bring in patented drugs that are sold in other countries at a lower price. These flexibilities within TRIPS have been the subject of considerable debate, the issues at stake being the extent of the exclusivity rights granted by the agreement and the level of the incentive system's fairness in terms of access to medicines.

One of the most effective mechanisms in the area of public health, especially, was compulsory licensing. Its legal framework is that permission has to be granted on a per-case basis, the license is chiefly for local consumption if Article 31 enables, some money is given as a form of remuneration, and the decisions are subject to the judgment. The Doha Declaration, while declaring that "each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency," did not leave it to interpretation only, but it also categorically named public health emergencies, including HIV/AIDS, tuberculosis, and malaria, as situations instructing it to be valid grounds for them[20]. This gave states the political and legal legitimacy to deploy compulsory licensing in practice.

One of the most convincing examples of a utility is demonstrated by several real-life instances. In 2007, Brazil chose to issue a compulsory license for Merck's antiretroviral drug Efavirenz after negotiations aimed at achieving voluntary price reductions failed. Moreover, the country not only cut down the cost of the treatment but also created its global HIV/AIDS program: by importing generics from India, it lowered the treatment price by more than 60 per cent, making it possible to sustain its widely acclaimed program[21]. Similarly, the case of Thailand in 2006-07 is quite parallel when the country issued compulsory licenses for Efavirenz and Abbott's Kaletra, which led to a substantial reduction of costs, but at the same time, it also attracted diplomatic criticism from the United States and the European Union[22].

It is the case of Natco Pharma Ltd. vs. Bayer Corporation (2012), the world's first compulsory license in India, that has captured the headlines far and wide. On the contrary, the Indian Patent Office allowed Natco to produce a generic version with a price of ₹8,800 (around $125), and

[20] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, ¶ 5, WT/MIN(01)/DEC/2 (Nov. 14, 2001), 41 I.L.M. 755 (2002).
[21] Ellen F. M. ’t Hoen, The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health 54–57 (2009).
[22] World Health Organization, Improving Access to Medicines in Thailand: The Use of TRIPS Flexibilities 5–8 (2008).

therefore, to drastically reduce the price by 97 per cent[23]. Along with the ruling, there was the notion of affordable public access to medicines as a fair and reasonable criterion of public interest recognized by the TRIPS agreement, which was also referred to by the highest courts in their verdicts. Broadly speaking, the Canada-Rwanda case of 2007 marked the debut of the Paragraph 6 mechanism on a global scale. In that instance, Canada authorized Apotex to manufacture and send antiretroviral drugs to Rwanda. Nevertheless, the steps that were involved in the process were slow and full of red tape, and thus, the case demonstrated the practical challenges of implementing Article 31bis, although it did serve the purpose intended.

The significant factors which result in the success of compulsory licensing are the substantial decrease in drug prices, the beginning of generic competition, and the influence exercised on patent holders to grant voluntary licenses or lower their prices. Just the mere prospect of a compulsory license that might have been quite possibly hovering like a shadow over a patent holder's head during negotiations would be enough to shift the process towards the government. However, the disadvantages of the latter are still numerous and range from political and economic retaliation by developed countries, difficulties in administrative management, and the possibility of investment disputes, which, over the years, have caused developing countries to restrain the use of this right. In addition, the intricate dealings of Article 31bis have been a major hurdle for the phenomenon of cross-border compulsory licensing to not becoming a new spectacular occurrence.

Nevertheless, compulsory licensing, despite all the difficulties, is still a very major component of the international law safeguards that provide for health rights and are not beyond intellectual property rights. It enforces the idea laid down in the Doha Declaration that public health concerns should be given priority over cases of conflict with private commercial gains[24]. Parallel imports are another instrument supporting this one, as they enable states to buy from other countries the cheapest versions of the drugs. Together, these two tools signify the precarious equilibrium within TRIPS: on the one hand, they facilitate the pace of technological breakthroughs, while on the other hand, they guarantee the availability of drugs on fair terms. The world has been and is still facing different health problems, including pandemics such as

[23] Natco Pharma Ltd. v. Bayer Corp., Compulsory License Application No. 1 of 2011, Indian Patent Office (Mar. 9, 2012).
[24] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, 4–6, WT/MIN (01)/DEC/2 (Nov. 14, 2001), 41 I.L.M. 755 (2002); World Health Organization, Public Health, Innovation, and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health 125–28 (2006).

COVID-19 and the increasing prevalence of non-communicable diseases; therefore, the efficient implementation of TRIPS flexibilities is going to be a crucial factor in achieving the coexistence of innovation and equity in global health governance.

3.1. The Doha Declaration

The tension was made public by the HIV/AIDS catastrophe in the late 1990s. Antiretroviral therapies were available, but the price for one patient per year was over $10,000, which is out of reach for sub-Saharan Africa, where the disease was rapidly spreading[25]. The governments' requests for generics were met with threats of WTO litigation and embargoes from the developed countries[26]. The Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in November 2001, was a moment of turning point in such a scenario[27]. The Declaration stated that TRIPS "does not and should not prevent Members from taking measures to protect public health" and highlighted that it "should be construed and executed in an arrangement which supports the right of the Members of the WTO to safeguard their public health, in particular, to give access to medicines for all.[28]" It confirmed again that every member had the authority to issue compulsory licenses and also to decide what the justifications were for granting them. It further pointed out that nations could have their own regimes for exhaustion, thus giving the possibility for parallel imports of patented products. Besides this, it pushed back the deadline by which the least-developed countries had to comply with patent protection for pharmaceuticals from 2006 to 2016 (later further delayed) and thereby acknowledged their limited ability to meet the TRIPS requirements.

One of the essential successes of the Doha Declaration was its recognition of the so-called "Paragraph 6 problem." Even though compulsory licensing was allowed under TRIPS Article 31, the limitation that such activity be "predominantly for the supply of the domestic market" created challenges for countries that did not have enough pharmaceutical manufacturing capacity[29]. Paragraph 6 of the Declaration instructed the WTO to find a quick solution, which resulted in the 2003 WTO Decision and the subsequent amendment of TRIPS Article 31bis that allowed countries to issue compulsory licenses for the sole purpose of manufacturing and

[25] Carlos M. Correa, Trade-Related Aspects of Intellectual Property Rights and Public Health 112–15 (2007)
[26] Id.
[27] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001), 41 I.L.M. 755 (2002).
[28] Id. 4.
[29] Council for Trade-Related Aspects of Intellectual Property Rights, Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540 (Aug. 1, 2003).

exporting medicines to countries with inadequate domestic capacity. The patent system has been criticised for its procedural difficulty, but it is still a legal route that allows international cooperation to solve public health problems[30].

4. Inefficiency of Indian legislation

India, being a great advocate of public health and a major supplier of medicines to the developing world, still faces a problem as the existing legal provisions under the Patents Act, 1970, are out of sync with the goal of striking a balance between innovation and access. The Act is also equipped with TRIPS-compliant provisions and flexibilities like compulsory licensing (Section 84) and exceptions for research use (Section 107A); however, the reality is that such applications have been sporadic and the authorities have adopted a narrow interpretation of them. The court decision in Bayer Corporation v. Natco Pharma Ltd. (2013) was the first compulsory license case which showed how India can use TRIPS flexibilities; nevertheless, the government's subsequent reluctance to issue new licenses even in situations of urgent public health emergencies indicates that the policy is stuck due to international pressure and the inflexibility of the procedures.

In addition to that, the lack of regulations on how to determine "reasonable requirements of the public" or "non-working of patents" has resulted in the situation where domestic generic manufacturers do not know whether they can approach the authorities for such relief. Therefore, although the statutory framework in India is designed to promote both innovation and access, the reality of its implementation is that it is still inefficient and too cautious, thus, it is in breach of the constitutional provision of the right to health under Article 21. India's patent system proved to be inadequate when the COVID-19 pandemic came along, and it became a matter of timely access to essential medicines and vaccines during a worldwide crisis. When COVID-19 vaccines were developed by Pfizer, Moderna, and AstraZeneca, the technologies, especially mRNA platforms, were patented, and the owners exercised full control over them. Thus, many developing countries that did not receive licenses and were not the recipients of technology transfer could neither produce nor import vaccines.[31]

To solve this problem, India and South Africa jointly filed a proposal at the WTO in 2020 for a temporary waiver of certain TRIPS obligations. The purpose was to let the production of

[30] Carlos M. Correa, Trade-Related Aspects of Intellectual Property Rights and Public Health 112–15 (2007).
[31] World Trade Organization: "TRIPS Waiver" for COVID-19 Vaccines (31, Aug, 2021)

vaccines, therapeutics, and diagnostics take place without the patent holders' consent. The major developed countries and large pharmaceutical companies attacked the proposal vigorously and were the main reasons why it took so long for the WTO to reach a consensus during the period when global action was most needed. On the home front, there are also some points to consider. India's Patents Act, 1970, contains the features like compulsory licensing under Section 84 and government use under Section 100. Still, the mechanisms at play are too long in procedure, and there is a lack of political will to even think about the option of using them when the shortage situation is so acute. The fact that the government resisted the issuance of compulsory licenses demonstrates how existing statutory instruments are not enough to respond quickly to emergencies.

Hence, their situation calls for introducing a legal provision that envisages the "patent freeze" concept, which means the temporary suspension of patent rights granted within the twenty-year protection period during a public health emergency. Having such a framework will not violate the intellectual property principles as it will allow governments to grant manufacturers the right to produce locally patented drugs and vaccines thereby creating a balance between innovation incentives and the right to health. The invention will be the guarantor of the humanitarian needs which will not be subordinated to commercial monopolies; therefore, it will be the enabler of fair and timely access to life-saving medical products at any place of the world.

5. Balancing Innovation, Public Health & Future Directions

Working the fine line between innovation, public health, and the future trajectories of pharmaceutical IPR entails a careful balancing act that recognizes, on the one hand, the need to reward innovation, and on the other, the need for fair and equal medical access, particularly for the most vulnerable. The contradictions within the IPR system serve as a mirror to this issue by showing how existing structures disproportionately Favor the monetary interests of big pharma companies at the expense of population health, especially in less wealthy countries. Patents have the power to secure a monopoly, which in turn encourages R&D by providing the possibility of getting back the invested money; however, such a monopoly also results in the high pricing of products, thus many people are left out without a chance to buy the essential medicines that are the demand[32]. Moreover, the intersection of the right to health under

[32] World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27–28, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

international human rights laws and the profit motives protected by trade-related intellectual property agreements widens the problem[33]. In a nutshell, companies cannot be denied the necessary rewards for billion-dollar investments in the creation of drugs and clinical trials, but the ethical consequence springs when innovation is out of reach, price-wise, for most people on Earth.

The whole COVID-19 pandemic saga could have been a powerful example of how IP rights can accelerate and, at the same time, hinder global responses to health emergencies[34]. Thus, scientific advancements immensely quickened by the good mix of public and private financing, turned out to be very important on one hand. However, the patent locking, technology transfer restrictions, along with vaccine nationalism, delaying the arrival of vaccines to the most vulnerable all over the world, thus deepening global inequalities, were on the other hand. Recognizing such calamities' lessons, the IPR system cannot be inflexible when the entire planet faces a health emergency, yet it should be endowed with built-in flexibility to respond to the collective urgent need for health security. For instance, mechanisms like compulsory licensing under the TRIPS Agreement are there but may not be totally used due to reasons such as political pressure, capacity deficits, or fear of trade sanctions, which makes us wonder whether they are effective in practice[35]. It is necessary for the reforms proposed and the future directions resulting from the reforms to emphasize going back to the original thought of giving innovators incentives while at the same time finding ways of making sure that the drugs are affordable, accessible, and equitable. One of the reform paths could be an overhaul of the patent lifespan or setting up a differential pricing system, where prices vary based on the income level of the country[36]. This would mean that more people could afford the drug without entirely spoiling the companies' share. Besides that, there could be an emphasis on building strong public-private partnerships in which funds for research come from the state and global health organizations and pharmaceutical companies only have the right to sell the fruits of their research. Moreover, models of open science and patent pools that are being utilized during the COVID-19 pandemic, because of attempts like the COVAX and the WHO's COVID-19 Technology Access Pool (C-TAP), should be institutionalized as a regular practice to ensure

[33] International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.
[34] World Health Organization, COVID-19 Technology Access Pool (C-TAP), WHO (2021),https://www.who.int/initiatives/covid-19-technology-access-pool .
[35] Carlos M. Correa, Trade-Related Aspects of Intellectual Property Rights and Public Health 112–15 (2007).
[36] Thomas Pogge, Pharmaceutical Patents, Prices, and Access to Essential Medicines 25–27 (2005).

that intellectual property does not become a barrier to collaborative innovation[37].

It is equally important to stress the matter that international coordinated efforts are necessary in this particular case, as health challenges are not averted by borders and cannot be solved within independent countries. History provides us with many examples of pandemics, antibiotic resistance, and neglected tropical diseases that have spread beyond national boundaries, and it logically follows that their solutions must be similarly mobile.

Deepened cooperation through global treaties, regional alliances, and putting more trust in institutions like the WHO and WTO will make it easier to govern pharmaceutical IPRs more effectively[38]. Addressing international cooperation also involves dealing with the power disparities between wealthy and poor countries, where the former conduct most of the pharmaceutical research, and the latter struggle with a lack of access. True collaboration implies technology transfer, capacity building in developing countries, and fairer negotiations in trade agreements. Also, the development of local pharmaceutical industries in the Global South, with the help of common patents and shared knowledge, will not only decrease dependency on multinational corporations but also alleviate the problem of supply bottlenecks during crises[39]. Equitable access with policy recommendations should indeed incorporate actions making health-related research a global public good, instituting global funding pools for neglected diseases, reforming the TRIPS framework to enhance health emergency flexibilities, and ensuring there is drug pricing and cost-sharing transparency.

At the very least, governments should keep the right to health as their top priority instead of enormous profits by bringing ethical values into policy making, while international organisations will have to make sure that both the states and the corporations are held accountable. Moreover, national policy should also be concentrated on strong generic industries, easier implementation of compulsory licensing mechanisms, and innovation incentives in areas neglected by the private sector, like rare diseases or drugs with limited profit potential[40].

[37] World Health Organization, COVID-19 Technology Access Pool (C-TAP), supra note 3; Gavi, COVAX Explained, https://www.gavi.org/covax-facility
[38] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001), 41 I.L.M. 755 (2002).
[39] World Health Organization, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008), https://www.who.int/publications/i/item/9789241596281.
[40] Carlos M. Correa, supra note 4, at 115–18.

At the same time, corporate social responsibility should not be merely a man's voluntary gift to society but firmly integrated as a legal obligation, with pharmaceutical companies being required to take care not only of their profitability but also to make public health commitments. The future of the intellectual property rights system must also consider digital health technologies, the use of artificial intelligence for drug discovery, and biotechnological progress, though the accessibility of these should always come first before the rich. The broad perspective is one where innovation has no value if the benefits are less for those who have it, and health systems in such a way that they are weakened by the presence of highly monopolized medicines.

By correcting the errors already existing in the IPR system, handling the ethical issues of access vs. profit, taking the COVID-19 situation as a lesson, applying true reforms, calling more occasions for international cooperation, and implementing concrete policies, the world can get closer to living in a future equally balanced where intellectual property is simultaneously the cause of innovation and the universal right to health.

This balancing is not just a matter of mere ideals but a deep health inequities scenario which would be a result, should the world fail to adhere to such a balance alongside the undermining of trust in global governance, as well as the insufficient preparation for future crises. The reimagined pharmaceutical IPR framework that does not depict innovation and public health as contradictory forces but rather as two interconnected and mutually supportive pillars of a sustainable and just global health system should be the ultimate end[41].

6. Policy Reforms for Equitable Access

In order to reform the intellectual property regimes to align the pharmaceutical innovation to the right to health, it is necessary to take precise and practical measures. The very first point to start with is the patent laws, which must limit evergreening and patent thickets that are the main ways to prolong monopolies in an artificial manner. National authorities may take India as a model to imitate during the implementation of section 3(d) of the Patents Act(1970), which prohibits patents for minor modifications to be justified by therapeutic benefits only[42].Besides

[41] Thomas Pogge & Aidan Hollis, The Health Impact Fund: Making New Medicines Accessible for All 55–58 (2008).
[42] The Patents Act, No. 39 of 1970, § 3(d) (India).

that, the competition authorities shall keep the eyes open to anticompetitive settlements and exclusivity arrangements[43].

Conclusion

The complex interactions among pharmaceutical patents, innovation, and the right to health reveal that there is an ongoing conflict between one of the main purposes of the patent system - to encourage scientific progress - and at the same time a guarantee that access to necessary medicines, especially the ones that are patented, would be maintained in a fair manner. Pharmaceuticals' patents are, in simple words, the way to push innovations and be the financial means to the costly research and development. However, in practice, patents have helped in such a way that monopoly pricing is kept, new rivals enter the market later, and research is carried out for the sake of profitable markets, while at the same time, uncovered populations of diseases in low- and middle-income countries remain. Ultimately, the extent to which a pharmaceutical system is just is determined by the degree to which it maintains that innovation should be for the benefit of humankind rather than for the sole purpose of generating profits.

Recommendations

In order to guarantee fair access to medicines without discouraging innovations, the worldwide intellectual property system should have a structured and time-bound patent waiver mechanism in place for pandemics or other serious health crises. This kind of waiver, in line with the flexibilities under the TRIPS Agreement and supported by the Doha Declaration on Public Health, would allow countries to temporarily lift patent rights and make it easier to manufacture in large quantities the drugs and vaccines that are indispensable.

The governments and institutions like the WTO and WHO, should work together to create standard procedures for the implementation of such waivers, thus ensuring both the rapidity and the equity. At the same time, compulsory licensing procedures should be made easier and standardized in different legal systems so that there are no administrative delays. The addition of technology transfer obligations, transparent royalty frameworks, and global funding mechanisms would thus guarantee that patent waivers are equitable to innovators while at the same time meeting urgent health needs. In the end, the international community has to

[43] Eleanor M. Fox & Mor Bakhoum, Making Markets Work for Africa: Markets, Development, and Competition Law in Sub-Saharan Africa 147–49 (2019).

transition towards a health-centered innovation model whereby the protection of intellectual property helps the public good instead of hindering it, especially during a global crisis.

Future Research

First, future research must consider the reorganization of intellectual property structures in such a way that access to essential medicines is ensured to remain fair, at the same time as innovation in the pharmaceutical sector is encouraged. Also, comparative studies between different jurisdictions could investigate the extent to which flexibilities of the TRIPS Agreement, as for instance compulsory licensing and parallel importation, are utilized in practical terms and what their actual effect on drug affordability and public health outcomes is. On top of that, additional empirical research may be required to fully disclose the differential pricing models and regional patent pools' roles in lessening the gap between wealthy and poor countries. Moreover, given the rise of AI and biotech, research should focus on these aspects in terms of how they affect the balance between innovation consents and access issues, specifically referring to data ownership, patentability, and digital health equity. It is also important to monitor and analyze the health implications of patent waivers granted during the pandemic over time and in this connection, it will be necessary to draft a more flexible international intellectual property framework that is able to respond quickly to the next crises if one is to envision a just and sustainable global health system.