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“Patents vs. Patients: A Reevaluation of Intellectual Property in Public Health”

By Himanshu Parmar and Zehra Naqvi

The COVID-19 pandemic acted as a significant worldwide health emergency and a crucial examination of the current international Intellectual Property system. This exposed a fundamental weakness: the intrinsic conflict between IP's function in fostering innovation and its ability to hinder fair access to crucial medical technologies. This report compiles an examination of the current global governance framework, referencing important legal precedents and contemporary policy changes. The report suggests that a novel, forward-thinking approach is needed, one that formalizes IP flexibilities, encourages decentralized production, and integrates shared responsibility as a core principle of international law. According to the facts, a balanced strategy is both a practical necessity and an ethical duty for a robust and linked global future. While vaccinations and treatments were developed at an impressive rate, there were notable inequalities in their distribution, with wealthy countries receiving the bulk of the first supplies while low- and middle-income countries faced significant delays. This mismatch brought to the fore a policy dilemma: the system designed to encourage life-saving innovation accidentally placed a considerable barrier to equitable access. By November 2023, 79.86 percent of individuals in high-income countries were fully vaccinated against COVID-19 and 32.82 percent of those in low-income countries were only vaccinated. After 9 months of the rollout, the pharmaceutical companies had sold 71 percent of their vaccine stock to upper-middle and high-income countries, and low-income countries only had a small portion of the stock.

The paper hence discusses why a new global framework is necessary to strike a balance between the paradoxical nature of intellectual property as an essential driver of innovation and an emergency to the required medical care. This global framework needs to be a proactive and forward-looking model of creating a more resilient and fairer global health system along with an examination of key jurisprudential precedents and the existing legal system. The Agreement on Trade-Related Aspects of Intellectual Property Rights is one of the pillars of the World Trade Organization, and it provides minimum standards of patent protection on a multilateral level. To provide an Intellectual Property legal framework, this agreement obligates member states to comply with laws that cover patents, copyrights, trademarks, with a minimum of twenty-years

patent period on pharmaceutical commodities. However, the structure of the TRIPS agreement considers several flexibilities that are meant to defend the interests of the public health, such as parallel imports and necessary licensing. The inherent contradiction of TRIPS was emphasized with the case of the HIV/AIDS pandemic which led to such a significant declaration as the Doha Declaration on the TRIPS Agreement and Public Health in 2001.

This assertion, that TRIPS does not have a right to stop actions taken by members to protect the health of the people of the countries they represent, emphasized the right possessed by each member to issue compulsory licenses and the freedom to decide on what reasons such a license should be issued. The usefulness of such clarification has been compromised repeatedly by the simultaneous and speedy proliferation of bilateral and regional trade agreements including TRIPS-plus clauses. Examples of such stricter regulations include data exclusivity, patent linkage and term extensions, which deliberately restrict the provisions made by the Doha Declaration. This movement biases the scales towards corporate intellectual property rights by revealing their structural vulnerabilities especially in the latest pandemic. The controversy around the suggested COVID-19 TRIPS waiver is a bigger fight between the promotion of innovation and the accessibility ensured on large scale. The Republics of South Africa and India made an offer to the World Trade Organization to temporarily waive intellectual property protection on all of their COVID-19-related technologies in October 2020.

Proponents maintained that the current patent process and voluntary licensing contracts did not succeed in reducing the sharp inequities in the distribution of vaccinations, and that the waiver was a crucial and urgent measure. Other opponents included the pharmaceutical industry and the rich nations who claimed that logistical challenges such as ineffective distribution, regulatory delays, and under-invested healthcare facilities were more important than intellectual property. Two years of negotiations followed, with a partial waiver of vaccines passed in June 2022, but the number of demanding vaccines decreased sharply, which reduced the effectiveness of the waiver in the first place. India plays a major role in the fierce global battle between the demands of the populace and the intellectual property rights. Before going too far into this aspect it is essential to ask whether patents actually benefit medical care or whether they actually complicate the lives of people seeking healthcare. The drug industry is arguing that without a strong patent protection, it would not be able to recover the huge expenses it goes through in developing new drugs and any future developments. Nonetheless, abiding by the arguments of

public health advocates, restrictive patents tend to make the essential drugs prohibitively expensive, denying millions of people the opportunity to use them, particularly in low-income- based regions. India in turn has taken a middle ground position. It aims to achieve a balance between affordability of drugs and incentivizing innovation through limiting “evergreening”, or modifying existing medications to extend a patent, and allowing compulsory licensing in certain cases. It is through this tactic that India has emerged as the symbol of resistance and role model in balancing innovation and preservation of life. The Controller General of Patents, Designs and Trade Marks (CGPDTM) is the one in charge of granting patents under the Patents Act of 1970 and must ensure as part of the act that an invention is new, functional, and not easily evident to those skilled in the technical field in question. It is important to note that the Patents Act of 1970 was specifically meant to safeguard the health of the people by only admitting process patents, which allow businesses to patent how a drug is prepared and not the drug itself. Since this model enabled multiple manufacturers to apply various methods to the production of the same type of pharmaceutical product, it made the price of drugs affordable. India, however, chose not to make all the details public at once.

It contained important protections, especially the Patents Act's Section 3(d) which forbids patents on trivial, cosmetic alterations to current medications unless the revised version shows real enhancement in effectiveness. This implies that companies cannot merely implement slight modifications to an existing medication to preserve their monopoly a strategy referred to as "evergreening". One famous case of this issue is the case of *Novartis AG v. Union of India*, involving an effort by pharmaceutical firm Novartis to obtain an Indian patent on a special crystalline structure of the anticancer drug Glivec. Referring to the Indian Patents Act, Section 3(d) that establishes that the modified versions of the well-known medications cannot be patented unless they prove the significant improvement to their effectiveness, the Indian courts affirmed the refusal to allow the patent application. In the narrower sense of the word efficacy, which the court understood as the efficacy of the therapy, the court found that the slight changes and increased bioavailability of the new crystalline structure failed to meet that requirement. This decision made international precedence, as it points to the fact that societal interests should be put into evaluation to find a solution whether to save intellectual property, especially in cases where saving life is of minimum importance. Public health agencies were happy about the move because it allowed those who could not afford the original Glivec to keep on using cheaper

generic substitutes. Nevertheless, the pharmaceutical industry furiously contested the decision stating that it discourages drug development financing and, therefore, impedes research and discovery. The legal and ethical dilemma between intellectual property rights and public health is a complicated legal and moral issue that requires weighing of conflicting interests. The Article 25 of the Universal Declaration of Human Rights (UDHR) in which access to medical treatment is specifically addressed

states that everyone has a right to a standard of living, which is adequate to their health and well-being. As most individuals agree that this right is vital, it is the primary responsibility of the states to make sure that citizens receive access to the needed drugs. Intellectual property is founded on the right to enjoy the protection of the moral and material interests of any scientific, literary or artistic work, whether in the form of the author, provided by Article 27 of the UDHR. Intellectual property, however, is a legal right that aims at encouraging innovation in the best interest of all people and thus, the wider social good. As such, this right is not unqualified. Reconciling these rights when they clash is the main legal difficulty; this is demonstrated by patent protections on essential drugs, which can lead to exorbitant prices and restricted access. As tools of public policy, intellectual property rights must be construed and implemented in a way that supports a country's ability to safeguard its citizens' health rather than hindering it. This interpretive method is a crucial feature of a cohesive and well-balanced legal system rather than a significant divergence from accepted legal concepts. This legal theory was highly contested in a notorious case, a legal case between *South Africa v Drug Giants*, where 39 large pharmaceutical companies were suing the South African government because of the 1997 Medicines Act. This policy included the introduction of mandatory licensing and parallel importation in its attempts to reduce the price of the required HIV/AIDS drugs. The public health discourse changed dramatically when the Treatment Action Campaign (TAC) argued that the actions of the pharmaceutical firms were threatening the constitutional rights of its members to life, dignity, and healthcare to have access to healthcare received an amicus curiae status. TAC insisted that corporate intellectual property rights were not more important than the right of the state to ensure the health of its citizens. The drug companies had to abandon the move due to legal and popular pressure that followed and was increased by global condemnation.

This case was a historic win in favor of the common good and it set a strong precedent that the constitutional responsibility of a government can effectively be pitted against the intellectual

property assertions of corporations. In the *Association for Molecular Pathology v. Myriad Genetics* an important case by the U.S. Supreme Court in 2013, a similar subject of restricting the reach of intellectual property to safeguard the public domain surfaced. The case took into account Myriad's patents on the BRCA1 and BRCA2 genes that were identified and exposed to ovarian and breast cancer. A monopoly on genetic testing was created by Myriad's patents, rendering it unaffordable and unavailable to most of humankind as a natural product, a naturally occurring DNA fragment cannot be patented based just on its isolation, the Supreme Court said in a majority decision. It stopped the commercialization of important aspects of human biology, opening the door for more research and improvements in genetic testing. This led to significant improvements in the cost and availability of genetic testing, highlighting the need of preserving access to fundamental scientific discoveries for the health of the broader population. The COVID-19 pandemic revealed a significant weakness: the heavy geographic concentration of drug manufacturing and research and development in a small number of affluent nations, placing low and middle-income countries (LMICs) last in line for crucial products. This reliance on the supply chain showed that IP flexibilities by themselves are inadequate without the manufacturing capabilities and expertise to create the medical technologies.

The hesitation of the private sector to willingly share its proprietary technology underscored the necessity for innovation, multilateral strategies. The worldwide reaction to COVID-19 was marked by a significant collapse of international cooperation, with "vaccine nationalism" dominating over collective accountability. The COVAX Facility was founded with the "vision of solidarity" to provide universal access to vaccines, but in the end, it fell short of its goals. Initiatives were hampered by vaccine nationalism, an excessive reliance on international agreements, and a failure to fortify regional health institutions for distribution. A major change from a reactive to a proactive approach to global health strategy is represented by the most current Pandemic Accord, which was signed by the WHO on May

20, 2025, and acknowledges these shortcomings. In this updated framework, the Pathogen Access and Benefit-Sharing (PABS) annex is a key topic of discussion.

This annex seeks to establish a multilateral framework in which nations quickly exchange pathogen materials and genetic data in return for assured, fair access to the advantages gained from their application, such as vaccines and treatments. The outcome of this discussion will ascertain if the new framework establishes solidarity or is still susceptible to the same failures of

trust and collaboration experienced during the COVID-19 pandemic. It is evident that intellectual property serves as a potential barrier to access as well as a stimulant for innovation. The COVID-19 pandemic experience, along with significant legal precedents, shows that when IP acts as an obstacle to universal health, it compromises of public good it was intended to support. Jurisprudential precedents established in cases such as *South Africa vs. the Drug Giants, Novartis, and Myriad Genetics* have provided a legal basis for a "public-interest-first" interpretation of IP law, demonstrating that the system has built-in flexibility for rebalancing. Consequently, a balanced policy framework is not an extreme overhaul but a practical requirement. It acknowledges that the sustainability of the global innovation ecosystem relies on meeting the health needs of everyone. This report presents a theoretical approach for establishing a balanced policy framework: the formation of a Global IP & Health Reserve (GIHR). This would be a fresh, autonomous, and multilateral organization established and financed through an international agreement. The GIHR would function based on a proactive model instead of a reactive one its primary role would be to pre-negotiate and secure non-exclusive, worldwide licenses for all health technologies created to tackle diseases with pandemic potential, well ahead of any crisis. This would encompass patents, information, and expertise the GIHR would implement a combination of "push" strategies, including direct public funding and research grants, along with "pull" strategies, like prize funds and milestone payments for successful product advancement.

In return for this secure, de-risked R&D financing, innovators must contribute their IP to the GIHR. This would act as an "Innovation Commons" for technologies related to pandemics, when WHO announces a Public Health Emergency of International Concern (PHEIC), the GIHR will promptly distribute the technology packages to a network of pre-approved and vetted manufacturers worldwide, including those located in low-income and middle-income nations. This would remove the lengthy and politically charged ad-hoc discussions that troubled the COVID-19 response. The GIHR would further focus on developing and enhancing decentralized manufacturing capabilities, skilled personnel, and beneficial regulatory frameworks in LMICs, evolving past the "charity" approach of COVAX. By converting collective responsibility into a formal, institutional obligation, this theoretical model could ensure that innovation is not only encouraged but also fairly distributed, securing both a flourishing innovation environment and comprehensive health safety.

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