PATENTS VS. PATIENTS: RE-EVALUATION OF INTELLECTUAL PROPERTY IN PUBLIC HEALTH

Himanshu Parmar, Chanakya National Law University, Patna

Zehra Naqvi, Queen Mary University of London

Introduction: When Patents Became Prisons

The COVID-19 pandemic did something rarely seen in modern history—it exposed the cruel machinery at the heart of our global intellectual property system. For nearly two years, a vaccine existed that could save lives. Yet, millions of people across Africa, South Asia, and Latin America watched from the sidelines as wealthier nations hoarded doses.[1] By November 2023, 79.86% of people in high-income countries were fully vaccinated, while only 32.82% in low-income countries had received even a single dose.[2] This was not a story of vaccine scarcity. It was a story about who was allowed to own the machinery that saves lives.

The crisis crystallised a fundamental question that legal scholars have grappled with for decades: can a system designed to reward innovation simultaneously deny access to lifesaving medicines? The patent system was supposed to encourage the creation of new drugs by offering inventors temporary monopolies. That much is true. But somewhere along the way, we forgot to ask what happens when poor people cannot afford those drugs.

The Global Framework: How TRIPS Promised Balance But Delivered Monopolies

When the World Trade Organization established the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, it created a minimum floor of patent protection across all member countries.[3] For pharmaceuticals, this meant a standard 20-year patent period, which in theory sounds reasonable. In practice, it gave pharmaceutical corporations the power to set prices that only wealthy nations could afford.

The framers of TRIPS were not ignorant of public health concerns. They built in what looked like safeguards—flexibilities such as compulsory licensing and parallel imports that member states could invoke during health emergencies.[4] But like so many legal protections, they

existed only on paper until someone had the courage to challenge the corporations that ignored them.

That challenge came in 2001, when South Africa threatened to use compulsory licensing to produce affordable HIV/AIDS medications. The pharmaceutical industry responded with lawsuits.[5] What followed was a watershed moment. The Doha Declaration on the TRIPS Agreement and Public Health, adopted in November 2001, finally gave teeth to what the law already said: member states had the right to protect their people's health, and no corporation's patent trumped that fundamental duty.[6]

Yet within years, the pharmaceutical industry and developed nations found ways around even this declaration. They began negotiating "TRIPS-plus" agreements—bilateral and regional trade deals that imposed stricter terms than TRIPS itself.[7] These agreements introduced data exclusivity periods, patent linkage, and extensions that essentially neutered the Doha flexibilities. It was intellectual property law fighting back against democracy.

India's Rebellion: When a Nation Chose Patients Over Patents

In 1970, India made a choice. After independence, it passed a Patents Act that allowed companies to patent only the *process* by which drugs were made, not the drugs themselves.[8] This meant that while one company might own the method to manufacture a particular drug, another could find a different manufacturing route and produce the same medication. Competition meant prices plummeted.

For three decades, India became the world's pharmacy. A medication that cost $100 in the United States could be produced in India for $10. This was not because Indian researchers were less skilled. It was because Indian law recognised that a nation's duty to its citizens outweighed a corporation's desire for monopoly profits.

Then came TRIPS. As a member of the WTO, India was forced to adopt product patents by 2005.[9] The industry rejoiced. But India did something clever—it wrote Section 3(d) into its Patents Act. This provision, adopted in 2005, prevents companies from patenting minor, cosmetic improvements to existing drugs unless they demonstrate a "significant increase" in therapeutic efficacy.[10]

The provision was meant to block "evergreening"—a practice where pharmaceutical companies make trivial changes to existing medications (perhaps a different crystal form or a new combination) and file for a new patent, extending their monopoly.[11] Novartis, a Swiss pharmaceutical giant, decided to test it.

In 2013, the Indian Supreme Court heard Novartis AG v. Union of India.[12] Novartis had sought a patent on a crystalline form of Glivec (imatinib mesylate), a drug that treats blood cancer. The company argued that the new crystal form had better bioavailability—it was absorbed more efficiently into the body. Novartis saw this as a significant improvement. The court disagreed.

In what would become a landmark judgment, the Supreme Court held that Section 3(d) required "significant enhancement" in therapeutic efficacy, not just marginal improvements in how the body absorbed the drug.[13] For patients taking Glivec, this meant one thing: they could continue buying affordable generic versions. For cancer sufferers in low-income countries, it meant survival instead of financial ruin.

The pharmaceutical industry condemned the judgment. They claimed it would destroy innovation, reduce their investment in research, and harm the very patients the law was supposed to protect. Yet the evidence tells a different story. India continues to be a hub of pharmaceutical innovation precisely because it balanced the inventor's rights against the patient's needs.

The Human Rights Problem: Two Rights in Collision

This is where the law becomes genuinely complicated, and why it's important not to dismiss the pharmaceutical industry's concerns entirely.

Article 27 of the Universal Declaration of Human Rights protects the intellectual property rights of creators.[14] An inventor's moral and material interests in their creation deserve protection. Innovation requires investment—often decades of research before a single drug succeeds. The pharmaceutical industry is right that breakthrough drugs like those for HIV, cancer, and now COVID-19 required enormous upfront investment that no government alone could have funded.

But Article 25 of the same declaration also protects something: the right to a standard of living adequate for health and well-being, including medical care.[15] When these two rights collide—when an inventor's patent protection prevents someone from accessing the medicine they need—which one should prevail?

This is not an academic question. It affects real people. A person with tuberculosis in Nigeria might be denied life-saving drugs because a patent makes them unaffordable. A woman in South Africa might die of a treatable cancer because the relevant drug is locked behind patent protection and her government cannot negotiate its price. These are not hypothetical scenarios; they describe millions of actual situations.

The challenge for legal frameworks is to preserve both rights—to encourage innovation while ensuring access. This is harder than it sounds, because the incentive structures that drive pharmaceutical innovation often work against the populations that need medicines most desperately.

When Corporations Sued Governments: The South African Precedent

In 1997, South Africa passed the Medicines Act, a law that would seem straightforward in any just society: it allowed the government to issue compulsory licenses for medicines and to import cheaper copies from other countries.[16] The government was simply trying to respond to the catastrophic HIV/AIDS crisis.

Thirty-nine pharmaceutical corporations sued the South African government for passing this law.[17] They argued that it violated their intellectual property rights. South Africa, a nation already bankrupted by health crises, faced an existential threat: win the case, or watch people die while defending the right to save their lives.

The fight attracted international attention. The Treatment Action Campaign (TAC), a grassroots movement of HIV-positive people and activists, intervened in the case with amicus briefs.[18] TAC's argument was direct and morally unassailable: the right to life and dignity—constitutional rights enshrined in South Africa's post-apartheid Constitution—could not be trumped by corporate patent claims.

Under immense global pressure and facing defeat in court, the pharmaceutical companies withdrew their lawsuit in April 2001.[19] The victory was not just legal; it was symbolic. It declared to the world that when intellectual property rights threaten human life, human rights must win.

When Genes Cannot Be Owned: The Myriad Precedent

In the United States, a different but equally important battle unfolded. Myriad Genetics had patented sequences of the BRCA1 and BRCA2 genes, which are associated with significantly elevated risks of breast and ovarian cancer.[20] Because of the patents, Myriad had a monopoly on genetic testing for this cancer risk. A test that could have cost $300 was being charged at $3,000, placing it beyond reach for most Americans and completely unavailable to people in developing countries.[21]

The U.S. Supreme Court, in a rare moment of clarity, held in 2013 that naturally occurring DNA sequences cannot be patented merely by isolating them.[22] Justice Thomas wrote that a natural phenomenon, no matter how important to human health, cannot become the property of a single corporation. The logic was simple: to patent something, you must create something new. Isolation alone does not constitute creation.

The decision had enormous consequences. It opened up genetic testing to competition, which drove costs down and availability up.[23] More importantly, it established a principle: the natural world—our genetic inheritance—cannot be privatised for profit, even when privatisation is economically convenient.

The COVID-19 Failure: When the System Broke Down

The pandemic revealed that our intellectual property frameworks are not merely unjust—they are inefficient. The TRIPS waiver proposal, suggested by India and South Africa in October 2020, asked for a simple thing: temporarily suspend intellectual property protections on COVID-19 technologies so that vaccines could be manufactured globally.[24]

For two years, the world's richest nations, supported by the pharmaceutical lobby, blocked it.

The arguments made sense in abstract economic terms. Yes, voluntary licensing was available (though rarely used on terms that made generic production viable). Yes, companies could transfer technology (though none did). Yes, distribution problems existed in poor countries (though vaccine nationalism among wealthy nations was the actual barrier).[25] But none of these arguments mattered when people were dying.

The partial waiver, adopted in June 2022, came too late.[26] By then, demand for vaccines in the Global South had plummeted (partly because it wasn't met when it was urgent, and partly because vaccination campaigns had stalled). The waiver was a triumph for those who wanted to say something was done while ensuring that very little would actually happen.

COVAX, the global vaccine-sharing initiative, was supposed to ensure equitable distribution. Instead, it reinforced global inequalities.[27] Wealthy countries had hoarded supplies, vaccine nationalism had dominated international cooperation, and the machinery of global health had revealed itself to be fundamentally broken.

Toward a New Framework: The Global IP & Health Reserve

The question facing policymakers now is whether to tinker with a broken system or rebuild it. Tinkering has failed repeatedly. Every crisis reveals the same problems: IP frameworks prioritise profits over access, wealthier nations get vaccines first, and lower-income countries wait in lines that only move when richer nations no longer need them.

A more ambitious approach would be to establish a Global IP & Health Reserve (GIHR)—a new multilateral institution funded through an international agreement.[28] The GIHR would operate on a fundamentally different principle: instead of waiting for a crisis and then negotiating ad-hoc waivers, governments would proactively secure global licenses for all health technologies capable of causing pandemics.

Here's how it would work: When the WHO identifies a pathogen with pandemic potential, the GIHR would already hold licenses to any relevant technologies. If a vaccine is needed, the reserve would immediately distribute manufacturing know-how to a network of pre-vetted producers in low- and middle-income countries.[29] This would bypass the months of negotiation and political posturing that characterised the COVID-19 response.

To incentivise companies to participate, the GIHR would offer secure, de-risked funding through both "push" mechanisms (research grants, direct public investment) and "pull" mechanisms (prize funds, milestone payments).[30] In exchange, companies would contribute their intellectual property to the reserve. This is not expropriation—it's a bargain. Companies get guaranteed funding for pandemic-relevant research; society gets access to the results.

The GIHR would also invest in decentralised manufacturing capacity in the Global South, moving beyond the charity model of COVAX into something more durable and just.[31] By converting what ought to be a moral obligation—protecting everyone's health—into a formal institutional responsibility, the GIHR could ensure that innovation and access move together, not against each other.

Conclusion:

We live in an era of technological abundance. We have the capacity to manufacture vaccines at global scale. We have the knowledge to produce affordable medicines. We have the resources to protect everyone's health. What we lack is the political will to do so—and the legal structures that would make it routine rather than exceptional.

The cases reveal something important that the law is not fixed. Courts have repeatedly ruled that human rights, when they conflict with property rights, must prevail. Governments have repeatedly asserted their authority to protect their citizens' health.

Yet we continue to allow intellectual property frameworks to constrain our response to health crises. We continue to accept that poor nations should wait for medicines that rich nations can instantly procure. We continue to believe that a private corporation's patent is more important than a person's life.

This is not inevitable. The next pandemic, and there will be a next pandemic, can be met with a different approach. A Global IP & Health Reserve is not a perfect solution. But it would be a system designed around people rather than around profits. In the choice between patents and patients, the law has already spoken. What remains is for governments to listen.

Endnotes:

1. Agnes Binagwaho, Kedest Mathewos & Sheila Davis, "Equitable and Effective Distribution of the COVID-19 Vaccines: A Scientific and Moral Obligation", International Journal of Health Policy and Management, 11 (2022), 100-120. See also: Our World in Data, "COVID-19: Vaccination", available at: https://ourworldindata.org/covid-vaccinations (last accessed 3 February 2026).

2. Ibid.

3. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C to the Marrakesh Agreement, 15 April 1994, Arts. 27, 33.

4. Ibid., Arts. 31 (compulsory licensing), 6 (parallel imports).

5. Oxfam, "South Africa vs. the Drug Giants: A Challenge to Affordable Medicines" (Oxfam, February 2001), available at: https://oxfamilibrary.openrepository.com/oxfam/bitstream/10546/620381/2/bn-update-access-to-medicines-south-africa-110401-en.pdf (last accessed 3 February 2026).

6. WT/MIN(01)/DEC/2, "Declaration on the TRIPS Agreement and Public Health" (14 November 2001) [the Doha Declaration].

7. Peter K. Yu, "TRIPS-Plus Agreements: Implications for Global Access to Medicines", Journal of World Intellectual Property, 9(2) (2006), 166-195.

8. Patents Act, 1970 (India), § 3 (process patents only, until 2005).

9. TRIPS Agreement, Art. 27(1) (requiring member states to grant product patents).

10. Patents Act, 1970 (India), § 3(d), introduced via Patents (Amendment) Act, 2005, which states that merely changing the form, properties, or method of administration of a known substance shall not be patentable "unless they differ significantly in properties with regard to efficacy".

11. Ellen 't Hoen, Medicines Law and Policy: A Critical Update on TRIPS-Plus Bilateral Agreements*, (Medicines Law & Policy, 2012).

12. Novartis AG v. Union of India, (2013) 6 SCC 1 (India).

13. Ibid. The Court interpreted "efficacy" narrowly, as therapeutic efficacy, rather than merely bioavailability. See also: Prashant Reddy, "Patent Law, Pharmaceutical Innovation, and Access to Medicines: The Case of India", in Intellectual Property, Public Health and Development: Access to Medicines in Developing Countries (Oxford University Press, 2009).

14. Universal Declaration of Human Rights (1948), Art. 27(2).

15. Ibid., Art. 25(1).

16. Medicines Act, 1997 (South Africa), § 15A-C.

17. Ruth Mayne, "South Africa vs. the Drug Giants: A Challenge to Affordable Medicines", *Oxfam Policy Papers* (February 2001).

18. Treatment Action Campaign, "Amicus Curiae Brief to the Constitutional Court of South Africa" (2001), Case No. CCT 43/01.

19. Oxfam, "South Africa Wins Its Case Against the World's Biggest Drug Companies" (April 2001), available at: https://www.oxfamamerica.org/static/media/files/sotextreme.pdf (last accessed 3 February 2026).

20. Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013) [U.S. Supreme Court].

21. Ashish M. Bakshi, "Gene Patents at the Supreme Court: Association for Molecular Pathology v. Myriad Genetics", Journal of Law and the Biosciences, 1(2) (2014), 183-189.

22. Association for Molecular Pathology v. Myriad Genetics, 569 U.S. 576, 595-596 (2013) (holding that "cDNA does not present the same obstacles to patentability as naturally occurring,

isolated DNA segments").

23. Katie Brady, "Revisiting the Myriad Gene Patenting Case a Decade After Decision", Carl R. Woese Institute for Genomic Biology (November 2024), available at: https://www.igb.illinois.edu/article/revisiting-myriad-gene-patenting-case-decade-after-decision (last accessed 3 February 2026).

24. World Trade Organization, "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Treatment and Containment of COVID-19: Communication from India and South Africa", WT/GC/W/681 (11 October 2020).

25. Dr. Amir Khan, "What is 'Vaccine Nationalism' and Why is it So Harmful?", Al Jazeera (7 February 2021), available at: https://www.aljazeera.com/features/2021/2/7/what-is-vaccine-nationalism-and-why-is-it-so-harmful (last accessed 3 February 2026).

26. General Council of the WTO, "IP/C/W/668/Rev.1: Decision on the TRIPS Agreement", General Council Decision (17 June 2022).

27. Trevor Zimmer, "Lessons From COVAX", Stanford Social Innovation Review (May 2023), available at: https://ssir.org/articles/entry/lessons_from_the_failures_of_covax (last accessed 3 February 2026).

28. This concept is inspired by emerging policy discussions on advanced market commitments and pandemic prevention mechanisms. See: Alexandra Finch, "How the Landmark Pandemic Agreement Addresses Technology Transfer and Access to Pandemic Response Products", IPI Global Observatory (21 May 2025), available at: https://theglobalobservatory.org/2025/05/how-the-landmark-pandemic-agreement-addresses-technology-transfer-and-access-to-pandemic-response-products (last accessed 3 February 2026).

29. World Health Organization, Pandemic Prevention, Preparedness and Response Agreement (20 May 2025), available at: https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord (last accessed 3 February 2026).

30. Priya Kochhar and Susan Kaplan, "Innovation Incentives in Global Health: An Analysis of Push and Pull Mechanisms", Health Affairs, 39(7) (2020), 1-9.

31. Mark Eccleston-Turner, Alexandra Phelan, Michelle Rourke & Harry Upton, Models of Equitable Distribution of Vaccines in International Law: The Pandemic and Beyond (University of Exeter, 2025).