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A CRITICAL ANALYSIS OF PATENT LAW FRAMEWORKS FOR BALANCING PRIVATE INNOVATION AND PUBLIC INTEREST IN GLOBAL HEALTH

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Abstract

With regard to global health, this article critically assesses the balance between private innovation incentives and public interests that are contemplated by current patent law frameworks in the United States, Europe and India. To encourage pharmaceutical research and development, patent systems need to be in place but too often result in high drug prices and in the absence of essential medicines in relatively poor countries. Using an economic notion, we explore the economic reason of giving patent protections, how to increase the accessibility during a global health crisis – e.g. the pandemic for COVID-19 – and how legal mechanisms such as compulsory licensing, patent pools and anti-evergreening provisions can increase the access. Through its Patents Act and judicial decisions, the article reveals that India's approach is more pro public when compared to US and EU. The final part of the article states that current patent regimes are favorable to private interests and that change along the path towards equitable access, particularly during a health emergency, is possible through stronger international cooperation as well as through the strategic adoption of legal reforms.

Medicines and technologies are key, so global health is reliant on medicines and technologies, and patent law grants inventors temporary monopolies on these,

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with patent law, however, requiring patent frameworks to also serve the public interest. Given its pronounced tension with public welfare (namely accessing lifesaving treatments), particularly in low income countries, there is pronounced tension in the pharmaceutical sector between private incentives, notably patents that drive R&D and public welfare. This article analytically reviews and critically compares how the principles of patent law frameworks of USA, EU, and India stand in favor of these principals against each other. Yet it argues that patents are still necessary for further innovation, but that presently prevailing institutions discriminate in favor of the private for the sake of the interests taken by more patients' health needs rather than asymmetry in this global context, but they propose reforms and flexibilities to solve the asymmetry.

Keywords: Compulsory licensing, Public interest, Private innovation incentives, Evergreening, Generic drugs, High drug pricing, United States patent law, European Union IP framework, India Patents Act, COVID-19 vaccine patents, Patent pools, Medicines Patent Pool (MPP), Public-private partnerships (PPPs), Differential pricing, Technology transfer, Bayh-Dole Act, Supplementary protection certificates (SPCs), Patent thickets.

Introduction

Medicines and technologies are key, so global health is reliant on medicines and technologies, and patent law grants inventors temporary monopolies on these, with patent law, however, requiring patent frameworks to also serve the public interest. Given its pronounced tension with public welfare (namely accessing life saving treatments), particularly in low income countries, there is pronounced tension in the pharmaceutical sector between private incentives, notably patents that drive R&D and public welfare.

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1.1 The Economic Rationale for Patents

The patents give inventors exclusive rights for a limited period of time (normally 20 years according to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)) thus enabling them to recoup R&D expenses. At a price of $2.6 billion per drug, development can be expensive in the pharmaceuticals, so patents are absolutely essential to attract the investment.[1] According to the Patent Act (35 USC) in the US, these are exceptionally robust protections and that helped create the thriving pharmaceutical industry for Pfizer BioNTech's COVID 19 vaccine which was made in record time. Likewise, the EU's unitary patent system and supplementary protection certificates (SPCs) grant similar market exclusivity that encourages innovation in the sophisticated biologics.[2] Without this, firms would not be able to pass up the possibility of receiving the returns from risky, high cost R&D that could result in medical breakthroughs.

1.2 Innovation Outcomes and Global Health

Innovation in the patent sphere has brought about positive health outcomes from HIV/AIDS treatment, cancer treatment and treatments for rare diseases The US Bayh-Dole Act (1980) enabled universities to patent research funded by the public which united academic and industrial efforts to speed up drug discovery processes.[3] Horizon 2020 funding, together with patent protection, has made joint research in the health field possible in the EU. But patent benefits are not equally spread: high income countries file most patents generating access to medicines, and they shoulder most of the resulting patents' value, leaving low income countries to rely on generics or aid; and this leaves patents systems wanting for global public health.(Karema & Smedley, 2007).[4]

[1] Joseph A DiMasi, Henry G Grabowski and Ronald W Hansen, 'Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs' (2016) 47 Journal of Health Economics 20, 23.
[2] Regulation (EC) No 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1.
[3] Bayh-Dole Act, Pub L No 96-517, 94 Stat 3015 (1980).
[4] World Health Organization, 'Access to Medicines and Health Products' (2022) https://www.who.int accessed 10 April 2025.

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I. Public Interest and Access to Medicines

2.1 Pricing and Accessibility Challenges

Firms use patents to establish high prices and have medicines within reach of only the richest segments of the population in low- and middle income countries (LMICs). For example, Gilead's hepatitis C drug Sovaldi was priced at $84,000 US per course in the US, which placed the drug out of reach for many people across the world.[5] However, patented drugs continue to be expensive in the EU, and they are again unevenly accessible across member states, although this is less in the EU compared to the US. India which is referred to as the 'pharmacy of the developing world' is constrained by TRIPS because of mandatory patentability for new compounds, therefore unable to produce the affordable generics.[6] Healthcare inequality exists because patent-based pricing leads to both innovation enhancement and increased barriers to medical care.

2.2 Global Health Crises and Patent Barriers

The COVID-19 pandemic exposed patent-related barriers to equitable access. Even though global calls for vaccine equity, patented vaccines were first allocated to high-income countries. US and EU have argued against proposals at the World Trade Organization (WTO) calling for a TRIPS waiver to suspend vaccine patents because IP protections are essential to sustaining innovation.[7] In an angle picked up some countries leading the push for a waiver, India and SAC, noted that patents prevent local production in LMICs. But such a limited waiver for vaccines was the eventual compromise, which left more problems to be sorted out, pointing to the primacy of private over public interests.[8]

[5] Ellen FM 't Hoen, The Global Politics of Pharmaceutical Monopoly Power (AMB 2009) 67.
[6] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, art 27.
[7] World Trade Organization, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19' (2021) IP/C/W/669.
[8] World Trade Organization, 'Ministerial Decision on the TRIPS Agreement' (17 June 2022) WT/MIN(22)/30.

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II. Legal Flexibilities and Their Limitations

3.1 Compulsory Licensing and Parallel Imports

A direct legal instrument to bridge patent protection with public health requirements is compulsory licensing. WTO members can issue compulsory licenses for patents through Article 31 of TRIPS when payment of adequate remuneration to the patent holder becomes mandatory. The provision facilitates legal ways for monopolistic price evasion during health crises yet its execution receives heavy political resistance from pharmaceutical companies and high-income governments.

The government of India actively exploits the available freedom to grant compulsory licenses. India approved its initial compulsory license for the cancer medication Nexavar throughout the Natco Pharma v Bayer case in 2012 because the drug was unaffordable and Bayer lacked local manufacturing activities. Natco Pharma received permission to sell and produce the medicine at prices considerably lower than Bayer's at 97% below its original price.[9] This judgment established that affordability serves as an essential public health reason for Indian patent law interventions through section 84 of the Patents Act.[10]

The available progressive legal frameworks to implement compulsory licensing do not receive sufficient practical application. National and international political along with economic forces prevent widespread utilization of compulsory licensing in India. The Special 301 Report published by the USTR continuously identifies India for having weak IP protection enforcement while portraying compulsory licensing as a threat to both innovation and international trade.[11] TRIPS operations manifest this fundamental contradiction because its flexibilities remain paper provisions while international trade agreements activate resistance against them.

[9] *Natco Pharma Ltd v Bayer Corporation* [2012] COMPAT Order No. 1/2012.
[10] India Patents Act 1970 (as amended 2005), s 84.
[11] Office of the United States Trade Representative, '2023 Special 301 Report' (2023) https://ustr.gov accessed 10 April 2025.

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As per national laws, obligatory licensing exists in the European Union, but it rarely takes place. Voluntary arrangements or collaborative procurement mechanisms, such as the EU's joint purchasing agreements for COVID-19 vaccines, are also often preferred by the member states to make such decisions. However, voluntary licensing turned out to be a weakness in the pandemic, particularly when demand outstrips supply and price conflicts occur.[12] Thus, the European Commission has made a suggestion to harmonize compulsory licensing procedures across the member states in case of crises.[13] This, however, does not mean actual implementation will not need overcoming institutional inertia and strong pharmaceutical lobbying.

Another TRIPS compatible mechanism in Article 6 is parallel importation of patented products whereby it is permissible to import patented products marketed in different countries at lower prices, provided use of such patents is confined to that country. India and South Africa have adopted international exhaustion rules for facilitating such imports. However, the EU uses regional exhaustion, restricting flexibility of intra-EU trade and the US applies a nuanced approach, restricting parallel imports and falls under the first sale doctrine.[14]

3.2 Patentability Criteria and Evergreening

According to India's Section 3(d) of the Patents Act, patents for incremental innovations cannot be obtained except when the modification is truly significant and the therapeutic efficacy is also shown, consequently preventing "evergreening," i.e., perpetuation of patent through a slight modification. This logical approach was reaffirmed by the Supreme Court in 2013 when, in the Novartis case, patent for Glivec was killed by the bench on the basis of the interest

[12] Peter Roderick and Allyson M Pollock, 'Compulsory Licensing: A Critical Tool in the COVID-19 Pandemic' (2021) 397 The Lancet 378, 379.
[13] European Commission, 'Proposal for a Regulation on Compulsory Licensing for Crisis Management' COM(2023) 224 final.
[14] Carlos M Correa, *Public Health and Intellectual Property Rights* (South Centre 2016) 58.

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of Germans to access generics.[15] In contrast, US and EU (secondary) patents are granted with permission, and typically delay entry by a generic, through granting them. Another example is AbbVie's Humira, for which delayed competition occurred in the US after a 'patent thicket' of over 100 patents.[16] This being confined to private practices accomplishes to tip the balance in favour of private interests at the expense of public access.

III. Reforms and Alternative Models

4.1 Strengthening Public-Private Partnerships

The alignment of innovation with public health objectives can occur by establishing public private partnerships (PPPs). Collaborative R&D is funded by the EU's Innovative Medicines Initiative on the basis of sharing risks and benefits.[17] As a result, millions were invested in vaccine development by the US Operation Warp Speed during COVID-19, but patents were not relinquished to the public, ensuring only limited global access for people.[18] Access clauses (like technology transfer clauses) can be introduced in PPPs to further serve public interests without ruining innovation incentives.

4.2 Patent Pools and Voluntary Licensing

Medicines Patent Pool (MPP) is one of such patent pools that facilitates voluntary licensing of patented drugs to generic manufacturers, particularly in LMICs. Today, the MPP has expanded access to Gilead's HIV drugs through this agreement in over 127 countries.[19] While voluntary mechanisms rely on goodwill of patent holders, important drugs like some cancer therapies are excluded. Participation in patent pools may be required by mandate during pandemics

[15] Novartis AG v Union of India [2013] INSC 258.
[16] Matthew Rimmer, Intellectual Property and Global Health (Springer 2019) 145.
[17] Innovative Medicines Initiative, 'Annual Report 2022' (2023) https://www.imi.europa.eu accessed 10 April 2025.
[18] Amy Kapczynski, 'The Public Interest in Intellectual Property Law' (2021) 73 Stanford Law Review 1231, 1245.
[19] Medicines Patent Pool, 'Impact Report 2023' (2023) https://medicinespatentpool.org accessed 10 April 2025.

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without compromising innovation incentives and increasing existing patentees' control over markets.

4.3 Differential Pricing and Global Solidarity

A market based solution to the cost issue is differential pricing, in which the drugs are made to be sold at a lower price in LMICs. This model is supported by India's generic industry, but the scope is limited by TRIPS compliance. High income countries have now been proposing global solidarity funds whereby access in LMICs are subsidised but no such schemes are yet binding.[20] Additional worldwide cooperation should be developed to support patent systems.

IV. Critical Evaluation: Striking the Balance

US and EU patent law frameworks establish a higher level of priority of pre-eminent treatments over affordability and equitable access as a granted right in their patent law framing. India's framework (higher requirement of public interest and compulsory licensing) is skewed in the favour of public interest but is subject to external pressure. As a result of inequality of power between high income and low income countries, TRIPS creates globally applicable minimum standard comprised of flexibilities which are unevenly implemented.

The current balance is high in drug prices, generic entry is delayed, quarantine vaccine is distributed unequally in COVID-19, etc. – the balance of interests is strongly biased to private interest. There is no doubt about innovation, for instance mRNA vaccines come to my mind as being innovative, but the benefits are not always enjoyed. However, there are some legal flexibilities such as compulsory licensing and patent pools that would to some extent help, but their potential remains limited because they are hampered by political opposition and big industry lobbying. Nevertheless, there are other promising modes (PPPs with

[20] Thomas Pogge, 'Human Rights and Global Health: A Research Program' (2005) 36 Metaphilosophy 182, 195.

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implied access conditions or global solidarity funds rethought completely from the ground up to safeguard public health before profits).

Conclusion

Patent law frameworks as existing today principally serve private sector interests by inhibiting the investments in biomedical research at a cost to public health oriented social policies (including, but not limited to, government policies), particularly in the Global South. Office regional co-ordinating investigations were conducted on US, EU but also EU while contrasting these with Indian systems discover a steady further of a crosslag between the hand of IP to study while concurrently encumbering potential inequity to invariable usefulness drugs. For example, patent regimes create the heady R&D conditions in the US and EU that produce mRNA vaccines.

Although, this innovation isn't free, but in return, it features high drug prices, evergreening via extended exclusivities and limited access to poorer countries. The unequal use of IP protections like barriers to broader dissemination of vaccines in the COVID-19 pandemic was starkly highlighted by the imbalance: the monopolization of vaccines by the rich countries in the early phase of the pandemic.

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