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BALANCING INNOVATION AND ACCESSIBILITY: PATENTS IN INDIA'S PHARMACEUTICAL INDUSTRY

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ABSTRACT

The pharmaceutical sector is a pillar of innovation, and research and development (R&D) is mostly driven by patents. Patents give pharmaceutical businesses the certainty they need to invest in the costly and time-consuming process of medication research by giving exclusive rights. India, a world leader in pharmaceutical manufacturing, especially in the generics sector, has improved its innovation environment by utilising patents to solve the issues of pricing and accessibility. Pharmaceutical businesses can develop ground-breaking treatments and technology with the help of patents, which are essential for promoting innovation. But they also pose moral and financial conundrums, especially in light of exorbitant prescription costs and the limited supply of life-saving drugs in developing nations. India's distinct strategy, which emphasises affordability and innovation, emphasises how crucial it is to strike a balance between the two goals of promoting innovation and protecting public health. This study looks at how patents support pharmaceutical innovation in India and how they affect the R&D environment, accessibility, and the economy. It also explores current developments that have changed the sector, like the emergence of biologics, biosimilars, and collaborative innovation models. The study emphasises the necessity of policies that prioritise fair access to medications, promote technological transfer, and expedite patent procedures. By tackling these issues, India can maintain its position as a leader in the pharmaceutical industry worldwide and show that public health and innovation don't have to conflict.

Keywords: Innovation, Patent, pharmaceutical sector, Research & development, Technology.

1. INTRODUCTION

Among all such technological spheres, drugs and pharmaceuticals fit this definition of globalisation the closest and most need a strong IP system to be protected. Knowing that the cost of introducing a new drug into the market may cost a company anywhere between $ 300 million to $1000 million along with all the associated risks at the developmental stage, no company will like to risk its IP becoming a public property without adequate returns. Creating, acquiring, protecting, and managing IP must be turned into a corporate activity as raising resources and funds is being done. The knowledge revolution we are sure to witness shall call for a special pedestal for IP and treatment in the overall decision-making process.[90]

Competition in the global pharmaceutical industry is driven by scientific knowledge rather than manufacturing know-how and a company's success will be largely dependent on its R&D efforts. Therefore, investments in R&D in the drug industry are very high as a percentage of total sales; reports suggest that it could be as much as 15% of the sale. One of the main problems in this sector is the management of innovative risks while one tries to achieve a competitive advantage over competing organisations. There is a high cost attached to the risk of failure in pharmaceutical R&D with the development of potential medicines that are unable to meet the

[90] Angell, M. (2000). The pharmaceutical industry—to whom is it accountable?. *New England Journal of Medicine*, *342*(25), 1902-1904.

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stringent safety standards, being terminated, sometimes after many years of investment. It will take about 8-10 years from the date when the compound was first synthesised for those medicines that actually clear development hurdles. Since product patents have emerged as the major tool for protecting IP, drug companies will have to shift the focus of R&D from development of new processes for producing known drugs toward developing a new drug molecule and new chemical entity (NCE). During the 1980s, following a few decades of successfully treating a number of short duration diseases, the R&D focus shifted towards long duration diseases, i.e. chronic diseases. While scouting for the global market, one needs to ensure that all requirements, different regulatory authorities must be met.[91] It is known that the documents submitted to regulatory authorities have nearly tripled in the last ten years. Moreover, regulatory authorities now take much more time to pass a new drug. Thus, the period of the patent protection gets decreased and therefore extra efforts are needed in order to earn enough profits. The situation may be more severe in the case of drugs developed through the biotechnology route especially those involving utilisation of genes. It is likely that the industrialised world would soon start canvassing for longer protection for drugs. It is also possible that many governments would exercise more and more price control to meet public goals. This would on one hand emphasise the need for reduced cost of drug development, production, and marketing, and on the other hand, necessitate planning for lower profit margins so as to recover costs over a longer period. It is thus obvious that the drug industry has to wade through many conflicting requirements. Many different strategies have evolved during the last 10 to 15 years for cost containment and trade advantage. Some of them are outsourcing of R&D activity, forming R&D partnerships and establishing strategic alliances.[92]

2. ESTABLISHING AND POLICY CHALLENGES OF IPR IN GLOBAL PHARMACEUTICAL MARKETS

The pharmaceutical industry involves not only manufacturing and distribution but drug discovery, Research & Development ("R&D"), planning, mapping and pricing of lifesaving medications. Intellectual property rights ("IPR") in pharma involve patents, trademarks, copyright, trade designs, and trade secrets, which help greatly in placing these medicines on the market. The interface between the pharmaceutical industry and IPR helps innovators protect inventions and get exclusive trade monopolies and monetary rewards. India has emerged as a global leader in the production and export of generic medicines and life saving vaccines all over the world. There is deep involvement of different IPR laws in the boosting of growth and development in this field. IPRs are generally understood to have two principal areas of impact in pharmaceuticals. First, there is the pricing and access issue, with debates centering on links among IPRs, most especially patent rights, competitor exclusion, and new drugs availability and price. This would be issues of incentives in R&D or rather, the function of IPRs as incentives for discovering, developing and bringing to the market new drugs and how IPRs impact the R&D expenditure as well as how it gets distributed among different diseases, countries and other organisations. The two topics are certainly interconnected and pose, therefore, a chain of some very tricky economic problems and policy dilemmas.[93]

Even within a single-country scenario, IPRs have faced quite serious challenges in achieving the proper balance between "static" consumer benefits in the form of relatively low prices and competitive drugs and "dynamic" innovations yielding new products. A rising R&D cost along with an abnormally short effective patent life places the whole burden of such pressure on this

[91] Lexchin, J. (2005). Intellectual property rights and the Canadian pharmaceutical marketplace: where do we go from here?. *International journal of health services*, *35*(2), 237-256.

[92] Mrudula, B. S., Durgadevi, N. K., Madhavi, B. R., Tejeswi, B., & Durga, P. V. (2010). Intellectual property rights pinpoint at IPR spotlights coveted R&D. *Drug Invention Today*, *2*(3).

[93] https://naiknaik.com/2024/06/27/pharmaceutical-industry-ipr-in-india-balance-between-innovation-access/

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industry. On the other, notwithstanding very substantial economic and health benefits associated with innovation in pharmaceuticals, even in relatively wealthy countries high prices for on-patent drugs tend to raise difficult political questions relating to equity and access for low-income or disadvantaged groups, and for setting priorities in allocating public health care budgets.

In principle, IPRs could support considerable (and potentially welfare-maximising) differential pricing across countries that reflects income differences and differences in demand's sensitivity to prices.

Yet such differences in price could themselves become another source of both domestic and international controversy, such as where governments in a number of developed countries impose regulatory action on the domestic prices of drugs that are under patent to reduce them to monopsony purchaser prices is seen by those who have to pay much higher prices as "free riding", but it is uncertain how far this can continue. Differential pricing also induces parallel or "grey market" trade, especially for products like pharmaceuticals that are easily transported. However, if significant arbitrage-induced trade of pharmaceuticals occurs, then while prices will fall in the importing country, they will also tend to rise in the exporting country. Thus, while parallel trade may provide cheaper drugs in some contexts, it may undermine the ability of producers to charge lower prices in lower income countries and affect their willingness to supply countries or distributors who serve as entrepôt facilities.

In addition, large volumes of legitimate products being bought for arbitrage purposes can provide openings for fraudulent or inferior manufacturers to get into the supply chain too, especially when products are repackaged or transshipped through several countries, making origin difficult to trace. Counterfeiting of drugs – manufacture of clandestine copies of the products of approved manufacturers, which are often packaged in such a way as to lead the consumer astray as to their origin and contain poor quality, incorrect, absent or impure ingredients – is said to be an emerging problem outside the most stringently regulated markets, although its extent is impossible to measure. Most important, for any particular country, the inherent trade-offs of IPR policy decisions in this sector are decidedly contingent upon the institutions and operation of its health-care system and the extent it has either domestic pharmaceutical research and development or manufacturing capability. Much attention has recently been paid to the IPR policy choices and the changing pharmaceutical markets of countries such as Brazil, China, and India, and the highly contentious and very public discussions about pricing and access to HIV/AIDS drugs in sub-Saharan Africa. We should be cautious not to generalise from such unique cases.

It is complex and consequently demands careful empirical analysis. However, there are also a number of rather serious gaps in our knowledge, especially as regards development of data that would support informative research into the impact of IPRs in this sector.[94]

3. GOVERNING RULES

The Indian legislation dates quite back with respect to the pharmaceutical industry, but the laws were stagnant and not compatible with the rampant industrialization and globalisation.

The developed countries were the largest holders of the IPR, and it was important for the laws of the developing nations to be in accordance with trade purposes. The first legislation for the Indian patent system was launched under British rule in 1857. A significant reform in the whole patent system came in India, having become a signatory to the TRIPS Agreement in 1995, was put under obligation to alter its patent law in such a manner so as to become compatible with the provisions of this international agreement. This first amendment came in 1999 when the Patents (Amendment) Act, 1999 conferred pipeline protection until pharmaceutical inventions received product patents. It put in place a framework for lodging

[94] https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1012-chapter5.pdf

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product patent applications in the fields of drugs and agrochemicals from January 01, 1995, onwards, and enabled the grant of Exclusive Marketing Rights for specific applications. To meet the second piece of TRIPS obligations, India further amended the Patents Act of 1970 through the Patents (Amendment) Act of 2002. Through this amendment, a 20-year unit patent term was provided for all categories of inventions, namely, patents will now have a fixed term of 20 years counted from the date of filing a patent application.

4. TRIPS AGREEMENT & THE PHARMA MARKET

In managing trade disputes and maintaining flexibility, India signed the Trade-Related Aspects of Intellectual Property Rights, or "TRIPS," agreement in 2005. It is an international legal agreement between the member nations of the World Trade Organization. Its purpose is to set minimum standards of IPR protection on an international level, while members are allowed to maintain regimes stricter than required. The Doha Declaration, 2001 on TRIPS advocates for flexibilities in favour of public health, access to medicine and encouraging innovation.

Compulsory licences, exclusion of new forms of known drugs from patent protection, parallel importation etc., are some of the flexibilities offered by TRIPS. Indian Pharma, in the post-TRIPS growth, has reached an unbelievable level and thus termed as the 'pharmacy of the world' commanding nearly 20% of the global pharma supply chain. Such high demand in the generic drug market has helped pharmaceutical companies like CIPLA, Dr. Reddy's, Sun Pharmaceutical, Natco Pharma, etc. to become the leading manufacturers and distributors. The supply chain of generic medicines has especially proved the test of time during the COVID pandemic as an outcome of parallel importation under TRIPS. Though India is facing the market, statistically, it has been self-sustaining and this aspect has helped improve the economy through exportation of medicines.

5. THE ROLE OF IPR IN PHARMACY

In the world of rapidly changing pharmaceuticals, intellectual property rights are essential to protecting innovation, encouraging research and development, and fair competition. Protection of intellectual property is vital for the growth of the pharmacy industry because it encourages creativity, fosters investment, and incites the development of groundbreaking medicines.

Encourage Innovation and Research

The legal protection of innovative ideas and discoveries of pharmaceutical companies is done by intellectual property rights that consist of patents, copyrights, and trademarks. Exclusive rights are given to the inventor through patents, where inventions can be protected and the invested money recovered through commercialization. Since patents give a limited monopoly, companies are more encouraged to invest in research and development, knowing their discovery will be protected and thus provide them with a competitive edge in the market.

Promote access to Safe, Effective Medicine

Intellectual property rights bring about a balance between the encouragement of innovation and the access to low-cost medicines. Patents confer exclusive rights but for a limited period, leaving room for exclusivity when pharmaceutical companies can recover their investments. After the expiry of the patent, generic copies of the medicine can be made, and competition increases as prices come down. It encourages innovation but allows patients around the world to have safe and effective medicines at affordable costs.

Fostering Interagency Collaboration and Technology Transfer

Such IP protection in the pharmacy business also fosters cooperation and technological transfer. There is mutual cooperation among various pharmaceutical businesses through partnerships, licensing deals, and collaborative research towards combining their resources, skill sets, and expertise in new medications. The presence of some level of guarantee in such respects provides the platform for this inter-

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resourcefulness among them and can therefore contribute to accelerated discovery and eventually to the greater benefit of patients.

Booster Economic Growth and Employment

Pharmacy sector is one of the main contributors to economic growth and job creation in many countries. Strong intellectual property protection attracts investments and encourages pharmaceutical firms to set up research and manufacturing facilities, thereby generating high-quality jobs. Moreover, robust IPR laws and implementation mechanisms enhance the overall business environment and ensure that foreign direct investment flows in with supportive entrepreneurship.

Safeguarding Quality Standards and Patient Safety

In a very important way, intellectual property rights also protect patients' safety because of the role they play in quality standards within the pharmaceutical industries. Intellectual property rights therefore prohibit the unlawful manufacture or marketing of counterfeit drugs or inferior drugs, so that patients' health is not compromised, trust in providers of healthcare is maintained, and integrity in pharmacy is protected.[95]

6. PATENT PROTECTION AND STRATEGIC ALLIANCES

Licence Agreement and joint ventures

Generally, patent holders licence their technologies to other firms to enable the distribution of those technologies in different regions or for handling specific production capabilities. These types of alliances are vital to the biopharma industries because the companies can be missing specific competencies, such as manufacturing biologics. In such a case, firms will seek partnership with others who possess competencies in specific processes. For example, a leading pharmaceutical firm may be licensed to utilise a patented compound via a biotech start-up which utilises advanced genetic engineering in the development of the product.

Corporate R&D and Intellectual Asset Sharing

Firms increase cooperation in conducting R&D whereby firms jointly work together while leveraging assets like knowledge and proprietary technologies with market access. Patent rights instil the confidence which gives assurance of firms whose assets cannot be stolen thus the firm partner up their innovative activities such as producing the joint COVID19 vaccine manufactured by Pfizer/BioNTech.

Joint ventures and cross-licensing

Some companies have established joint ventures or cross-litigated patents in developing a common resource pool and furthering market reach. Joint ventures are most useful with the development of cell and gene therapies, which might divide expertise and split the costs of individual risks. They can be supported through the protections of patents, providing a definition of rights as well as shares of revenue for any company involved in such ventures. This can help promote more secure and effective agreements.

7. CHALLENGES FOR INDIAN HEALTHCARE SYSTEM

Despite its robust pharmaceutical industry, India cannot provide affordable health care and medicines to its poor and marginalised populations for various reasons. Patent medicines are usually the costliest because they have expensive prices to recover the huge cost of expenses during R&D and manufacturing incurred by the owning companies. As observed in the case *Bayer Corporation v. Natco Pharma* the Court granted a compulsory license to Natco Pharma Ltd. under section 84 of the Patent Act, 1970. Comparing the price point, accessibility and fulfilment of the public demand by Natco Pharma, a generic medicines manufacturer was awarded a compulsory licence for the patented, expensive drug 'Nexavar'. Foreign corporations do not want to lose their monopoly in the market. Patent application is filed for introducing a new drug with just slight difference in the composition from

[95] https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1012-chapter5.pdf

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the original one. The process is termed as evergreening. It keeps the drug out of public domain and, as a consequence, the drug would not reach the bulk of people. The Supreme Court defined the scope of Sec 3(d) of the Patent Act 1970 by historic judgments delivered in *Novartis v. UOI*, which prohibits the evergreening of patents.

The Patents and Designs Act of 1911 established a product patent system for all inventions in India. However, pharmaceuticals and agrochemical goods were not eligible for patents when the government issued the new Patents Act in 1970. This exclusion was put in place to help India become less dependent on imports for formulations and bulk medications and to allow for the growth of an independent domestic pharmaceutical sector. The absence of protection for pharmaceutical and agrochemical product patents had a major effect on the Indian pharmaceutical industry and led to the development of a great deal of expertise in reverse engineering drugs that are unprotected in India but patentable as products throughout the industrialised world.

Because of this, the Indian pharmaceutical industry expanded quickly by creating less expensive versions of several patented medications for the Indian market. When the worldwide patents on these medications expired, the Indian pharmaceutical industry then aggressively entered the global market with generic medications. The Patents Act also offers other protections to improve access to medications and stop the misuse of patent rights. However, recent changes to the Drug Price Control Orders from 2013 and 2021 have once again led to the entry of foreign competitors.

The government's decision to guarantee universal access to necessary items, rather than giving patent holders' exclusive priority, is reflected in the Patents Act's provisions permitting compulsory licensing. Anybody interested in working on the patented invention may apply for a compulsory licence with regard to the invention once three years have passed since the patent was sold. The Controller of Patents can only order the patent holder to grant a licence on terms that may be considered appropriate if she is convinced that the patented invention is not reasonably priced or that the public's reasonable requirements have not been satisfied.

8. STRATEGIC IPR REFORMS TO HARMONISE INNOVATION WITH ACCESS TO LIFESAVING DRUGS

Strengthening the Compulsory Licensing System

Compulsory licensing is a TRIPS Agreement provision that grants the government's permission to issue approval for generic versions of patented drugs without the consent of the patent holder, specifically in circumstances where public health is endangered. Such a provision guarantees access while ensuring the rights of the patent holder to get royalties.

- **Streamlining the Process**: It could make compulsory licensing more responsive and less bureaucratic if simplification of procedures for it, especially in public health emergencies, is done.
- **Defining Clear Criteria for Use**: Defining clear guidelines of when compulsory licences can be issued, such as in pandemics, severe public health crises, or even situations where essential medicines become unaffordable, can make this tool more effective and predictable.
- **Ensuring Fair Compensation**: Effective royalty structures for compulsory licences ensure that there is a fair compensation to the patent owners with a balance between the incentive for innovation and affordability.

Case Study: In 2012, India granted a compulsory licence for Nexavar, a cancer drug. It sold the same drug at a fraction of its original price, increasing its accessibility significantly.

Application of Tiered or Differential Pricing Models

Tiered pricing will allow pharmaceutical companies to price drugs according to the economic realities of a country. This pricing strategy may make drugs affordable in Low and

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Middle Income Countries (LMIC) while maintaining the profitability level in high-income marketplaces.

- **Structured Guidelines for Pricing**: Governments and international institutions could collaborate on guidelines that promote fair pricing according to local economic conditions, such as GDP per capita.
- **Transparency in Pricing**: It would make pharmaceutical firms reveal their pricing structures and foster a balance and slow the rate of astronomical markups of drugs in LMICs.
- **Rewarding for Compliance**: Tax incentives and subsidies are likely to be used to draw out tiered pricing from firms without governmental dictate.

Case Study: Gilead Sciences is using price tiering for HIV as well as hepatitis drugs at very cheap prices in developing countries which make it accessible without decreasing the overall profitability.

Encouraging Public Private Partnerships

- **Government-Backed Funding for PPPs**: Governments may provide grants or tax relief to motivate companies to collaborate on R&D programs for drugs that are basic in nature.
- **Co-sharing Joint Ownership of IP**: A process through which public entities can partner with pharmaceutical companies by agreeing to share the IP, thereby cutting down costs and risk for the companies while ensuring access.
- **Flexible Terms Licensing of IP**: This process occurs in PPPs, through agreements whereby governments and companies would undertake flexible terms of the agreement, such as in PPPs, allowing low-income countries to produce generics if and when the primary markets had been satisfied.

Case Example: The Medicines for Malaria Venture is a PPP that has successfully developed and distributed antimalarial drugs by combining funding from public sources with pharmaceutical expertise.

Reducing Patent "Evergreening" Practices

Evergreening refers to minor alterations of already existing drugs, which extends patent exclusivity, and hence, may postpone the advent of affordable generics.

- **More stringent standards of patentability**: granting patents only for really innovative variations, but not minor alterations, may limit evergreening.
- **Enforcing Section 3(d) Standards**: Section 3(d) of Indian Patent Act is the most spectacular example of curtailing patentability on minor drug modifications. Such standards need to be exercised globally, which would obviate evergreening.
- **Transparency in patent extensions**: Disclosing a basis by the companies requesting patent extension would ensure that only relevant improvements are rewarded with prolongation of protection.

Case Example: The landmark Novartis AG v. Union of India decision vindicated Section 3(d), which prohibits patents for new drugs that are modifications of known substances.

Patents Pool for Essential Medicines

A patent pool is an arrangement in which several patent owners pool their patents with one entity, and generic producers gain access to patented technologies. Such a global patent pool could target drugs that are critical in the treatment of infectious diseases and other global health priorities.

- **Establish WHO-Administered Patent Pools**: A WHO-administered patent pool would serve to manage IP for essential medicines, allowing for generic production in low-income markets, but compensating patent owners.
- **Royalties of the Pool for Patentees**: Generics manufactured within the pool may provide financial benefits to patentees, especially in terms of rewarding them by providing access.
- **Expansion of Benefits**: Non-

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communicable disease drugs, such as drugs for diabetes or cancer, may be included under the pool's coverage benefit, which is an expanding feature of the NCD burden among LMICs.

Case Example: The Medicines Patent Pool (MPP) has successfully enabled accessible treatment for HIV, hepatitis C, and tuberculosis through obtaining voluntary licences from pharmaceutical companies.

Prize Funds and Government Incentives for Critical Innovation

Prize funds and government incentives may offer an additional reward for pharmaceutical companies in delivering new treatments for specific conditions with high public health needs where the market incentive system is less robust.

- **Government-sponsored Prizes**: Breakthroughs in a particular area might have prizes for drugs on issues like antibiotic-resistant infections; innovation will be encouraged with minimal reliance on patent-based systems.
- **Tax Incentives or Grants**: Tax incentives or grants could help to develop R&D on drugs for priority diseases that will take long times to recover costs such as vaccines for tropical diseases.
- The incentive will be established in regard to making the milestone payments for attaining a particular goal in some defined R&D areas as concerns target disease, cutting at first expense risk at the front-stage R&D stage.
- The HIF approach rewards companies on the line basis of health impact along its drugs produced, treatments particularly to under-serviced markets thereby linking them by making financial incentives dependent with results seen in terms of healthy results.

Harness Technology Transfer and Capacity Building

Technology transfer enables low-income countries to acquire the required knowledge and skills to locally produce their drugs, making them capable of self-reliance in the manufacture of essential medicines.

- **Promote Domestic Manufacturing**: Rich countries as well as multilateral institutions may encourage these technology transfer agreements that also improve capacity-building in Low-Income Countries so that they are empowered to manufacture the drugs there.
- **Incentives for Voluntary Licensing**: Multinational pharma firms can be incentivized to licence technology to companies in low-income countries to help bridge the gap in production capacity.
- **Local IP Hubs**: International institutions can develop regional hubs for IP and innovation, which will train LMICs in R&D, manufacturing, and regulatory processes.

Case Example: In order to facilitate sharing of data and technology related to expanding global manufacturing capabilities during the pandemic, WHO created the COVID-19 Technology Access Pool (C-TAP).

Removing Post-Patent Expired Barriers to Generic Entry

This will promote entry of generics quicker after patent expiry without upsetting the incentives for innovation.

- Expedite regulatory approvals of generics to be available in the market as soon as the patent expires.
- Reduce litigation barriers that may prevent generic entry either by delaying the entry or using the regulatory process and, thus reduce unnecessary delays to access.
- Promote competitive generic markets through policies which create incentives for competition amongst the generic manufacturers, like tax benefits to multiple players that can keep the price low for the patients.

Case Example: Provisions in the U.S. Hatch-Waxman Act includes post-patent encouraging generic competition provisions, such as streamlined regulatory pathways.

9. CONCLUSION:

The pharmaceutical sector carries huge costs of

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R&D and the time it takes to produce a new treatment, where patent protection has become increasingly important for making returns from investment. Patent protection in this sector helps provide an exclusive time-bound monopoly, facilitating the discovery of new treatment options. However, the exercise of patent control does come with implications that impact accessibility and affordability to drugs. In low-income regions,differential pricing through compulsory licences and public-private partnerships should be used to find ways for improving access without deterring innovation.

India is an outstanding example of how a developed country, or a developing nation for that matter, could shape flexible IP policies in line with the interests of both the innovator and the society. With a dominant status in generic drugs production all over the world, its patent system aligns it with international standards through the TRIPS while providing some room for mechanisms such as compulsory licensing, thereby keeping in hand the balance for local production requirements. Bayer Corporation v. Natco Pharma and Novartis v. Union of India cases establish a place for limitations imposed on "evergreening," a practice otherwise limiting the production of inexpensive generics. Improving IP policies that balance better incentives for innovation with equitable access to medicines is the next step. Some steps that can be taken to address these problems include building up the system of compulsory licensing, adoption of tiered pricing, and facilitation of technology transfer. Continued reform by the pharmaceutical industry will promote innovation and ensure better health for all populations while ensuring access to lifesaving treatments to those in need.