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**PHARMACEUTICAL PATENT AND RIGHT TO HEALTH**- Deepika Sejwal<sup>1</sup>**Abstract:**

Pharmaceutical patents serve as critical incentives for innovation in the development of new drugs, granting inventors exclusive rights to their creations for a limited period. However, the intersection of these patents with the right to health presents complex ethical and human rights challenges. While patents encourage investment in research and development, they can also impede access to essential medicines, particularly in low- and middle-income countries where affordability is a significant concern.

This abstract examines the tension between pharmaceutical patents and the right to health, exploring how intellectual property rights can sometimes conflict with public health objectives. It discusses various mechanisms, such as compulsory licensing, differential pricing, and patent pools, that have been proposed and implemented to balance innovation incentives with the need for affordable medicines.

By analyzing the global landscape of pharmaceutical patents and access to medicines, this abstract underscores the importance of finding equitable solutions that promote innovation while ensuring the realization of the right to health for all individuals. It highlights the ongoing debate among policymakers, pharmaceutical companies, and advocacy groups regarding the appropriate balance between intellectual property rights and public health imperatives in the pharmaceutical sector. Ultimately, addressing this complex issue requires a nuanced approach that considers the interests of all stakeholders and prioritizes the well-being of patients worldwide.

**INTRODUCTION**

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The development and implementation of pharmaceutical patents have revolutionized the landscape of healthcare by incentivizing innovation, driving research and development, and ultimately bringing life-saving medicines to market. However, the juxtaposition of these patents with the fundamental human right to health raises profound ethical and practical questions. While patents are intended to reward inventors and foster continued innovation, they can also pose significant barriers to accessing essential medicines, particularly for vulnerable populations in low-resource settings.

The Indian pharmaceutical sector has experienced consistent growth and is now a burgeoning high-tech industry. Over the last three decades, numerous private Indian firms have emerged as critical players in the market, capitalizing on factors like favorable government policies and limited international competition. However, as these companies expand beyond domestic borders and face greater global competition, India's economic liberalization is driving significant changes.<sup>2</sup>

India serves as a prime example of this evolution within the pharmaceutical industry. With the opening of its markets to global trade, Indian pharmaceutical firms are reevaluating their long-term strategies and business models. As the importance of safeguarding valuable assets in research and development becomes more pronounced, issues such as intellectual property rights gain increasing relevance.

Efforts are underway to address challenges related to the effective implementation of existing intellectual property laws in India. The government is actively engaged in shaping a patent regime that not only fosters technological advancement but also aligns with international obligations. This concerted effort underscores India's commitment to fostering innovation while navigating the complexities of the global pharmaceutical landscape.

The issue of pharmaceutical patenting in India holds particular significance amid current public health concerns, given India's role as a major supplier of affordable generic drugs. Access to medicines has garnered global attention since the turn of the millennium, with India's inclusion in the Doha Declaration on the TRIPS and Public Health Agreement of 2001.

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<sup>2</sup><https://www.ijddr.in/drug-development/patenting-of-pharmaceuticals-an-indian-perspective.pdf>

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However, India has faced sluggish growth in this area due to limited public health spending and inadequate healthcare infrastructure. The marginalized, economically disadvantaged, and inexperienced segments of society bear the brunt of this disparity, posing a significant challenge in safeguarding the health of millions of vulnerable individuals.

In this context, the role of Indian patent law vis-à-vis the TRIPS Treaty and its impact on the health of ordinary citizens assumes critical importance. Balancing the provisions of these legal frameworks with the imperative of ensuring accessible healthcare for all remains a pressing concern.

### **PATENT – Meaning & Importance**

Patents are issued to safeguard inventions, granting the inventor an exclusive right<sup>3</sup> bestowed by the government. The inventor or an appointed representative can seek this right. It entails the authority to prevent unauthorized manufacturing, usage, offering for sale, sale, or importation of the patented invention. Essentially, a patent represents a negative right, empowering the patent holder to prohibit or halt third parties from utilizing the invention without consent rather than granting the right to create, use, or sell the invention.

Moreover, a patent encompasses the right to authorize others to produce, use, or sell the invention. It signifies an agreement between the applicant or inventor and the government, wherein the government grants protection to the invention for a defined period after full disclosure by the applicant or inventor. In essence, patenting offers a strategic avenue for safeguarding inventions without relying on confidentiality measures.

Patents are only awarded for inventions that fulfill a set of requirements known as the patentability criteria. A patent's maximum validity period is 20 years from the date of issuance<sup>4</sup>. Patents are sovereign rights, but they are only enforceable in the country in which they are issued. A single patent applicant can submit an international patent application in multiple countries through the Patent Cooperation Treaty (PCT). However, after submitting the PCT application, each patent office will still have the final say over whether to grant a patent.

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<sup>3</sup>Wipo.int

<sup>4</sup>Ipindia.gov.in

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## PHARMACEUTICAL PATENTS

Pharmaceutical patents refer to patents granted for inventions related to pharmaceutical products or processes. These patents provide inventors or assignees with exclusive rights to manufacture, use, and sell their pharmaceutical inventions for a specified period, typically around 20 years<sup>5</sup> from the date of filing the patent application.

Pharmaceutical patents play a crucial role in incentivizing innovation and investment in the development of new drugs and therapies. They provide inventors and pharmaceutical companies with exclusive rights to their inventions, allowing them to recoup the significant costs associated with research, development, and regulatory approval.

However, granting pharmaceutical patents also raises essential considerations related to access to medicines, public health, and affordability. Balancing the need to incentivize innovation with the imperative of ensuring access to essential medicines for all individuals remains a complex challenge for policymakers, pharmaceutical companies, and public health advocates. Strategies such as compulsory licensing, patent pools, and differential pricing have been proposed to address these challenges and promote equitable access to pharmaceutical innovations.

## RIGHT TO HEALTH

The "right to health" and the area of patent law intersect in complex ways, particularly concerning access to essential medicines. The right to health is recognized as a fundamental human right, encompassing access to timely, acceptable, and affordable healthcare services and basic medicines.

In the context of patents, the right to health raises essential considerations regarding access to patented pharmaceuticals, especially in low- and middle-income countries where affordability can be a significant barrier to access. Patents grant pharmaceutical companies exclusive rights to manufacture, use, and sell their inventions, often leading to high prices for patented medicines.

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<sup>5</sup>Mondaq.com

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Human rights are claims held by individuals against the state by their humanity. At root, we see that human rights are those that people deserve to have realized irrespective of their legal regime.

Access to health care focuses mainly on the availability of medical care as part of a person's right, the various international conventions like the Universal Declaration Of Human Rights, 1948<sup>6</sup>, the International Covenant on Civil and Political Rights, 1966<sup>7</sup>, the International Covenant on Economic, Social and Cultural Rights, 1966<sup>8</sup>, Convention on the Elimination of all forms of Discrimination Against Women, 1979<sup>9</sup>, and Convention on the Right of the Child, 1989<sup>10</sup>, recognize access to health care at the international level. Article 27(2) of the Universal Declaration of Human Rights (UDHR) and Article 15(1) (c)<sup>11</sup> of the International Covenant on Economic Social Cultural Rights (ICESCR) try to equate IPRs with other types of human rights; this has led some authors to conclude that they provide a human rights basis for patent rights and other forms of IPRs<sup>12</sup>.

This situation can conflict with the right to health, as high prices may limit access to essential medicines, particularly for disadvantaged and marginalized populations. In response, there have been debates and initiatives to strike a balance between protecting intellectual property rights and ensuring access to medicines as a fundamental human right.

## RELATIONSHIP BETWEEN PATENT AND RIGHT TO HEALTH

The right to health and patent law are interconnected in several ways, especially concerning access to essential medicines:

**Affordability and Access:** Patents grant pharmaceutical companies exclusive rights to produce and sell their inventions, often leading to high prices for patented medicines. This

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<sup>6</sup>Article 25 Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control, United Declaration of Human Rights, 1948

<sup>7</sup>International Covenant on Civil Political Rights, 1966.

<sup>8</sup>Art. 7, 11 and 12, International Covenant on Economic Social and Cultural Rights, 1966

<sup>9</sup>Art. 10, 12 and 14, Convention on elimination of discrimination Against Women

<sup>10</sup>Art. 24, Convention on the Right of the Child.

<sup>11</sup>Right of everyone to "benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

<sup>12</sup>Joseph Millum, "Are Pharmaceutical Patents Protected By Human Rights?" 25 Journal of Medical Ethics 34 (2008).

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can pose a barrier to access to essential medicines, particularly for individuals and communities with limited financial resources. Thus, the right to health, which encompasses access to affordable healthcare services and medicines, is directly affected by the pricing and availability of patented drugs.

**Public Health Concerns:** The right to health includes the right to access preventive, curative, and palliative healthcare services, including essential medicines. In situations where patented medicines are unaffordable or inaccessible, it can impede individuals' ability to realize their right to health. This is particularly relevant in the context of infectious diseases, chronic conditions, and other public health crises where access to medicines is critical for disease prevention, treatment, and control.

**Intellectual Property Rights and Access:** Intellectual property rights<sup>13</sup>, including patents, are designed to incentivize innovation by granting inventors exclusive rights to their creations. However, when it comes to essential medicines, patents can sometimes limit access, leading to tensions between protecting intellectual property rights and ensuring access to drugs as a fundamental human right.

**Balancing Interests:** Achieving a balance between protecting intellectual property rights and promoting public health is essential<sup>14</sup>. While patents incentivize innovation and investment in research and development, it is crucial to ensure that they do not unduly restrict access to critical medicines. This requires policymakers, pharmaceutical companies, and other stakeholders to explore mechanisms such as compulsory licensing, patent pooling, and differential pricing to address public health concerns while respecting intellectual property rights.

## ISSUES DUE TO PHARMACEUTICAL PATENT

Pharmaceutical patents can give rise to several issues, especially concerning access to medicines and public health. Some of the critical issues associated with pharmaceutical patents include:

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<sup>13</sup>Wto.org

<sup>14</sup>Oke EK. The Interface between Patent Rights and the Right to Health under International Human Rights Law. In: Patents, Human Rights, and Access to Medicines. Cambridge University Press; 2022:69-103.

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**High Drug Prices:** Patented pharmaceuticals often come with high prices due to the monopolistic control granted to the patent holder. This can result in limited access to essential medicines, especially for patients in low- and middle-income countries who cannot afford expensive treatments<sup>15</sup>.

**Barriers to Access:** Pharmaceutical patents can create barriers to access to medicines<sup>16</sup>, particularly when patent holders enforce their exclusive rights through pricing strategies or litigation. This can delay or prevent patients from obtaining life-saving treatments, leading to adverse health outcomes.

**Evergreening:** Some pharmaceutical companies engage in evergreening strategies, where they make minor modifications to existing drugs and obtain new patents for these modified versions. This extends their monopoly protection and delays the entry of generic competition, further exacerbating issues of affordability and access.

**Patent Thickets:** In some cases, multiple patents may cover a single drug, creating a "patent thicket" that makes it difficult for generic manufacturers to enter the market. This can delay the availability of lower-cost generic alternatives, prolonging the period of high drug prices.

**Impact on Public Health:** Access to affordable medicines is a crucial component of public health. When pharmaceutical patents restrict access to essential treatments, it can have a detrimental impact on public health outcomes, particularly in developing countries where access to healthcare resources is limited<sup>17</sup>.

**Global Health Disparities:** Pharmaceutical patents can contribute to global health disparities by limiting access to medicines in low- and middle-income countries. This exacerbates inequalities in healthcare and perpetuates the cycle of poverty and ill health in vulnerable populations.

**Compulsory Licensing:** In response to concerns about access to medicines, governments may issue compulsory licenses to allow generic manufacturers to produce patented drugs

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<sup>15</sup>Iprd.com

<sup>16</sup>Globalpatentfiling.com

<sup>17</sup> Xu C, Zhu D. On Conflicts between Pharmaceutical Patent Protection and the Right to Life and Health Based on a Stackelberg Game. *Int J Environ Res Public Health*. 2021 Jan 27;18(3):1119. doi: 10.3390/ijerph18031119. PMID: 33513961; PMCID: PMC7908086.

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without the consent of the patent holder. While this can increase access to essential medicines, it can also lead to tensions between governments and pharmaceutical companies<sup>18</sup>.

Addressing these issues requires a multifaceted approach that balances the need to incentivize innovation with the imperative of ensuring access to affordable medicines for all. Policymakers, pharmaceutical companies, civil society organizations, and international institutions must work together to develop solutions that promote innovation while safeguarding public health and ensuring equitable access to medicines.

## **SOLUTION FOR THE PROBLEM OF PUBLIC ACCESS TO HEALTH**

Improving public access to healthcare while considering the impact of patents requires a balanced approach that promotes innovation while ensuring the affordability and availability of essential medicines. Here are some potential solutions:

**Patent Pooling:** Encourage pharmaceutical companies to participate in patent pooling initiatives, where multiple patent holders voluntarily share their intellectual property rights to essential medicines. This can facilitate broader access to patented drugs by allowing generic manufacturers to produce and distribute affordable versions of these medicines in low- and middle-income countries.

**Compulsory Licensing:** Utilize compulsory licensing provisions within patent laws to allow generic manufacturers to produce patented medicines without the consent of the patent holder in cases of public health emergencies or when access to essential medicines is restricted due to high prices. This mechanism helps ensure access to life-saving treatments while safeguarding public health interests.<sup>19</sup>

**Negotiated Pricing Agreements:** Governments and international organizations can negotiate pricing agreements with pharmaceutical companies to ensure that patented medicines are affordable and accessible to patients in need. These agreements may include tiered pricing models, differential pricing based on income levels, or voluntary licensing arrangements to facilitate generic production and distribution.

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<sup>18</sup>Wei C. The influenza A/H1N1 epidemic and compulsory licensing of drug patents.

<sup>19</sup>Li Z. Implementation to compulsory license system of the pharmaceutical patent in China. *Tribune Political Sci. Law.* 2017;

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**Research and Development Incentives:** Implement incentives for pharmaceutical companies to prioritize research and development (R&D) efforts towards the development of medicines that address unmet medical needs and public health priorities. This may include offering tax incentives, research grants, or market exclusivity for innovative treatments that demonstrate significant public health benefits.

**Technology Transfer and Capacity Building:** Facilitate technology transfer and capacity building initiatives to enable developing countries to produce generic medicines locally and reduce dependence on imported pharmaceuticals. This includes supporting technology transfer agreements, knowledge-sharing partnerships, and investments in local manufacturing infrastructure and regulatory capacity.

**Flexibilities in Trade Agreements:** Advocate for the incorporation of flexibilities in international trade agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to safeguard public health interests and ensure access to medicines for all. This may include preserving the right of countries to utilize compulsory licensing and other public health safeguards without undue trade restrictions.

**Public-Private Partnerships:** Foster collaboration between governments, pharmaceutical companies, civil society organizations, and international institutions through public-private partnerships to develop sustainable solutions for improving access to healthcare and medicines. These partnerships can leverage the strengths and resources of each stakeholder to address complex challenges and promote equitable access to health services.

By implementing these solutions in a coordinated manner, it is possible to mitigate the barriers to public access to health posed by patents while fostering innovation and improving health outcomes for all individuals and communities.

## Conclusion

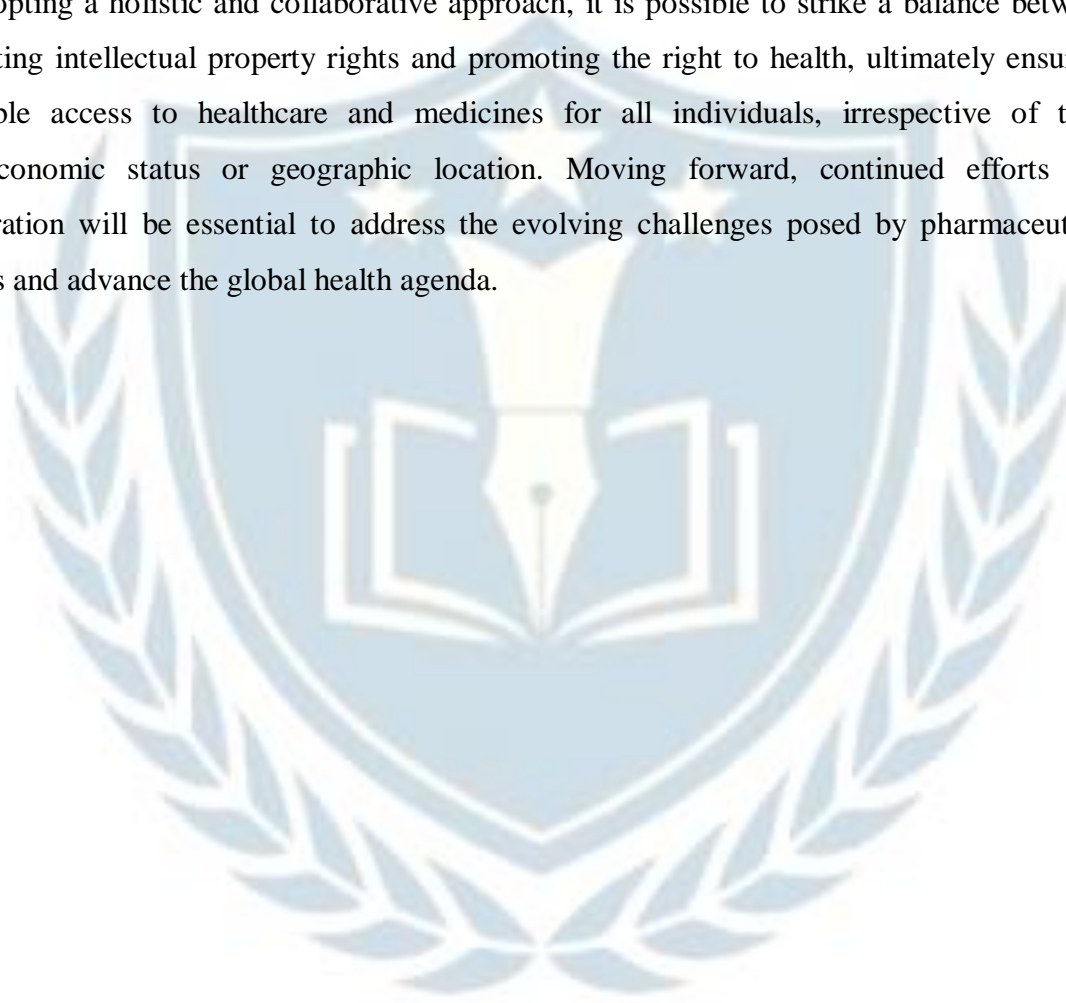
In conclusion, navigating the intersection of pharmaceutical patents and the right to health requires a delicate balance between promoting innovation and ensuring access to essential medicines for all individuals. While patents play a crucial role in incentivizing research and development of life-saving treatments, they can also create barriers to access, particularly for vulnerable populations in low- and middle-income countries.

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To address this complex issue, policymakers, pharmaceutical companies, civil society organizations, and international institutions must collaborate to develop and implement comprehensive strategies that promote innovation while safeguarding public health. This includes leveraging flexibilities within patent laws, promoting generic competition, negotiating affordable pricing agreements, and investing in capacity-building and technology transfer initiatives.

By adopting a holistic and collaborative approach, it is possible to strike a balance between protecting intellectual property rights and promoting the right to health, ultimately ensuring equitable access to healthcare and medicines for all individuals, irrespective of their socioeconomic status or geographic location. Moving forward, continued efforts and cooperation will be essential to address the evolving challenges posed by pharmaceutical patents and advance the global health agenda.



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