Legal issues on patent law as per pharmaceutical company

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Abstract:

The overlap of patent law and the pharmaceutical industry requires a careful approach to balancing the need for innovation with public health considerations. A patent provides inventors with exclusive rights to their new, non-obvious, and industrially applicable inventions, allowing them to manufacture, utilize, and market the product for 20 years in accordance with the Patents Act of 1970. In the pharmaceutical sector, patents are essential for safeguarding the expensive and lengthy research and development process; however, the actual duration of market exclusivity is frequently reduced due to the time required for clinical trials. India's participation in the Patent Cooperation Treaty (PCT) supports international patent applications, while the TRIPS agreement requires that product patents are applicable across all technologies, including pharmaceuticals, along with provisions for public health measures such as compulsory licensing.

India's Constitution supports the right to health through the judicial interpretation of Article 21, which creates a conflict between patent exclusivity and the affordability of medicines. Provisions such as Section 84 (compulsory licensing) and Section 3(d) (preventing evergreening) play a role in maintaining this balance. Prior to the 2005 amendment for TRIPS compliance, India permitted only process patents, which contributed to the development of a robust generic drug sector. The transition to product patents raised concerns about pricing while still keeping health protections in place. Pharmaceutical patents can be rejected due to lack of novelty, inventive step, industrial applicability, or as per exclusions in Section 3. In the case of Novartis AG v. Union of India (2013), the Supreme Court denied a patent for a modified cancer medication on the grounds of insufficient enhanced efficacy.

India's policy demonstrates a complex strategy adhering to TRIPS while emphasizing accessible medication. By denying patents for trivial modifications and employing compulsory licensing, India shows that national regulations can support public health without diminishing incentives for innovation. The persistent challenge is to maintain this equilibrium in the face of international trade pressures and changing health emergencies.

Keywords:

Patent, Patent cooperation treaty, TRIPS, Equilibrium, Efficacy, Licensing.

Introduction:

The pharmaceutical business, where the drive for innovation frequently collides with public health concerns, is significantly shaped by patent rules. An inventor who obtains a patent has the sole right to produce, sell, and distribute their creation for a predetermined amount of time, usually twenty years. Given the substantial amount of time, money, and research required to develop new medications, patents are very important in the pharmaceutical industry. Because they allow businesses to recoup their expenses and turn a profit, these legal protections promote innovation. But there are also complicated issues brought about by this system, particularly with regard to the cost and accessibility of necessary prescription drugs.Pharmaceutical patents are closely linked to international agreements that harmonize intellectual property laws across countries, such as the Trade-Related Aspects of

Intellectual Property Rights (TRIPS). Global patent protection has been enhanced under TRIPS, but it has also raised debates about how to combine advancing innovation with protecting the fundamental right to health. Developing countries, where significant portions of the population lack access to quality healthcare, are hampered when patent restrictions hinder the supply of affordable generic drugs. Mandatory licensing, parallel imports, and public interest exceptions have become legal tools to ease these concerns, albeit they remain contentious.Pharmaceutical patents are closely linked to international agreements that harmonize intellectual property laws across countries, such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS). Global patent protection has been enhanced under TRIPS, but it has also raised debates about how to combine advancing innovation with protecting the fundamental right to health. Developing countries, where significant portions of the population lack access to quality healthcare, are hampered when patent restrictions hinder the supply of affordable generic drugs. Mandatory licensing, parallel imports, and public interest exceptions have become legal tools to ease these concerns, albeit they remain contentious.

Furthermore, legal disputes often arise when patent applications are denied for lacking novelty, inventive step, or industrial application, especially in cases involving evergreening strategies where companies attempt to extend patent life by making minor modifications to existing drugs. Courts and regulatory authorities thus play a decisive role in interpreting patent laws to prevent abuse while fostering innovation. In sum, the pharmaceutical industry highlights the inherent tension within patent law: the need to protect inventors' rights and encourage scientific advancement, while also ensuring equitable access to life-saving medicines. These legal challenges remain central to the global discourse on patents and healthcare.

What is a patent?

One of the most important types of intellectual property rights (IPR) is a patent, which is given by the government to an inventor as the sole legal right to create, utilize, market, or distribute an invention for a set amount of time. A patent, to put it simply, is a governmental monopoly that safeguards a new creation and forbids others from using it for profit without the creator's consent. It serves as a catalyst for technical growth as well as a reward for inventiveness.A patent is defined as a right given for any novel product or technique that incorporates an inventive step and has the potential for industrial use under the Indian Patent Act, 1970 (as modified in 2005).

In order to ensure uniformity of regulations controlling innovation, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1995, establishes basic requirements for patent protection among World Trade Organization (WTO) member states.

An innovation must meet three requirements in order to be eligible for patent protection:

1. Novelty: The invention ought to be brand-new and unreported in previous works.
2. Inventive Step/Non-Obviousness: There must be a creative step that is not readily apparent to an expert in the subject.
3. Applicability/Utility in Industry: The invention must be able to be manufactured or utilized in an industry.

Typically, patents are awarded for 20 years from the date of filing, after which the innovation becomes publicly available for use by anybody. While society eventually gains from unfettered access to information and technology, this time-bound exclusivity guarantees that inventors receive compensation for their labors.

Pharmaceuticals, biotechnology, mechanical engineering, electronics, and information technology are just a few of the many industries that are covered by patent protection. But not everything is patentable. For instance, inventions that violate morality, public order, or environmental health are not included, nor are laws of nature, abstract theories, or simple findings.As a result, patents strike a compromise between the public interest and private rights. By rewarding innovators, they promote innovation, but they also benefit the greater.

As a result, patents strike a compromise between the public interest and private rights. By rewarding inventors, they promote creativity, but they also further the broader goal of disseminating technology by publishing inventions.

As a key component of intellectual property rights, patents are now an essential tool for economic expansion, international trade, and competitive advantage.[1]

Term of patent:

The time frame that the patentee's exclusive rights are in effect is known as the patent's term. Patents are time-limited monopolies that provide inventors the legal power to stop others from producing, utilizing, selling, or distributing their invention without permission under the framework of intellectual property rights (IPR). Following the expiration of this term, the invention enters the public domain and is freely used by society as a whole.

The Patents Act, 1970, which governs India, has undergone substantial revisions to conform to the World Trade Organization's (WTO) TRIPS Agreement (1995). Before the 2005 amendment, product and method patents had varying terms (5 years for some compounds and 14 years for others). Nevertheless, the Act now offers a consistent 20-year patent term for both product and process patents following revision. The 20-year period begins on the date the patent application was filed, regardless of whether it was a complete or provisional application.As required by TRIPS, the typical patent protection period is 20 years worldwide as well. However, in order to make up for delays in regulatory approvals, some jurisdictions may use procedures like patent term extensions or supplemental protection certificates to extend the effective patent life in particular industries, such as biotechnology and pharmaceuticals. It is crucial to remember that simply acquiring a patent does not guarantee that it will remain in effect for the entire 20 years. To maintain the patent's validity, the patent holder must pay yearly renewal costs. The patent may lapse before its natural expiration if such fees are not paid.[2]

Patent Cooperation Treaty:

An international agreement known as the Patent Cooperation Treaty (PCT) offers a consistent method for submitting patent applications in various countries. It is managed by the World Intellectual Property Organization (WIPO). It became effective in 1978 after being completed in Washington in 1970. The PCT simplifies the procedure for seeking patent protection across multiple nations through a single international application, despite the absence of this type of system. Nonetheless, it does not provide "international patents" by itself. Prior to the PCT, inventors seeking protection under the Paris Convention for the Protection of Industrial Property had to submit distinct patent applications in each jurisdiction, frequently in multiple languages, and within a rigorous 12-month window from the initial submission. This procedure was costly, time-consuming, and difficult.

By enabling inventors to submit a single "international application," which effectively seeks protection in every contracting state at the same time, the PCT solves these issues. The PCT's goals are as follows:

1. Making it easier to apply for patents in several nations.
2. Cutting expenses by postponing translations and national filings.
3. Giving applicants a written opinion on the invention's patentability as well as an International Search Report (ISR).
4. Encouraging consistency and effectiveness in the international patent system.[3]

How patent rights in pharmaceutical companies are interrelated to the TRIPS Agreement?

The pharmaceutical industry functions at the crossroads of safeguarding intellectual property and fulfilling public health responsibilities. In this industry, patent rights are essential as the process of discovering and developing drugs demands significant investments in research, clinical trials, and regulatory approvals, which can take more than ten

[1] Patent - Wikipedia https://share.google/2z17zhgLpZXUue0n4
[2] Term of a patent in India and Strategies to reap maximum benefits from the patent term | Invntree https://share.google/2WG9kVvtt0JU5pztm
[3] Patent Cooperation Treaty - Wikipedia https://share.google/65Lj0v3RLU6TPuna3

years and cost billions. Patents grant exclusivity, enabling pharmaceutical firms to recover costs and earn profits, thus encouraging innovation. Nonetheless, these rights are not unconditional. They are greatly influenced by global commitments, especially under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Minimum requirements for intellectual property protection throughout all WTO member countries were harmonized by the TRIPS Agreement, which went into effect in 1995. According to Article 27, patents must be granted for innovations that are novel, inventive, and have industrial applications across all areas of technology, including pharmaceuticals. Additionally, it establishes a consistent patent duration of 20 years from the date of application, which promotes worldwide uniformity. This requirement was a turning point for many developing nations, including India, which had previously outlawed product patents for drugs and only permitted process patents. Acknowledging the delicate balance between public health and innovation, TRIPS includes protective measures. Articles 30 and 31 allow for specific exceptions to patent rights, such as compulsory licensing, enabling third parties to produce a patented medication without permission under particular circumstances. The 2001 Doha Declaration on TRIPS and Public Health reinforced that member countries have the authority to prioritize public health and guarantee access to essential medications. This assertion is vital for developing countries, as it validates actions such as compulsory licensing and parallel importation to tackle pressing health requirements.India has made strategic use of TRIPS flexibilities. Section 84 of the Patents Act allows compulsory licenses if the reasonable requirements of the public are not met, the patented invention is not affordable, or it is not worked in India. The landmark case Bayer Corporation v. Natco Pharma (2012) exemplified this, where a compulsory license was granted for the cancer drug sorafenib (Nexavar) because of its prohibitively high cost. Similarly, Section 3(d) of the Act, designed to prevent "evergreening," limits patents on new forms of known substances unless they show enhanced therapeutic efficacy, consistent with TRIPS but safeguarding public health.[4]

Fundamental Right to health:

The right to health holds a distinctive status at the crossroads of constitutional law, intellectual property rights, and public policy. For pharmaceutical firms, patents act as the foundation of innovation, providing exclusivity that secures the recuperation of substantial research and development (R&D) expenses. Nonetheless, the monopoly provided by patents frequently leads to elevated drug costs, causing a direct clash with the constitutional obligation to accessible healthcare. This dispute emphasizes the conflict between private business interests and societal well-being, presenting important legal challenges. In India, the Constitution does not explicitly guarantee the right to health. Nonetheless, judicial interpretation has recognized it as an essential element of the right to life in Article 21. In the cases of Consumer Education and Research Centre v. Union of India (1995) and Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996), the Supreme Court ruled that access to healthcare and essential medications is vital for maintaining a dignified life. Likewise, Article 47 of the Directive Principles of State Policy requires the state to improve public health and ensure proper nutrition. These conditions necessitate that the government align patent enforcement with its obligations to public health. Pharmaceutical firms, under the Patents Act of 1970, benefit from 20 years of exclusivity for innovations that satisfy the conditions of novelty, inventive step, and industrial applicability. This exclusivity frequently results in high drug costs, making vital medications unreachable for low-income groups. For instance, patented cancer medications such as Glivec and Nexavar were priced well beyond what typical Indian patients could afford. This gap creates legal discussions regarding whether stringent patent enforcement jeopardizes the basic right to health. Indian legislation includes methods to address this conflict. Section 84 of the Patents Act allows for compulsory licensing when patented medications are not accessible, too expensive, or not produced locally. The significant case Bayer Corporation v. Natco Pharma (2012) reinforced this

[4] WTO | Intellectual property (TRIPS) and pharmaceuticals - technical note https://share.google/2qeyTf2uirS0AXRpe

principle by permitting Natco to manufacture a generic alternative to Bayer's cancer medication Nexavar at a much lower price. Moreover, Section 3(d) prohibits the "evergreening" of patents, guaranteeing that only truly innovative drugs are granted protection, as confirmed in Novartis AG v. Union of India (2013).

On the global stage, the TRIPS Agreement, while requiring pharmaceutical patents, allows for flexibility as stated in Articles 30 and 31. The 2001 Doha Declaration reinforced that TRIPS "should not hinder members from safeguarding public health" and affirmed the right to enhance access to medicines for everyone. This acknowledgment reinforces the constitutional dedication to health rights by validating state actions aimed at promoting public welfare.

Pharmaceutical Companies not granted patent rights under patent Act 1970

Pharmaceutical patents hold an essential role in today's legal and economic framework. Patents encourage innovation by providing exclusive rights to inventors, enabling them to recover the significant expenses of research and development (R&D). For pharmaceutical firms, the risks are especially significant, as creating a new medication requires lengthy periods, considerable risks, and large financial commitments. Nonetheless, patent rights within the pharmaceutical industry are not unconditional. According to the Indian Patents Act of 1970, revised in 2005 to align with the TRIPS Agreement, not every invention is eligible for patent protection by default. The Act establishes stringent requirements for patent eligibility and omits specific types of inventions to protect public health, maintain medication affordability, and hinder the exploitation of patent monopolies.

Case laws:

Novartis AG versus the Union of India (2013)

The most significant case involved the denial of Novartis's patent for Glivec based on Section 3(d). The Court concluded that "efficacy" meant "therapeutic efficacy," and since the new drug formulation did not enhance therapeutic outcomes, it could not be patented.

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