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Harmonizing Access to Medicine: Exploring India's Process Patent in Intellectual Property Rights Amid Global Pressures

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ABSTRACT

This paper examines the impact of the pharmaceutical patent system, particularly under the TRIPS Agreement and the Indian Patent Act of 1970, on access to medicines. The TRIPS Agreement aims to balance private and public interests by protecting patent holders while allowing countries to safeguard public health. However, this balance has been contentious, especially in developing countries where patent protections can lead to high drug prices and restricted access to life-saving medications.

India's approach has been pivotal, initially excluding medicine patents under its 1970 Patent Act, which fostered a robust generic drug industry and kept drug prices affordable. With the TRIPS compliance amendments in 2005, India shifted to recognizing product patents, significantly impacting the generic drug market and accessibility of affordable medicines. The amendments, however, incorporated mechanisms such as compulsory licensing and safeguards against patent abuse, reflecting attempts to maintain access to essential drugs.

This study highlights the tension between global intellectual property laws and national public health objectives. It discusses India's strategic use of TRIPS flexibilities and the ongoing challenges posed by stringent global patent policies. The paper argues for the necessity of maintaining a balance that does not compromise public health for intellectual property rights, with a focus on India's role in the global pharmaceutical landscape and its efforts to navigate these competing demands.

Keywords: Access to medicines, TRIPS agreement, Indian patent act, Pharmaceutical patents, Generic drugs.

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INTRODUCTION

Patents give inventors the legal power to stop others from making, using, or selling their new creations for a while, with a few exceptions. But it's important to remember, patents don't automatically mean a green light to sell. According to the TRIPS Agreement, any invention, whether it's a product like medicine or a process like making medicine ingredients, can be protected by a patent for up to 20 years.

TRIPS (The Agreement on Trade-Related Aspects of Intellectual Property Rights) tries to find a balance between private and public interests. It protects the interests of pharmaceutical companies that invest a lot in developing new drugs, while also letting countries look out for the health of their people. But sadly, pharmaceutical patents have hurt countries that are still developing, making it hard for them to make good health policies[1]. For example, these patents have made life-saving drugs way too expensive for most people in the world.

This article delves into how the pharmaceutical patent system, as outlined in the Indian Patent Act of 1970 and the TRIPS agreement, affects regular people's access to medicine. The author wants to shed light on the challenges ordinary folks face and the unfair advantages that patent holders enjoy under this system[2]. Quoting Indira Gandhi's statement at the 1982 World Health Assembly, "The idea of a better ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death".

The patent system isn't just about legalities; it's also a way to encourage innovation. Globally, patent protection is managed by the World Trade Organization (WTO) through the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS don't lay down a single international law but sets minimum standards that all WTO members must meet[3]. Developed countries have already adopted this agreement, and others like India joined in 2005. However, least-developed countries aren't required to do so until 2016.

Medicines can get really pricey when they're still under patent protection. Basically, the company that owns the patent has the exclusive right to sell the drug for about 20 years, and they often use that time to make as much money as possible. But once generic versions hit the market, prices can drop significantly[4]. For example, when Brazil started making generic AIDS drugs back in 2000, the prices dropped by a whopping 82%.

India had people's health in mind when they were negotiating the TRIPS Agreement. Back in 1970, their Patent Act didn't allow patents on medicines, except for the way they were made, and even those only lasted about seven years[5]. This strategy paid off big time over the years, helping India build up a strong industry for making cheaper, generic drugs while keeping essential medicines affordable. During the TRIPS talks, India fought hard to make sure the agreement wouldn't hurt the health of their millions living below the poverty line. That's why they made sure to include provisions from TRIPS and the Doha Declaration when they updated their Patent Act in 1999, 2002, and 2005.

But the problem is, a lot of people still can't get the medicine they need, mainly because it's just too expensive. And a big reason for those sky-high prices is because of strict patent rules. Developing countries that try to lower drug costs often get pressure from richer countries and big pharmaceutical companies. Even though TRIPS has some rules to help out when patents get in the way of medicine, it's not always clear how countries can use those rules effectively.

Back in the day, India didn't have patents for medicines and certain agricultural chemicals, and that was a game-changer for their pharmaceutical industry. They became experts at making knock-off versions of drugs that could be patented in other places but not in India. That helped their industry grow fast, making cheaper versions of drugs for their own market and then breaking into the global market with generic drugs once those international patents expired. Plus, India's Patents Act has a bunch of safeguards to stop companies from abusing their patent rights and to make sure people can still get the medicine they need. When they updated the Patents Act in 2005[6], it was all about keeping their promise to the World Trade Organization and making sure patents were fair for everyone.

Pharmaceutical Patent Regulations Pre-TRIPS Agreement

Before the TRIPS Agreement, India was focused on making sure its people could afford essential medicines. India had a special position among other developing countries because it had a strong industry making generic drugs, which were often much cheaper than elsewhere in the world[7]. A big part of this success was because of the Patents Act of 1970.

This law did two important things: first, it allowed patents for how drugs were made, not just for the drugs themselves. Second, it made the time period for these patents shorter, just 7 years instead of the usual 15[8]. The goal of the Patents Act was to help Indian drug companies grow and make sure people in India could get medicine they needed without it costing too much. Instead of following the old British laws, India started its own system, where companies could make generic versions of drugs without having to pay big fees to the original patent holders.

This change was a game-changer for India's drug industry. Companies could now make their own versions of important drugs and sell them for much less[9]. This made medicines more affordable for everyone in India.

Amendment to the Indian Patent Act of 2005, Compliant with the TRIPS Agreement

The Indian Parliament passed the Patent (Amendment) Bill in 2005, making it the third update to the Indian Patent

Act of 1970. This amendment was in line with the rules laid out by the World Trade Organization's TRIPS Agreement. However, since its implementation on January 1, 2005, there have been concerns about how it affects the local generic drug industry and the availability of affordable essential medicines.

To comply with TRIPS, India changed its patent laws in March 2005. They got rid of the old "process" patents and brought in "product" patents for pharmaceuticals, food, and chemicals, similar to what's seen in the West. This meant Indian pharmaceutical companies lost the protection they had for 36 years[10]. Now, if Indian companies want to make copycat drugs, they have to pay a fair fee to the foreign patent holders. Also, the law made it illegal to copy patented drugs after January 1, 1995.

The new law only allowed two types of generic drugs in India: ones that were no longer under patent protection and ones that were patented before 1995. Luckily, most of the drugs made in India fall into these categories, so they won't be affected[11]. The amendment also made provisions for special licenses to export drugs to countries that don't have enough drug-making capacity of their own.

Another big change was that new patent holders now get a 20-year monopoly from the date they file the patent. This means no one can make generic copies without their permission during that time.

Compulsory Licensing

Compulsory Licensing is a process where a government can grant permission to any company, agency, or designated individual to produce a patented product or use a patented process under license without needing the original patent holder's approval. Under the amended Act, an application for compulsory licensing can be made three years after the patent is granted: "At any time after the expiration of three years from the date of the patent grant, any interested party may apply to the Controller for a compulsory license".

Pharmaceutical Patents under the TRIPS Agreement and Access to Medicines

The World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) has faced criticism due to concerns about increased patent protection leading to higher drug prices. While TRIPS does offer safeguards against negative patent effects or abuse, it's uncertain how countries can effectively use these safeguards when patents become obstacles to medicine access.

The Fourth WTO Ministerial Conference in Doha, Qatar, in 2001 adopted a Declaration on TRIPS and Public Health ("Doha Declaration"), affirming governments' sovereign right to protect public health. Although seen as a milestone for prioritizing public health over private intellectual property, the Doha Declaration didn't fully resolve issues related to intellectual property protection and public health. Recent WTO negotiations have failed to address the issue of generic medicine production and export to countries lacking production capacity, possibly indicating premature optimism following the Doha Declaration.

Indian generic drug manufacturers have long produced generic versions of branded drugs. Under the Act, these manufacturers who had invested significantly and were marketing their products before January 2005 can continue marketing under the new regime. They are protected from infringement suits by patent holders and are required only to pay a reasonable royalty. Indian generic makers still have room to legally or illegally replicate patented Western drugs without penalties. Western companies have seen few patent applications approved. Expectations for India's IPR climate to change rapidly after the 2005 Act may have been overly optimistic.

India is one of the few developing countries to use the full ten-year transitional period under the TRIPS Agreement. During this period from 1995 to 2004, India received many product patent applications, which the Indian Patent Office started examining in 2005. The outcome of these applications will have a significant impact on continued access to generic medicines.

Flexibilities under TRIPS and their Use by the Indian Government to Ensure Access to Essential Medicines: The introduction of pharmaceutical patents in India has been controversial. India, like other developing countries, attempted to use TRIPS flexibilities to mitigate potential negative effects of pharmaceutical patents on medicine supply. India waited until 2005 to introduce pharmaceutical product patents, using its full transition period. Applications received from 1995 onward are still under examination. UNAIDS and civil society groups defend section 3(d) and view India as a model for using TRIPS flexibilities to promote public health.

When India reintroduced the product patent regime in 2005, Parliament adopted a pragmatic approach to use TRIPS flexibilities to secure medicine availability, affordability, and accessibility. TRIPS don't set a universal standard for patent law, allowing each WTO member to use TRIPS provisions flexibly. The implementation strategy was to find competitive ways to offset adverse patent price effects on developing country consumers with minimal damage.

Various amendments to India's patents law introduced flexibilities at both pre- and post-grant stages of patent applications. This study explores three key flexibilities for enabling continued generic medicine production:

1. Medicines invented before 1995 are not obligated to receive patent protection under TRIPS.
2. India restricts the scope of patentability for known substances. Section 3(d) of the Patents Act prohibits patenting known medicines unless the applicant demonstrates increased therapeutic efficacy.

3. Section 11A(7) allows companies already producing and marketing a product before January 1, 2005, for which a patent application was made, to continue manufacturing the product upon payment of a reasonable royalty. These flexibilities, if strictly applied, offer significant room for generic production.

How India's Pharmaceutical Patent Laws Respond to Global Pressures

India's patent system is at a critical juncture, posing challenges for both the generic pharmaceutical industry and public health. Access to affordable medicines is vital for vulnerable communities worldwide, and India, known as the "pharmacy of the world," must address the complexities of patents and intellectual property rights. It must firmly oppose any efforts to limit waivers for drug and vaccine patents.

India's journey as a major producer of generic drugs began with the Patents Act of 1970, which recognized process patents but excluded product patents in pharmaceuticals. This allowed new drugs to be produced in India as long as manufacturers used a different manufacturing method from the patent holder.

The revised Patents Act of 2005 introduced provisions like pre-grant opposition and compulsory licensing to prevent patents for minor changes to existing products. These measures aimed to protect both the generic drug industry and public health.

In the fiscal year 2022-23, India's pharmaceutical and drug exports totalled 5.7% of its total exports, valued at ₹2.04 lakh crore. These exports reached 200 countries, highlighting India's significant role in the global pharmaceutical landscape. However, India's patent system is now facing challenges that could harm both the generic drug industry and public health.

Proposed amendments to the Patent Rules 2003 could limit the ability of patient groups to oppose undeserved patents for medications. This could delay access to affordable generic drugs. Additionally, changes may extend the time for submitting working statements and eliminate the need to disclose manufacturing details and pricing of patented products, impacting healthcare access.

While these proposals aren't directly influenced by external pressure, they resemble lobbying efforts by big pharma. It's crucial for the government to address these concerns. While streamlining the patent process is important, changes should not unfairly benefit large global pharma companies.

India must uphold its commitment to ensuring access to affordable medicines and resist any attempts to limit patent waivers for drugs and vaccines. Affordable medicines are essential for vulnerable communities globally, and the government should work to maintain their availability and affordability.

Draft Patents Amendment Rules 2023 and its effect on the Indian pharmaceutical sector

A few months ago, the Ministry of Commerce and Industry introduced the Draft Patents (Amendment) Rules 2023, proposing several changes to rules, regulations, and fees. These proposals were open to public feedback and are expected to have significant effects, especially on the pre-grant opposition process. While these changes might benefit pharmaceutical companies, they could negatively impact patients in India.

According to the Draft Patents (Amendment) Rules 2023, the Controller would evaluate the validity of representations made by individuals or organizations during pre-grant opposition. Additionally, a fee would be required for filing pre-grant opposition, potentially discouraging some due to financial constraints.

Furthermore, the draft rules modify the frequency of filing Form 27 - Working Statements from annually to once every three financial years. This change overlooks the requirement to disclose whether patented products are manufactured in India or imported, along with pricing details. Such oversights could hinder patient access to medicines and affect the generic drug industry.

Pre-grant opposition is seen as crucial in combating patent evergreening and unfair monopolies. It enables generic medicine manufacturers to prepare for production once patents expire. However, attempts by patent-holding pharmaceutical companies to extend their rights could delay the availability of affordable generic alternatives.

In a recent instance, the Indian Patent Office rejected a secondary patent application for the Tuberculosis drug Bedaquiline, filed by Janssen Pharmaceuticals (Johnson & Johnson). The rejection came following pre-grant opposition, citing lack of innovation and similarity to previous patents. This case underscores the importance of pre-grant opposition in protecting public interest.

If a fee for pre-grant opposition is introduced as per the Draft Patent Rules 2023, it may raise concerns about access to justice, potentially limiting the ability of patient groups and individuals to oppose patents and bring about meaningful change in society.

CONCLUSION

Since 1970, India's Patent Act has empowered Indian manufacturers to lawfully produce generic versions of medicines patented in other countries. India's proficiency in reverse drug engineering and the effectiveness of its pharmaceutical manufacturing sector swiftly positioned it as a leading source of generic medicines globally. However, 2005 signifies a fundamental and potentially significant shift in access to medicines in developing nations: countries like India, which previously didn't grant patents on medicines, are now obligated to enact patent laws in alignment with the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Despite this, the Act includes clear provisions to safeguard the interests of domestic

generic manufacturers. It has struck a reasonable balance between stringent IP measures and utilizing some of the flexibilities provided by TRIPS. The amended Patents Act features an effective opposition system for challenging baseless patents, limited exceptions to patentability, detailed provisions regarding compulsory licensing, and parallel importation.

These modifications to the new Patents Act could empower India to maintain its pioneering role in providing affordable drugs to consumers both domestically and worldwide, as it did before the TRIPS era.

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