Public Health and Patent Law to Access Medicine in India

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ABSTRACT

India's 1970 decision to include a process patent regime in its patent legislation is regarded as a reformative step that was a well-considered reaction to internal issues including the nation's then-current socioeconomic realities. The primary goal of this research project has been to critically analyse the connections among public health, the global intellectual property law, and the availability of necessary medications, with a particular emphasis on India. The study's main focus is the persistent issue of developing and least developed nations' lack of access to reasonably priced medical care in the post-crisis age. This study aims to investigate the inherent barriers to intellectual property that impact medical access, excluding the impact of non-intellectual property impediments such as distribution, infrastructure, quality, and medical facilities. The purpose of this study is to examine how patent law affects drug accessibility while accounting for drug costs.

1. Introduction

A patent is a privilege that the State grants for a set period of time to prohibit third parties from engaging in particular activities within that State that are outlined by the patent's claims. The foundation of the patent system is the idea of a contract wherein the state gives the patent holder a restricted monopoly over the activities covered by the claims for a predetermined amount of time, provided that the patent holder keeps the invention secret after the patent expires [1]. However, the state will only issue such a monopoly in cases when the claimed innovations meet specific requirements, such as being unique, demonstrating a significant advancement over prior work, and being of a technical character. Although the inventor is not required by the patent system to patent their invention in order to commercialise it, in certain situations they may feel it is preferable to keep it as a trade secret. However, in these situations, the inventor runs the risk of others independently creating the same invention, patenting it, and thereby restricting the original inventor's ability to use the invention. Intellectual property rights, and especially patents, have historically been defended as the result of an agreement between the people and the government. The primary goal of intellectual property is to protect and recompense, which encourages innovation and production while making sure that the resulting rights and obligations fairly balance the interests of the creator, his rivals, and the users. [3].

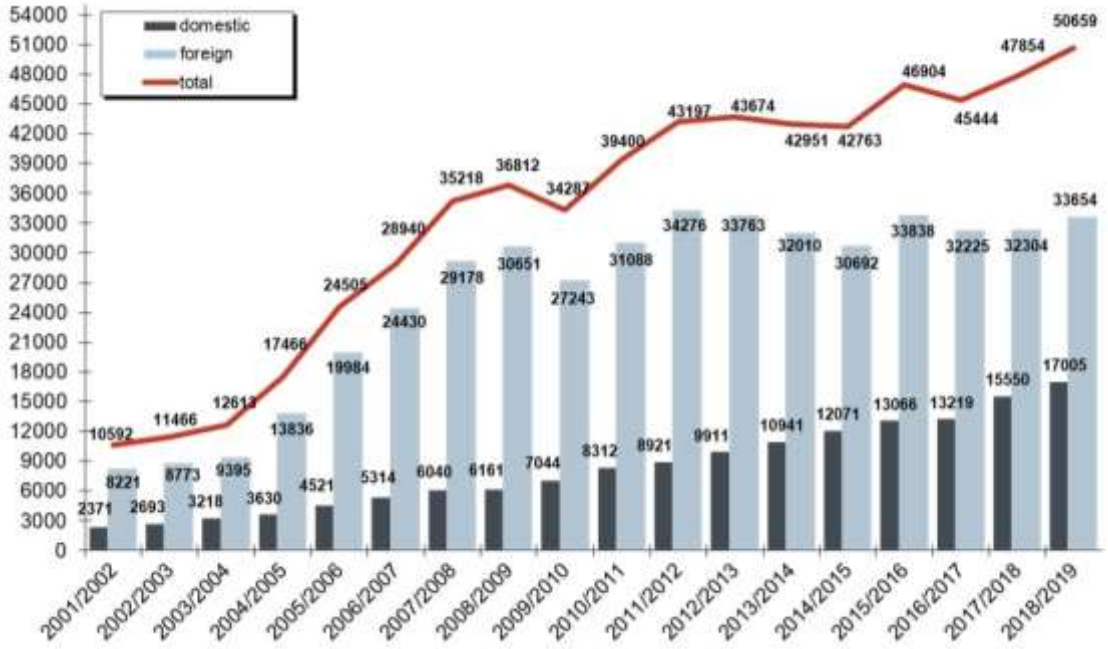

Figure 1: application of patent in domestic vs foreign

In this instance, section 1 of the article examines the introduction, while section 2 examines the relevant review. The purpose of the patent goal work is explained in Sections 3 and 4, the work is discussed in Section 5, and the project is concluded in Section 6.

2. Review Of Literature

Human civilization has progressed because of our ability to continuously evolve as well as our determination to invent and get better. There is a longer history behind the notion that giving someone a monopoly in a market will encourage individuals to develop and create new things. The origins of intellectual property rights as a legal framework may primarily be found in the Western European cities of Venice, France, and Britain. Scholars of law and history argue on when exactly the patent system began, with scholars pointing to the Greeks, Byzantines, Italians, and English as among those who planted the seeds of modern patent law [4]. The rationale underlying patent protection is the necessity to spread invention among the populace, which would subsequently spur the development of the nation's industry and technology and, ultimately, its economy [6]. The researcher begins reading them critically to identify pertinent themes and issues that are related and associated, after carefully examining a number of documents, including books, journals, and articles, which are relevant and useful to this research work. The researcher then conducts an extensive literature survey related to the problem. The researcher searches through abstracts, indexes, and pertinent books, journals, government reports, and other study resources for this purpose. The researcher finds that during the entire process, one specific source leads to another, which in turn makes room for a new one [8]. The researcher defined boundaries by analysing the literature in reference to the principal issue important to the study topic, even if the evaluation of the pertinent material is an ongoing activity. The investigator has made an effort to track the history of the topic selected for investigation all the way up to the present. To reach a dismissive conclusion, the pertinent statutes have been analysed from fresh perspectives and through the prism of current research.

The Evolution Of Patent Law In India

Indian patent rules were created during the British colonial era, primarily to benefit British patent holders. From 1757 to 1947, or over two centuries, the British dominated India. The first patent laws were established in India in 1856 at this time. The laws pertaining to patents in India can be broadly divided into two categories: "pre-independent India" and "post-independent India." This chapter discusses India's pre-independence patent laws. It then examines the post-independence patent laws, focusing primarily on the Patents Act of 1970, and discussing the changes made to the Act under the following headings.

Pre – Independence Era

The requirements of the colonial rulers shaped the advances in colonial India, and the British legal system's evolution was precisely duplicated in India without taking into account the country's unique social and economic context or industrial features. The British attempted to codify patent law in India for the first time with the Patents Act of 1856, which may have been a response to the continuous discussion about the application of patents awarded in England to India that had been going on since the mid-1800s [9]. For nearly twenty years, the interested parties had been pressuring the British government to enact a framework for patent protection. The Act was primarily based on the British Patents Act of 1852, which provided British patent owners the option to register their invention in India in less than six months and granted inventors "exclusive privileges" for a fourteen-year period. This legislation was only going to be in effect for a year or so. However, it was the first statute to include the concept of giving inventors the exclusive right to their creation through "law." The set of rights held by the patent holder under this Act is referred to as "exclusive privileges" instead of "patent" anywhere.

Post- Independence Era

One of the main discussions at the outset of independence concerned how to effectively balance the requirement to protect the public interest and promote industry development with the incentives to invention provided by patent rights. Almost 85% of pharmaceuticals were supplied by foreign multinational firms at the time of India's independence, and the country undoubtedly had some of the highest drug prices in the world. In response to the issue and to guarantee that the patent law is consistent with one of the goals of providing affordable medications, the Indian parliament discussed the matter and proposed numerous changes to the patent legislation between the years of 1947 to 1970. Following independence, the authorities of independent India quickly came to the conclusion that the Act of 1911's provisions were insufficient to meet the needs of a sovereign India; rather, these provisions had effectively aided foreign entrepreneurs in establishing their hegemony over the Indian market [11]. Thus, shortly after emerging from British rule, the Union Government established a Patents Enquiry Committee, led by Bakshi Tek Chand, a retired judge of the Lahore High Court and member of the Constituent Assembly that drafted the Indian Constitution, to reexamine the patent system.

Government Intervention In Regulating The Cost Of Drugs

Over half of the world's poor reside in India, despite the country having made great strides in the recent ten years (2011–2019) to eradicate extreme poverty. The World Bank's recently released report 67 states that between 2011 and 2019, India's extreme poverty decreased by 12.3 percentage points, with rural areas experiencing a greater pace of poverty reduction than urban ones. For the past five years, up until 2017–18, the federal and state governments' spending on public healthcare as a proportion of GDP has stayed between 1.1 and 1.5 percent annually. [12].

Out of Pocket Expenditure (OOPE) decreased from 64.2% in 2013–14 to 48.8% in 2017–18 as a percentage of overall health expenditure [5]. The OOPE decreased significantly from 2013–14 to 2017–18, going from 2,336 in 2013–14 to 2097 in that year.69 However, the OOPE is still high, particularly in the wake of the COVID-19 pandemic, when many people lost their jobs and daily inflation has driven up the cost of both consumables and non-consumables. Furthermore, it says that 43% of Indian households' out-of-pocket expenses went towards buying medications [7]. The only way to remedy this problem is for the government to purchase medications and provide them to the underprivileged via government-run hospitals. In this context, the cost of medications significantly affects people's ability to obtain them, particularly in India where the vast majority of people have poor incomes and private institutions primarily provide healthcare [2]. In order to guarantee that everyone has access to medications, almost every nation in the world has developed some kind of system to regulate drug costs. Following India's independence, foreign multinational corporations controlled the country's pharmaceutical sector, driving up drug prices. The Indian government launched numerous programmes to make inexpensive medicine available to the general public. The government's attempt to regulate medicine prices was one of these measures [10].

Since 1970, when pharmaceutical prices were among the highest in the world and foreign multinational corporations (MNCs) controlled the pharmaceutical industry, India has achieved great strides in the field.1. Prior to 1970, India was subject to British-imposed patent regulations that benefited foreign innovators over local pharmaceutical producers. During the colonial era, the primary aim of multinational corporations (MNCs) was to optimise their earnings by taking advantage of India's patent laws and establish their dominance over the country's pharmaceutical industry by impeding local producers from producing less expensive medications. Despite being among the world's poorest nations, India was forced to purchase life-saving medications like penicillin from other nations, where they were subsequently sold for far more than in wealthier nations.

India should also take care of a few issues that significantly limit the availability of medications, such as its reliance on China for essential raw materials for pharmaceutical manufacturing. The government needs to exercise caution when relying too much on other nations, particularly with the introduction of COVID-19. This is because the pharmaceutical business relies on a single source for the supply of necessary chemicals. About 40% of the generic medications used in the USA are produced in India, but 70% of the active pharmaceutical ingredients are imported from China. Although the Indian government has established the Uniform Code of Pharmaceutical Marketing Practices and the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 to regulate the medical industry, these regulations are routinely broken and have not been successful in stopping pharmaceutical companies' unethical practices, such as providing freebies to doctors in exchange for boosting drug sales. It is important to realise that these purported "freebies" are not really free because pharmaceutical companies frequently include the cost of these unethical marketing practices in the price of their drugs, adding to the burden already placed on patients and making it more difficult for a sizable portion of the population to access medicine.

3. Results and discussion

India currently ranks fourth in terms of value and third in terms of volume produced worldwide in the pharmaceutical industry.4 As of 2021, India was the world's biggest manufacturer of vaccinations, producing around 60% of all vaccines distributed globally. With a 20% market share in the world's generic medication supply, India is recognised as the leading supplier [13]. The pharmaceutical

businesses of India hold a vital and noteworthy position in the global pharmaceutical industry, providing economical and life-saving pharmaceuticals. Nearly two-thirds of the world's supply of antiretroviral medications comes from India, which also contributes significantly to the global effort to combat HIV/AIDS by facilitating greater access to treatment in underdeveloped nations. Despite the fact that India's pharmaceutical industry is among the world's top exporters of generic medications, a sizable portion of the country's population lacks access to reasonably priced basic medications [15]. Pharmaceutical companies charge marked-up pricing for generic medications that are substantially more expensive than their unbranded generic counterparts, even though both have comparable therapeutic benefits. Many of the same medication formulations are available in the Indian market under multiple brand names due to the proliferation of the pharmaceutical industry [14].

4. Conclusion and future scope

India was rightly dubbed the "Pharmacy of the World" for its generosity in providing supplies of vital life-saving medications to other developing nations lacking the manufacturing capacity to combat life-threatening diseases, thanks to the process patent regime, which also made the country self-sufficient in the production of generic drugs. Due to the dominance of foreign pharmaceutical companies whose only goal was to maximise profit, India had the highest cost of healthcare during colonial rule. However, the process patent regime implemented after independence not only made life-saving medications accessible to the general public, but it also enabled indigenous pharmaceutical companies to stand on their own two feet and continue to serve humanity.

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