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RESEARCH ARTICLE

ACCESS TO ESSENTIAL MEDICINES IN INDIA: THE ROLE OF INNOVATIONS, PATENTS, AND INTELLECTUAL PROPERTY RIGHTS

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ABSTRACT

The role of essential medicines is to smoothen life and overall improvement of health in the society. However, increased demand for medications and the role of patent rights are forcing a lack of access to essential medicines. Innovations in crucial times helped solve many population issues. Despite the availability of medication technology, there is a shortage or non-availability of essential medicines in various parts of the world. This is indirectly attributed to the existing patent laws and intellectual property rights. This paper argues in favour of and against the pharmaceutical sector's patent laws in the context of access to medicines. Further, access to medicine is discussed in the context of the non-availability of medications among the vulnerable population in India and the world. The Indian setup helps in acquiring world technologies in various business negotiations. There is also a need for support in terms of resources and ecosystems in India for further development. Given that multi-national companies are interested in the Indian market, many things can be done quickly. However, the gain in the patent rights may not help solve the issues of access to essential medicines. Public financing for research can be much more useful for access to medicine. Overall, patent rights must not be a hurdle for addressing public health issues in the process of increasing access to medicines.

KEYWORDS

Pharmaceutical Industry, Food and Drug Administration, Access to Medicine, Patent exploitation, Research and Development, Vulnerable population, Generic drugs

INTRODUCTION

Essential medicines are used to treat "diseases that destroy human lives" [1]. The diseases that require essential medicines include cancer, HIV/AIDS, malaria, tuberculosis, and many more in human history. The present paper highlights the impact of patents and Intellectual Property Rights (IPRs) in accessing essential medicines irrespective of the disease. The price of individual essential medicines is not a matter of concern for patients or the government. A basket of essential medicines' price, availability, and affordability is measured on an authentic scale to know the accessibility [2]. Millions of lives can be saved if access to essential medicine becomes a reality. The essential medicines are distinguished from medicines for hair loss, acne, impotence, and many more diseases. To be precise, the smoothening of life is not a big concern for improving health in society. However, increased demand for medical sciences forces the research and innovation to develop many medications used for overall well-being. World Health Organization (WHO) recognises essential medicines with features like population priority, healthcare needs,

relevance, efficacy, safety, and cost-effectiveness [1]. Hence, essential medicines are socially valuable goods, and they should not be obstructed from access for vulnerable people due to patent protection laws; every individual should get essential medicine irrespective of his social or economic status.

Before we get into the unequal accessibility to essential medicines and consider patent laws as one of the most decisive factors affecting access, it is necessary to discuss the rationality of the law. Overall, in a nation, patents are granted as an exception to reward hard-earned discoveries and inventions in lieu of complete disclosure of the entire process for the benefit of further development in the domain of knowledge. That means if all patents are granted, the objective stands for the clear benefit of society in the long run. However, scientific innovation is often hampered due to the high level of commercialisation in the world. The fruits of research must reach many people, especially those suffering from illness. Many intellectual circles discuss public health issues that must be out of the ambit of dirty patent protection to save millions of lives. The innovators, governments, multilateral bodies, and other stakeholders must solve the problem of access to medicine across the globe. The sharing of knowledge for a disease-free society is in the interest of the entire population. The high-income countries seldom face problems accessing essential medicines due to their high-paying capacity. On the other hand, low and middle-income countries (LMIC) have suffered heavy losses due to a lack of financial provision and regulatory challenges. Public health laws across the world have to serve the vulnerable population to bring goodwill rather than hurdles for most of the world's population.

LITERATURE REVIEW

This paper tries to determine the impact of IPRs in modern-day pharmaceutical industries and the provision of essential medicines to the Indian population. Further, the roles of the Indian government in ensuring the provision of medications to vulnerable people have been discussed. The study critically reviewed various positive and negative aspects of IPRs from relevant authoritative literature curated from Scopus, WoS, J store, Proquest, PubMed, and Embase. The following thematic areas are highlighted with logical arguments in the Indian context of IPR issues and access to essential medicines. This paper is a commentary on an important issue that is leading to inaccessibility to essential medicines, which is patenting on drugs. Critical inferences are drawn from research papers published across the aforementioned reputed databases.

ARGUMENTS IN FAVOR OF THE PHARMACEUTICALS PATENTING

Despite the constant need for new medicines to combat emerging diseases and health challenges, drug development is costly, risky, and challenging. Scherer [3] writes a pharmaceutical producer wants a patent to protect his market interests for a product that has survived rigorous scrutiny from regulatory authorities. A pharmaceutical producer faces costs, risks, and challenges that should be compensated with patent protection rights. The pharmaceutical industry is a field that thrives on innovations [4], which provides the industry with optimal sales and profits [5]. Pharmaceutical firms are driven by innovation competition [6, 7]. The companies that innovate more and more can gain and sustain themselves in the pharmaceutical market competition. The competitive environment keeps the industry moving and transforming itself with positive changes [8].

Growth in the Indian Pharmaceutical Industry (IPI)

Due to affordable patent regime, the Indian pharmaceutical industry grew by leaps and bounds over several decades. Indian government vehemently tried to protect the access to medicine by Indians initially, but in the latter part, it also succumbed to the pressure of world trade-related laws, which served the interest of the Western world. Sethi et al. [5] and Kamiike [9] analysed that in the post-TRIPs agreement, Indian pharmaceutical companies have grown faster than ever, and due to other conducive environments, the industry has attracted Western pharmaceutical companies to establish in India. India has quickly recorded its presence in the global pharmaceutical sector. Now, India is a leading manufacturer and supplier of drugs, active pharmaceutical ingredients, and vaccines [5, 9].

TABLE 1: CONCURRENT FEATURES OF THE INDIAN PHARMACEUTICAL INDUSTRY (IPI)

Global vaccine demand met by IPI	50%
Global pharmaceutical production by volume	Rank 3rd
Global pharmaceutical production by value	Rank 14th
The expected growth by 2030	$130 billion
Generic export contribution globally	20%

Source: (India Brand Equity Foundation, 2021)

Although IPI is not a patented drug hub but is well-grown in the generic pharmaceuticals market, the patented pharmaceutical market has yet to be developed in India. The large pharma companies that have generic drug manufacturing units has to increase their investment in R&D in India to compete in the international patented pharmaceutical competition [10]. Few pharma companies are engaged in R&D, but the industry has to go a long way to be called innovation driven [11].

The case of the U.S. pharmaceutical industry and rationale behind IPRs

Taking the U.S. as an example, Scherer [3] defined the innovation and market strategy situation for pharmaceutical firms. Pharmaceutical R&D/sales ratios were nearly five times those of their all-manufacturing counterparts in other sectors (1999-2003). Despite expedited timetables, time lags in various phases of research to produce new pharmaceutical products for rare and incurable diseases is a matter of concern for producers. Despite significant advances in computer-aided drug design, low-cost molecular manipulations, and screening, the expected pace of drug discovery was not realised. It either stagnated or declined between 1990 and the early twenty-first century. The reason for this stagnation was identified as inventory costs of long-established pharma products. The new drug must prove safer and more efficacious than the earlier established drug. The process of identifying new drugs has become lengthy and elusive in recent decades [3].

The drug companies highly favoured product patents because the involvement of patents gives them the right to regulate the prices of their products. Price regulation is a right of pharmaceutical companies because they invest hugely in drug development. The time lag in finding a new product, clearing all clinical trials, and assuring FDA regulations makes them eligible for patented earnings of several years. In the absence of patent laws, imitators can immediately erode the quasi-rent of the R&D process [3]. The environment of innovation directly benefits the consumers, whereas no patent regime negatively affects the interests of innovators and discourages innovations [5].

Pharma companies were ranked as the highest margin earning industry. They were allegedly flourishing on consumer expenses. However, as argued by pharma companies, there is a methodological error in calculating the margin. The evaluations are done using the current year's expenditure and sales outlay, while the costs are almost a decade-long investment [3]. Due to high failure rates, repeated clinical trials, and lags in administrative processes to carry forward the research, ensuring the safety and efficacy of medicines causes the final product price to go up incessantly [12]. Hence, drug companies do not earn supranormal profits, but they try to compensate for the expenses incurred in the long run [3].

Developing new drugs and vaccines for third-world diseases is left unanswered in the patent regime. Only a few relaxations and subsidies were agreed upon, but no sustainable solution was provided. "Rich consumers in developed countries are able and willing to pay, either directly or through taxes and transfers, for an ample array of drugs to combat the diseases and debility affecting them" [3]. However, some diseases are common in developing or low-income countries but not in developed countries. Drug companies are interested in developing medicines for diseases prevalent in low-income countries [3]. People can hardly afford to pay for patented medicines [13]. Drug producers see a meagre chance of getting a positive return [3]. The question arises: who will pay for the impoverished citizens of low-income countries on the discretionary prices set by pharma companies? Developed countries invest in research and development (R&D) of essential medicines while developing and least-developed countries (LDCs) lack the resources to invest in R&D [3]. LDCs are recognised as needy of essential medicines, but developed nations still allow pharmaceutical companies to take advantage of patents

to ensure profits [1]. For example, the demand for essential medicines in African countries was so high that only 30% of the population had access to these medicines, combining private and public health facilities [14]. Also, the share of medicine cost to total healthcare spending is around 61.83% and 72.7% in rural and urban areas, respectively, in India [15].

Dropping pharmaceutical prices and improving medication accessibility could have both positive and negative financial implications for pharmaceutical companies, impacting their revenue, market demand, supply chain costs, profit margins, competitive landscape, and relationship with government policies [16].

ARGUMENTS AGAINST THE PHARMACEUTICALS PATENTING

IPRs were adopted in the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreements in 1995 [13]. Although, from 1990 onwards, developed countries have started introducing IPRs in their economies. World Trade Organization (WTO) made it mandatory for all the members and those interested in being member countries to accept all the provisions in the TRIPs agreement. The member countries were obliged to ensure patent protection on every invention, which applies to products and processes for a minimum duration of twenty years. Developing countries were given a transition period relaxation to implement the patent protection laws by 2005, while least developed countries (LDCs) were provided patent protection relaxation till 2033 [13]. Despite these relaxations, low-income countries still lack essential medicines. The inaccessibility in LDCs was not a new phenomenon post-TRIPs compliance. Other factors, such as poverty, small market size, the absence of generic substitution regulations, and low local production capacity, were older issues affecting accessibility [13, 17]. Nevertheless, TRIP compliance was stringent enough to aggravate the inaccessibility issue further. In a non-patent regime, the poor can afford generic medicines, but they are left under-treated or untreated in the patent regime [13].

Government intervention to reduce pharmaceutical prices can have significant financial implications for pharmaceutical companies, affecting their profitability, R&D capabilities, market position, and global operations [16]. Further, a country may face international sanctions if that country acts against international agreements like TRIPs of 1995 [18].

To tackle the problem of providing essential medicines at an affordable price, countries (Australia, Japan, and the Republic of Korea) have implemented measures such as tax exemptions, reference pricing policies, and regulatory interventions in the pharmaceutical supply chain [19]. These steps aim to improve access to essential medicines while ensuring affordability for the population. However, the other side of this is the loss of revenue for national governments; therefore, these measures are not sustainable for low-income countries [16].

The flaw in the idea of IPR

The intellectual property rights of drug innovators go against the logic of owning physical property rights [12]. For example, if somebody owns a piece of land, he decides to make a house with an entrance in the north direction. Another owner with another part of the land wishes to make the same house with access facing north. Then, the earlier landowner should not enforce or threaten another landowner of the legal suit. Principles of physical property rights can be contradictory to intellectual property rights. It raises a valid question: Why should an owner of a particular asset not be free from disposing of his asset as he wishes? There could be several chemical owners that produce a specific medicine molecule, so why should only one owner be entitled to make that molecule? In contrast, others are debarred from making that molecule.

Flaws in the arguments of R&D

It is argued that patent protection will help pharmaceutical companies to invest in R&D [13]. The TRIPs patent protection was granted on both compound and process. The first originator firm will get primary patent protection. Later, when R&D progresses, and other medicines develop using the same compound, they will be granted secondary patents based on forms, dosages, and formulations. Reverse engineering was prohibited in the patent regime to protect the interest of innovators [13]. Over the years, R&D has favoured the least important health issues against several severe illnesses and diseases prevalent in developing countries in the patent regime [13]. Pharmaceutical firms avoid investments in primary patenting to create new molecules to treat serious health problems because it involves uncertainties and risks. Despite that, they prefer to invest in secondary patenting of low-risk and high-profit R&D [20].

Failing the generic medicine market

In the patent protection environment, generic medicine manufacturers were ruled out to ensure the profit of

innovator firms [13]. Generic pharmaceutical manufacturers were blamed for maximising their profits by expanding their market by lowering the prices of medicines; in reality, it is a healthy competition that protects the interests of consumers [13]. Large pharmaceutical companies limit the availability of patented drugs. They practice the power of a monopolist by holding patent rights. Large firms with patents do not wish to enter patent-free markets due to low prices set by generic competition [21, 22].

Positive discrimination against the majority population

The availability of new innovative drugs is not a function of supply and demand in a patented regime. New drug availability becomes subject to price control policies, firm characteristics, and the regulatory environment. If drug prices are high, firms are profit-oriented, and they have the autonomy to decide their production level. There is a very high chance that low- and middle-income countries face the unavailability of new medicines [23]. The positive discrimination of firms operating under a patent regime was evident in a study undertaken by Cockburn et al. [24]. Taking into consideration the various income levels in deciles for the year 2005, Pogge [12] had shown that the wealthiest twenty percent of the world population accounted for 87.4% of total earnings, and the patent holders target to serve only those twenty percent population while neglecting the remaining eighty percent. Although there is the capacity to produce large-scale essential medicines, the patent holders had to reduce the prices drastically, but they lacked motivation [12]. The TRIPs agreement has enhanced the profit-seeking nature of pharmaceutical R&D. The income inequalities have led pharmaceutical innovators to prioritise the health problems of the affluent class. Minor issues such as hair loss, erectile dysfunction, and minor skin problems attract most of the R&D resources because there are higher margins in profit. In contrast to minor ailments, serious diseases such as dengue, malaria, and tuberculosis receive the least R&D resources [3, 12]. Pharmaceutical innovators are incentivised to smaller volumes over smaller markups [12].

In the TRIPs agreement, developed nations lobbied to pressure the developing countries to open their markets for global trade. The market's opening had never helped the poorest people access their needed medicines. The market opening helped originator drug developers maximise their customer base and profiteering by serving the rich everywhere, including developing countries [12].

Tier or differential pricing

The R&D-based firms can tier the prices of products based on local income distributions. However, originator firms lack interest in the tier pricing scheme in countries with high-income inequality. Instead, they sell lesser quantities, serving only a tiny population with high incomes [25, 26]. Differential pricing was suggested to promote availability and accessibility across the countries under the patent regime. Differential or tiered pricing systems allow firms to sell their products at different prices in different markets. For example, firms can sell their patented product at lower prices in lower- and middle-income countries while charging a higher fee in high-income countries [27]. This mechanism demands income homogeneity or marginal income inequality within the country where the drug is introduced. However, low-income countries show high income inequalities. In that case, when a drug innovator launches a product, he sets a price based on the average per-capita income. Although average per-capita income is misleading in the high-income inequality case, it will exclude many people from access to essential medicine [12, 26].

However, originator drug price differentiation has shown minor adjustments to local income levels, while generic drugs have higher price differentiation to local income levels. Therefore, generic price differentiation is better than originator drug price differentiation [13]. The provision of generic medicines for infectious diseases (i.e., HIV/AIDS, malaria, and tuberculosis) is much more adjustable to local income levels. Low- and middle-income countries have extensively benefitted from infectious disease generic medicine [13].

Also, the affordability of essential drugs for people living in LMICs is often measured in terms of the number of days' wages needed to purchase the medication. In the context of China, the affordability of essential medicines was measured in terms of the number of days' wages of the lowest-paid unskilled government worker. It was found that the median affordability of essential medicines in China was equal to 0.88 day's wage for the lowest-paid unskilled government worker. This suggests that essential medicines would become unaffordable if they cost more than the equivalent of one day's wage for the lowest-paid unskilled government worker [28].

PATENT REGIME AND ITS IMPACT ON DRUG MANUFACTURING

In independent India, the first formal patent act was introduced in 1972. This law allowed patents on the process and not on the product. However, in 1995, with the introduction of Trade-Related Intellectual Property Rights (TRIPs), patented drugs were protected by both process and product [29, 30]. In the pre-TRIPs era, generic manufacturers benefitted from a flaw in the patent law. Generic manufacturers produced large-scale generic drugs by reverse-engineering the patented process. The reverse engineering included the alternate manufacturing method by adding or subtracting some molecules, ensuring that the generic medicine should maintain safety and efficacy same as the patented drugs [31]. The capital expenditure of producing a drug is lower than the capital cost of discovering a new molecule [5, 12]. Generic brands established in India highly benefitted from the Patent Act 1972. Pharmaceutical firms in India quickly developed an alternate patent process for new drug manufacturing and enjoyed higher revenue without investing in R&D [5].

Being a member of WTO, India had to sign and accept the TRIPs agreement. The TRIPs agreement was detrimental to the capacity of domestic generic brands and, hence, the availability of affordable drugs in the country. India was provided ten years to become TRIPs compliant [32]. The pre-TRIP patent rights provision was extended from seven to twenty years [12, 33]. Domestic generic drug manufacturers were forced to invest in R&D as they could not pursue different processes or reverse engineering to make a similar drug as patented [5].

There is no large-scale research on increased R&D and its impact on India's patenting and profitability [5]. However, there are sufficient studies on trends in R&D activity, the effect of innovation on export, and patenting activity in India [34–36]. The positive impacts of R&D on India's drug manufacturers are yet to be researched and documented in the research sphere.

THE RATIONALE BEHIND THE IPR TRADE REGIME

The economic problem of knowledge generation is that it is non-rivalrous and easy to replicate and reproduce [21, 22, 37]. The innovator cannot control the accessibility of their invention after the knowledge comes into the public domain. The innovator may seek benefit or reward in return for his knowledge creation. There is a social need to reward inventions by providing economic and social incentives for innovations. The case is valid for essential drugs when innovators were left with the option to collect their rewards directly from the users of their products in international trade negotiations. Essential goods like life-saving drugs are desired and sought for the public interest. If essential drug inventions are treated the same as other non-essential inventions, i.e., malaria treatment equal to a hair transplant procedure, significant losses of lives would be inevitable. People suffer physically for a longer time and die despite a cure because they cannot pay for the cost of R&D involved in the needed treatment [38]. Duplication and the problem of free riding can be applied to non-essential and luxurious inventions, but providing essential drugs promptly is a social right of all human beings across the globe. However, the economic incentives for innovators remain unanswered within the 'essential drugs provision to all' argument, i.e., who will pay for those who cannot afford it? The role of governments becomes pivotal in ensuring the balance between innovators' economic rights (rewards) and individuals' social ownership [38]. The early IPR policies of the industrialising countries in the nineteenth century were such that governments mediated in solving the economic problem of innovators while keeping the greater public interest for essential goods easily accessible (the active social welfare policy). That led to the technological and economic progress of the Global North [37].

However, developing countries resist the stringent IPR regime called TRIPs [39]. The burden of IPR provisions was such that governments in developing countries could not pay for the discretionary prices set by innovator firms. Brazil and India led anti-TRIP lobbying in international trade negotiations of the last Uruguay round (1995). However, they failed to make necessary changes in the statute [39].

CONCLUSION

The paper clearly shows evidence regarding the lack of access to essential medicines due to various aspects of the patent regime. Providing patent rights needs to be relooked to facilitate access to medicines, especially in LMIC. The support for innovation must be there from the government to take new initiatives to discover drugs, assuming that someday, the drug innovators would serve humanity better through their new molecules. Being heavily relied upon by Western countries for technology, India has to augment research and development. Public funding for research can help bridge the inconvenience in access to medicine. Despite patent rights, some public health arrangements must exist to increase access.

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