Journal of Advances and Scholarly Researches in Allied Education
Vol. 15, Issue No. 12, December-2018, ISSN 2230-7540

Indian Pharmaceutical Industry's Patent System and Development

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Abstract – Patents are proprietary ownership privileges of intangible mental inventions. This paper studies the Patent system and the Indian Pharmaceutical Industry. In this we studied the pharmaceutical industry on patents, Indian pharmaceutical companies, patent regime in India, patents work differently in different industries, pharmaceutical patents problems, patents and research and development in developing countries and effect of product patents on the Indian pharmaceutical industry and patents.

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INTRODUCTION

As India's markets open up to foreign trading, the pharmaceutical sector in India is a prime illustration of an industry that is being pressured to reconsider its long-term policies and business models. As the need to protect lucrative properties in research and growth becomes more evident, factors such as intellectual property rights are becoming more relevant (R&D). In India, attempts are being made to resolve problems with the enforceability of existing intellectual property regulations, and the government is seeking to establish a patent regime that is welcoming to technological innovations and consistent with the country's foreign obligations.

Ravi Kiran, Sunita Mistra (2011), which, because of the Amended Patent Act 2005, focuses on the changed situation. India marked TRIPs for the protection of the item patent as a signatory part, and Primer India refused the change. This can be a result of n number of reasons such as whether compulsory licensing can be affected by item patent winds up, solution cost can increase and so forth patented item resembles an asset to the organisation. It builds the profitability of the respective organisation and the item will not be discounted for future competition or turnover, but it will be on the amount of patent held by an organisation. The need for research activity to be due on the market was understood by Indian residential and also worldwide organisations, and most of them are changing these days from impersonation to innovation by expanding R and D activity to support advertising (1).

Tyron Stading (2014), When cash turns out to be tight, organisations search for choices to build their income and find two ways to I) innovate items, and ii) case. A few organisations that dismiss innovation or innovation protection for cutting costs or keeping away from risk will be off guard both in current downturn advertisements and, to a more noteworthy degree, once again when the economic tempest passes and exchange exercises increase. Organizations that keep focusing in the midst of the downturn on their IP assets will pick up an aggressive edge after it. The majority of pharmaceutical organisations were assembled in the field of R&D regions during the retreat season. The IP approach states that, as a research and technology-driven association, they firmly trust IP creation, maintenance and respect (2).

Pharmaceutical Industry on patents:

For the pharmaceutical industry, the current patent system is rather beneficial and the protection provided is greatly enjoyed. When looking at the pharmaceutical industry figures and after realizing how much money and effort is placed on the development of a new drug, this is easily understandable.

The existing system of pharmaceutical innovation depends largely on patent protection and the 20-year exclusivity granted by patents, allowing time for research and development expenses to be covered "It should also be borne in mind that other factors affect access to medicines besides price and patents, such as "irrational use, inadequate health financing, unreliable supply of medicines, quality of medicines and lack of R&D for new medicines all play a role (3). The International Federation of Pharmaceutical Manufacturers &

Associations (IFPMA) has argued that the world would not have the creative medicines that have saved countless lives if we did not have the patent protection we have today (4). Approximately 60 to 65% of pharmaceutical inventions have been estimated not to have been developed or introduced in the absence of patents (5).

Today, like any other industry, the pharmaceutical industry focuses on profit generation and loss minimisation. The current patent protection helps the pharmaceutical industry to cover the losses caused by long and dangerous R&D, where only a fraction of the drug will pass through and become profitable.

INDIAN PHARMACEUTICAL COMPANIES

In 2017, India's pharmaceutical sector was worth US$33 billion, and generic drugs accounted for 20% of global volume exports, rendering it the world's largest producer of generic medicines (6). The domestic pharmaceutical industry was worth Rs 129,015 crore in 2018 (US$18.12 billion), growing 9.4 percent year-on-year, and export revenue was US$ 17.28 billion in FY18 and US$ 19.14 billion in FY19, according to the Pharmaceuticals Department, Ministry of Chemicals and Fertilizers. Hyderabad, Mumbai, Pune, (Baddi, Himachal Pradesh), Chennai, Bangalore, Ahmedabad, Vadodara, Ankleshwar, Vapleshwar, Vapleshwar,

In the early 1960s, and with the Patents Act in 1970, the government began to encourage the development of drug production by Indian companies (7).

Indians are almost completely hired by the majority of Indian pharmaceutical firms, including multinationals, from the lowest levels to the highest levels of management. Like several other industries in India, homegrown pharmaceuticals are also a combination of public and private companies.

India is the world's pharmacy and largest generic retailer, and it already has a significant portion of the global industry. India is the world's biggest maker of generic drugs. The Indian pharmaceutical industry provides more than half of all vaccine production worldwide, 40% of generic demand in the United States, and 25% of all drugs in the United Kingdom. With a commitment of about 50-60%, India is the largest donor to UNESC (8).

Patent regime in India:

The 1970 Patent Act saw the mass departure of multinational organisations (MNCs) as they perceived patents that were just processes. Without paying any kind of charge, Indian organisations had the opportunity to recreate drugs made by patent holding organisations. They were protected by the patent demonstration to legitimately identify and offer universally patented drugs within India and, moreover, in those business sectors that did not fit in with sedate patents.

The Indian pharmaceutical organisation has taken a tremendous lead in light of the amended Patent Act 2005. Section 5 of the Indian Patents Act, 1970 explicitly permitted just process patents and disallowed item patents prior to the amendment of the Patent Act 2005. The Patents Amendment Act, 2005 revoked it after the implementation of TRIPS and offered an approach to item patents along these lines as well. The item patent is a very strict restriction compared to the process patent. The contrast between the process patent and the item patent is that another manufacturer can produce drugs or drugs that have been patented under a process patent, but using an alternate process. Be that as it may, by any method, patented drugs in an item cannot be manufactured. As a result of India's consent to the TRIPS Arrangement and the WTO, India acknowledged, from 1-1-2005, the item patent as required by Article 27(1) of the TRIPS.

Patents work differently in different Industries:

Nearly all inventions, regardless of the technology involved, are patented prior to being made available to the market. In the field of consumer electronics, for example, patents are widely shared among competitors via cross-licensing. Chemical compound patents, on the other hand, are seldom licensed to anyone, and exclusivity is tightly guarded.

In terms of morals, economies are amoral. They function on the basis of scarcity. Items that are scarce cost more than products that are readily accessible. Customers spend much more for expensive, high-end technological products, such as plasma television displays, than for much narrower cathode ray television screens. The higher price represents the monopoly control granted to plasma screen makers through patents on the technology embodied in them, while the lower price of cathode ray TV screens is attributed in part to the reality that patents on the technologies embodied in them have long expired. Patent rights allow market exclusivity and premium pricing, which serve as an incentive for those who have invested in innovative technology-driven research and growth. As a result, plasma tv panel premiums are out of reach for low-income consumers, who must make do with older cathode ray displays or no television at all. This scenario highlights a significant point: a large portion of the world's populace remains without purchasing any patent-protected goods because they are unable to afford new technologies.

Intellectual property legislations in India:

The obligation of the part state emerging out of the traditions can be authorized based on reciprocity as it were. No privilege or obligation is enforceable singularly. Subsequently to pass possess laws on Intellectual property is in light of a legitimate concern for each nation. In 1999, a circumspect section of significant legislations concerning

protection of Intellectual property rights in harmony with global practices and in consistence with India's obligations under TRIPS.

The below are the foreign bodies in charge of managing the patent system:

- National Patent Offices
- The World Intellectual Property Organization (WIPO)
- The World Trade Organization (WTO)

It is important to remember that the TRIPS Agreement was designed to establish a more fair foreign trading environment. Wealthy countries have promised to lower barriers to competitive imports from other countries, while emerging countries have agreed to expand their doors to high-value-added goods from rich countries. This high-value-added exports are disproportionately made up of intangible technology that must be secured in order to be used efficiently through strict intellectual property regimes. Pharmaceutical goods are one of the most significant types of high-tech products.

Special problems of pharmaceutical patents:

One of three technology-based industries in which the patent is virtually equal to the product is the pharmaceutical industry. The other sectors are the chemical industry (including agricultural chemicals) and the biotechnology sector, whose innovations range from engineered plant varieties to pharmaceutical therapies for human use. These three sectors, such as computers and electronics, are very different from other patenting industries. While the computer and electronics industries are responsible for many patent filings, they are characterised by the widespread use of other techniques for the management of inventions, including the use of trade secrets and the pooling of patents with those of competitors to meet technical standards of government and industry. More notably, unlike businesses that manufacture goods that need expensive and complicated production infrastructures, pharmaceutical firms' proprietary products can be quickly and cheaply reproduced by copiers with little capital expenditure. Since the pharmaceutical industry's capital spending is overwhelmingly geared toward laboratory testing and clinical studies rather than end product development, patent exclusivity is the most viable way of preserving and recouping the expenditure.

The pharmaceutical industry has a unique aspect that distinguishes it from other businesses that depend on patent security. In certain technology-based companies, it is possible to hold innovations a secret before they are sold. This enables inventors to postpone submitting patent applications until the last practicable moment, maximizing the benefit of the 20-year patent term that follows the submission of a patent application. The culture of medical science, on the other side, stresses very early disclosure of innovations, typically well before a resulting product can be introduced on the market. This is because scientists employed in the field of human anatomy have a duty to discuss their discoveries with their peers as quickly as possible so that other friends working on related projects will profit from the new details. Moreover, unlike other sectors such as computers and electronics, the pharmaceutical sector is tightly regulated by federal authorities to guarantee the quality and effectiveness of drugs marketed to customers. In the United States, this work is carried out by the Food and Drug Administration. Most of the money spent on experimental medications goes into clinical studies, which are used to appease protection and effectiveness regulators. In comparison to other sectors, the pharmaceutical sector has a rather poor tolerance for the "buyer bewares" ideology.

None of the patent incentives have been more successful in attracting technology investment than in the United States' commercial pharmaceutical industry. A strong patent system caused a massive flow of investment into the American industry, combined with a market without price controls (9). A large part of this increase was a shift in investment from Europe, where increasingly onerous price controls threatened the return on capital of investors. This shift is reflected in the fact that in 2002, 82% of global pharmaceutical companies' investments were spent in the U.S. versus 18% elsewhere, including Europe. The outcome for the economy of the United States is that the patent-driven pharmaceutical industry has grown twice as fast as the economy as a whole since 1990. And in the United States, pharmaceutical companies now employ over 223,000 workers (10).

This is not to dismiss the fact that many patients in the world are unable to pay and have no access to these drugs. It is the result of the lack of a source of drug purchase funding for those who are currently too poor to buy them on their own. While Medicaid provides a safety net in the United States for those without health insurance or other means of paying for drugs, no similar source of public funding exists in many parts of the world. However, this has been recognised by the Bush Administration, and Congress is currently in the process of appropriating U.S. tax money for the 2004 fiscal year to subsidise public health authorities' purchases of HIV drugs in poor countries.

Patents and research and development in developing countries:

Few developing countries have private sector industries which are characterised by research and development investment. These countries' economies are based on agricultural commodities,

mineral extraction or low-tech, low-wage manufacturing. And, the scientists and engineers most likely to invent are employed in the public sector in most developing countries, either in state-run laboratories or universities. Historically, these countries have lacked the institutions and policies that encourage and make the patenting and commercialization of public sector employee inventions possible. This is in contrast to developed countries, such as the United States, which have sophisticated publicly funded research commercialization systems in place. This is shown in statistics on patent filings published by WIPO. Over 95 percent of all patent filings in the world are by OECD nationals (11).

Furthermore, many developing countries' national patent offices are under-funded and under-staffed, making it difficult for them to provide local inventors with services.

And the cumbersome and costly global filing formalities make it difficult, if not impossible, for inventors in developing countries to obtain patent protection in the world's major markets, such as Europe, the United States, and Japan.

The controversy over aids medications and the Doha declaration:

The HIV/AIDS epidemic has caused many to question whether new barriers to meeting public health emergencies are created by a stronger global patent regime.

Article 31 of the TRIPS Agreement allows WTO Member States to restrict the exclusive rights of proprietors of patents where it is necessary for a national government to use the patent itself, or where a compulsory licence has to be issued to a third party, such as in a health emergency. While government use is permitted only upon notice to the proprietor of the patent, provided that it is "considered on its individual merits," compulsory licences may be granted only if "attempts to obtain a voluntary licence under reasonable terms and conditions" are made first. And the scope and duration of the use must be limited and it must be non-exclusive for the compulsory licence or government use.

No compulsory licences under Article 31 of the TRIPS Agreement, including compulsory licences involving imports under the Decision of 30 August 2003, have been issued as of this writing. Brazil is, however, in the process of enacting legislation authorising the use of compulsory licences of this kind. The author was also informed that the Government of Brazil requested that patent owners reduce, or face compulsory licencing, already discounted prices for HIV/AIDS therapies used in that country to a level equivalent to those charged in the least developed countries. Such a request clearly violates the provisions of Article 31 of the TRIPS Agreement, reaffirmed in the recent WTO Council decision, that "in the circumstances of each case, the right holder shall be paid adequate remuneration, taking into account the economic value of the authorisation." The "economic value" of a licence is clearly greater in Brazil, a middle-income country, than in the least developed country.

Inadequate patent protection discourages the development of a market for pharmaceuticals addressed to the disease burden of developing countries:

The global pharmaceutical products market was estimated to have a value of $406 billion in 2002. (12). The United States, the European Union, and Japan collectively account for 80% of this sector, while the rest of the planet, which includes Africa, Asia, Latin America, and the Middle East, accounts for just 20% (13). In pharmaceutical research and development occurring in these developed countries, patents play an integral role. And, combined with the ability to ensure a profitable return on investment, the presence of strong patent protection means that commercial pharmaceutical research and development is overwhelmingly focused on producing drugs that will meet patient needs in these developed countries, particularly the needs of patients in the USA. This is confirmed by economic research that has compared the relationship between pharmaceutical companies' gross profit margins with research and development spending (14).

The power of these economic forces to focus pharmaceutical research and development on the disease burden of rich countries with strong patent systems can be seen in the fact that of the 308 essential drugs identified by the WHO in 2002 as essential to developing countries' public health systems, only 5% were patented in any jurisdiction (15) and the WHO estimates that at least one third of all patients worldwide were patented in any jurisdiction (15, 16).

Promising developments:

In some developing countries, there are signs of change. India is one example. This programme involves identifying and patenting useful inventions not only in India, but also in big markets like the United States. CISR received 6 patents from the Patent & Trademark Office of the United States in 1991. The number of U.S. patents granted to CISR increased to 145 in 2002. Many of these patents include pharmaceutical products derived from studies based on traditional knowledge and India's local ecosystem. The product is now on the Indian market and is available in that country for asthma sufferers at a price they can afford (17). As a result of partnerships between CISR and private Indian pharmaceutical companies such as Cadila Pharmaceuticals, Ltd, similar commercialization

activities involving new therapies for leprosy, HIV and cancer are in development (18).

University research in Brazil is leading to biotechnology spin-off companies specialising in products based on the Amazon region's rich genetic resources (19). And organisations such as the Gates Foundation and the Global Malaria Initiative are financing efforts in developing countries to create viable pharmaceutical industries that can address the burden of disease in those countries. An example of these attempts is the innovative efforts of One World, Health, Inc. of San Francisco to transfer patent rights and technology to such companies (20).

Product patents' effect on India's pharmaceutical industry:

After making concessions under the Intellectual Property Rights Agreement on Trade-Related Aspects (TRIPS), the emphasis of India's intellectual property regime has remained on the country's need to provide frameworks to ensure that its people have access to drugs at reasonable rates. India is unusual among developed countries in that it has a large generic pharmaceutical sector that has been able to produce drugs at the world's lowest rates. The Patents Act, passed by India in 1970, is primarily responsible for this extension. Two essential laws helped this process. The first was the creation of a method patent regime for chemicals, and the second was the decrease in the length of issued pharmaceutical patents.

Nonetheless, the TRIPS Agreement's compliance provisions have altered the conditions that have enabled the Indian pharmaceutical industry to flourish. The reintroduction of the commodity patent regime (21) and the limitations placed by this reform on its capacity to manufacture inventions by reverse engineering became crucial issues. The willingness of politicians to take advantage of the stability offered by the TRIPS Agreement was generally believed to be crucial to the industry's potential prospects.

India was expected to completely enforce the TRIPS Agreement by three sets of changes to the country's Patents Act. Although developed countries were usually able to comply with their TRIPS patent laws by an adjustment to be adopted by January 1, 2000, countries like India, which had a method patent system covering pharmaceuticals and agricultural chemicals, will have a longer transition time before being forced to enforce product patents.

While it is commonly held that the immediate impact of India's undertakings under the TRIPS Agreement on access to medicines would have been felt by the 1970 amendment to the Patents Act, more recent developments have somewhat altered that perception. Another dimension of uncertainty for the generic industry has been the requirement under Article 39.3 of the TRIPS Agreement to introduce the protection of tests and other data submitted by pharmaceutical companies to regulators to obtain marketing approval for pharmaceuticals and agrochemicals. This has occurred because the US and the EU have requested that when a company seeks marketing authorisation for a product using a new chemical entity, the data submitted by a pioneering company must be granted a fixed period of protection during which the marketing authorisation of the same or similar product should not be granted to the generic producers. In other words, the US and EU have requested market exclusivity for the 'pioneer' firm for a fixed period.

The prospect of Indian pharmaceutical companies and patents:

Many international corporations have restricted their holdings to patent-expired or chosen proprietary products owing to the absence of product patent security for pharmaceuticals and agrochemicals. Local manufacturers' market share was eroded as reverse engineering enabled them to launch the most advanced medicines. 6 For international medicines, multinational firms were forced to pay royalty, while Indian companies were able to access and reformulate the newest molecules from around the globe for domestic selling (50). As a result, India's medicinal patent privileges have been systematically weakened, contributing to the migration of many foreign research-based pharmaceutical firms.

An exponential growth in R&D expenditure would be the key to survival for Indian pharmaceutical companies. To encourage research into the development of inexpensive drugs that fit the Indian disease profile, Indian businesses need product patent protection.

The larger companies are already increasing their total R&D expenditure as a percentage of sales and are beginning to move in the direction of new molecule discovery rather than focusing exclusively on research in development. While some companies may not make the transition, signs so far indicate that a number of Indian companies will weather the transition successfully and emerge as more innovative businesses (22)

Moreover, the advent of product patents is bound to be a boost for multinational companies which, in the absence of product patent protection, have previously been reluctant to invest in India and will increase competition in the domestic market.

The lack of product patent protection for pharmaceuticals and agrochemicals led numerous multinationals to restrict their portfolios to expired patent items or a few patented items selected. This resulted in their piece of the pie being disintegrated in light of the fact that

By finding out nearby producers presented the most developed prescriptions.

Remote companies were required to pay world drug eminences, while Indian organisations were able to get to the most up-to-date molecules from around the world and reformulate them available for purchase on the local market.

CONCLUSION:

India is slowly moving into global markets and competing with international quality standards and prices. Although R&D is an important factor to ensure a competitive edge in the international arena, the future of the Indian pharmaceutical industry hinges on patent protection. Many developed countries have the ability to grow research-intensive pharmaceutical enterprises that can function profitably by offering drugs aimed at diseases that impact their own population and can be funded by local market economics. Instead of trying to transfer the expenses of drug production to others, customers in both countries should spread the risk of drug development equitably by paying for drugs at a price range that is compatible with their means.

REFERENCES:

1. Kiran, R. & Mishra, S. (2011). Research and development, exports and patenting in the Indian pharmaceutical industry: a post TRIPS analysis. Eurasian Journal of Business and Economics, 4(7), pp. 53-67.
2. S Tyron, http://www.innography.com/blog/will–a-recession-impact-the-patent-industry.htm
3. Meir Perez Pugatch (2011). Patent Pools and Collaborative Initiatives: Assessing the Efficacy of Alternatives to IP in the Development of New Pharmaceutical Drugs, Especially for Neglected Diseases – An Empirical Analysis, European Journal of Risk Regulation, Volume 2, pp. 566-567
4. Ellen F.M. Hoen (2009). The Global Politics of Pharmaceutical Monopoly Power; Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health, p. 3
5. Meir Perez Pugatch (2004). The International Political Economy of Intellectual Property Rights, p.101
6. "Indian Pharmaceuticals Industry Analysis: A Sectoral Presentation". India Brand Equity Foundation. Retrieved 27 May 2019.
7. "Archived copy". Archived from the original on 30 April 2010. Retrieved 14 June 2015.
8. "Pharmaceuticals Market overview and trends"
9. Id at 16
10. WIPO, Industrial Property Statistics, Publication A: 2001
11. Interview with observers at recent Global Fund Board meetings
12. Id.
13. F. Michael Scherer, Ph.D. and J.D. Kleinke (2001). Measuring the Value of Health Innovation: The Policy Implications of New Medical Technology, Congressional Briefing organized by the Alliance for Health Reform and the National Pharmaceutical Council, September 7, 2001.
14. International Federation of Pharmaceutical Manufacturers Association, News Release: TRIPS Council Special Session (Sept. 21, 2001) http://www.ifpma.org/pdfifpma/tripscouncil.pdf
15. World Health Organization [hereinafter "WHO"], The Impact of Essential Drugs http://www.who.int/medicines/strategy/whozip16e/ch04.htm (last visited Apr. 15, 2002).
16. Information supplied by R.K. Gupta, Head, Intellectual Property Management Division, CISR, India. September, 2003.
17. Information supplied by Prabuddha Ganguli, Ph.D., Mumbai, India, September 2003.
18. Information supplied by Prabuddha Ganguli, Ph.D., Mumbai, India, September 2003.
19. Information supplied by Antonia Paes de Carvalho, President, Extracta Molecules Naturais, Rio de Janeiro, Brazil, September 2003.
20. See http://www.oneworldhealth.com for a description of this program
21. The 1970 Patents Act had amended the Patents and Designs Act of 1911, which provided a product patent regime.
22. Jean O Lanjouw, "The introduction of pharmaceutical product patents in India: Heartless exploitation of the poor and suffering?", Center Discussion Paper No. 775.

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