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TRADEMARK PROTECTION AND PHARMACEUTICAL INNOVATION: NAVIGATING THE LANDSCAPE OF GENERIC PHARMACEUTICALS IN INDIA

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ABSTRACT

India's pharmaceutical business has experienced substantial changes due to shifts in the intellectual property system. This study intends to examine how changes in the IP system affect the introduction of generic medications into the market.

The study analyzes the historical background of the Indian pharmaceutical business, The study explores the legal framework, which includes the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and later revisions to trademark laws.

This involves examining the impact of legal disputes, mandatory licensing regulations, and the growth of research and development partnerships between local and global organizations.

The study provides insights into the evolving landscape of generic pharmaceutical businesses and the impact of intellectual property rights, particularly trademarks and patents, on the pharmaceutical industry in India. It discusses key provisions affecting the industry, including trademark laws aimed at protecting brand names and the challenges posed by non-conventional trademarks. Moreover, it delves into the implications of the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement on pharmaceutical patents and the adjustments required in Indian patent legislation. The abstract also explores the concept of compulsory licensing as a mechanism to ensure access to essential medications and the future trajectory of the Indian pharmaceutical industry in light of patent reforms and innovation-driven growth strategies. Additionally, it touches upon the

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debate surrounding evergreening and incremental advances in drug patents, highlighting the recommendations and controversies surrounding patent law reforms in India.

KEY WORDS: Trademark, Generic Pharmaceutical industry, Market entry

Generic pharmaceutical businesses help to make vital treatments more accessible and inexpensive to a larger market. Their techniques are designed to help them navigate the complex pharmaceutical landscape while producing and distributing generic pharmaceuticals at a low cost. These companies often prioritize speedy development and approval, portfolio diversity, international expansion, partnerships, and upholding high-quality standards. By implementing these tactics, generic pharmaceutical businesses play an important role in providing healthcare solutions to communities around the world.

Key Provisions Affecting the Pharmaceutical Industry

Over the past few decades, the Indian pharmaceutical business has grown significantly in terms of market share and contribution to GDP. India's domestic pharmaceutical market is expected to grow from USD 41 billion in 2021 to USD 65 billion by 2024 and USD 120-130 billion by 2030.[2]The Indian government is supporting the pharmaceutical industry by implementing laws that align with global norms, recognizing its growth potential. As the market expands and industry participants spend, protecting intellectual property rights becomes increasingly important for companies.

Trademark Law and Pharmaceutical Industry

Trademark registration protects and adds value to pharmaceutical companies' brand names in the market. The pharmaceutical industry registers more trademarks than any other sector in India.Pharmaceutical trademarks require more protection than other types of trademarks. Section 9(a) of the Trademark Act, 1999, prohibits the registration of trademarks that are descriptive or lack distinctiveness. These trademarks cannot distinguish between goods or services and are likely to deceive the public or cause confusion.However, a trademark can obtain a secondary meaning or distinctive character through long-term use and market familiarity.Pharmaceutical trademarks are typically derived from the drug's treatment, salt

[2] Indian Brand Equity Foundation. Pharma Industry in India: Pharma Sector Overview, Market Size, Analysis. Available at: [Accessed 2 June 2021].

composition, or related medical terms, and lack inherent distinctiveness. However, 'distinctiveness' is required for a mark to qualify as a trademark.

Section 11 of the Trade Marks Act, 1999 states that a trademark cannot be confusingly similar to a previous trademark. To prevent errors in pharmaceutical procurement, clients should be able to discern between items based on brand name, medicine name, and trade dress. Protecting a brand or drug name can be tough. Evidence of secondary meaning or acquired distinctiveness is used to determine the distinction.Section 13 of the Trade Marks Act, of 1999 prohibits trademarks from being names of chemical elements, compounds, or World Health-designated International Non-proprietary Names (INNs).

In 2012, the Registrar of Trademarks alerted organizations that their trademarks were deceptively similar to INNs. Because the listed INNs are generic names of active medicinal compounds, no pharmaceutical company has exclusive rights to them, allowing for widespread use.

To avoid trademark resistance and protect a brand or medicine name, the trademark should not include:

- **Generic words or terms** – Avoid using common terms like "pharma" or "anti" to describe pharmaceutical items. These marks are unlikely to be protected because they merely show the ingredient and not the source of the product, thereby misleading customers.
- **Descriptive terms** define the properties or quality of pharmaceutical medicines or provide related information, such as "REMOVEPAIN" for a muscle relaxant.
- **Suggested words or terms:** Non-descriptive words for pharmaceutical products and services, such as "GRROW" for a children's health supplement.

Non-conventional Trademark Protection

Pharmaceutical companies are developing novel strategies to distinguish their products from competitors in the market. Pharmaceutical businesses are using non-traditional methods to protect their pharmaceuticals' trademarks, beyond just using the brand name or drug name. This prevents customer confusion and underlines the trademark's distinctiveness.

Non-traditional marks in the pharmaceutical sector include medication shapes, color combinations, and trade dress.Pharmaceutical businesses in India have filed sound marks, including Hisamitsu Pharmaceutical Co. Inc.'s "HI-SA-MI-TSU" from Japan. Color trademarks, such as "The Purple Pill" for AstraZeneca's Nexium and "Red and White" for SK&F's Dyazide, assist corporations establish a distinct brand image.

In Cadila Health Care Ltd v. Cadila Pharmaceuticals Ltd[3], the Supreme Court of India established criteria for detecting misleading resemblance between pharmaceutical trademarks. These reasons include:

- The type of the marks, that is, whether they are word marks, label marks, or composite marks;
- The degree of resemblances between the marks, that is, similarity of thought or sound;
- The nature of products:
- Consider the purchaser's education, intelligence, and likely level of care while purchasing and using things.
- The method of purchasing the products or placing orders for them; and
- Consider any additional factors that may impact the level of difference between competing marks.

The European Court of Justice clarifies the nature of confusion in pharmaceutical trademarks. Section 11(1) of the Trade Marks Act, 1999 categorizes the likelihood of deception into three categories: direct public confusion, indirect confusion, and strict association.

In the case of SABEL BV vs. Puma AG, Rudolf Dassler Sport[4], the European Court of Justice evaluated the risk of confusion based on whether the infringed and infringer's drugs treat the same disease. The consumer base differs depending on the ailment, the amount of time spent ensuring correct administration by end-users and pharmacists, and whether the drug is over-the-counter.

The criteria for testing confusion, as outlined in Smith Hayden & Co. Ltd.'s Application[5] and Amritdhara Pharmacy vs Satya Dev Gupta[6] (AIR 1963 SC 449), consider the average

[3] 2001 (5) SCC 73
[4] C-251/95
[5] (1946) 63 RPC 97, p.101
[6] AIR 1963 SC 449

intelligence and imperfect recollection of the layman. Deceptive resemblance can only be established by determining which trademark is likely to deceive.

Patent Law and the Pharmaceutical Industry

The pharmaceutical industry has always been knowledge-intensive and requires significant investment. Pharmaceutical items require a longer development period to achieve success than other businesses. As a result, pharmaceutical companies must take steps to safeguard their ideas by obtaining patents. Patents protect investments in research and development, providing an incentive for inventors to innovate.The patentability of pharmaceutical inventions is a contentious issue, especially in India, due to legal hurdles. Pharmaceutical and related innovations must meet the litmus test outlined in Sections 3 (d), (e), and (i) of the Patents Act, 1970, in addition to the global patentability requirements of novelty, inventive step, and industrial applicability.

Protection of Pharmaceutical Patents:

Section 3 of the Patents Act, 1970 identifies inventions that are not patentable, even if they meet the patentability criteria.Section 3(d) of the Patents Act, of 1970, is particularly relevant to pharmaceutical inventions. It states:

"the mere discovery of a new form of a known substance which does not result in theenhancement of the known efficacy of that substance or the mere discovery of any newproperty or new use for a known substance or of the mere use of a known process, machineor apparatus unless such a known process results in a new product or employs at least one newreactant.

Explanation - For this clause, salts, esters, ethers, polymorphs, metabolites,pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and otherderivatives of known substance shall be considered to be the same substance, unless theydiffer significantly in properties about efficacy".

The goal of 3(d) of the Patents Act, of 1970, is to prevent the ever-greening of pharmaceutical patents and make ideas related to drugs or chemical compounds patentable. This section states that an invention claiming a new form or subsequent use of a known

substance with established medicinal activity is not patentable unless it significantly improves therapeutic efficacy compared to the known compound.

In Novartis AG vs. Union of India (UOI) and Ors[7], the Supreme Court of India stressed the genuine legislative meaning of Section 3(d) of the Patents Act, 1970, stating that –

"Section 3 (d) is meant specially to deal with chemical substances, andmore particularly pharmaceutical products. The amended portion of section 3(d) clearly setsup a second tier of qualifying standards for chemical substances or pharmaceutical productsin order to leave the door open for true and genuine inventions but, at the same time, to checkany attempt atrepetitive patenting or extension of the patent term on spurious grounds"

The Court interpreted "efficacy" in pharmacological patenting as the ability to achieve a desired result.Changing the form of an existing form without altering its intrinsic qualities does not result in "enhanced therapeutic efficacy". To be patentable, a novel form must clearly demonstrate medicinal efficacy.

The Indian Patent Office allows applicants to provide additional documents or experimental studies to support the "therapeutic efficacy" of their inventions that were not disclosed in the specifications at the time of filing.

Section 3(e) of the Patents Act of 1970 addresses the patenting of combination inventions in chemical and microbiological sciences. It states that –

"a substance obtained by a mere admixture resulting only in the aggregation of theproperties of the components thereof or a process for producing such substance" is notpatentable"

The Indian Patent Laws state that a simple combination of components that performs a function separately is not patentable. This notion is widely acknowledged. The patentable subject matter involves the interrelationships between components that lead to novel or improved results.

The Indian Patent Office typically rejects pharmaceutical composition claims under Section 3(e) of the Patents Act, 1970, as they involve a recognized composition or admixture without synergistic effects. Objections to patent applications often stem from vagueness in wording

[7] MANU/SC/0281/2013

like "mere admixture" and "aggregation of the properties" under Section 3(e) of the Patents Act, 1970.

In LallubhaiChakubhaiJarivala v. ShamaldasSankalchand Shah[8], the Bombay High Court defined "mere admixture" as mixing recognized chemicals with the anticipation of an additive effect. A synergistic composition occurs when an admixture produces a greater effect than predicted.If a substance and its qualities are unknown, it is impossible to create an admixture. The chemical compositions of the new substance or compound cannot be deemed a "mere admixture" because they were not disclosed in the prior art and their properties were unknown.

The case of Ram Pratap v. Bhaba Atomic Research Centre[9]clarifies that aggregation of properties does not constitute a patentable invention. It is simply a juxtaposition of features that were already known prior to the priority date and chosen arbitrarily from various combinations.

According to Section 3(i) of the Patents Act, 1970, "any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or animals to render them free of disease or to increase the economic value or that of their products" is not a patentable invention.Pharmaceutical companies frequently claim treatment methods as composition claims. However, treatment-related claims are not patentable in India. Patents can be granted for surgical, medicinal, or diagnostic devices and apparatus.

Under the Patents and Designs Act of 1911, India had a product patent regime that applied to all inventions under its jurisdiction. The new Patents Act, which was established by the government in 1970, stipulated that pharmaceuticals and agrochemical products were not eligible for patent protection. India's dependency on imports for bulk pharmaceuticals and formulations was the impetus for the introduction of this exclusion, which was designed to facilitate the growth of an indigenous pharmaceutical industry that is capable of generating its own revenue. There was a significant impact on the Indian pharmaceutical industry as a result of the absence of product patent protection in the pharmaceutical and agrochemical industries. This led to the development of a considerable amount of expertise in reverse

[8] (1934) 36 BOMLR 881
[9] (1976) IPLR 28 at 35

engineering of drugs that are patentable as products in the industrialised world, but are not protected in India.

As a consequence of this, the pharmaceutical business in India experienced rapid expansion through the creation of more affordable copies of a number of pharmaceuticals that were patented for the domestic market. Eventually, the sector moved aggressively into the worldwide market with generic drugs after the international patents expired. In addition, the Patents Act includes a variety of measures that are designed to prevent companies from abusing their patent rights and to improve access to pharmaceutical remedies.4. Despite the fact that there has been a recent adjustment in the Drug Price Control Orders in 2013 and 2021, which has once again resulted in the entry of foreign players, the situation has not changed.

In addition, the Patents Act has provisions that provide compulsory licencing. This is a measure made by the government to ensure that important items are accessible to everyone, rather than giving priority to the monopoly that patent holders have. Any anyone who is interested in working on the patented innovation may submit an application for a compulsory licence with regard to the invention after the completion of three years from the date the patent was sold. If the Controller of Patents is satisfied that the reasonable requirements of the public with regard to the patented invention have not been met, or that the patented invention is not available to the public at a price that is reasonable, then she has the authority to direct the patent holder to grant such a licence on terms that may be deemed appropriate.

THE IMPACT OF THE WORLD TRADE ORGANIZATION ON PHARMACEUTICAL PATENTS

An enormous paradigm change has occurred in the realm of international trade as a direct result of the founding of the World Trade Organisation (WTO). It was during the Uruguay round of trade negotiations of the General Agreement on Tariffs and Trade (GATT) that the agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was negotiated. According to the documents, "one of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry." It was on April 15, 1994 that India signed the General Agreement on Tariffs and Trade

(GATT), which made it obligatory for India to comply with the obligations of the GATT, including the agreement on TRIPS.

As a result, India is obligated to fulfil the minimum requirements stipulated by the TRIPS Agreement in regard to patents and the pharmaceutical business. In order to ensure that pharmaceutical items and process inventions are eligible for patent protection, the patent legislation in India must now incorporate requirements for patent availability. Patents are to be issued for a minimum term of twenty years to any invention of a pharmaceutical product or process that satisfies the requirements that have been specified.

Compulsory licence provisions under Indian law will be required to be limited and conditional in order to comply with the TRIPS Agreement. The government will only give such licences based on the merit of each individual case, after providing the patent holder with the opportunity to be heard.[10] In addition, in the case of process patents, there will be no discrimination between local and imported products, and the party that infringes will be the one who is responsible for providing evidence of their infringement.

India has made the decision to take advantage of the full transition period that is available to developing countries. The country has until January 1, 2005, to extend patent protection to pharmaceutical items. India has begun the process of modifying the Patents Act in accordance with the TRIPS commitments5. This would involve the provision of exclusive marketing rights (EMRs) and the establishment of a mailbox system for patent applications for a period of five years, or until the patent is granted or denied, whichever comes first.

Pipeline protection is a provision that was included in the Patents (Amendment) Act of 1999. This clause provides the inventors with the ability to protect their inventions. If the applicant has already submitted an application for his or her invention in any convention country and a patent or EMR has been granted in that country on or after January 1, 1995, then the applicant would be qualified to submit an application for a patent in India as it pertains to

[10] Nilesh Zacharias- Patents and the Indian Pharmaceutical Industry, https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Patents_and_the_Indian_Pharmaceutical_Industry.pdf, Last visited 30th March 2024.

pharmaceutical and agrochemical products. Until further notice, these patent applications will remain pending.

If India follows the advice of the World Trade Organization and makes adjustments to its patent legislation, then the pending patent application will be eligible for product patent. The applicant will be given electronic medical records (EMRs) in India if the application is judged to be qualified for such a patent. This will continue for a period of five years, or until the patent is either granted or refused. The updated Patents Act also includes a provision that prohibits Indian inventors from applying for patents outside of India without the approval of the Indian government. Additionally, the amended Patents Act includes a section that provides for a compulsory licencing for the electronic medical record (EMR) in the same manner as patents.

The newly enacted legislative provisions that are intended to fulfil India's commitments under the TRIPS agreement are currently in the process of being completed. The Patents (Second Amendment) Bill 1999, which amends India's patent law to include product patents for pharmaceuticals and agrochemicals, has not yet been approved. However, recent press sources have indicated that the Bill is likely to be presented to the Indian parliament in the near future.

COMPULSORY LICENSING: MECHANISMS AND IMPACT

The debate over patent law reforms often overlooks the importance of compulsory licensing, which is a crucial component of the patent system. Compulsory licenses prohibit patent holders from abusing their statutory rights to prevent competitors from entering the market. This is widely acknowledged.

The Paris Convention has established the context for this issue. Article 5A of the Stockholm Act of the Paris Convention defines "failure to work"or "insufficient working" of a patent as an "abuse" of patent rights. If patent rights are abused due to insufficient or non-working, the awarding authority can offer a license to anyone willing to "work" on the patent.

From a functional perspective, compulsory licensing allows developing countries to get access to patented technologies. The obligatory licensing approach could benefit generic

enterprises in the Indian pharmaceutical industry, which cannot match technical standards through reverse engineering.Implementing a compulsory licensing system may result in inconsistent outcomes due to differing interpretations of how a TRIPS-compliant system should work among patent owners and potential users of patented technologies in developing countries. The patent community believes compulsory licenses should only be used in extraordinary circumstances.[11]Developing countries have used compulsory licensing to allow domestic firms to produce pharmaceuticals, which is considered as a crucial step towards improving access to medicines.[12]

The Commission on Intellectual Property Rights (CIPR), established by the UK Department for International Development, also supported compulsory licensing. In the publication of its study, "Integrating Intellectual Property Rights and Development Policy" , the European Commission pointed out that "developing countries should establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use"[13]

The CIPR recommends that developing nations implement efficient compulsory licensing arrangements that are easy, transparent, and do not impede license execution. The CIPR emphasized that developing nations should fully utilize TRIPS flexibilities for compulsory licensing and non-commercial government use, such as export production.Although India's new Patents Act includes a compulsory license scheme, it may not fully meet the needs of the indigenous pharmaceutical industry. We have this opinion for the reasons mentioned below.

According to the Indian Patents Act, compulsory licenses can only be granted after three years from the patent grant date, unless exceptional circumstances such as a national or extreme emergency justify granting the license earlier. The three broad grounds for granting compelled licenses are as follows:

(a) The public's reasonable needs for the patented innovation were not met.

[11] According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the association of the global pharmaceutical majors, “Compulsory licenses, are an exceptional remedy for use only in the case of market failure or significant abuse of a patent (e.g. a demonstrated antitrust violation linked to use of a specific patent, or a state of national emergency under which normal rules of commerce are suspended)”. For details see Coalition for Intellectual Property Rights (2002)

[12] South Africa and Brazil are among the more prominent countries that have included compulsory licensing provisions in their patent laws.

[13] Commission on Intellectual Property Rights (2002), , p. 44

(b) The patented invention is not cost-effective for the general public.

(c)) The patented invention is not applicable in India. The Patents Act defines when "reasonable requirements of the public" are not met.

If a patent holder refuses to issue a license on reasonable terms, it can lead to:

(i) Developing new trades or industries in the country.

(ii) Establishing or developing commercial activities in India,

(iii) The expansion of the export market for a patented product developed in India.

The final provision allows India to export products developed under patent holders' licenses. This clause might significantly impact the pharmaceutical sector, with India potentially becoming a major exporter of generic medications to poor countries without adequate domestic manufacturing facilities.

The Act requires the appropriate authorities to consider four additional reasons before granting obligatory licenses, but the above-mentioned conditions may facilitate the process. This includes:

(a) The nature of the invention, period since patent sealing, and actions taken by the patentee or licensees to fully use the invention;

(b) The applicant's ability to benefit the public through their invention.

(c) The applicant's willingness to accept the risk of supplying funds and working on the invention.

(d) Attempts to get a license from the patentee on acceptable terms and conditions failed within a reasonable timeframe.[14]

Considering these considerations when giving forced licenses causes many issues. Procedural requirements may cause delays due to their excessive complexity. Second, it is unclear whether granting a forced license invariably follows a patentee's reluctance to offer a voluntary license on reasonable commercial conditions. Third, neither the Patents

[14] The third amendment provided some crucial clarifications pertaining to this condition. The designated authority has been allowed to interpret the term “reasonable period” to mean a period not ordinarily exceeding six months (Section 84(6))

Act nor the Competition Act specify the criteria for determining anti-competitive actions.[15]

Finally, there is no limit on patent holders' payment, which may result in excessive royalties and unneeded litigation. The issue described below may hinder the implementation of compulsory licensing.

Foreign corporations operating in India have complaints about the Patents Act, 1970, as amended, which includes compulsory licensing restrictions. Some firms argue that the current triggers for compulsory licensing are overly broad and go beyond the scope of public health emergencies. The Doha Declaration clarifies that CL provisions should only apply to "national emergency" situations.

The payment that a patent holder may claim after the decision to grantCompulsory licenses for "working" patents in the grant nation can hinder the licensing system's efficiency. The TRIPS Agreement gives copyright holders a significant advantage in negotiations. According to Article 31(h) of the TRIPS Agreement, the right holder is entitled to adequate remuneration based on the economic worth of their authorization.This Article may make obtaining a license prohibitively expensive for drug companies, as bringing a new medicine to market often costs at least a billion US dollars.[16]

Foreign firm colleagues say that the legal definition of "economic value of licenses" is unclear, leaving it up to the Controllers' discretion to determine license terms and conditions.According to these corporations, the compulsory licensing rules in Indian law prioritize the interests of the applicant over those of the patentee, making it harder for patent holders to protect their interests.

Implementing the compulsory licensing scheme outlined in the Indian Patents Act requires careful consideration of royalty payments. Developing countries often struggle to acquire patented technologies due to their high cost, in addition to the issues mentioned

[15] In fact, India's Competition Act (enacted in 2002) does not address abuses of patent rights. Section 3(5) of the Competition Act, states: "Nothing contained in this section shall restrict … the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under … the Patents Act, 1970. See Govt of India (2003)

[16] The Pharmaceutical Research and Manufacturers of America (PhRMA) states that it takes as long as 15 years and cost nearly 1 billion dollars to bring a new medicine from the laboratory to a pharmacy shelf. This figure has, however, been challenged by several public interest groups. See PhRMA (2006).

above. Technology owners have leveraged their better bargaining position to secure favorable conditions.

In today's world of several patents covering a single product (called as patent thickets[17]), companies typically need to negotiate multiple licenses before starting production. Patent thickets have led to royalty stacking issues. An OECD research found that royalty payments can sometimes surpass 20% of net sales [18]. In South Africa, GlaxoSmithKline requested a 25% royalty before judges intervened. Higher royalty rates will raise the cost of generic drugs, threatening the survival of generic makers who aim to provide affordable medicines.

In South Africa, GlaxoSmithKline requested a 25% royalty before judges intervened. Higher royalties will raise generic drug prices, threatening the survival of generic firms who aim to provide affordable medicines.

India's own experience with technology licensing agreements is fascinating reading.Historically, licensors have received royalties for their innovations, even without relinquishing proprietary technologies. Over a three-decade span, the Reserve Bank of India conducted surveys on overseas collaboration agreements and found that proprietary technologies were only transferred in approximately 50% of cases.[19]

The Indian Patents Act's royalty and remuneration provisions do not address the issues outlined above. Section 90 states that remuneration should incorporate the patentee's perspective, including expenses for invention development, patent acquisition, and renewal. concerns for determining royalties and remuneration may strengthen the patentee's bargaining power, but must be balanced with public interest concerns.[20]

The Doha Declaration on TRIPS Agreement and Public Health emphasizes the importance of flexibility for Member nations to implement efficient compulsory licensing systems. Based on the conversation, it is clear that India's compulsory licensing system does not adequately meet public interest issues. Licensing can be delayed due to

[17] 8 A more formal definition of patent thicket is the following: it is a “dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology”, see Shapiro (2001) quoted in Federal Trade Commission (2003).
[18] OECD (2002), p. 15
[19] Reserve Bank of India (1974); Reserve Bank of India (1985), p. 36.
[20] Dhar and Rao (2004).

procedural complexity, but ambiguities in assessing patentee remuneration might provide significant challenges. The latter issue, in our opinion, deserves concerted attention.

Consider two alternative approaches for estimating the value of licences issued through compulsory licensing provisions. These were sections of two measures brought to the 107th Congress of the United States in 2001. The Affordable Prescription Drugs and Medical discoveries Act (HR 1708) proposes amending the US Patent Law (Title 35, United States Code) to require compulsory licensing of certain health-related discoveries. The Public Health Emergency Medicines Act (HR 3235) amends the US Patent Law to require compulsory licensing of certain patented technologies related to healthcare emergencies.

Given the limits of the compulsory licensing system, we recommend a reassessment based on the experience of implementing the modified Patents Act. India lacks a successful compulsory licensing system, making this experience valuable[21]. Prior to 1970, there were just five applications for compulsory licensing under the product patent regime. Only two licenses were given and one denied. The remaining two applications were later withdrawn.[22]

After 1970, India implemented a process patent framework for all chemicals, including medicines. Pharmaceutical process patents have a five to seven-year term[23]. The process patent regime in India enabled Indian pharmaceutical firms to develop alternative manufacturing processes that were previously protected by product patents in other jurisdictions. However, the shorter term of pharmaceutical (process) patents discouraged foreign firms from seeking patents.

BARRIERS FACED BY GENERIC PHARMACEUTICAL COMPANIES

[21] Although India had introduced the Patents and Designs Act in 1911, provisions specifically dealing with compulsory licenses for pharmaceutical patents were introduced only in 1953. See, Rao (2002)
[22] Chaudhuri (1984).
[23] The term was five years from the date of grant of a patent, or seven years from the date of its application, whichever was shorter.

Several obstacles and challenges exist in the distribution of generic pharmaceuticals in India, resulting in a lower level of acceptance of pharmacy products drugs in the country. Some of the concerns and challenges are addressed here.[24]

The majority of generic medications supplied in retail pharmacies are branded and hence cost more. However, it should be mentioned that unbranded generic pharmaceuticals are comparable to branded drugs on the market. The quality of the molecule is determined by its research, processing, and manufacture. These generic drugs are just as effective in treating patients as branded medicines, as long as the required precautions are taken during the manufacturing process to ensure product quality. If good manufacturing practices (GMP) are followed, pharmaceutical products may become more affordable to the average person.The Medical Council of India (MCI) has issued a code of ethics, which presents another obstacle. In 2002, the MCI issued instructions to physicians directing them to prescribe pharmaceuticals to patients using only generic names and to avoid including branded names in the prescription. The medical community is expected to implement MCI's 2016 announcement, which altered clause 1.5 of the Indian Medical Council (Professional).

However, for a variety of reasons, this is rarely implemented in practice. Doctors continue to provide branded drugs to their patients without hesitation. This raises the issue of the market's increasing prevalence of counterfeit and harmful pharmaceuticals. Doctors prescribe it to improve their business and retain their partnership with these brand holders.[25]

Due to a lack of openness in drug licensing procedures, there has been an increase in the availability of low-quality, counterfeit, and substandard pharmaceuticals. According to a WHO report, the Mashelkar Committee has concluded that over 30% of pharmaceuticals in the Indian market are counterfeit, substandard, or spurious. Although numerous bodies exist, their actual execution to ensure drug quality is insufficient, as the government itself reports that there are 8-10% substandard pharmaceuticals and 0.3 to 0.5% counterfeit drugs in the Indian market.

However, it should be noted that, despite being the world's third largest pharmaceutical market (by volume), the regulatory agencies established to enforce drug production

[24] Asher, Mukul G (2014) Social Protection Initiatives in India. Lee Kuan Yew School of Public Policy Research Pp: 17-12.
[25] Dixit A, Kumar N, Kumar S (2018) Use of Generic Medicines. Journal of Health.

regulations are not working efficiently. If this is accomplished and all manufacturers adhere to GMP/ICH guidelines, India may ensure that its generic pharmaceuticals are of comparable quality to branded drugs. India can learn from China's experience in implementing such an approach.

The third difficulty is that, even if the doctor prescribes a generic drug, the pharmacist only offers branded medicines since they are more profitable, regardless of the cost to the patient. This approach strikes at the heart of the goal of making medical care affordable to all segments of society.This refers to the reality that prescription generic pharmaceuticals by doctors will just move the focus of the pharmaceutical industry's unethical drug promotion to the pharmacy rather than the prescriber. This will lead to the spread of business and bogus commissions.[26]

The next difficulty is the lack of adequate generic name equivalents of branded drugs on the market. This issue affects over 90% of the Indian pharmaceutical sector, which contains over 1,00,000 crores of pharmaceuticals. Add to this the problem of naming a fixed dose combination (FDC): when two or more Active Pharmaceutical Ingredients (API) are combined to form a single dosage form or drug, a Fixed-Dose combination (FDC) is formed, which is manufactured, dispensed, and distributed in fixed doses.There are numerous FDC medications and brand names for the same purpose FDCs. More issues develop when FDCs have more than two APIs, which can sometimes reach eight or nine. Choosing a generic name for each of the eight or nine elements is both time-consuming and impracticable.

PATENTS AND THE FUTURE OF THE INDIAN PHARMACEUTICAL INDUSTRY

Patents have a huge impact on the future of the Indian pharmaceutical business, especially in terms of innovation, competitiveness, and access to medications. Historically, India's patent rules supported the development of generic medications, earning the nation the moniker "pharmacy of the developing world." However, in 2005, India introduced product patents as part of its compliance with the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which had a substantial impact on the industry's landscape.

[26] Bell RG, DeStefano A, Jeiven M, Kak N, Kancijanic S, et al. (2015) Improving the Quality of Generic Drugs.

With the introduction of product patents, Indian pharmaceutical businesses encountered difficulties in creating generic versions of copyrighted pharmaceuticals, particularly those with monopoly protection. This transition pushed them to change their strategy in order to remain competitive and grow in the global marketplace. Some important aspects about patents and the future of the Indian pharmaceutical sector include:

- ***Innovation and Research Investment:*** Product patents encourage innovation by giving pharmaceutical businesses exclusive rights to their ideas for a set time. In response, Indian pharmaceutical companies have increased their investment in research and development (R&D) to produce novel drugs and protect their own patents. This change toward innovation-driven growth has the potential to reshape the Indian pharmaceutical industry and boost its global competitiveness.
- ***Focus on Niche Markets and sophisticated Generics:*** While producing generic versions of proprietary medications may become increasingly difficult, Indian pharmaceutical businesses can continue to thrive by concentrating on niche markets and sophisticated generics. They might carve out a position in the global market by gaining competence in manufacturing complex formulations or meeting unmet medical demands.
- ***Strategic Partnerships and Collaborations:*** Indian pharmaceutical businesses are increasingly developing strategic alliances and collaborations with multinational corporations to gain access to new technologies, markets, and R&D capabilities. These alliances allow them to capitalize on their strengths while minimizing risks and growing their worldwide footprint.
- ***Regulatory Compliance and Market Access:*** To get access to global markets, Indian pharmaceutical businesses must comply with international patent laws and regulatory requirements. Investing in regulatory competencies and ensuring compliance with intellectual property rights (IPR) legislation is critical for preserving market access and building confidence with foreign partners and customers.
- ***Affordable Medicines and Access to Healthcare:*** Despite the hurdles faced by patents, Indian pharmaceutical companies remain devoted to their aim of providing affordable medicines to patients around the world. They continue to help improve healthcare access in both developing and developed countries through programs

including voluntary license agreements, technology transfers, and differential pricing schemes.

Update on Evergrening

At the moment, there is a powerful lobby that is attempting to convince the government to permit evergreening, which is the process of patenting molecules that differ slightly from the parent molecule. The contention is that compounds are patented at a very early stage in the process of drug development; yet, distinctive clinical qualities or benefits are not discovered until a significant amount of time later, when clinical studies are carried out, assuming such trials are carried out at all. Therefore, it is illogical to want that the distinctive properties of a molecule that has been significantly modified be detailed at the time that the patent application is being submitted inside the patent itself. It is not always the case that India is at a disadvantage through evergreening. In the event that evergreening is allowed, for instance, Indian businesses might be able to create and patent modest improvements on patented medications.

A committee on patent laws that was appointed by the government and led by R. A. Mashelkar, who had previously served as the president of the Council for Scientific and Industrial Research, advocated for the granting of patents to all incremental advances made to a drug, but they did not allow patents to be granted for frivolous evergreening. The majority of people believed that the report allowed for the majority of evergreening practices. Moreover, the paper advocated for the granting of patents on microorganisms in order to make the Indian Patents Act more compatible with the TRIPS agreement. After it was discovered that a portion of the study had been lifted, without acknowledgment and verbatim, from a paper that had been published by an organisation located in the United Kingdom that had been funded by the pharmaceutical business, the report was withdrawn in the middle of February of 2007. In March of 2007, the government placed a request to the Mashelkar committee, requesting that they modify and resubmit their report that had been criticised.[27]

In a comparable vein, the Patents Act does not specify the degree of originality that the novel molecule must possess; hence, the decision-making process for the granting of a patent incorporates a degree of subjectivity. Taking this into consideration, the pharmaceutical

[27]Mashelkar Committee Report [Last accessed on 2006 Jan27] Available from: http//www.patentoffice.nic.in/ipr/patent/mashelkar_committee_report.doc, Last visited 30th March 2024.

sector is afraid that the authorities who are involved in the process of granting patents might not have the necessary qualifications to comprehend the subtleties in molecular behaviour that are necessary to justify novelty and, consequently, the giving of a patent.