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Patent Rights and Public Health: Examining Infringement Trends in the Indian Pharmaceutical Landscape

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Patent Rights and Public Health: Examining Infringement Trends in the Indian Pharmaceutical Landscape

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Abstract
Patents are among the main kinds of Intellectual Property Rights (IPRs) utilized in the pharmaceutical sector. India's patent system underwent substantial modifications following its ratification of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement in 1995.
Patent law's main task is to strike a balance between access and innovation. Pharmaceutical patents are a major point of dispute between industrialized and developing nations. The pharmaceutical business claims its right to patent ownership, generating profits from elevated prices and research and development expenses. Developing nations demand lower prices for manufacturing and acquiring medications. India has been amending pharmaceutical patent laws to meet the country's health requirements, especially for individuals who are unable to buy costly medications. Technology has played a crucial role in the progress and development of civilization, and mandatory licensing in the TRIPS Agreement can assist in tackling health concerns. Indian pharmaceutical businesses play a significant role in distributing low-cost drugs, highlighting the need of pharmaceutical licensing for public health. Compulsory licensing in the TRIPS Agreement permits generic drug manufacturers to make patented pharmaceuticals, ensuring cost-effective availability of these medications for individuals requiring them. This study intends to examine Nature and scope of patent infringement in the pharmaceutical industry. The text explores the legal framework, which includes the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and later revisions to national patent laws.

Key Words: *Patent, Pharmaceutical industry, TRIPS*

IPR And Patents

India's intellectual property regime, established after committing to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), prioritizes creating mechanisms to ensure affordable access to medicines for its citizens. India stands out among developing countries due to its robust generic pharmaceutical industry, enabling the production of medications at highly competitive costs globally. The Patents Act enacted by India in 1970 deserves much credit for this progress. Two crucial provisions enabled this approach. The first change involved implementing a process patent system for chemicals, while the second change was reducing the duration of patents issued for pharmaceuticals. The requirements to enforce the Agreement on TRIPS altered the circumstances under which the Indian pharmaceutical industry had established itself. The main problem was the reinstatement of the product patent system and the restrictions it placed on the ability to develop technology through reverse engineering. The industry's future prospects were seen to depend significantly on the policymakers' capacity to utilize the flexibilities within the Agreement on TRIPS.
India needed to make three sets of adjustments to its Patents Act to fully fulfil the Agreement on TRIPS. Developing countries were given the opportunity to align their patent laws with TRIPS standards by January 1, 2000. However, countries like India, which had a process patent

system for pharmaceuticals and agricultural chemicals, were granted an extended transition period until January 1, 2005, before they had to implement product patents.[1]

India's obligations under the TRIPS Agreement were first expected to primarily affect access to pharmaceuticals through amendments to the Patents Act, 1970. However, a recent development has altered this perception. Article 39.3 of the TRIPS Agreement mandates the protection of test and other data provided by pharmaceutical companies to regulators for marketing approval, creating uncertainty for the generic industry. The US and EU require that a firm seeking marketing approval for a product containing a new chemical entity must provide data protection for a fixed period. During this time, generic producers are not allowed to obtain marketing approval for the same or a similar product. The US and the EU have requested fixed duration commercial exclusivity for the pioneer firm.

Pharmaceutical corporations invest billions of dollars in research. Out of every thousand prospective medications tested, approximately 4-5 advance to clinical trials, with only one ultimately authorized for sale. Pharmaceutical corporations patent their developed pharmaceuticals to get exclusive marketing rights. They recover research costs and income for shareholders by setting prices for patients who use the copyrighted drugs. Drug patents and exclusive marketing rights are granted internationally for a 20-year period, during which no other pharmaceutical company can produce or sell the same drug. Once the patent expires, other companies can produce and sell the drug under their own brand names, which are referred to as generic versions. This paper examines the consequences of India's commitments under the Agreement on TRIPS upon joining the World Trade Organization (WTO) in 1995, with a focus on the pharmaceutical industry's interests.

In the pharmaceutical industry, research costs are measured in the billions of dollars. Out of every thousand possible treatments that are evaluated, it is believed that only four to five of them make it to clinical trials, and only one of them is really approved for commercialization. With the help of suitable pricing mechanisms, pharmaceutical companies are able to recover the expenses of research and the profits that are owed to shareholders from the patients who receive the patented pharmaceuticals.[2] Pharmaceutical businesses obtain exclusive marketing rights by patenting the drugs that they produce.

On a global scale, medication patents and the exclusive marketing rights that are associated with them are granted for a duration of twenty years. During this time period, no other pharmaceutical company is permitted to manufacture or market the same drug. Following the expiration of the patent, other businesses are granted permission to manufacture and sell the medication; the brands that they produce are referred to as generic versions.

At the beginning of the 1970s, the government of Indira Gandhi enacted the Indian Patents Act in order to make it possible for the less fortunate people in the country to have easier access to medications at more affordable prices. According to the Act, patents on processes would be recognised, but patents on products would not be recognised. To put it another way, India would not grant patents to specific medications but rather to the manufacturing process that was used to produce the individual medication. On account of this, Indian pharmaceutical companies were able to produce the same medicine by employing different manufacturing procedures (this is often referred to as reverse engineering). In light of the fact that Indian corporations spent very little money on the research and development of new medications, it became feasible to make new medications accessible to the nation at prices that were within their financial means.

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[1] Biswajit Dhar and KM Gopakumar, "Effect of Product Patents on the Indian Pharmaceutical Industry".

[2] Chittaranjan Andrade, Nilesh Shah, et.al., "The New Patent Regime: Implications for Patients in India" 1 Indian Journal of Psychiatry 56-59 (2007).

1 Evolution of Patent Laws In India

In India, it was difficult for the general populace to access the medicines needed for human treatment. These medications were primarily imported from other nations. Due to a shortage of natural medications and considerable demand, prices are quite expensive. The local law was impacted by the external law. India had some of the highest drug prices in the world.

Patent law is crucial because it encourages technological innovation. By defending the rights of the innovators, it promotes scientific investigation and progress. Regularization and assistance with patent registration are provided by patent law. The primary goal of the development of patent law was to guarantee that innovation is unrestricted and to encourage people to continually innovate by providing protection for their creations. As a result, patent law is crucial because it safeguards innovators' rights. The value of patents is acknowledged on a global scale.

Promoting new scientific discoveries, cutting-edge technologies, and industrial progress was the main objective of patents. Under patent law, an inventor has the exclusive right to use their patented products, however others may use them under certain conditions and for a charge.

In the past, the goal of patent protection was to encourage innovation and the transparent sharing of the details of new concepts. By providing a temporary monopoly on their use, patent protection encourages the sharing of ideas—something that inventors may be reluctant to do for fear that someone else would copy their creation. The innovation is fully disclosed in the application that is available to the public.

The inventor can recover the cost of inventing the innovation during the patent protection term by:

- Enforcing the patent to exclude competitors, monopolising the market, and setting a high price
- Granting the invention to others under a licence in exchange for royalties.
- Filing a lawsuit for damages if a person or company violates the patent.
- Selling the invention to a third party

Patent protection is significantly more reliable than other types of intellectual property protection, such as copyright. Copyright just protects the method an idea is communicated; it does not prevent others from expressing the same idea in different ways. Furthermore, using patents as a negotiating tool can be successful. If a Cooperation wishes to use a patent that is owned by another company but also has patents that the company may use, it may be able to negotiate a zero-sum contract or a reduced licencing fee. One scientist's scientific discoveries influence and inform those of other scientists. Industries would stall if discoveries were kept a secret, therefore promoting dissemination is advantageous for society and business as a whole.

A patent gives the inventor the authority to produce, use, market, sell, and import the invention for the predetermined time. In other words, the patent holder has the exclusive authority to forbid or halt anyone from making use of the protected invention for commercial purposes. Without the permission of the patent holder, the innovation cannot be made, utilised, disseminated, imported, or sold for a profit. It safeguards against patent infringement, meaning that the original inventor can take legal action against any products that attempt to copy their invention or infringe on a patent that has already been issued.

Science would undoubtedly advance slowly if everyone kept their discoveries a secret. So encouraging people to disclose their discoveries appears to be an effective method to advance science and useful arts. However, letting others benefit from your discovery by sharing it with them is an excellent method to do so.

Pharmaceutical Industry Patenting System

In spite of the fact that it operates under rigorous price-related rivalry and government price regulations, the pharmaceutical sector in India is a technologically advanced industry that has shown signs of expansion over the course of the previous three decades. It would be beneficial to undertake a concise analysis of the primary regulation and the economics of patents6 in order to gain an understanding of the concerns that are related to the pharmaceutical business. A patent is a particular privilege that is awarded to the creator of an invention, allowing them to construct, manufacture, employ, and advertise the creation, provided that the innovation satisfies certain conditions that are defined in the law. There are certain selective rights that state that the innovation cannot be used, manufactured, marketed, or manufactured by anyone else without the consent of the patent holder. With the exception of the fact that it can be transferred, the patent in India is only valid for a period of twenty years and cannot be renewed. A country is able to create and advertise an innovation in that country that is connected with protected data lines when the patent is designated in that country. Additionally, organisations are able to supply the significance associated with the profits of their finances in research and development when the patent is designated in that country. Additionally, many nations in the southern regions of the world have struggled to make patents available for pharmaceutical products. This is occurring at the same time that patenting in the pharmaceutical business is becoming more commonplace in the northern portions of the world. [3]

Patents that are primarily concerned with treatments for medical conditions are known as pharmaceutical patents. The active medications, innovative formulations, and strategies that are utilised are all included in it. [4]As a result of the fact that public health has always been at the forefront of any government's concerns, a significant amount of attention is placed on the availability of pharmaceuticals, which in turn leads to an increase in the price that society is ready to pay for that drug. This issue has been resolved as a result of the contract on Trade-Related Aspects of Intellectual Property Rights, which ensured that a blanket period of twenty years would be in place. The concept of compulsory licencing was also introduced as a result of this contract, which was draughted with the understanding that it is essential for pharmaceuticals to be accessible in regions that are experiencing growth. Therefore, patent protection for drugs is a prime example of changing the period of the patent while simultaneously making it accessible to the public. [5]

Remedies for Infringement of Patents

Section 108(1)[6] Specifically, the remedies that are available to the plaintiff in the event that his patent rights have been violated are outlined in Section 108(1) of the Patents Act. This means that the court has the authority to grant reliefs such as injunctions and, at the discretion of the plaintiff, either damages or an account of profits in any case involving infringement. None of these treatments are cumulative; rather, they are alternate.

In addition, the court has the authority to issue an order that the goods that are found to be infringing, as well as the materials and implements that are primarily used in the production of infringing goods, shall be seized, forfeited, or destroyed, as the court deems appropriate under the circumstances of the case, without any payment of compensation.

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[3] Deepak Kumar Dash, Riya Vaiswade, *et.al.*, "A Review on the Indian Patent System and its Implication on the Pharmaceutical Industry" *Journal of Health Science and Medical Research* (2022).

[4] Ibid

[5] Id 63

[6] The Indian Patents Act, 1970 (Act 39 of 1970), s. 108(1)

1. **Injunction**: It is a preventive civil remedy. It is of two kinds:
2. **Temporary/ interlocutory injunction**: It is restricted to a particular time frame or until the point at which the case is fully determined on the basis of merit. It is possible to award relief in the form of an interlocutory injunction in order to reduce the likelihood of the plaintiff being treated unfairly during the time period before the uncertainty might be resolved. If the doubt were resolved in the plaintiff's favor during the trial, the purpose of this provision is to safeguard the plaintiff from suffering an injury as a result of a violation of his right for which he would not be able to receive enough compensation in the form of damages recoverable in the case. In the beginning phases of the lawsuit that the plaintiff has filed, the court will consider the possibility of issuing an interlocutory injunction. The defendant is prohibited from obtaining further revenues through the utilization of other patented products as a result of this legislation. For the patentee to be able to successfully invoke a temporary injunction, it is essential for them to demonstrate that the patent is legitimate in every respect and that the defendant has violated the patent in some way. In addition to this, the subsequent violation of his patent rights has resulted in a loss that cannot be recovered.

3. **Permanent injunction**: When the judgment of the court is fully rendered on the basis of the merits of the case, a permanent injunction is issued. In the event that the defendant is determined to be in violation of patent infringement rights and the result is in favor of the plaintiff, the interim injunction will be converted into a permanent injunction. In the event that the defendant is found to be innocent and exonerated of any wrongdoing, the interim injunction will be deemed null and void and will not be converted into a permanent injunction. During the time that the patent is in effect, it is restricted.

4. Ex- parte interim injunction:[7]

Before deciding whether or not to award an ex-parte ad interim injunction, the trial courts may take into consideration the following guidelines:

- When both the plaintiff and the defendant are located outside of the state and their personal information, such as their identity, address, and other details, are readily available to the public.
- In cases when the products that are being infringed upon are not being sold on a commercial scale.
- In the event that the defendant is likely to be forced to shut down their operations or business as a result of the interim injunction. • In the event that there is a disagreement regarding a patent or trade mark, the trial court should carefully examine the certificates, infringing markings, and other documentation.
- If the plaintiff has not shown any evidence of infringement, then an ex-parte temporary injunction cannot be given without the plaintiff's presence.

Damages or account of profits: An account of profits or damages may be awarded to the owner of a patent, depending on the circumstances. Either he can seek damages for losses that were caused by the defendant's infringing activity or he can seek an account of profits obtained by the infringer; but, he cannot seek both of these things at the same time under any circumstances. When the claimant is preparing the particulars of their claim, they will typically

[7] Tanisha Rhuja, "Infringement of Patents and Remedies for Infringement of Patents", Lawbhoomi, May 22, 2021, available at: https://lawbhoomi.com/infringement-of-patents-and-remedies-for-infringement-of-patents/#:~:text=Section%20108(1)%20of%20the,or%20an%20account%20of%20profits

propose these remedies as an alternate course of action. In addition to the remedy of injunction, it will be given without question. When the plaintiff opts for the remedy of account of profits, he will have the right to claim only the portion of the profit that the defendant was able to enjoy as a result of the defendant's use of the plaintiff's intellectual property. The patentee should not be entitled to the earnings that were not gained via the use of his invention. This is an absurd request.[8]

In Ravi Raj Gupta v. Acme Glass Mosaic Industries[9], the court held that the patent sought to be enforced and alleged to have been infringed by the defendant was not an invention within the meaning of Section 2(j) of the Patents Act, 1970. Therefore, the plaintiff was not entitled to the grant of an ad interim injunction as prayed for. However, to protect the interest of the plaintiff in the event of his ultimately succeeding in the suit, the defendant was directed to maintain a complete, true and accurate account of the manufacture and sale of the tiles.

Seizure or forfeiture of infringing goods: Other reliefs that a court may grant include the order that the goods that are found to be infringing and the materials that are predominantly used in the creation of infringing goods shall be seized, forfeited, or destroyed, as the court deems fit under the circumstances of the case, without any payment of compensation. This is in addition to the other reliefs that a court may grant.

A. Novartis AG v. Union of India & Others[10]

The facts

Imatinib, the initial medication, serves as the foundation for Glivec. A patent application for "imatinib" was submitted by Novartis in the year 1992. The application also included salt versions of "imatinib" that were approved for use in pharmaceuticals. The United States Patent and Trademark Office (USPTO) is the entity that handed down this patent. "imatinib mesylate" was the name of the salt form of imatinib that Novartis was granted permission for by the Food and Drug Administration (FDA) of the United States in the year 2001. When compared to the original substance imitanib, which is referred to as the "free base," the salt form, which is known as mesylate, is soluble in the human body. The United States Patent and Trademark Office (USPTO) eventually issued a patent to Novartis for a particular version of imatinib mesylate, which was referred to as its "beta crystalline form." This patent application was submitted by Novartis in 1997. Oral administration of imatinib mesylate is made possible on account of the beta crystalline form.

In addition, Novartis submitted an application for product patent protection in India in 1998 for the beta crystalline form of imatinib mesylate. In 2006, the Indian Patent Office denied this application for a number of reasons, one of which was that Novartis did not demonstrate that the beta crystalline form of imatinib mesylate was significantly more effective than its original salt. This was a requirement that was imposed under Section 3(d) of the Indian Patents Act. Furthermore, on June 26, 2009, the Indian Intellectual Property Appellate Board (IPAB) affirmed that this consideration was taken into account. An appeal was filed by Novartis with the Supreme Court. The pharmaceutical company Novartis carried out research in 2005 to demonstrate, among other things, a thirty percent improvement in the bioavailability of beta crystalline imatinib mesylate in comparison to the original substance imatinib. This was done in order to fulfil the statutory requirement of enhanced efficacy that was outlined in Section 3(d). On the legal front, the: The pharmaceutical company Novartis asserted that the subject matter of its patent application, which was beta crystalline imatinib mesylate, was founded on two distinct inventions that were eligible for patent protection-

i. The process of selecting the imatinib mesylate salt from the imitanib material that was initially extracted;

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[8] United Shoe v. Stewart, (1888)5 RPC 260 at Pp.266-67

[9] Ravi v. Acme Glass Mosaic Industries, 56(1994) DLT 673

[10] NOVARTIS AG V. UNION OF INDIA & ORS., (2013) 6 SCC 1

ii. The creation of a beta crystalline form of imatinib mesylate that is completely unique. Imatinib mesylate (IMAT) After considering the fact that imatinib mesylate was already incorporated into the claims made for the original substance imatinib, the court arrived at the judgement that it did not possess any novelty.

An assortment of scientific journals served as the foundation for the Court's decision. These articles not only detail the free base, which is known as matinib, but also its salt form, which is known as imatinib mesylate, and the anti-tumor characteristics that it possesses. Furthermore, Novartis had asserted that the imatinib patent embraced claims to the salt mesylate in the course of patent infringement procedures that were taking place in Europe. According to the Court, a patent holder cannot claim a broad scope of an existing patent in infringement litigation, but then claim a small scope of the same patent when analysing the novelty of a salt derivative. This is because the Court makes it clear that patent holders cannot do both. Therefore, the teachings that are relevant for the novelty test are defined by the breadth of the original patent claims.

B. Merck Sharp & Dohme Corporation v. Glenmark Pharmaceuticals Ltd.[11]

Merck Sharp & Dohme (hence referred to as MSD) is an American pharmaceutical corporation and a subsidiary of the German firm Merck. MSD initiated legal proceedings against Glenmark Pharmaceutical Ltd., an Indian pharmaceutical business, seeking a permanent injunction over any salts of SITAGLIPTIN, an anti-diabetic medication. The Delhi High Court issued the inaugural permanent injunction in a patent infringement case and affirmed the validity of MSD's patent. This ruling was a precedent-setting order since the enactment of the Patents Act, 1970.

Brief facts of the case are as follows:

MSD's patent 'Sitagliptin' (Patent No. IN 209816) pertains to substances that function as inhibitors of the dipeptidyl peptidase-IV enzyme (DPP-IV inhibitors), beneficial for the management of diabetes, particularly type 2 diabetes.

MSD, in conjunction with its licensee, Sun Pharmaceutical Industries Ltd. (hereinafter referred to as Sun Pharma), initiated a patent infringement lawsuit against Glenmark in April 2013 for the production and commercialisation of generic versions of MSD's anti-diabetic medication 'Januvia' (Sitagliptin) and 'Janumet' (a combination of Sitagliptin and metformin).

The compound 'Sitagliptin' was developed by Merck. It asserts the base chemical 'Sitagliptin' in its free base form, together with its pharmaceutically acceptable salts.

On March 28, 2008, the medication received marketing approval in India. MSD has licensed the medicine to Sun Pharma in India, which markets it under the brand names Istavel and Istamet.

Glenmark was prohibited from producing, marketing, or engaging in transactions involving "Sitagliptin Phosphate Monohydrate" or any derivative of 'Sitagliptin'. The generic equivalents of "Januvia" and "Janumet" were introduced under the brand names "Zita" and "Zitamet," respectively.

MSD introduced "Sitagliptin" in India at a price decreased to one-fifth of that charged in the USA, in alignment with broader public interest.

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11 MERCK SHARP & DOHME CORPORATION V. GLENMARK PHARMACEUTICALS LTD, (2015) 63 PTC 257

The Single Judge of the Delhi High Court first dismissed MSD's appeal for an interim injunction. The Division Bench of the Delhi High Court, upon appeal, overturned the previous ruling and determined that MSD's patent is prima facie valid and has been infringed by Glenmark's products.

Subsequently, Glenmark contested this order in the Supreme Court.

Judgement:

Court relying on various judgements held that:

"On 7th Oct, 2015, the Hon'ble Supreme Court upheld the decision of Delhi High Court and also took cognizance of the "commercial" nature of the matter. An expedited trial ordered by Delhi HC resulted in disposal of the law suit within 5 months from the date of order. The whole case was decided within 2 years. The Delhi High Court judgement smothered Glenmark by a decree of permanent injunction from making, selling, distributing or using, etc. and any dealings in Sitagliptin Phosphate Monohydrate, infringing the patent in question. The Court held that since the patent relates to an invention of a chemical molecule/compound in the medical filed it must be analyzed by technical experts as well. The court conceded with MSD's argument that the conversion of salt to a free base and then to another salt is a very basic chemical transformation and hence the patent claims Sitagliptin and all its pharmaceutically acceptable salts. It also observed that the disclosure in the suit patent is not for a lay person but is addressed to a person of ordinary skill. Further, the provisions under Section 64 of the Patents Act, 1970 make it clear that the court may or may not revoke the patent in the given facts and circumstances of the case. The court gave a lot of weightage to expert testimony in this highly technical matter. On the question of lack of industrial applicability the court holds that Sitagliptin free base is the moiety that possesses the therapeutic effects claimed. The court also stated that in Glenmark's drug there is no material effect. The Delhi High Court conclusively held that all the three ingredients i.e., prima facie, irreparable injury and balance of convenience for passing the order of injunction were established by MSD and hence injuncted Glenmark from manufacturing and selling of Zita and Zitamet."

The Hon'ble Supreme Court issued a unique order that entailed the cross-examination of seven witnesses. This ruling signifies that the Indian judiciary established Commercial Courts; the Commercial Division recognises the pressing necessity for a proper, effective, and efficient framework to protect all intellectual property.

Sugggestions

- Altering the focus from one that is directed towards exporting to one that is focused on global marketing is necessary. In order to accomplish this, strategic marketing alliances will need to be established in developed countries. These alliances will allow Indian pharmaceutical businesses to function as profit sharing partners and would offer access to distribution networks. In addition to this, it is necessary to implement vertical integration in a strategic manner into the distribution and utilisation chain, beginning with developing markets and progressing all the way up to developed markets.
- Research and development that is both cost-effective and efficient for the development of low-cost bulk pharmaceuticals, formulation and discovery research, and clinical studies for the global market are all things that need to be carried out. Discovery research on a therapeutic segment for a single molecule costs between Rs 150 and Rs 200 crore in India, whereas in developed countries it costs between US $ 650 and US $ 800 million. This research is expected to be carried out over a period of 8 to 10 years.
- **Streamline the Patent Examination Process:** Improve the effectiveness and openness of the patent examination process in order to guarantee the timely granting of patents for real

inventions while also preventing the granting of patents that are either frivolous or evergreening, which hamper generic competition.

- **Encourage the Implementation of Compulsory Licencing Mechanisms:** In order to promote the timely issue of licences for critical medications, you should strengthen the implementation of compulsory licencing regulations. This is especially important in situations where there are public health emergencies or unmet medical demands.
- **Encourage Research and Development in Generic Pharmaceuticals:** In order to encourage innovation, improve product quality, and enhance competitiveness in both domestic and foreign markets, it is important to provide incentives and support for research and development activities in the generic pharmaceutical sector.
- **Increase the level of collaboration between the business world and academic institutions**: It is important to encourage collaboration between pharmaceutical companies, research institutes, and academic organisations in order to facilitate the sharing of knowledge, the transfer of technology, and the creation of capacity in the process of developing and manufacturing generic drugs.
- **Establish systems to Monitor Patent Litigation and Enforcement:** In order to prevent the abuse of patent rights, such as patent evergreening or strategic litigation targeted at delaying generic market entrance, it is important to establish systems that will monitor intellectual property litigation and enforcement activities.
- **Encourage Public-Private collaborations:** In order to address issues in the healthcare industry, increase access to medications, and support the creation of innovative and affordable healthcare solutions for underprivileged communities, it is important to encourage public-private collaborations.

Conclusion

The pharmaceutical industry is widely recognised as a sector that is very "knowledge driven" and is characterised by extreme levels of competition. Research in the pharmaceutical industry is extremely expensive and frequently unpredictable in nature. Therefore, it is of the utmost importance for pharmaceutical businesses to secure a patent monopoly on any novel, imaginative, and helpful product that may emerge as a result of years of dedicated research labour.

In the past few decades, the pharmaceutical industry in India has seen substantial modifications, mostly as a result of the development of a robust generic industry. The passage of the Patents Act in 1970 was the primary impetus behind the growth of the industry as well as its final centralization. A couple of significant elements of the Patents Act of 1970 were crucial in facilitating the development of the generic industry in India. In the beginning, the only entities that were allowed to get process patents were chemical entities, which included pharmaceuticals. As a consequence of this, the length of time that pharmaceutical patents are protected at the patent level was shortened.

Since the advent of the process patent system, generic manufacturers have been able to acquire alternative procedures for products that were previously available on the market much more easily. Although there were some critiques, the practices of the generic companies that involved reverse engineering were judged to be akin to counterfeiting. On the other hand, the multinational corporations, whose products they were reverse engineering, were not able to compete with any of the generic manufacturers. Following the implementation of India's responsibilities under the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the Patents Act of 1970 brought about a reform to the patents system. This alteration was brought about as a result of the enforcement of India's obligations. The TRIPS-compliant patent system raised uncertainties for generic manufacturers over their power to reverse engineer items, which would greatly constrain their ability to do so. In addition, India is confronted with the necessity of implementing data exclusivity, a move that has the potential to dramatically influence the chances that generic manufacturers will have in the future.

It would appear that the influence of the TRIPS Agreement on intellectual property rights (IPI) is rather minimal in the short term. To be more specific, the Trade Related Intellectual Property Rights (TRIPS) does not permit the retroactive patenting of pharmaceuticals in India that are already on the market or that are covered by patent applications that are already being processed in other countries. After that, however, there will be a gradual increase in price pressure as a result of the launch of fresh compounds by multinational corporations (MNCs) as the patents on previous medicines expire.It is expected that generic competition will continue to exercise its influence on the remaining 85 percent of the market. A number of worries regarding the high cost of patented pharmaceuticals have been resolved as a result of the government's aim to limit the prices of these medications to the lowest international cost.

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