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Research Article

The Supreme Court Of India On Evergreening Of Patents

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ABSTRACT

This paper focuses on Section 3(d), the historic Novartis case of 2013, adherence to Trade-Related Aspects for Intellectual Property Rights (TRIPS), particularly focusing on the issue of evergreening within the pharma industry. It also conducts a comparison of patent infringement cases in India and the United States. The paper provides an in-depth examination and investigation of important components of the Indian patent law framework. The main goal of the study is to shed light on these legal structures' complex aspects, their effects on creativity, public health, and the availability of necessary medications.

In a detailed analysis of the legal dispute involving Novartis AG and the Union of India, the Novartis case 2013 became a primary focus, highlighting the interpretation and implementation of 3(d) of the Indian Patent Act regarding the medication Gleevec. The fundamental question for evaluation involves how the situation affects healthcare concerns, availability and reasonably priced medication, and obtaining patent standards. This article carefully assesses how well the Indian Patent Act complies with the agreement on TRIPS. It investigates if the provisions of the Act meet global standards and looks at India's flexibility under the treaty, particularly in protecting public health and establishing patent requirements.

This study involves a comparative analysis of patent infringement instances and regulations in the US and India. Furthermore, the study also provides details about the patent enforcement systems across the two jurisdictions by highlighting differences in methods, litigation processes, and case results.

Keywords: Patent, Patent Infringement, Evergreening, TRIPS, Indian Patents Act.

INTRODUCTION

A patent is a monopoly right given to a person who has developed a novel, useful product, an enhancement of an already existing product, or a novel method of producing a product. It consists of the exclusive right, for a set amount of time, to create the newly discovered article or create an article using the newly discovered method. Anyone may utilise the invention after the patent's validity period has passed (Narayanan, 2001).

The domain of intellectual property rights, including patents, is crucial in stimulating creativity, promoting the expansion of the economy, and maintaining equilibrium between individual rights and the general good. The Patent Act of 1970 in India was significantly modified in 2005 to bring it into compliance with international standards by the TRIPS agreement, and to include important new provisions like Section 3(d). With its strict criteria for patent eligibility, Section 3(d) marks a turning point in Indian patent law. The main objectives of Section 3(d) were to protect patents against infringement and restrict the pharmaceutical industry from "evergreening" patents (Du, 2013). The practice of applying for multiple and/or cumulative patents on the various aspects of a single invention at times of strategic importance to extend the patent protection beyond the legally permitted 20 years to stifle generic competition is known as "evergreening" of patents (Bhardwaj, 2013). "Evergreening" is the practice of securing patents for little or inconsequential changes to the initial idea, which aims to profit from patent monopolies. Patent evergreening is a common tactic that is mostly seen in the pharmaceutical industry (Stubb & Kasiva, 2023). Since there is a strong correlation in this sector between creativity, safety for the public, and access to medications, the need for the addition of section 3(d) was crucial. This section lays out requirements to ensure that minor alterations or modifications made to existing medications may not qualify for a patent. The Supreme Court of India determined that pharmaceutical corporations are no longer eligible to get patents for drugs that have minimal modifications. This helps find a balance between the desire for novel concepts, and the need for affordable treatments (Vu, 2012).

The 2013 Novartis case has significant importance in the discussion around Section 3(d) regarding the evergreening of patents. The Union of India and Novartis AG engaged in a historic judicial struggle that raised important questions about how to read and apply Section 3(d) for the leukemia medication Gleevec. The judgement rendered by the Supreme Court in India had profound implications that not only altered the parameters of patenting requirements, it also significantly impacted the availability of reasonably priced medications or the overall structure of intellectual property laws. Furthermore, the Indian Patent Act functions within the framework of global commitments, particularly the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which outlines the bare necessities for safeguarding intellectual property.

INNOVATION AND ECONOMIC DEVELOPMENT IN INTELLECTUAL PROPERTY RIGHTS AND PATENTS

Intellectual property rights safeguard patents, which are vital for encouraging both innovation and societal progress. Innovations attract money, time, and creativity from inventors, researchers, and commit to producing unique technologies, items, or methods by offering exclusive advantages and rights to their ideas.

Promoting Invention

Patents and other forms of intellectual property rights are very effective in encouraging development. By giving creators, investigators, or companies an exclusive licence to use their creations for a predetermined amount of time, they honour their efforts to innovate. It promotes development and research (R&D) spending and provides a safe space for invention to grow.

Encouraging Research and Development (R&D)

By providing protections or financial gains to expenditures in novel technologies, goods and procedures, patents encourage R&D efforts in a variety of industries. Companies are encouraged to engage in extensive or dangerous investigation efforts because of the exclusivity that patents provide, leading to innovative findings and developments.

Raising Standards of Living and Resolving Social Issues

Patents encourage the creation of fresh approaches to pressing social issues. Patents promote the growth of innovations and ethical procedures in industries including medical care, technology, solar power and life-saving medications. These advancements eventually raise everyone's standard of living.

EVOLUTION OF PATENT'S LEGAL FRAMEWORK IN RESPECT OF SECTION -3 IN INDIA-

In the year 1856, civil engineer George Alfred DePenning of Calcutta submitted the first patent application in India. The Indian government released the Patents Act, which granted "exclusive privileges for the encouragement of inventions of new manufactures," on February 28, 1856 (Government of India., n.d.). George Alfred DePenning requested exclusive rights for his creation, "An Efficient Punkah Pulling Machine," in a petition to the Government of India on March 3, 1856. DE Penning submitted the details of his invention on September 2, along with drawings that showed how it operated. These were acknowledged, and the invention received India's first-ever intellectual property protection. The Act VI of 1856 was the first piece of patent-related legislation in India. The goal of this legislation was to promote the development of innovative and practical products and to persuade innovators to divulge their creations' secrets. Act IX of 1857 subsequently abolished the Act since it had been passed without the sovereign's consent. Act XV of 1859, new legislation for the granting of "exclusive privileges," was introduced. This legislation included certain changes to the former legislation, including the restriction of exclusive privileges to valuable innovations and an increase in the priority period from six to twelve months. Importers were not included in the Act's definition of an inventor. The United Kingdom Act of 1852 served as the basis for the 1856 Act, which made a few changes, including permitting assignees to file applications in India and taking into account earlier public usage or publication in India or the UK when determining novelty (World Intellectual Property Organization, 2023). The UK has been preserving designs since 1842, but the Act of 1859 only offered protection for inventions. The "Patterns and Designs Protection Act" (Act XIII) was passed in 1872 to improve this. This Act revised the 1859 Act to define "new manufacture" as any brand-new, unique pattern or design or the application of such a pattern to any substance or object of manufacture. The Act XV of 1859 was amended in 1883 by the XVI of 1883, which included a provision to safeguard the novelty of inventions that had been made public in Indian exhibitions before filing for protection. To make changes to the law relating to inventions and designs that were consistent with those made under UK law, new legislation was introduced in 1888.

BEFORE 2005

Before the significant revisions made to the Indian Patent Act in 2005, it tackled growing or establishing stringent requirements for incrementally improving patentability. Issues about drug companies expanding their patent monopoly by implementing small changes to already-approved medications while significantly improving their therapeutics arose from the lack of defined criteria. Section 3(d) of the Indian Patent Act has undergone a substantial modification. This change is mostly because of the issues posed by the above evergreening with the necessity to set strict standards for patenting, notably in the drug sector.

Restricted Patenting Guidelines: The Indian Patent Act of 1970 permitted protection by patents but failed to specify the validity requirements for perpetual renewal or modest changes. Issues over the possible granting

of rights for small adjustments or gradual alterations devoid of significant new developments arose from the absence of clear criteria.

Absence of Greening Provisions: The pre-2005 legal structure failed to tackle the method of prolonging intellectual exclusivity by small modifications to already marketed medicines while appreciably improving their clinical performance. This sparked worries regarding the likelihood of rights in patents being abused to extend market dominance as a result of evergreening.

Effects on the Supply of Medicines: If rigorous patent standards are not followed, there may be a rise in the number of patents awarded for small-scale inventions. This could limit the supply of reasonably priced substitute drugs, especially in the drug sector.

AMENDMENT

India's patent system had perhaps its biggest change in 2005. These changes were introduced in response to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, mainly to bring them into compliance with global regulations. Growth issues prompted the introduction of Section 3(d), which sets strict requirements for a patent. The addition of Section 3(d) clarified the patentability requirements, especially for the pharmaceutical industry. It resolved the uncertainty that had previously related to the assessment of minor enhancements, therefore preventing the spread of patent rights for small changes that did not yield significant health benefits.

It had a noticeable effect on patent inspection procedures, requiring a strict evaluation of applications—particularly in the pharma industry—and requiring adherence to the higher requirements of higher efficacy specified in the clause. The Novartis case in 2013 served as a prime example of landmark rulings by courts for restricting the evergreening of patents, which further cemented the validity and significance of Section 3(d). The Supreme Court's decision categorically maintained strict standards, confirming that minor adjustments lacking major advances in medicinal effectiveness could not qualify for patent safeguards.

RECENT INITIATIVES TO PROMOTE PATENTS IN INDIA

In recent years, the government of India has taken various initiatives to facilitate innovation and growth in various industrial sectors. Some of the steps taken are:

Make in India

The 'Make in India' project was announced on September 25, 2014, to facilitate investment, stimulate innovation, establish best-in-class manufacturing infrastructure, make it simple to do business, and increase skill development. The Make in India programme, along with action plans produced for 25 sectors, has been reassessed and is now focused on 27 sectors. The Department for Promotion of Industry and Internal Trade coordinates action plans for 15 industrial sectors, while the Department of Commerce coordinates action plans for 12 service sectors.

Invest India-

Invest India was formed as a non-profit joint venture involving the Department of Promotion of Industry and Internal Trade, the Federation of Indian Chambers of Commerce and Industry (FICCI), CII, NASSCOM, and different state governments. Invest India is India's National Investment Promotion and Facilitation Agency, and it serves as the first point of contact for foreign investors in the country. Invest India is changing the country's investment climate by making it easier for investors to do business.

Its specialists, who specialise in various countries, Indian states, and industries, walk clients through every step of the engagement phases, from pre-investment to after-care. Invest India provides a wide range of services, such as market entry strategies, in-depth into the sector, partner recruitment, and policy advocacy with those making decisions.

Startup India

Start-up India is the flagship program of the Government of India to promote start-up culture and create a strong and inclusive environment for innovation and entrepreneurship in India. Start-up India has undertaken a variety of programs since its foundation on January 16, 2016, to aid entrepreneurs, build a strong start-up ecosystem, and transform India into a country of job creators rather than job seekers. These initiatives are managed by a Start-up India team that reports to the Department for Promotion of Industry and Internal Trade (DPIIT). Qualifying firms can be recognized as start-ups by DPIIT under the Start-up India Scheme, getting access to a host of tax advantages, simpler compliance, speedier IPR monitoring, and other benefits.

International Search Authority and International Preliminary Examining Authority-

On October 15, 2013, India became the International Search Authority/International Preliminary Examining Authority (ISA/IPEA). As of March 31, 2019, the Indian Patent Office ISA had received 5255 international applications asking for international search reports and 175 applications requesting international preliminary

examination through India (IPEA). Over the years, the Indian Patent Office has successfully increased the timeliness of establishing International Search Reports (ISR). In 2015-16, around 41% of search reports were issued on time, i.e. within three months of the search copy being received by ISA, whereas approximately 68% of reports were issued on time in 2016-17. During 2017-18, the percentage of ISRs issued on time grew to over 97%, which increased to 99.3% at the end of 2018-19 (Intellectual Property India, 2023).

TRIPS AGREEMENT AND INDIAN PATENT ACT-

The World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a broad international agreement. It defines basic requirements for intellectual property (IP) rights, such as trademarks, copyright, patents, or trade secrets, and geographic indications to make sure the participating countries' IP frameworks are consistent. It sets minimal criteria for WTO countries' IP protection and aims to strike an equilibrium between safeguarding intellectual property and the promotion of creativity and technology transfers (World Trade Organization., n.d.).

TRIPS Flexibilities in India-

The only exception is Section 3(d), regarded as crucial for providing the availability of cheap medications, particularly in poor nations. Under specific circumstances, government entities may provide licences under Article-31 of the TRIPS agreement to produce protected medications at a lower cost (World Trade Organization, n.d.-a). India is using the TRIPS flexibilities to defend public health goals, particularly in the drug sector. When necessary, medications are inaccessible or costly, government utilizes the power to grant compulsory licences to enable access to medicine at a reasonable price. This is consistent with TRIPS which allows for mandatory licencing in the public interest.

India's requirements for originality, creative process, and practicality are TRIPS-compliant, which sets the patent standards under Article 27; however, the interpretation might influence the availability of medicines. Growing techniques of evergreening that extend patent life despite major advances raise issues. They had opportunities to improve regulations to avoid erroneous inventions and foster real development. TRIPS establishes baseline requirements for licencing and flexibility to impose severe patenting rules. Its significance effectively increases to avoid the award of patents for minor discoveries lacking major medical advantages.

Each WTO participant maintains unique national intellectual property laws, especially the regulation of patents. Those laws ought to be based on TRIPS commitments. TRIPS permits wholly patenting but excludes medical and therapeutic procedures for individuals or animals, animals and plants apart from microbes, and truly biological procedures for the creation of living things or animals.

COMPARATIVE ANALYSIS OF INDIA AND UNITED STATES PATENT LAW

India and the United States have patent systems based on the "trifecta" infringing test: innovation, concealment, and relevance to the industry. They provide for financial penalties and restraining orders as well as having legal mechanisms in place to settle disputes over patents (USPTO, 2019).

UNITED STATES

The United States adheres to a rigid literal violation theory, which states that infringing arises when the alleged object or procedure fits under the specific limits of the maintained allegations. Invasion remedies are greater, comprising revenue losses, fair royalty payments, and aggravated damages in the US.

Furthermore, the USA adopts the concept of equivalents, which allows for infringement to be established even though the alleged item and the technique do not physically violate but are rather equal to the claimed innovation. In the United States, the plaintiff bears the obligation to prove violation with a majority of the proof. Thus, the lawsuit process was extremely difficult and time-consuming, with substantial pre-trial investigation as well as argument training. The judges frequently serve in deciding disputes.

IMPORTANT JUDGEMENTS OF THE US COURT-

1.MAYO COLLABORATIVE SERVICES V. PROMETHEUS LABORATORIES, INC, 566 U.S. 66 SC, 2012

The Supreme Court of the United States (SCOTUS) made a significant ruling concerning the patenting of healthcare ways of diagnosing. The patents for techniques for modifying the amount of thiopurine medications used for managing autoimmunity were held by Prometheus Labs. Using these approaches, they monitored the substance amounts in the individual's blood following medication administration ("Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)," n.d.).

The primary inquiry posed to the Supreme Court proved the suitability of Prometheus' invention claims as patentable topics according to 35 U.S.C. § 101.The Supreme Court's task was to ascertain when the allegations made novel contributions to the already known connection between thiopurine metabolites and drug hazards or effectiveness.

The Supreme Court created the "Mayo/Prometheus test" to ascertain whether clinical techniques for diagnosis qualified for protection under patents. An argument is ineligible using this criterion if it solely states a simple law. In this instance, the relationship exists naturally among pharmacological impacts and residue

concentrations. These metabolites are naturally occurring phenomena throughout the circulatory system. The abstract intellectual procedure is altering medication dose by a recognised natural occurrence.
The Supreme Court determined that Prometheus' claims were ineligible for patent immunity because they lacked sufficient creative "phases" above the request of the laws of nature. When it comes to deciding whether technological advances, including ways to diagnose, qualify for granted patents, the Mayo/Prometheus test has established an important standard.

2. ALICE CORP V. CLS BANK, 573 U.S. 208 (2014)

The Supreme Court's famous Alice Corp. v. CLS Bank Int'l decision had a big influence on patents, especially for technology or industrial process inventions. A technique to minimise "settling risk" in dealings with money was patent-owned by Alice Corp. To reduce the possibility that one party in particular would perform their pledge, the process employed an outside facilitator to permit simultaneous disclosure of responsibilities among both parties. Alice accused CLS Bank of violating her patent ("Alice Corp. V. CLS Bank Int'l, 573 U.S. 208 (2014)," n.d.).
The matter introduced the "Alice/Two-Step Guidelines," which improved the process considerably. This structure checks if the description mentions a qualifying machine, manufacturing substance or method. If yes, it ensures that the assertion includes an original idea.
The Alice/Two-Step Model is utilised to invalidate assertions in banking, insurance, programmes, or online shopping, among various technology domains. The ruling caused controversy; some say it stifles creativity, while others commend its purpose of infringing ideas from being copyrighted.
It is becoming harder to get licences for technological or company discoveries because of the Alice/Two-Step Framework, which is a key requirement for qualification.

3. PFIZER V. TEVA PHARMACEUTICALS AND SUN PHARMA, 2013

The popular 2013 case of Pfizer v Teva pharmaceuticals and Sun Pharma greatly highlights the severe consequences of infringing a patent's rights (Reuters, C. W., 2013). The case revolved around Pfizer's pharmaceutical drug Protonix, which is a medication used to treat acid-reflux (Writer, G. S., 2013).

History

The dispute first began in the year 2005. The Japanese pharmaceutical company, Takeda was also involved in this case as it was Pfizer's partner on the drug Protonix, which was the focal point of the patent infringement lawsuit. Furthermore, the United States patent number 4,758,579 for pantoprazole, was possessed by Takeda. Wyeth, a subsidiary of Pfizer, had obtained a license for it. Both, Takeda and Pfizer initiated a patent infringement case against Sun Pharma's new drug, containing pantoprazole, the same crucial component which was found in Pfizer's medication, Protonix.
The patent for pantoprazole was scheduled to expire in January, 2011. However, the judge concluded in 2010, that Teva had violated the patent for Protonix by introducing an imitation of the drug, prior to the patent's expiration.
Both, Sun as well as Teva had introduced their imitated products 'at-risk' before the expiration of Pfizer's patent of January 2011.

The action taken

This prolonged legal struggle, spanning about a decade, reached its conclusion in 2013 when both, Sun and Teva confessed their infringements.
The judge ruled that both the pharmaceutical corporations (Sun and Teva) were required to collectively pay a sum of 2.15 billion dollars as compensation to Pfizer's two subsidiaries, Takeda as well as Wyeth for the losses they endured.
The future prospects, as well as the economic performance of the enterprises involved, have been greatly impacted by this legal dispute. Furthermore, this particular case has also significantly impacted trends related to market and competitiveness within the pharmaceutical business.

INDIA

India interprets the literal claims of patents but offers a certain degree of freedom. To guarantee fairness and avoid unduly detailed opinions, judges view allegations very generously. The court process in India is designed to be less complicated and is much faster. Furthermore, there is less emphasis on pre-trial evidence, and the majority of cases are decided by a jury. The burden of proof falls on the defendant to demonstrate non-infringement of the case, and the remedies tend to be awarded at a lesser level, frequently confined to real damage by the courts.

IMPORTANT JUDGEMENTS ON EVERGREENING OF PATENTS AND PATENT INFRINGEMENT

Patent infringement cases have been on the rise with the increase in patent filing in the country many important judgements have been passed in the recent few years, drastically changing the IP framework in the country.

This was possible by extending the concept of patent infringement and the court decisions have rendered it simpler for patent holders to obtain injunctions to stop infringers from infringing their patents, increasing the amount of compensation granted from infringement of patent cases. Some of the important cases in the past few years are analysed here to understand their impact on patent infringement:

1. NOVARTIS AG V. UNION OF INDIA & OTHERS, 13 S.C.R. 148

The pharmaceutical company Novartis acquired a patent for the cancer medicine "Glivec" (Gleevec in the United States) in 2006 and claimed an altered or beta version of the active component, imatinib mesylate. This change was termed a gradual innovation aimed at improving the drug's effectiveness. It implies that the body's tissues may absorb the beta form more quickly, which enhances treatment. The Indian Patent Office, and later the Supreme Court, disapproved, noting two important justifications, Section 3(d) of the Indian Patent Act prohibits the validity of patents for medicine, food, and pharmaceuticals. While Novartis maintained that the beta form was not a new treatment, the court emphasised the importance of avoiding "evergreening" procedures, which include registering small alterations to the current pharmaceuticals to widen monopolies as well as restricting the entry of alternatives (Alam, n.d.).

The Supreme Court turned down Novartis's request for the beta crystalline form of Imatinib Mesylate in 2013. The beta crystalline form, according to the court, did not provide a sufficiently notable advancement above the existing chemical of Imatinib Mesylate to obtain patent immunity (Palwala, 2019).

The verdict has far-reaching consequences not solely for Novartis but also for pharmaceutical companies and the overall health of India. It strengthened the meaning and significance of Section 3(d), prohibiting patent exclusivity from being extended for small changes, thus reaffirming the significance of severe validity requirements. The Supreme Court recognised the significance of protecting patents in driving creativity but stressed the significance of this against having the right to affordable medical care, especially for important medications such as Gleevec.

At last, the ruling in the Novartis case supported the general public's availability of Gleevec by maintaining Section 3(d) of the Indian Patent Act and dismissing Novartis' patent claim owing to the absence of an innovative step. This decision has enormous and significant implications for how patent regulations are interpreted, forced licencing, and the relationship between rights in intellectual property and safety concerns. The fine line between encouraging development and protecting people's concerns, especially the availability of health, is that while TRIPS establishes the ground criteria for safeguarding patents, it additionally empowers member nations to introduce adaptability, such as Section 3(d), to fulfil their unique requirements. This judicial action is a prime example of India's proactive response to issues surrounding the evergreening of pharmaceutical practices.

2. FMC CORPORATION & ORS. VS. NATCO PHARMA LIMITED, 2022

Patents grant exclusive rights to inventors, allowing them to prevent others from creating, utilising, or commercialising the patented good or procedure. An inventor must demonstrate that the invention is new, non-obvious, and suitable for commercial use to assert rights under a patent that has been awarded. In addition, the patent registration application must include precise claims describing the components of the invention over which the inventor seeks exclusivity.

However, strict adherence to the literal language of patent claims can enable infringers to circumvent them. Courts established the doctrine of equivalents to address this issue. Originating in Winans v. Denmead SC, the doctrine holds infringers accountable for using elements equivalent to those in the patented invention, even if not explicitly claimed. The US Supreme Court developed the "triple test" and "all elements test" to identify indirect patent infringement ("Winans v. Denmead, 56 U.S. 330 (1853)," n.d.).

While this doctrine is well-established in the US, it has not been officially addressed in India. Nevertheless, Indian Courts have recognized similar principles. In Raj Parkash vs. Mangat Ram Chowdhry, the Delhi High Court adopted the "pith and marrow" doctrine, noting that even in cases where there was no direct violation of patent claims, an action for infringement would be successful if the essence of the claimed subject matter was copied ("Raj Parkash vs Mangat Ram Chowdhry and Ors. On 25 March, 1977," n.d.). Furthermore, in Ravi Kamal Bali vs. Kala Tech, the Bombay High Court emphasized that cosmetic variations or non-essential changes cannot distinguish a product from a patented innovation (Vazifdar, n.d). From these cases it is evident that although the doctrine of equivalents originated in the US, Indian Courts have also acknowledged similar principles to protect inventors' rights and prevent infringement.

In FMC Corporation v. Natco Pharma Limited, the Delhi High Court restated the law of equivalents and rejected FMC Corporation's ("FMC") claim of patent infringement against Natco Pharma Ltd. ("Natco"). A process patent for "Method for preparing N-Phenylpyrazole-1-Carboxamides" bearing the number 298645 ("IN' 645"/"Suit Patent") was filed by FMC together with many other patents for the production of chlorantraniliprole ("CTPR") (Bakhru, n.d.).

In a lawsuit brought before the High Court of Delhi, Natco was accused of violating FMC's patent, IN' 645. FMC claimed that the claims contained in Natco's patent application with the filing number PCT/IN2019/050321 ("Natco's patent application") for a "method of preparing CTPR" were the same as those contained in IN' 645. The Single Judge refused to grant an ad-interim injunction in favour of FMC in a judgement dated September

19, 2022. The Single Judge had initially observed that FMC Corporation had claimed a procedure that uses sulfonyl chloride, but Natco had used thionyl chloride in the process. According to the Single Judge, this difference was not "minor or insubstantial." FMC Corporation was dissatisfied with the judgement from September 19, 2022, and appealed it to a Division Bench of the High Court of Delhi (Bakhru, n.d.).

Despite acknowledging that Natco's method (the "Natco's Process") did not precisely match the claims stated in IN '645, FMC argued that Natco's Process violated their patent because the doctrine of equivalents was applied. FMC emphasised that the modified reagent, sulfonyl chloride was unnecessary for IN '645 and that Natco's process was equivalent to the challenged patent, IN'645 since it carried out essentially the same function (Bakhru, n.d.).

Natco responded by claiming that FMC's activities amounted to an ever-greening of its patent rights that had already expired. Natco said that the method described in their patent application was distinct since it was a two-step procedure requiring two reactors and, unlike IN '645, did not result in any harmful by-products. According to Natco, such differences could not be regarded as non-essential. Additionally, Natco claimed that method patents had a limited range of
equivalents (Bakhru, n.d.).

The Division Bench declined to challenge the Single Bench's conclusions while rejecting FMC's appeal. The Division Bench stated that the notion of equivalents "basically seeks to address infringers who introduce minor variations as a ruse to defeat patent rights." By rejecting any insignificant, small, or trivial changes intended to deny the patentee the advantages of his invention, the concept is used to determine whether there is an infringement (Bakhru, n.d.).

The Court also debated whether determining equivalents should be done using the triple test—that is, by looking at the function an element serves, how it performs that function, and the results it produces—or by determining whether the differences are substantial. A product may violate a patent's rights if it does the same task in the same way and with the same outcome. However, this test may need to be appropriately changed regarding a procedure or a method. Reaching essentially the same outcome would not be relevant in a situation where a method of reaching a result is the key component of the invention. The technique of the conclusion will be crucial in ascertaining if a patent has been violated (Bakhru, n.d.).

Applying the triple test to processes, the Division Bench noted that the test of the substantial identity of the competing methods must necessarily be viewed by identifying the key components and steps of the said process and then examining how the key components interact in each step that is necessary for the process or method to produce the desired result. The Court further noted that every step of the procedure had to be subject to the notion of equivalents (Bakhru, n.d.).

Sulfonyl chloride produced large yields; thus, the Court reasoned that it was crucial to Natco's technique. It was also referenced expressly in the allegations. Therefore, it had to be considered an integral part of the procedure. The stark disparities in the processes, particularly because of the two-step nature of Natco's process, further aggravated this viewpoint. After contrasting the two procedures, the Division Bench agreed with the Single Judge's decision to dismiss FMC's appeal (Bakhru, n.d.).

Both the Single Bench and the Division Bench have made major decisions that have advanced the notion of equivalents in India. The Division Bench modified and established a more appropriate test after correctly recognising the triple test's limited relevance to processes, creating a precedent for comparing processes and methodologies. Indian courts have not yet fully explored the concept of equivalents, despite the fact that courts throughout the world have supported it. The Division Bench's decision has also clarified the criteria for determining whether or not a process's components are necessary, simplifying the process for comparable future cases.

3. SOTEFIN SA AND OTHERS VS. INDRAPRASTHA MEDICAL CORPORATION LTD. (2020) 15 SCC, SC

A recent ruling by the Delhi High Court clarified several patent law concerns that Indian courts had not previously looked into. These include the Patents Act of 1970's exemption for parallel imports, the idea of equivalence, and a patent's enforceability as it expires.

In the current case, Sotefin SA accused multiple defendants of infringing on its registered invention for a "carriage for the horizontal transfer of motor vehicles in automatic mechanical car parks" (carriage). A patent covering the plaintiff's invention, frequently referred to as a dolly or a diplomat dolly, was filed in March 2002 and is valid until March 2022 (Narula, n.d.).

Pictures of the defendants' smart dollies that resembled the plaintiff's diplomat dollies were discovered during the patent's validity, and the plaintiff used these images to establish its rights against the defendants. To determine if the plaintiff's patent was violated, the court ordered a group of scientific experts to compare various components of the parties' respective dollies (Narula, n.d.).

Based on the scientific advisors' results and the fact that seventeen of the nineteen parts of the two dollies were identical, the claimant alleged that this represented an example of a violation. The plaintiff asserted that since both served the same purpose—acting as vehicle dollies—the input-output functions of the patent claims in the lawsuit were equivalent to those of the smart dollies. However, the defendants denied these assertions. They claimed that their smart dollies lacked two crucial components. Furthermore, rather than comparing the smart

dollies to each of the claims of the suit patent, the plaintiff had chosen the improper standard of comparing the competing items. The defendants further asserted that they were protected from accountability under the "Bolar Exemption" since they imported the dollies into India (Narula, n.d.).

The key issue before the Court was determining whether the two different characteristics of the dollies were "essential" in determining patent infringement. Based on submissions from both sides, the Court concluded that the lack of the two features could not be interpreted as being so crucial as to make the dollies substantially different. It was mentioned that there could be instances of non-literal infringement where the infringing items do not have every single element of the patent specification. This does not, however, preclude infringement entirely. Relevantly, the Court stated that when comparing the specifications, it is important to consider the heart and soul of the innovation. Additionally, it emphasised that the importation of a product that violates an existing patent is prohibited under the Indian patent system and that patent protection is territorial in scope (Narula, n.d.).

The Court stated that even when a patent is about to expire, the patent holder has the exclusive right to use the innovation without competition. This privilege includes the ability to secure an injunction against infringers, if necessary. It was argued that there is no distinction between a new term and a finishing term under Indian patent law. Instead, the advantage of registration lasts the entire duration of the patent. In light of this, the Court ruled that it must uphold a patent holder's rights while the patent is in effect, regardless of how much time is left on its term (Narula, n.d.)

It was decided that the defendant's clever dollies violated the plaintiff's diplomat dollies. Therefore, the Court ultimately awarded an interim injunction in the plaintiff's favour prohibiting the defendant from producing, marketing, exporting, importing, or offering smart sale dollies (Narula, n.d.).

4. MSN LABORATORIES PVT. LTD VS NOVARTIS

The cardiovascular medicine Vymada by Novartis is patented in India, and a single bench of the Delhi High Court has issued an interim injunction prohibiting various Indian producers from producing, offering for sale, or selling any pharmaceutical preparations that violate the patent. In addition, the Court ordered Eris Lifesciences to deposit Rs. 5 crores as restitution for allegedly continuing to advertise the medicine after the Court issued a restraining order on December 21, 2022 (Sharma, n.d.).

Eris Lifesciences Ltd., Windlas Biotech Pvt. Ltd., and Chhabra Healthcare Solutions Pvt. Ltd. were sued by Novartis for violating its Indian patent No. IN 229051. Novartis also requested damages, the rendering of accounts, delivery, and other relief. The pharmacological combination of sacubitril and valsartan covered by the patent treats cardiovascular disease (Sharma, n.d.).

Novartis has been involved in patent litigation with several pharmaceutical businesses to defend the drug's patent protection. In December 2020, the Telangana Court issued a status quo order in a lawsuit against MSN Laboratories Pvt. Ltd. The Telangana High Court's Division Bench authorised the sale of the number of medications that MSN had created before the status quo ruling in February 2021 and reported the sales' specifics to Novartis and the Court (Sharma, n.d.).

In a separate situation, Eris Lifesciences was threatened with legal action by Novartis. As a result, the Delhi High Court ordered Eris to provide a declaration detailing the extent to which its inventory retained the existing condition of affairs (Sharma, n.d.).

The product Zayo was purchased by Eris Life Sciences from MSN Laboratories, and the batches it got in December 2020, before the status quo ruling, were distributed to hospitals and pharmacies nationwide by stockists and distributors. Eris Life Sciences disclosed this information to the court (Sharma, n.d.).

Eris Lifesciences has stated that it received certain batches of the product from Windlas Biotech in February and March 2021 and sold it to distributors and stockists, who sold it to numerous hospitals and pharmacies nationwide. The Court also ordered the company to disclose the stocks it received from Windlas Biotech. According to an affidavit submitted by Eris to the Court on July 5, 2021, the value of the goods received from MSN for the tablets bearing the trade name Zayo is approximately Rs. 43 crores, and the total value of the goods received from Windlas Biotech on an MRP basis is approximately Rs. 60.5 crores, of which approximately Rs. 43 crores would be realisable in the company's hands because it sells the product on a wholesale basis (Nath, n.d.).

The legal representative for Novartis said that MSN Laboratories, Eris Lifesciences, and Windlas Biotech had used an illegal strategy to get around the Telangana High Court's injunction decision. MSN Laboratories is mentioned in Zayo's literature (Sharma, n.d.).

Eris maintained that the lawsuit's patent does not cover the medicine combinations that Novartis sells. It was further stated that the order enforcing the status quo on Eris on December 21, 2020, only applied to MSN products and excluded any Windlas products. Only on March 26, 2021, was the order against Windlas issued, and the business has not flouted the prohibition (Sharma, n.d.).

The question of whether MSN Laboratories manufactured the products manufactured by Windlas is still being litigated, but the court has permitted MSN Laboratories to sell the products manufactured before December 11, 2020. The judge said that, at this point, it is unclear why MSN Laboratories appears in Windlas' product brochure (Sharma, n.d.).

The patent in question is set to expire in January 2023, and the Court also considered that the data provided by Novartis needs to be updated for more than ten months. It was noted that recalling products from distributors or merchants would be a very laborious process that would cause panic.
Following this, the Court ordered on March 25, 2022, that there be an interim injunction prohibiting all of the defendants in these cases from producing, offering for sale, or selling any pharmaceutical preparations that are a combination of sacubitril and valsartan, whether in tablet form or any other form, either packaged as strips or in bottles or containers, and from violating the Novartis patent in any way.
After the order's passing on December 21, 2020, Eris Lifesciences is obligated to submit a payment of Rs. 5 crores with the honourable Registrar General of the Court for the stocks it has captured and marketed. Last year, Novartis AG obtained a favourable judgment in four petitions involving the same patent that it filed against Natco Pharma, Torrent Pharmaceuticals, Eris Life Sciences, and Windlas Biotech. According to Novartis, the combination is an efficient treatment for heart failure and hypertension developed after extensive testing (Sharma, n.d.).
The Delhi High Court granted a temporary order in Favor of Novartis in October 2023, prohibiting MSN from legally manufacturing and selling sacubitril until the primary lawsuit was resolved (Sharma, n.d.).

CONCLUSION

In India, the growth of patent laws and the environment of intellectual property rights depict a fascinating path marked by ongoing expansion, flexibility, and significant breakthroughs. From the passage of the first patent legislation in 1856 to the present day, India has worked to promote innovation, safeguard the rights of inventors, and align its intellectual property policy with global norms. As shown by the 2013 Novartis case and following court challenges, businesses use evergreening to extend patent protection for incremental improvements or modest tweaks to prolong monopolies while hindering generic competition. However, the implementation of Section 3(d) and the recent decision of the Supreme Court will serve as another evidence that dishonest attempts to obtain patents or evergreen will fail, hurting both the economy and the most vulnerable customers.
Furthermore, recent efforts like "Make in India," "Invest India," and "Startup India" demonstrate the government's dedication in creating an environment that encourages innovation, investment, and entrepreneurship. These programmes sought to develop an innovation culture and assist innovators and businesses in a variety of sectors. The judiciary's strong involvement in evaluating patent claims, particularly in recognising the concept of equivalents, exemplifies their capacity to adapt to novel innovations and technology. While issues like case backlogs exist, measures have been taken to expedite patent-related processes and increase efficiency in general. The creation of specialised patent courts and other dispute-resolution methods shows a commitment to addressing these concerns.
The future of patents in India is hopeful as the country aligns itself with worldwide intellectual property norms and adjusts to the needs of an evolving and inventive society. Rising patent registrations, rising technological capabilities, and continuing legislative reforms all point to a good future for intellectual property protection and innovation in India. This changing climate not only allows innovators and patent holders to capitalise on their inventions but also promotes an environment conducive to investment and economic progress. As India develops, its patent laws will play an important role in establishing the country's innovation environment, ensuring that it remains a magnet for innovative minds and entrepreneurs. The development of intellectual property rights in India is continuing, full of possibilities and challenges.

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