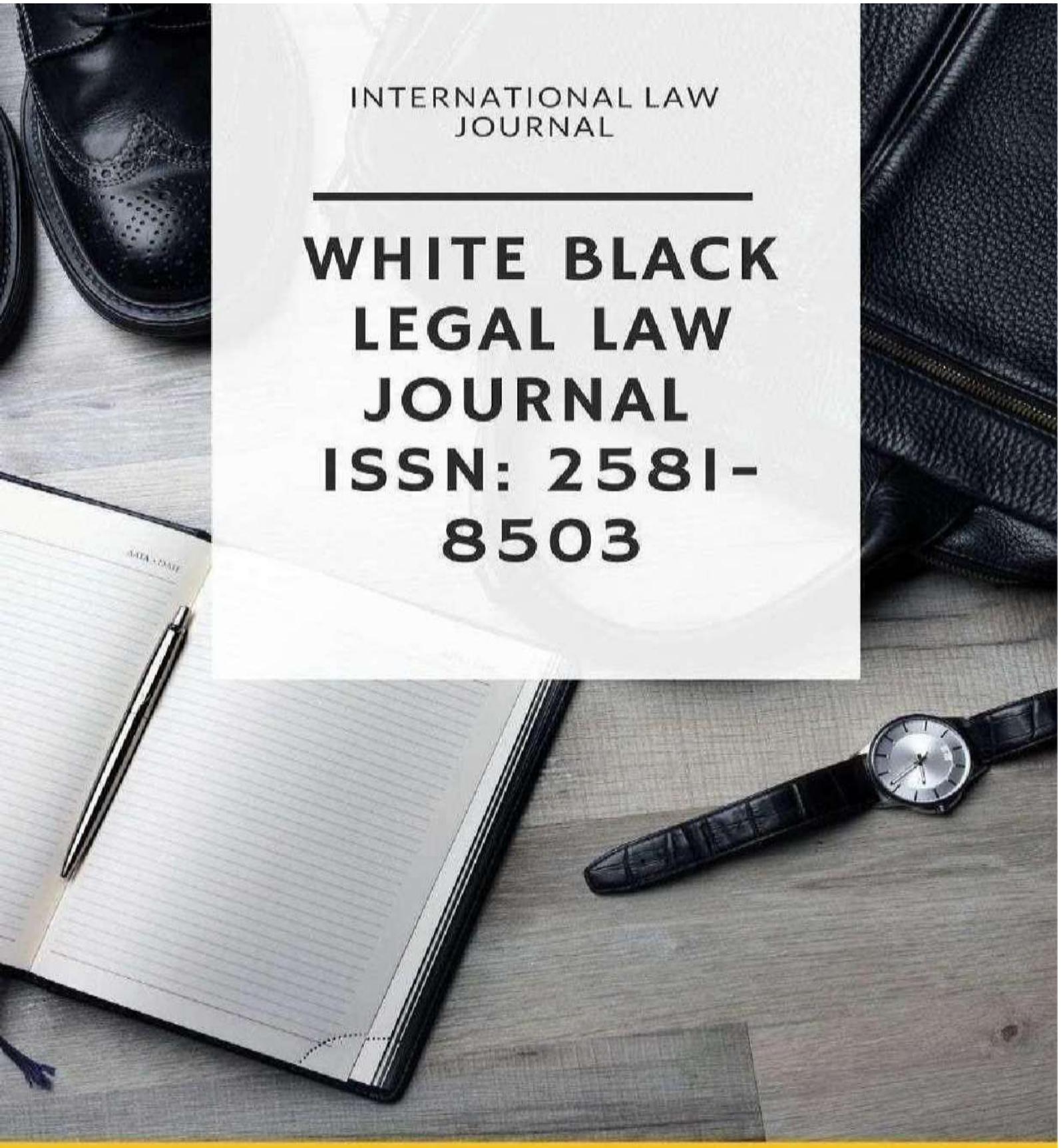

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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal provide dedicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

FROM GENERICS TO INNOVATION: ANALYZING THE ROLE OF PATENT LAW IN SHAPING INDIA'S PHARMACEUTICAL SECTOR

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ABSTRACT

This research paper delves into the complex realm of Indian patent laws and their significant influence on the strategies and activities of pharmaceutical companies. It examines how these laws have evolved over time, particularly in relation to international agreements like TRIPS[1], and explores the consequences of these changes, especially the introduction of product patents in pharmaceuticals in 2005[2]. The study employs a multifaceted approach, combining legal analysis, economic assessments, and case studies of pharmaceutical companies to understand the practical impact of these legal reforms on market competition, access to medicines, innovation, and investment in the pharmaceutical sector. The findings highlight a complex relationship between patent laws and pharmaceutical companies, emphasizing the need for a balanced approach that protects intellectual property rights while ensuring access to essential medicines. This research serves as a valuable resource for policymakers, industry stakeholders, and academics interested in the pharmaceutical industry and intellectual property rights in India.

INTRODUCTION

The pharmaceutical sector in India has undergone a significant transformation, becoming a global leader in the production of cost-effective generic drugs. This transformation is intricately linked to the complex landscape of patent laws, which govern intellectual property protection in the pharmaceutical industry. The pharmaceutical industry is a dynamic and critical sector that relies heavily on Intellectual Property Rights (IPR) to shape its landscape. IPR,

[1] Trade Related Aspects of Intellectual Property Rights
[2] To comply with TRIPS, India amended patent law a re-introduced product patent protection in pharmaceuticals from 1january 2005 leading to global concerns about the continuing ability of Indian generic companies to supply the medicines.

encompassing patents, trademarks, and copyrights, plays a pivotal role in influencing the research, development, and market dynamics of pharmaceutical companies. This introduction sets the stage for an exploration of how IPR profoundly impacts the pharmaceutical industry, from incentivizing innovation and protecting investments to influencing pricing, market competition, and access to life-saving medicines. Understanding the intricate relationship between IPR and the pharmaceutical sector is essential in navigating the complexities of this vital industry. In an era marked by global health challenges and constant innovation, understanding India's patent laws [3]is vital, affecting not only the pharmaceutical industry but also access to medicines, international trade, and the balance between intellectual property rights and public health concerns. Over the past thirty years, the Indian pharmaceutical industry has experienced consistent growth due to its technology-driven approach and favourable government policies, enabling local companies to dominate the domestic market. However, with India's increased participation in global trade through economic liberalization, industries like pharmaceuticals are required to reassess their long-term strategies and adapt to international competition. The protection of intellectual property has gained prominence as a result of the recognition of the necessity to safeguard substantial investments in research and development (R&D). India is actively addressing issues related to the enforcement of existing intellectual property laws and aligning its patent system with global standards, demonstrating its commitment to technological advancement.

The pharmaceutical industry plays a vital role in global healthcare, with far-reaching effects on public well-being and economies worldwide. This sector's dynamics are profoundly influenced by the interplay between patent laws and the strategies employed by pharmaceutical companies. This literature review investigates this intricate relationship, focusing on essential research, legal changes, and industry trends, particularly in the context of pharmaceutical firms in India. The historical evolution of Indian patent regulations, signifying a significant shift triggered by India's compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2005, is a central point of exploration. Prior to this alignment with TRIPS, India had a distinctive patent system that did not encompass pharmaceutical products, a transformation widely examined in studies like Chaudhuri et al. (2017).

Patent rights were introduced in India for the first time in 1856, and in 1970, the Patent Act

[3] The Patent Act, 1970

1970 ("the Patents Act") was enacted, replacing all previous laws. India is also a signatory to the Paris Convention for the protection of industrial property in 1883 and the Patent Cooperation Treaty in 1970. The Patents Act states that any invention meeting the criteria of being novel[4], not obvious, and useful can be patented. However, some inventions are not eligible for patents under the Patents Act. These include methods related to agriculture or horticulture, processes for the medical, surgical, curative, prophylactic, or other treatment of humans, animals, or plants, and substances formed by simple mixing that only combines the properties of their components.

Regarding pharmaceuticals, in the case of substances meant for use as food, drugs, or medicines, or substances created through chemical processes, patents are only granted for the manufacturing processes of such substances, not the substances themselves. Therefore, pharmaceutical products do not currently receive patent protection under Indian law.

India had a product patent system for all inventions under the Patents and Designs Act 1911. However, in 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from patent eligibility. This exclusion aimed to reduce India's reliance on imports for bulk drugs and formulations and promote the development of a self-reliant domestic pharmaceutical industry.

Under the existing patent laws in India, molecules resulting from chemical reactions cannot be patented, and the same goes for standard drug formulations where the ingredients act as mere mixtures without showing any synergistic effects. In such cases, only the process, meaning the method of producing the product, can be patented.

THE IMPACT OF THE WORLD TRADE ORGANISATION IN PHARMACEUTICAL PATENTS:

The establishment of the World Trade Organization (WTO) has brought about a significant shift in global trade. The Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) agreement was negotiated during the Uruguay Round trade talks of the GATT[5], with a primary focus on the pharmaceutical industry. India became a signatory to the GATT on April 15, 1994,

[4] New
[5] General Agreement on Tariffs and Trade

obliging it to adhere to GATT's requirements, including the TRIPS agreement.

Consequently, India is required to meet the minimum standards set by the TRIPS Agreement, especially in relation to patents in the pharmaceutical sector. India's patent laws must now include provisions for patent availability for both pharmaceutical products and process inventions, with a minimum patent term of 20 years for qualifying inventions.

To comply with TRIPS, India's compulsory license provisions will need to be limited and conditional. The government will grant such licenses based on individual merit, offering the patent holder an opportunity to present their case. Additionally, there should be no discrimination between imported and domestic products regarding process patents, and the burden of proof will be on the party accused of infringement.

India has chosen to utilize the full transition period for developing countries and has until January 1, 2005, to extend patent protection to pharmaceutical products. To adhere to TRIPS commitments, India has introduced exclusive marketing rights (EMRs) and a mailbox system for patent applications for five years or until the patent is granted or rejected, whichever comes first.

This provision, known as "pipeline protection,[6]" was introduced in the Patents (Amendment) Act 1999. It allows inventors to file for patents on pharmaceutical and agrochemical products in India if they've already filed an application in a convention country and received a patent or EMR there after January 1, 1995. These patent applications will remain pending until India amends its patent law according to WTO recommendations. The amended Patents Act also permits compulsory licensing for EMRs, similar to patents, and removes a provision that required Indian inventors to seek government approval before applying for patents abroad.

The legislative measures to meet India's TRIPS obligations are currently being finalized. The Patents (Second Amendment) Bill 1999, which introduces product patents for pharmaceuticals and agrochemicals, is yet to be enacted. Recent reports suggest that this bill is soon to be presented to the Indian parliament.

[6] The first amendment in this series was in the form the patent (Amendment) act ,1999 to give pipeline protection starts giving product patents for pharmaceutically based inventions.

PRODUCT PATENT

This patent claim designates the active chemical substance as a new chemical entity, often considered a robust assertion. With a product claim on the drug, only the patent holder or a licensee is authorized to manufacture, sell, or import the chemical for any purpose without infringing the product patent.

This type of patent claim is now permitted in many economically significant countries, although it is relatively recent in others. For example, Japan, Switzerland, Sweden, and Italy introduced product patents for pharmaceuticals in the 1970s, with Austria following in 1987 and Portugal, Spain, and Greece in 1992.

The novel drug can be claimed using its chemical name or structure, or both. This claim might encompass a Markush structure, a core chemical structure with optional chemical groups. This is known as a generic compound claim. A specific claim to the chemical can also exist alongside the generic claim. Some Markush structures are so broad that they can encompass millions of real chemicals. It is important to note that, in patent terminology, the term 'composition of matter' signifies a product claim.

In the case of ‘Novartis v. Union of India,’ Novartis applied for a patent for its drug 'Gleevec' under Section 3 of the Patents Act, 1970, claiming it as an invention. However, after a prolonged legal battle lasting seven years, the Supreme Court rejected the application, citing two main reasons. Firstly, the court emphasized that the mere discovery of an existing drug did not constitute the invention of a new drug. Secondly, the Supreme Court upheld the requirement, under the Indian Patent Act, for pharmaceutical patents to demonstrate not only traditional criteria like novelty, inventive step, and application but also a new criterion of enhanced therapeutic efficacy. Novartis's drug failed to meet this criterion.

This landmark judgment was significant because it went beyond technical considerations, addressing the issue of companies attempting to 'evergreen' their patents. The court aimed to prevent such practices, ensuring that patents were not extended merely to restrict access to drugs at affordable rates.

PRODUCT BY PROCESS PATENT

This type of claim 'claims' a chemical or other process used to manufacture the drug whenever the drug is made by the patented process. It is the 'next best' type of claim as it also confers protection against importation of a product. However, the drug can be made and sold if another company can devise a commercially viable process not covered in the patent.

Process patent-

This claims the chemical or other process used to manufacture the drug. The chemical product itself is not covered. Because of the difficulty of proving that another company is using the patented process, many countries have a 'burden of proof reversal' clause where the potential infringer must prove that the patented process is not being used. In the USA, the patent law was amended to made importation of the product of a patented process an infringing act, although this is not generally the case.

In the case of **'Teva vs. Natco,'** Teva Pharmaceuticals Industries Ltd. initiated a significant process patent infringement lawsuit against Natco Pharma Ltd. The lawsuit, known as the First Suit (CS (OS) 1708 of 2007), was filed before the Delhi High Court. Teva sought a permanent injunction to prevent Natco from infringing on Patent No. 190759, which covered a method for manufacturing "Co-polymer I fraction." This patented process was crucial for producing the drug glatiramer acetate, used in treating multiple sclerosis.

Natco argued that its manufacturing process for glatiramer acetate differed substantially from Teva's patented method. Additionally, Natco filed a counterclaim to revoke Teva's patent. However, in an order dated August 20, 2014, the Single Judge of the Delhi High Court dismissed both the First Suit and Natco's counterclaim. The dismissal was based on the absence of evidence supporting the claims made by both parties in the lawsuit.

While the First Suit and the counterclaim were still pending before the Delhi High Court, Teva initiated another legal action in 2012, known as the Second Suit (CS (OS) 3193 of 2012). This time, Teva sought a quia timet permanent injunction to prevent Natco and its agents from infringing Patent No. 190759. The case underwent a series of appeals, first before the Division Bench of the Delhi High Court and later the Supreme Court. Ultimately, the Supreme Court directed the matter back to the Single Judge of the Delhi High Court.

In a subsequent development, the Single Judge, on January 16, 2015, reserved judgment in the Second Suit, marking a crucial phase in the ongoing legal dispute between Teva and Natco.

Formulation patent-

This claims the pharmaceutical dosage form on the drug, commonly also known as a composition but not to be confused with 'composition of matter' (see previously). It may take the form of a formulation of a particular drug or class of drugs, or a general formulation applicable to many drugs with different actions, such as slow-release technologies, transdermal patches, etc. There may also be formulation process patents covering the manufacturing processes used to make the formulation.

Method of use-

This covers the use of the drug to treat a disease. This type of claim is originally allowed in the USA and Germany, but is now being accepted in other countries including the UK. However, a careful wording of the claim in European patent application allows this type of claim. The European claim usually goes '... use of drug x to manufacture a pharmaceutical dosage form to treat ...,' thereby avoiding a direct method of treatment claim.

IN INDIA, PHARMACEUTICAL PATENTS ARE CATEGORIZED AS FOLLOWS:

1. Drug Compound Patents: These patents involve Markush Claims, allowing multiple functionally equivalent chemical entities within a drug compound. They offer high protection, preventing others from using the compound for drug creation until the patent expires.
2. Formulation/Composition Patents: These patents pertain to the specific technology used to create a formulation of key ingredients, ensuring others cannot replicate the same composition for a new drug.
3. Synergistic Combination Patents: Patents can be obtained for combining multiple drugs to enhance their effects.
4. Technology Patents: These patents relate to the innovative manufacturing techniques used in drug production, addressing technological challenges like taste masking and solubility.
5. Polymorph Patents: These cover different physical forms or crystal structures of known compounds, used to enhance stability and purity.
6. Biotechnology Patents: They involve using biological materials or living organisms in

pharmaceutical development, including therapeutic, immunological, and diagnostic products.

7. Process Patents: These patents claim innovative processes for drug creation, such as chemical synthesis methods.

The pharmaceutical industry can protect various aspects of its products, processes, and innovations through these patent categories, fostering continued development and uniqueness in the market.

PATENTS AND FUTURE OF INDIAN PHARMACEUTICAL INDUSTRY:

The absence of product patent protection in the pharmaceutical and agrochemical sectors led many multinational corporations to limit their product portfolios to expired patents or a select few patented products. This strategy caused a decline in their market share as local manufacturers used reverse engineering to introduce the latest medications. Foreign companies had to pay royalties for global drugs, while Indian firms could reformulate new molecules for the domestic market. Consequently, patent rights for pharmaceutical products in India eroded, prompting several international research-based pharmaceutical companies to exit the market.

India's obligations under the TRIPS Agreement will significantly impact its bulk and formulation-oriented pharmaceutical industry. Indian firms must compete by focusing on drug development, creating patented products, or producing patented drugs under foreign licenses. There is a debate within the Indian pharmaceutical sector regarding the transition to a product patent regime. Some believe it will encourage innovation, while others are concerned about high R&D costs.

Survival for Indian pharmaceutical companies hinge on increased R&D investment, fostering innovation for cost-effective drugs that address India's disease profile. Larger firms are already shifting toward new molecule discovery. The introduction of product patents will attract multinational corporations and intensify domestic market competition.

LANDMARK JUDGEMENTS:

1. F. Hoffmann-La Roche Ltd vs Cipla Ltd., Mumbai Central[7]: -

First Patent Litigation in India post India’s 2005 Product Patent Regime which included public interest and pricing issues-

[7] Hoffmann- La Roche ltd vs. Cipla Ltd

Over the years India has seen many patent disputes between Foreign Multinational Pharmaceutical companies and Indian generic drug companies. But the suit between Roche and Cipla has surely set the standards when it comes to a patent infringement suit.

In this case, two plaintiffs, namely, F. Hoffmann-La Roche Ltd. and OSI Pharmaceuticals Inc., filed the suit for permanent injunction restraining infringement of patent, rendition of accounts, damages, and delivery against Cipla Ltd. Mumbai. Indian Generic manufacturer Cipla won this landmark case in the Delhi High Court. The case is the first Patent Litigation in India post India's 2005 Product Patent Regime which included public interest and pricing issues in addition to India's Section 3d that prevents evergreening. The case was followed by Pharma Giants worldwide.

Roche sued Cipla in 2008 before Delhi High Court claiming that Cipla's generic product Erlocip violates former's Indian '774 patent claiming "Erlotinib Hydrocloride". The trial Judge rejected Roche's appeal to grant interim injunction restraining Cipla from selling generic version of Tarceva on the grounds of public interest and the fact that there was an ongoing patent revocation proceeding against '774 patent. Cipla's generic version costs about 1/3rd of Roche's patented drug. Roche's subsequent appeal to Division Bench also failed when not only did the bench uphold the findings of Trial Judge but also imposed costs on Roche for suppression of material patent information about Roche's later filed application in India (IN/PCT/2002/00507/DEL). This was the Patent Application which was actually on Polymorph Form B of Erlotinib Hydrocloride but was rejected in 2008 following the opposition filed by Cipla primarily on Section 3d. Cipla argued that Tarceva corresponds to Polymorphic Form B (which is not a product of '774 patent but a '507 rejected application) and that it is Form B which is more stable and suitable for solid oral dosage form than the compound disclosed in '774 patent comprising a mixture of Forms A and B. Roche's subsequent appeal before the Supreme Court (SC) challenging the order passed by the division bench got dismissed due to the ongoing trial at the Delhi High Court.

2. Novartis v. Union of India (2013) 6 SCC 1[8]: -

Rejection of a patent for a Drug which was not 'inventive' or had a superior 'efficacy'-

Novartis filled an application to patent one of its drugs called 'Gleevec' by covering it under

[8] Novartis vs. Union of India

the word invention mentioned in Section 3 of the Patents Act,1970. The Supreme Court rejected their application after a 7 yearlong battle by giving the following reasons: Firstly, there was no invention of a new drug, as a mere discovery of an existing drug would not amount to invention. Secondly Supreme Court upheld the view that under Indian Patent Act for grant of pharmaceutical patents apart from proving the traditional tests of novelty, inventive step and application, there is a new test of enhanced therapeutic efficacy for claims that cover incremental changes to existing drugs which also Novartis's drug did not qualify. This became a landmark judgment because the court looked beyond the technicalities and into the fact that the attempt of such companies to 'evergreen' their patents and making them inaccessible at nominal rates.

3. Bayer Corporation vs Union of India[9]: -

India's First Compulsory License-

On March 9, 2012, the Indian Patent Office granted its first Compulsory License to Natco Pharma Ltd. for producing generic version of Bayer Corporations' patented medicine Nexavar (Sorafenib Tosylate), which is used in the treatment of Liver and Kidney cancer. While the multinational giant was selling the drug at INR 2.80 lakh for a month's course, Natco promised to make available the same at a price of about 3 % (INR 8800) of what was charged by Bayer. Natco was directed to pay 6 percent of the net sales of the drug as royalty to Bayer. Among other important terms and condition of the non-assignable, non-exclusive license were directions to Natco to manufacture the patented drug only at their own manufacturing facility, selling the drug only within the Indian Territory and supplying the patented drug to at least 600 needy and deserving patients per year free of cost.

Aggrieved by the Controller's decision, Bayer immediately moved to the Intellectual Property Appellate Board (IPAB) for stay on the order alleging that the grant of compulsory license was illegal and unsustainable. The Board rejected Bayer's appeal holding that if stay was granted, it would jeopardize the interest of the public who need the drug at the later stage of the disease. It further held that the right of access to affordable medicine was as much a matter of right to dignity of the patients and to grant stay at this juncture would really affect them.

Bayer then filed an appeal challenging the compulsory licence granted to Natco by the

[9] Bayer Corporation vs. Union of India

Controller-General. The Board stated that the invention must be available to the public at a reasonably affordable price and if not, compulsory licence can be issued and observed that the Sub-sections (a), (b) and (c) of Section 84(1) are separated by the disjunctive 'or' and therefore, even if one condition is satisfied, the Controller will be well within his rights to order compulsory licence.

The Board further noted that the R&D costs and the prices of other drugs do not assist in deciding what the public can afford reasonably. It stated that the reasonably affordable price necessarily must be fixed from the view point of the public and the word 'afford' itself indicates whether the public can afford to buy the drug.

It also stated that even if it takes the appellant's own number (i.e., the number of affected patients) it finds that the supply made by it cannot be said to be adequate and the price is the factor that will determine whether the public will reach out for a particular invention.

The Board held that the Controller was right in holding that the sales of the drug by the appellant at the price of about 280,000/- was alone relevant for the determination of public requirement and he was also right in considering the purchasing capacity of the public and the evidence available to conclude that the invention was not reasonably affordable to the public.

On the percentage of royalty that was to be paid by the Respondent to the Appellant (6% that was fixed by the Controller), IPAB increased it by 1 percent but did not change any other terms and conditions of the licence.

The IPAB dismissed the appeal and confirmed the grant of Compulsory license stating that it has dealt with each of the issue in detail in view of the significance of the order of compulsory licence made in India for the first time.

REPORTS AND STATISTICS:

https://www.pharmaceutical-technology.com/patents/patent-activity-pharmaceutical-industry/

https://ipindia.gov.in/writereaddata/images/pdf/report-of-technical-expert-group.pdf

https://www.bcp.edu.in/Patent%20filed_granted%20updated%206.6.2021.pdf

CONCLUSION:

The pharmaceutical landscape in India is a dynamic and complex ecosystem, deeply influenced by the intricate web of patent laws. This research paper has undertaken an in- depth analysis of the historical evolution of these laws, their implications for pharmaceutical companies, and the broader impact on access to essential medicines, innovation, and global trade. The liberalization process that began in 1991 has led to the formulation of policies aimed at attracting foreign capital and establishing India as a global industrial hub. This approach has resulted in an influx of foreign direct investment and technology transfers, fostering an environment conducive to dynamic growth and enhanced competitiveness in the Indian industrial sector.

> *"The current revenues of the Indian pharmaceutical industry is estimated at US$5.5 billion and it is expected to grow at a compounded annual growth rate of 19% and touch US$25 billion in revenue by 2010."*

India is gradually expanding its presence in the global market, where it competes based on international quality standards and pricing. While research and development (R&D) is a crucial factor for maintaining a competitive advantage on the global stage, the future of the Indian pharmaceutical industry primarily depends on the protection of patents.