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PATENT INFRINGEMENT IN THE INDIAN PHARMACEUTICAL INDUSTRY: BALANCING INNOVATION, ACCESSIBILITY AND LEGAL CHALLENGES

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ABSTRACT

Patent infringement in the Indian pharmaceutical industry presents a complex interplay between encouraging innovation, ensuring access to affordable medicines and responding to evolving regulatory processes. Commonly referred to as a "global commodity", India has a pharmaceutical industry that provides the world with affordable medicines. The country's adoption of product patent protection under the TRIPS agreement in 2005 marked a significant change that created tensions between the multinational pharmaceutical companies seeking to protect their innovations and domestic manufacturers focusing on affordable medicines. While patent laws in India aim to protect innovation, they also emphasise the need to make essential medicines accessible to millions of citizens. A nuanced approach, encompassing legislative reforms, judicial clarity and stakeholder collaboration is essential to strike an equitable balance. This study aims to explore the fundamental issues of patent infringement in India, including the challenge of balancing intellectual property rights with the welfare of the public. It examines important cases such as Novartis v/s Union of India and Bayer Corporation v/s Natco Pharma ltd. which addresses patent errors, patentability procedures and legal approaches to infringement. The paper also examines how Section 3(d) of the Indian Patent Act,1970 can be an important tool in protecting the patent environment while encouraging innovation, interference, poor governance and India's compliance with international obligations. It highlights the need for a

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legal framework that supports the local actors while ensuring the compliance with international intellectual property rights. The research concludes by suggesting policy measures that will foster a balanced approach that encourages innovation without hindering access and ensures that the Indian pharmaceutical industry remains a global leader in healthcare solutions. By addressing the legal complexities surrounding the patent infringement while prioritising public health, India can maintain its status as the "pharmacy of the world" while promoting innovation and accessibility.

Keywords: Indian pharmaceutical industry, patent infringement, TRIPS, pharmacy of the world.

INTRODUCTION

The Indian pharmaceutical industry is among the largest in the world, ranking third globally by volume and 14th by value. It plays a crucial role in supplying affordable, generic medicines, particularly to developing nations. However, the growth of the sector has not been devoid of controversy, particularly those surrounding patent infringement, and the balance between innovation and accessibility.[2]

This paper examines the historical evolution of India's patent laws, landmark legal battles, and the challenges associated with enforcing patent rights while ensuring affordable access to medicines. It also provides a comparative perspective with other countries and suggests a way forward for balancing the competing interests of innovation and public health.[3] The evolution of Patent Laws in India:

IPre-1970: The Era of Process Patents

Before 1970, India followed the British Patents and Designs Act of 1911, which granted both process and product patents. This regime favoured multinational pharmaceutical companies, leading to monopoly and high drug prices. Indian firms lack the ability to compete due to limited technical capabilities and restrictive patent laws.[4]

[2] *An International Guide to Patent Case Management for Judges*. (n.d.).
[3] *Ibid.*
[4] *History of Indian Patent System | About us | Intellectual Property India | Government of India*. (n.d.-b).

II The Patent Act of 1970: Fostering Accessibility

The patent act of 1970 marked a paradigm shift. India abolished product patents in pharmaceuticals and restricted process patents to 7 years. This allowed Indian companies to reverse engineer patented drugs, using alternative processes, thereby creating a competitive generic drug industry.[5]

III TRIPS Agreement and Post- 2005 Regime

India became a signatory to the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1995, necessitating a return to product patent protection by 2005.[6] The amended patent act of 2005 introduced stricter patentability criteria(section 3(d)) to prevent 'ever-greening' of patents and included provisions like compulsory licensing to ensure affordable access to medicines.[7]

Patent Infringement in the Indian pharmaceutical sector:

I.Definition and types of patent infringement.

Patent infringement occurs when an entity manufactures, uses, sells or distributes a patented invention without authorisation. In pharmaceuticals, this often involves disputes over generic and innovative drugs. In India, both direct and indirect infringements have been prevalent.

II. Key cases of patent infringement in India

[5] *WTO | intellectual property (TRIPS) and public health: Members accepting amendment*. (n.d.).

[6] *Compulsory Licensing in India and changes brought to it by the TRIPS Agreement*. (2021b, October 12). IP Helpdesk.

[7] *Compulsory Licensing in India and changes brought to it by the TRIPS Agreement*. (2021b, October 12). IP Helpdesk.

- **Novartis AG v. Union of India (2013)[8]**: The Supreme Court upheld the rejection of a patent for the cancer drug Glivec under section 3(d), emphasising the need to prevent evergreening.

- **Bayer v. Natco (2012)[9]**: India issued its first compulsory license to Natco pharma for Bayer's Cancer drug Nexavar, citing affordability concerns.

- **Roche v.Cipla (2008)[10]**: Cipla launched a generic version of Roche's lung cancer drug,Tarceva. The Delhi High Court ruled in favour of Cipla emphasising the public interest.

Innovation versus accessibility: A dichotomy[11]

IIncentivising innovation through patent protection

Pharmaceutical innovation is costly and time consuming. Patents provide innovators with a temporary monopoly to recover research and development costs. However, stringent patent enforcement can limit access to affordable medicines.[12]

II Ensuring accessibility to medicines.

India's emphasis on generic drugs has ensured affordable healthcare for millions. The country supplies 60% of the global demand for vaccines and 20% of generic medicines. Balancing patent protection with public health needs remains a central challenge.[13]

III. The Role of compulsory licensing

Compulsory licensing is a TRIPS-compliant tool, allowing governments to authorise generic

[8]UNCTAD's Intellectual Property Unit. (2013). Novartis AG v. Union of India & Others. In the Supreme *Court of India*.

[9]Iplf. (2022, October 18). *Case Analysis of NATCO v. Bayer | Compulsory licensing*. IPLF.

[10]Km, J. (2021, December 8). Hoffman La Roche V. Cipla. *IP Matters*.

[11]Collier, R. (2013b). Drug patents: innovation v. accessibility. *Canadian Medical Association Journal*, *185*(9), E379–E380.

[12]Collier, R. (2013). Drug patents: innovation v. accessibility. *Canadian Medical Association Journal*, *185*(9), E379–E380.

[13]Khachigian, L. M. (2020). Pharmaceutical patents: reconciling the human right to health with the incentive to invent. *Drug Discovery Today*, *25*(7), 1135–1141.

production of patented drugs under specific conditions. India has used this provision sparingly but effectively to address the public health crisis. Compulsory licensing in India serves as a critical mechanism to balance patent rights with public interest, ensuring that essential innovations, particularly in healthcare, are accessible to the populace.[14] Under the Indian Patents Act of 1970, a compulsory license permits a third-party to produce a patented product or process without the consent of the patent holder, primarily to prevent the misuse of patent rights and address public health needs.[15]

OBJECTIVES

1. ToEncourage innovation in drug development: The primary aim of patent laws is to protect intellectual property and incentivise pharmaceutical companies to invest in research and development. Patents provide a period of exclusivity allowing innovators to recover their investments and generate profits.
2. To Ensure access to affordable medicines: A significant objective in India is maintaining the delicate balance between patent rights and public health needs. India, as a major producer of affordable generic drugs, prioritises the accessibility of essential medicines, especially for life threatening diseases, such as HIV/AIDS and cancer.
3. To Navigate TRIPS compliance and flexibilities: India's patent system alliance with the trade related aspects of intellectual property rights. (TRIPS) agreement while leveraging flexibility to address national health priorities. Managing patent entrenchment requires careful global standards without compromising the country's ability to produce cost-effective medicines.
4. To Promote a fair competitive environment: Resolving patent infringement cases aims to establish a fair marketplace. We are both innovators and generic drug manufacturers can coexist. This includes preventing unethical practices like ever-greening where patent holders attempt to extend monopoly rights through minor modifications of existing drugs.

[14] *Compulsory Licensing in India and changes brought to it by the TRIPS Agreement*. (2021c, October 12). IP Helpdesk.
[15] Shah, R. (2021, August 16). *Compulsory license: India - Kluwer Patent blog*. Kluwer Patent Blog.

5. To Strengthen legal mechanisms and dispute resolution:Addressing patent entrenchment involves creating robust legal mechanisms to handle disputes effectively and transparently. This includes developing specialised quotes or tribunals and ensuring timely resolution of conflicts to reduce uncertainty for stakeholders in the pharmaceutical industry.

METHODOLOGY

The methodology adopted for examining patent infringement in the Indian pharmaceutical industry revolves around a multidisciplinary approach, integrating legal, economic and policy perspectives. This research is primarily conducted using a qualitative framework that encompasses both doctrinal and empirical analysis.

Legal framework analysis:

A comprehensive examination of Indian patent law, particularly the Patents Act of 1970 and its subsequent amendments, forms the backbone of the study. The research critically evaluates key provisions related to pharmaceutical patents such as section 3(d), which limits the patentability of incremental innovations. Judicial decisions in landmark cases such as ***Novartis AG v/s Union of India*** are studied to understand the judiciary ‘s role in balancing innovation in public health.

Case Study Approach:

The study employees case studies of major patent infringement disputes in the Indian pharmaceutical industry. These include instances where multinational Corporation and domestic generic manufacturers have clashed over intellectual property rights. Such cases provide insights into the practical challenges faced by stakeholders and the dynamics of patent enforcement in India.

Policy and industrial analysis:

The research evaluates government policies on pharmaceuticals and intellectual property to assess their impact on innovation and accessibility. It also explores the role of compulsory licensing with particular focus on cases like ***Natco Pharma v/s Bayer Corporation***. Industry reports, white papers and data from organisations such as Indian pharmaceutical alliance(IPA) and the World Trade Organisation (WTO) are utilised to understand broader trends.

Empirical Insights:

The study integrates qualitative interviews with key stakeholders, including legal experts, industry leaders and policymakers to gain first hand perspectives on the implications of patent law. These interviews are complemented by an analysis of secondary data from academic journals, court rulings and patent databases.

Comparative Perspective:

A comparative analysis with patent regimes in other jurisdictions such as the United States and the European Union is conducted to contextualise the Indian framework. This helps identify best practices and areas for reform with the aim of achieving a balance between fostering innovation and ensuring access to affordable medicines.

By combining doctrinal, case-based and policy oriented approaches, the research provides a holistic understanding of patent infringement challenges in the Indian pharmaceutical sector.

LEGAL FRAMEWORK FOR PATENTS

The Indian Patents Act outlines specific conditions under which compulsory licenses can be granted:

i. Non-satisfaction of public requirements: If the reasonable requirements of the public with respect to the patent invention have not been met.

ii. non-availability at reasonable price: If the patented invention is not available to the public at a reasonably affordable price.

iii. non-working of patent in India: If the patented invention is not being worked in the territory of India.

An application for a compulsory license can be made any time after three years from the date of grant of the patent.

I. International obligations

India's compulsory licensing provisions are in alignment with the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which allows member countries to issue

compulsory licenses under certain conditions, especially concerning public health. The Doha declaration[16] on TRIPS and public health reform is this flexibility, enabling countries to protect public health and promote access to medicines for all.[17]

II Notable instances

In 2012, India granted its first compulsory license to Natco pharma for producing a generic version of Bayer's cancer drug[18],Nexavar (Sorafenib tosylate). The license was issued on grounds that included the drugs, non-availability at an affordable price and it's limited availability in India. This decision significantly reduced the cost of the medication, improving accessibility for patients[19].

III Implications

The issuance of compulsory licenses in India underscores the country's commitment to prioritising public health over exclusive patent rights when necessary. While it ensures that lifesaving drugs become more accessible, it also raises discussions about the balance between encouraging pharmaceutical innovation and addressing public health imperatives[20]. By adhering to both national legislation and international agreements, India navigates these complex issues to serve the broader interests of its population.[21]

Legal challenges and enforcement

IChallenges faced by innovators

•Ambiguity in patentability criteria[22] (section 3(d))[23]

[16]*WTO | Ministerial conferences - Doha 4th Ministerial - TRIPS declaration*. (n.d.).
[17]*WTO | intellectual property (TRIPS) and public health: Members accepting amendment*. (n.d.-b).
[18] Iplf. (2022, October 18). *Case Analysis of NATCO v. Bayer | Compulsory licensing*. IPLF.
[19]*Ibid.*
[20]*Balancing public health and IP rights: compulsory licensing and evergreening practices*. (n.d.).
[21] Bonadio, E. (2012). India grants a compulsory licence of Bayer's patented cancer drug: The issue of local working requirement. *European Journal of Risk Regulation*, *3*(2), 247–250.
[22]*India - Protecting intellectual property*. (2024, January 12). International Trade Administration | Trade.gov.
[23]Parliament. (1970). THE PATENTS ACT, 1970. In *THE PATENTS ACT, 1970*.

•Delays and patent approvals and disputes[24]

•Limited enforcement mechanism for patent holders.

II Enforcement mechanisms in patent disputes

Indian courts have established specialised benches to handle intellectual property cases. However, inconsistent judicial interpretations and procedural delays hinder efficient resolution. In India, enforcing patent rights involves a combination of judicial and administrative mechanisms designed to protect patents from unauthorised use of their inventions. The primary enforcement methods include civil litigation, injunctions, and alternative dispute resolution (ADR) techniques[25]:

Civil litigation:Patent infringement cases in India are addressed through civil suits. The patentee initiates legal proceedings by filing a suit in a court of appropriate jurisdiction, typically, a district court or a High Court. If the defendant counterclaims for revocation of the patent, the case is transferred to the High Court. The court examines evidence, hears expert testimonies and determines whether infringement has occurred. Upon finding infringement, the court may award remedies such as damages, or an account of profits.[26]

Injunctions: Injunctions are critical tools in patent enforcement, serving to protect the patentee's rights during and after litigation. There are two primary types[27]:

- Preliminary Injunctions: Temporary measures granted at the outset of litigation to prevent ongoing or imminent infringement. The criteria for granting a preliminary injunction include establishing a prima facie case of infringement, demonstrating irreparable harm

[24]Barnabas, A. (n.d.). *Fresh amendments to India's Patent Rules to streamline filing system*. IAM.
[25] Isaiah, J. (2024, October 15). Patent litigation in India: enforcement and defence strategies. *DePenning and DePenning*.
[26]Isaiah, J. (2024, October 15). Patent litigation in India: enforcement and defence strategies. *DePenning and DePenning*
[27]*Ibid.*

to the patentee, if the injunction is not granted and showing that the balance of convenience favours the patentee.[28]

- Permanent injunctions: Issued after full trial, permanently prohibiting the infringer from engaging in the infringing activities. This remedy is typically granted following a finding of patent validity and infringement, serving as a final measure to prevent further violations of the patentee's rights.[29]

Alternative dispute resolution (ADR): To mitigate the time and expense associated with court proceedings, parties may opt for ADR methods such as negotiation, mediation or arbitration. These approaches facilitate mutually agreeable solutions without resorting to litigation. Mediation involves a neutral third party, assisting the disputants in reaching a settlement, while arbitration entails a binding decision from an impartial arbitrator[30].

Administrative mechanisms: The Indian patent office IPO provides administrative avenues for challenging patents through opposition proceedings[31]:

- Pre-grant opposition: Allows any person to oppose a patent application after its publication, but before the patent is granted on grounds, such as lack of novelty or invented step.
- Post grant opposition: Permits any interested person to challenge a granted patent within one year of its grant, based on similar grounds.[32]

These mechanisms ensure that patents granted meet the requisite legal standards and provide a cost-effective means to contest questionable patents.

Challenges in enforcement: Despite the available mechanisms, enforcing patent rights in India presents challenges, including judicial delays due to case backlogs and lack of specialised knowledge in patent law among some judiciary members. Additionally, the absence of criminal

[28] *Ibid.*
[29] *Ibid.*
[30] *Ibid,*
[31] *Ibid.*
[32] *Ibid.*

remedies for patent infringement, unlike in cases of copyright infringement, may result in insufficient deterrence against potential infringers.[33]

Judicial trends in patent litigation

Indian courts often prioritise public health over commercial interests. This has led to landmark rulings that promote accessibility while maintaining a check on patent misuse. In recent years, India's judicial landscape concerning patent litigation has undergone significant transformation aimed at enhancing the efficiency and effectiveness of intellectual property rights enforcement. A pivotal development was the abolition of the intellectual property Appellate board IPAB in 2021, which led to the transfer of its pending cases to various high courts. This shift necessitated the establishment of specialised mechanisms within the judiciary to manage the increased Caseload and the technical complexities inherent in patent disputes.[34]

Establishment of the intellectual property division(IPD): In response to the dissolution of the IPAB, the Delhi High Court pioneered the creation of the intellectual property division IPD in July 2021.[35] This division was instituted to streamline the adjudication of IP cases, including patent, litigation, and to address the challenges imposed by the influx of cases transferred from the IPAB. The IPD operates under the Delhi High Court, intellectual property rights division rules 2022 and the High Court of Delhi rules governing patent suites, 2022. These rules introduce several innovative features[36]:

- Evidence Recording: Adoption of methods, such as hot-tubbing[37] and remote recording to facilitate efficient evidence collection.
- Preservation of evidence: Implementation of litigation holds notices to ensure the integrity of pertinent information.[38]

[33]Mittal, S. (2024, September 6). UNRAVELLING THE COMPLEXITIES OF PATENT LAW IN INDIA: AN INSIGHT OVERVIEW. *Jus Scriptum*.
[34]*The South Centre | The Novartis decision by India's Supreme Court: a good outcome for public health*. (n.d.).
[35]Delhi High court Intellectual property rights divisions rule 2022. (n.d.). In *Indian Kanoon*.
[36]Vidhi Centre for Legal Policy, & Vidhi Centre for Legal Policy. (2022, January 8). *[Vidhi speaks] Setting up an IP Division in High Courts: Delhi High Court bites the bullet*. Bar And Bench - Indian Legal News.
[37]Expert's in a hot tub- certifying concurrently- an expert witness. (n.d.). *Alvarez & Marsal*.
[38]*Patent litigation: Litigation hold notice (Accused infringer) | Practical law*. (n.d.).

- Damages, computation: Provision of clear guidelines for calculating damages in patent infringement cases.[39]
- Case consolidation: Authority to consolidate related cases to prevent contradictory judgements and promote judicial economy.[40]
- Confidentiality measures: Formation of confidentiality, clubs, and protocols for information redaction to protect sensitive data.[41]
- Summary adjudication: Mechanisms for expedited resolution of disputes without a full trial, when appropriate.[42]
- Expert panels: Engagement of technical experts and recruitment of law researchers with specialised knowledge in fields such as engineering and pharmaceuticals to assist in complex cases.[43]
- Alternative dispute resolution ADR: encouragement of mediation and early neutral evaluation to resolve disputes amicably.[44]

The establishment of the IPD has been instrumental in reducing delays and improving the quality of judgements in patent cases. The division has managed approximately 4000 IP disputes with around 600 - 650 pertaining to patents. The disposal rate for IP cases, particularly patent matters, has seen substantial improvement since the IPD's inception.[45]

[39] *Patent Case Management Judicial Guide* (3rd ed.). (n.d.).
[40] Federal Judicial Center, Marcus, S., Koeltl, J. G., Sanders, B., Motz, J. F., Birnbaum, S., Rosenthal, L. H., & Ray, F. A. (2004). *Manual for Complex Litigation, Fourth*.
[41] Menell, P. S., Berkeley Center for Law & Technology, Almeling, D. S., O'Melveny & Myers LLP, Cundiff, V. A., Paul Hastings LLP, Pooley, J., PLC, Rowe, E., University of Virginia School of Law, Toren, P. J., Wexler, R., Berkeley Center for Law & Technology, University of California, Berkeley School of Law, & Federal Judicial Center. (2023). *Trade Secret Case Management Judicial Guide*.
[42] *Patent Case Management Judicial Guide* (3rd ed.). (n.d.).
[43] Menell, P. S., Berkeley Center for Law & Technology, Almeling, D. S., O'Melveny & Myers LLP, Cundiff, V. A., Paul Hastings LLP, Pooley, J., PLC, Rowe, E., University of Virginia School of Law, Toren, P. J., Wexler, R., Berkeley Center for Law & Technology, University of California, Berkeley School of Law, & Federal Judicial Center. (2023). *Trade Secret Case Management Judicial Guide*.
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[45] Indulia, B. (2021, July 7). *Delhi High Court establishes Intellectual Property Division to deal with Intellectual Property Cases | SCC Times*. SCC Times.

A COMPARATIVE STUDY OF PATENT INFRINGEMENT GLOBALLY

1. Patent infringement in the US and EU

The US and EU[46] have robust patent enforcement systems that heavily favour innovators. However, they also have provisions for compulsory licensing in public health emergencies[47].

2. Balance of innovation accessibility

Developing countries like Brazil and South Africa have adopted policies similar to India, using compulsory licensing and local manufacturing to ensure affordable medicines while complying with international obligations. India has made significant strides in innovation and technology, but patenting challenges persist. Analysing global practices can offer valuable lessons for fostering an environment of innovation while ensuring intellectual property protection is ethical and transparent.[48]

3. Strong IP framework of U.S.A

- Well defined patent laws: The US patent and trademark office, (USPTO) maintains clear and detailed patent clauses. India could focus on further simplifying and aligning its laws with global standards like the TRIPS agreement[49].
- Emphasise stringent checks to avoid granting low quality or trivial patents.
- Support for start-ups and MSMEs: Programmes like patent pro bono in the US support start-ups in filling patterns.[50] India could enhance similar initiatives to help small businesses and innovators.

4. Collaborative innovation of Germany

- Encouraging joint innovation: Germany promotes collaborative RND through partnerships between academia, industry and government. India can replicate this model to foster joint IP creation.[51]

[46] *Questions and Answers on Compulsory Licensing*. (n.d.). European Commision.
[47] Compulsory licensing of patented inventions. (n.d.). *Compulsory Licensing of Patented Inventions*.
[48] *WTO | intellectual property (TRIPS) - TRIPS and public health: Compulsory licensing of pharmaceuticals and TRIPS*. (n.d.).
[49] Compulsory licensing of patented inventions. (n.d.). *Compulsory Licensing of Patented Inventions*.
[50] Compulsory licensing of patented inventions. (n.d.). *Compulsory Licensing of Patented Inventions*.

- Focus on green patents: Germany Excel in green technology patterns. India can incentivise green innovation to tackle pressing environmental issues.[52]

5. Simplified procedures by Japan

- Fast Track Patents: Japan's streamlined processes for specific technologies(example AI, renewable energy) ensure faster grant timelines. India's patent prosecution Highway, PPH programme can be expanded for broad adoption.[53]
- Avoiding patent thickets: Japan's emphasis on patent clarity ensures fewer overlapping patents, reducing legal disputes. India can focus on clear drafting to avoid ambiguity.[54]

6. Ethics and plagiarism prevention guidelines by South Korea

- Strict antiplagiarism measures: South Korea enforces rigorous checks to ensure Patents are original. India could strengthen and scrutiny mechanisms during the patent examination process.[55]
- Education on IP ethics: South Korea emphasises IP education at all levels. India could incorporate IP ethics into academic and industrial training.[56]

7. Open innovation platforms of the European Union[57]

- Open access initiatives: the EU promotes sharing non-commercial IP for broader Society benefit. India could enhance platforms like the traditional knowledge Digital Library (TKDL) to safeguard indigenous knowledge while encouraging global collaborations.[58]
- Balancing IP and public interest: Policies like the EU's compulsory licensing during the public health crisis could guide India in navigating patent laws during emergencies.[59]

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[51] Ani. (2024, August 12). *India-Germany partnership takes a leap forward with launch of knowledge paper on sustainable innovation*. India narrative.
[52] *Ibid.*
[53] Patent Prosecution Highway (PPH). (n.d.). *Japan Patent Office Journal*.
[54] *Ibid.*
[55] Volodzko, D. (2015, January 21). Korea's plagiarism problem. *The Diplomat*.
[56] *Ibid.*
[57] *Questions and Answers on Compulsory Licensing*. (n.d.). European Commision.
[58] *Ibid.*
[59] *Ibid.*

Recommendation of effective measures:

1.Strengthen patent examination processes: Increase funding and training for patent examiners to ensure quality and originality.

2.Promote IP awareness: Run awareness campaigns, targeting start-ups, students, and small businesses about the ethical use of patents.

3.Encourage global collaboration: Foster cross-border R&D partnerships to enhance innovation and patenting processes.

4.Leverage technology: Use AI tools to detect plagiarism in patent applications and improve the integrity of the systems.

Policy recommendations:

I. Strengthening patent protection without stifling, generics
- Streamline patent approval processes
- Define clearer patentability criteria to avoid disputes.
- Encourage voluntary licensing agreements between innovators and generic manufacturers

II. Collaborative models for R&D in pharmaceuticals
- Public private partnership for drug development.
- Government incentives for local RND.
- Open innovation platforms for collaborative research.

III. Addressing gaps in patent enforcement
- Established specialised intellectual property courts for faster resolution.
- Enhance training for Judiciary and patent office staff.
- Promote alternative dispute resolution mechanisms.

India's patent laws play a crucial role in fostering innovation and protecting intellectual property. To enhance the effectiveness of these laws, several policy recommendations can be considered:

- Simplification of patent laws: The Indian government is contemplating simplifying the Indian patents act, 1970 to make it more resource friendly and to encourage product-oriented results. This initiative aims to reduce the time taken for patent filing and granting, which currently averages three years in India, compared to the global average of two years.
- Review of patent ineligible subject matters: The Parliamentary standing committee on commerce has recommended reviewing provisions of the Indian patents act, 1970, particularly those dealing with patent in eligible subject matters. This includes amending section 3(b)[60] to prevent arbitrary refusal of patterns on moral grounds and exploring the feasibility of granting patterns to non-living substances occurring in nature.
- Strengthening patent enforcement: Addressing challenges in enforcing patent rights is essential. This includes reducing the backlog of patent applications, establishing specialised intellectual property quotes to handle patent disputes efficiently and enhancing the capabilities of the Indian patent office through increased staffing and training.
- Promoting awareness and education:Launching comprehensive awareness campaigns, targeting businesses, entrepreneurs, and academia can educate stakeholders about the benefits of patents. Integrating intellectual property education into academic curriculum can also instill an understanding of the importance of protecting innovation from an early stage.
- Encouraging private sector participation in R&D: With approximately 0.69% of the budget being spent on research and development in India, there is a need for increased private sector investment in R&D. The government is urging the private sector to contribute more significantly to research funding to match and support government efforts, creating a win-win proposition for innovation.
- Facilitating compulsory licensing: The government should explore the prospect of issuing compulsory licences during emergencies, such as the COVID-19 pandemic to ensure the

[60]Parliament. (1970). THE PATENTS ACT, 1970. In *THE PATENTS ACT, 1970*.

availability and accessibility of essential vaccines and drugs. This involves temporarily waving patent rights to address public health needs effectively.[61]

Implementing these policy recommendations can strengthen India's patent regime, fostering an environment conducive to innovation and economic growth.

CONCLUSION

Balancing innovation, accessibility and legal challenges in the Indian pharmaceutical industry requires a nuanced approach. India's judicial approach to patent litigation is evolving, with significant strides made towards specialised adjudication and procedural efficiency. The creation of the IPD in the Delhi High Court serves as a model for other jurisdictions, reflecting a commitment to strengthening the enforcement of patent rights. Addressing the remaining challenges through continued reforms and capacity building will be crucial in fostering an environment conducive to innovation and IP protection.

While Patents are essential for fostering innovation, accessibility must remain a priority in a country where healthcare affordability is critical. By addressing gaps and patent enforcement, fostering collaborative R&D and leveraging TRIPS flexibilities, India can continue to be a leader in affordable healthcare while supporting innovation.

Challenges and recommendations

Despite these advancements, several challenges persist in India's patent litigation framework:

- Lack of specialised knowledge: judges in district and some High Court may lack specialised training in patent law, leading to inconsistent decisions. The technical nature of patent disputes necessitates a higher degree of understanding to accurately assess infringement claims.
- Delays in case disposal: prolonged timelines for resolving patent cases remain a concern. While the commercial courts act 2015, prescribe strict timelines for pleadings and trials,

[61] *Compulsory Licensing in India and changes brought to it by the TRIPS Agreement*. (2021b, October 12). IP Helpdesk.

systematic issues such as judicial vacancies contribute to delays. The Supreme Court has emphasised the need for adherence to procedural timelines to expedite proceedings.

- ➢ Need for specialised trial courts: the abolition of the IPAB has increased the burden on High Courts, potentially leading to multiplicity of suits and conflicting decisions. Establishing specialised patent trial courts with expert judges could enhance decision making efficiency and consistency.

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