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PATENT BARRIERS AND THE ACCESSIBILITY OF BIOSIMILARS: A HUMAN RIGHTS PERSPECTIVE ON AFFORDABLE BIOLOGIC MEDICINES IN INDIA

AUTHOR - AKHILA ANAND, LLM (INTELLECTUAL PROPERTY & TRADE LAW) SCHOLAR AT CHRIST (DEEMED TO BE) UNIVERSITY BANGALORE

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ABSTRACT:

The accessibility of biosimilars presents a critical challenge in the global healthcare landscape, particularly in developing economies such as India, where affordability and equitable access to life-saving biologic medicines remain significant concerns. The author of this paper examines the patent barriers impeding the widespread availability of biosimilars and explore the human rights implications of limited access to these essential drugs. Biologics, which play a crucial role in the treatment of cancer, autoimmune disorders, and other chronic diseases, are often subject to complex and expensive manufacturing processes, leading to high costs and restricted availability. Biosimilars, approved based on demonstrated similarity in quality, safety, and efficacy to reference biologics, offer a viable alternative. However, the regulatory and patent landscapes continue to pose formidable obstacles to adoption.

This study investigates how patent thickets, extended exclusivity periods, and strategic litigation by originator companies delay the market entry of biosimilars, thereby affecting accessibility and affordability. A comparative analysis of biosimilar patent assertions in India and other jurisdictions reveals that while some countries have established streamlined approval pathways, significant legal and regulatory gaps persist. The paper argues that the current intellectual property regime disproportionately favors innovator companies at the cost of public health, necessitating reforms that balance innovation incentives with broader access to critical medicines.

A significant gap exists in reconciling intellectual property rights with the fundamental right to health, especially in low- and middle-income countries. This paper contributes to the ongoing discourse by proposing legal and policy recommendations to overcome patent-related hurdles and promote the ethical imperative of equitable healthcare access. The study seeks to bridge the gap between biopharmaceutical innovation and the right to affordable treatment by advocating for regulatory clarity, competitive pricing mechanisms, and strengthened global cooperation.

Keywords: Biopharmaceuticals, Biosimilars, Patent law, Human rights, Regulatory framework

1.INTRODUCTION

Access to specialty biological products remains an unmet medical need in numerous countries. To address this issue and establish an effective regulatory framework—one of the significant contributing factors— the World Health Organization (WHO) has implemented global standards to ensure the quality, safety, and efficacy of biological products throughout their life cycle. The WHO has made substantial efforts to facilitate the implementation of these standards, particularly for biotherapeutic products, commonly known as biosimilars, which must demonstrate comparable quality, safety, and efficacy to their reference products.

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Enhanced access to approved biosimilars, which are generally more affordable than innovator products, can offer additional therapeutic options for patients suffering from serious or debilitating conditions, such as cancer, autoimmune diseases, and diabetes. To enhance competition among biologics and reduce their high prices, the U.S. Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which establishes an abbreviated approval pathway for biosimilars, also referred to as follow-on biologics.Biologics are crucial in cancer treatment and form integral components of many therapeutic regimens. The BPCIA defines a biologic as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." In simple terms, biologics are large therapeutic protein molecules created by living cells. (Dov Hirsch, 2017)

Biological products (or biologics) are medicinal products generally derived from living material for the prevention, treatment or cure of human disease.' They are highly targeted, efficacious against diseases such as cancer, diabetes, rheumatoid arthritis, and other inflammatory conditions. (Brian 2018) However, their complex manufacturing processes lead to high costs and occasional supply shortages, thereby limiting patient access to necessary cancer treatments. Although several countries have established abbreviated pathways for biosimilar approval, challenges remain regarding their effective utilization. These challenges include the design of appropriate clinical trials to assess bio similarity, the extrapolation of indications, immunogenicity, interchangeability with reference drugs, limited awareness and acceptance among healthcare providers, and potential political barriers.

The obstacles to biosimilar market entry are often more substantial than those encountered by generic manufacturers, paralleling the challenges faced by specialty injectable producers. Competitive responses from pioneering companies are likely to play a critical role in this context. The capital costs and associated risks of developing biosimilars frequently necessitate alliances and partnership arrangements.

This paper aims to investigate whether patent thickets surrounding biologic drugs contribute to delayed biosimilar market entry by comparing patent assertions against the same biosimilar drugs across two countries.

2.REGULATORY LANDSCAPE

The global regulatory framework for biosimilars is influenced by key organizations such as the European Medicines Agency (EMA), the World Health Organization (WHO), and the United States Food and Drug Administration (FDA). These entities have developed stringent guidelines to ensure that biosimilars adhere to high standards of safety, quality, and efficacy. Although regional variations exist, the core principles governing biosimilar approvals are largely consistent across these agencies. The regulatory landscape has rapidly evolved since the EMA initiated the first approval pathway in 2005, prompting the WHO and other national bodies to establish their own regulatory guidelines.

2.1. EMA Regulations

The European Union has led the way in biosimilar regulation, with the EMA implementing a structured approval process in 2005. The EMA was the first agency to grant commercial authorization for biosimilars, initially for biologics such as somatropin, erythropoietin, and filgrastim. The agency has since refined its guidelines, introducing an updated framework in 2013. The EMA requires comprehensive analytical, pharmacokinetic (PK), and pharmacodynamic (PD) studies to establish biosimilarity. Recent guidelines permit

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the use of non-EEA reference products, contingent upon bridging studies that demonstrate comparability. Unlike the FDA, the EMA does not provide guidance on interchangeability or automatic substitution, leaving these decisions to individual EU member states. Many European countries, including Spain, Italy, and the UK, restrict automatic substitution, although perspectives on interchangeability are evolving as further data on biosimilar efficacy becomes available.The EMA allows extrapolation but mandates a robust scientific rationale and supporting evidence. Its extensive experience in biosimilar approvals has led to a well-established regulatory framework that influences global standards.

2.2.WHO GUIDELINES

The WHO introduced its biosimilar guidelines in 2009, closely aligning with EMA standards to promote international harmonization. The WHO framework employs a stepwise assessment process, starting with quality comparisons and progressing to preclinical and clinical evaluations. These guidelines are instrumental in assisting countries lacking established regulatory frameworks in adopting biosimilar approval pathways. Many nations have integrated WHO principles into their domestic regulations, thereby facilitating broader access to biosimilars while ensuring their safety and efficacy. By establishing a global benchmark, WHO regulations have significantly enhanced biosimilar market entry, especially in emerging economies.

2.3. US FDA REGULATIONS

The US FDA established its biosimilar approval pathway through the Biologics Price Competition and Innovation Act (BPCI) of 2010. The FDA's framework diverges from other regulatory systems by emphasizing exclusivity provisions and interchangeability. Reference biologics receive exclusivity periods, which can delay biosimilar market entry and affect competition. The FDA distinguishes interchangeable biosimilars, permitting pharmacy-level substitution without physician approval; however, achieving this designation requires additional clinical trials, rendering the process more stringent than that of other regulatory bodies.Biosimilars operate under a distinct approval process separate from the Hatch-Waxman Act, which governs generic drugs, as outlined in the Patient Protection and Affordable Care Act (PPAC). The FDA mandates that biosimilars demonstrate "high similarity" to a reference product and limits approvals to indications already authorized for the reference biologic. The agency has issued multiple guidance documents detailing PK and PD study requirements and exclusivity periods. The publication of the "Purple Book" in 2015 provided a comprehensive list of licensed biologicals and biosimilars. While the FDA's rigorous standards ensure biosimilar efficacy and safety, its exclusivity and interchangeability provisions present additional challenges for market entry.

2.4.CDSCO REGULATIONS IN INDIA

The Central Drugs Standard Control Organization (CDSCO), in collaboration with the Department of Biotechnology (DBT), has developed and revised the "Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India" to address the challenges associated with the development of biosimilars. Initially introduced in 2012 and updated in 2016, these guidelines focus on regulating the manufacturing process, quality, safety, and efficacy of similar biologics, while also outlining pre- and post-marketing regulatory requirements. The DBT, through the Review Committee on Genetic Manipulation (RCGM), oversees the development and preclinical evaluation of biologics. In India, similar biologics are regulated under the Drugs and Cosmetics Act (1940), the Drugs and Cosmetics Rules (1945), and the Rules for Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells (1989), notified under the Environment (Protection) Act, 1986.These regulations establish criteria for quality, safety, and efficacy while considering

the Indian healthcare landscape. CDSCO mandates extensive comparative studies to demonstrate biosimilarity, ensuring that domestically produced biosimilars comply with international standards.

The 2016 revision of the guidelines introduced significant changes. Earlier, the reference biologic for which a biosimilar was developed had to be approved and marketed in India. However, the revised guidelines now permit reference biologics approved in India or in countries affiliated with the International Council for Harmonisation (ICH), such as the European Union, Japan, the United States, Canada, and Switzerland. This change aligns India's regulatory framework with international standards set by agencies like the European Medicines Agency (EMA) and the World Health Organization (WHO). The guidelines emphasize a sequential approach to demonstrate the molecular and quality similarity of a biosimilar to its reference product.

Another key update in the 2016 guidelines is the increased focus on post-marketing studies. CDSCO mandates that biopharmaceutical companies conduct Phase IV clinical trials involving at least 200 patients within two years of marketing approval. These studies aim to further reduce the residual risks associated with similar biologics. Additionally, the guidelines introduced a new section on non-comparative safety and efficacy studies.The regulatory framework established by CDSCO and DBT not only facilitates the development of biosimilars but also aligns India with international standards, fostering innovation and accessibility in the biologics sector.

2.5.TRIPS AGREEMENT

The TRIPS Agreement allows countries to decide whether to grant patents for new uses of existing substances, providing flexibility to balance innovation with preventing extended monopolies. Section 3(d) reflects this flexibility, requiring significant enhancement in therapeutic efficacy for patent eligibility. While TRIPS mandates patent protection for inventions, it also allows member states to incorporate safeguards. Article 1.1 permits innovative approaches to implementing TRIPS principles, and Article 27.1 provides discretion in defining patent criteria. This flexibility enabled India to craft Section 3(d) to prevent patent abuse in pharmaceuticals. Pharmaceutical innovations are categorized as "major" or "minor." While groundbreaking discoveries are rare, many patents are granted for minor modifications. TRIPS does not prevent countries from denying patents for new uses if they fail to meet novelty, inventiveness, or industrial application criteria. Articles 7 and 8 of TRIPS emphasize a balance between protecting intellectual property and public welfare. Adhering to these principles, India introduced Section 3(d) to ensure patents are granted only for genuine innovations, not trivial modifications.

2.6. PATENT LAW FRAMEWORK: INDIA VS. EU

Patent evergreening is addressed differently in India and the European Union (EU), with India relying on strict patentability criteria under Section 3(d) of the Patents Act, 1970, while the EU emphasizes competition law enforcement to regulate abusive patent practices. Both approaches aim to balance innovation incentives and market competition but they differ in execution and effectiveness. This can be understood by analyzing patent laws as well as competition laws, and their approach to patent evergreening in both India and EU.

2.6.1. EU APPROACH: EFFICACY AND INVENTIVE STEP CRITERIA

The European Patent Convention (EPC) is fundamental to patent law in the European Union (EU), defining patentability criteria and guiding the European Patent Office (EPO). Under EU Patent Law, patents can protect products, processes, or medical indications. Article 52(1) of the EPC stipulates that an invention is patentable if it meets three essential criteria:

(1) novelty
(2) an inventive step

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(3) industrial applicability.

In pharmaceuticals, the novelty requirement is particularly significant. An invention is considered novel if it does not comprise part of the existing state of the art, which refers to knowledge accessible to a hypothetical person skilled in the relevant technical field. Although the EPO does not formally acknowledge evergreening as a patenting strategy, it permits secondary patents that involve modifications to existing drugs, such as formulation changes, dosage variations, and new medical applications.

3. MANUFACTURERS' STRATEGIES TO EXTEND PATENT PROTECTION

3.1. PATENT THICKETS

A patent thicket is defined as "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees." Patent thickets can manifest in two distinct contexts. The first context involves multiple parties holding overlapping patent rights for a single product, necessitating negotiation among competitors to secure the required licenses for market entry. This scenario raises concerns regarding the inefficient exploitation of technology, as coordination among multiple patent owners is essential for cross-licensing. The second context features a single entity creating an extensive network of patents that effectively deter or delay competitors from entering the market, eliminating the need for coordination with others. Both contexts pose anticompetitive risks: the first increases market entry costs, while the second can exclude competitors entirely.

3.1.1 PHARMACEUTICAL THICKETS

Pharmaceutical patent thickets are primarily constructed from "secondary patents," which involve minor modifications to existing drugs rather than the development of new chemical entities. Such modifications may include changes in formulation (e.g., extended release), dosage, or administration route (e.g., capsules, tablets, topicals). In contrast, "primary" patents cover new chemical entities, offering stronger protection due to their broader scope and greater difficulty in invalidation. Primary patents typically provide the most substantial protection, as any competitor utilizing the same chemical compound infringes the patent, irrespective of dosage, formulation, or method of use. Additionally, primary patents are harder to invalidate due to the comprehensive indexing of "prior art" related to chemical compounds in commercial databases.

3.1.2. HIGH-TECHNOLOGY THICKETS

The high-technology sector presents a different landscape. Patent thickets are prevalent, as noted by the U.S. Department of Justice Antitrust Division and the Federal Trade Commission (FTC), which state that "in many industries, the patent rights necessary to commercialize a product are frequently controlled by multiple rights holders." In high technology, a single product may encompass hundreds or even thousands of patents; for instance, one estimate suggests that a smartphone contains approximately 250,000 patents. While licensing can create opportunities for dominant firms to reinforce their market position and complicate the entry of new competitors, it also serves as a mechanism to mitigate potential bottlenecks caused by patent thickets. Given the extensive patent coverage of products in this industry, licensing becomes essential.

3.1.3 CONTINUATION PATENTS

A key method for creating patent thickets is the use of continuation patents. Continuation patents are derived from the same invention description and drawings as a previously filed application, maintaining nearly identical disclosures. A defining characteristic of continuation patents is their inability to introduce new material, illustrations, or information beyond what is presented in the parent application. Due to their restriction on new disclosures, continuation patents typically progress through the patent examination process more rapidly than standard

applications. However, it is crucial to note that continuation patents were not designed to serve as a strategic barrier to hinder competitors' market access.

3.2. EVER GREENING & SECONDARY PATENTS:

India's leadership in generic drug production is attributed to its competitive manufacturing processes, skilled workforce, and a favorable regulatory framework, particularly the Patents Act of 1970, which initially permitted the production of generics without infringing on product patents. Entry barriers in the pharmaceutical market often arise from patent law or strategic manipulation of these laws to hinder new entrants, thereby providing established companies with an unfair advantage. Generic competition is restricted during the lifespan of a patent protecting a drug's active compound, commonly referred to as a "basic" or "primary" patent. This patent protects the active ingredient itself, offering substantial protection for the product. Consequently, generic competition may commence only after patent expiration or if a generic company successfully challenges and invalidates the patent.

Historically, pharmaceutical companies relied on a single patent covering the active compound to protect their products. However, many companies now seek additional patent protections for various aspects of a drug to strengthen their market position. These additional protections are known as secondary patents. Secondary patenting, or evergreening, involves acquiring extra patents for variations of the original drug, such as new release forms, altered dosages, combination changes, or different formulations. This strategy is particularly lucrative when applied to blockbuster drugs that generate significant revenues. Critics argue that these secondary patents, often granted for minor modifications to the original drug, typically meet only minimal standards of novelty and inventiveness, offering little to no substantial improvement in health outcomes. These practices are commonly referred to as "evergreening," "life-cycle strategies," or "strategic patent planning." Thus, when a patent holder seeks to extend protection beyond the standard 20 years by obtaining patents for multiple attributes of a single product, this practice is termed 'Evergreening of Patents.

4. LEGAL FRAMEWORK FOR PATENT PROTECTION IN INDIA

The Indian Patents Act, 1970, replaced the Indian Patent and Design Act of 1911 to encourage innovation while safeguarding public interests. Initially, the Act excluded product patents for food, chemicals, and pharmaceuticals to promote accessibility. However, after India's compliance with the TRIPS Agreement, amendments in 1999, 2002, and 2005 reintroduced product patents, particularly for pharmaceuticals. The Drug Policy of 1978 represented India's first comprehensive approach to drug regulation, with its foundational framework remaining largely intact until the 1990s. The primary aim of this policy was to achieve self-sufficiency in drug production. Both the Patent Act of 1970 and the Drug Policy of 1978 were instrumental in advancing indigenous R&D. India's capacity to develop generic drugs significantly evolved between the mid-1970s and the 1990s.

Subsequent sections will explore specific provisions of the Patent Act, particularly the 2005 amendment and Section 3(d), which prevents the misuse of patent rights in the pharmaceutical industry.

Patent Protection Under Section 3(d) For an invention to be patentable, it must not fall under Section 3, which lists non-patentable inventions. Section 3(d) ensures that mere improvements do not qualify for patents unless they result in a new substance with enhanced efficacy.

Section 3(d) states that:

- A new form of a known substance is not patentable unless it enhances efficacy.
- A new property or use of a known substance is not patentable.

- The use of a known process, machine, or apparatus is not patentable unless it results in a new product or involves a new reactant.

The explanation clarifies that salts, esters, polymorphs, and other derivatives of a known substance are considered the same unless they significantly differ in efficacy.

The Efficacy Requirement :The 2005 amendment to the Patents Act introduced Section 3(d) to address issues related to evergreening practices. Nonetheless, concerns have emerged regarding its strict enforcement and the judiciary's limited interpretation of 'efficacy' as strictly 'therapeutic efficacy,' which may adversely affect incremental innovations. The Mashelkar Report underscored the importance of preventing evergreening while affirming the patent office's responsibility to differentiate between trivial modifications and substantive advancements.

Section 3(d) presumes that structurally similar variants of known substances exhibit comparable functionality. Consequently, patent applicants are required to demonstrate a meaningful enhancement in efficacy to obtain a patent.

In the case of Novartis AG v. Union of India, the Supreme Court denied Novartis' attempt to patent a beta crystalline salt form of imatinib mesylate (Glivec), citing insufficient evidence of significant therapeutic efficacy compared to the existing formulation. This ruling reaffirmed

4.1. COMPULSORY LICENSING UNDER INDIAN LAW

Sections 84 and 92 of the Indian Patents Act of 1970, along with its revisions, govern the issuance of compulsory licenses .According to these sections, after three years from the sealing date of a patent, any interested party may apply to the Controller for a compulsory licenses. The application must assert that the reasonable requirements of the public regarding the invention have not been met, or that the invention is not available at a reasonable price. Additionally, the government can initiate the process for the grant of a compulsory licenses under Section 88 by endorsing a 'licenses of rights.' This provision allows any individual to request the patentee to grant them a license to utilize the patent in India under mutually agreed terms. In the event of a disagreement between the parties, the Controller has the authority to determine the terms under which the license will be granted by the patentee.

The first compulsory license in India was granted in 2012 to the generics producer Natco for the production and sale of the patented cancer drug "Nexavar." This license was issued because the patent owner, Bayer, did not provide the medication at an affordable price. The ruling raised questions due to the interpretation of TRIPS Article 27(1). In the Natco/Bayer case, the Controller applied the standard of "worked to the fullest extent that is reasonably practicable" to Bayer's practices in relation to the local working requirement. Sections 84 and 89 stipulate that mere importation of a product does not satisfy the local working requirement. Given that TRIPS prohibits discrimination regardless of the origin of the products, this interpretation is noteworthy. A combination of Article 30 with Article 31, which offers alternatives for unauthorized use of patents, may have been more appropriate.A significant challenge in the dissemination of green technology is the pricing, which frequently remains prohibitively high for lower-income and impoverished nations. There is a prevailing belief that stringent intellectual property rights (IPRs) contribute to these elevated costs.

4.2 CHALLENGES AND LIMITATIONS

Despite notable progress in the development of biosimilars, several challenges hinder their broader acceptance and utilization. Key issues include:

1. Manufacturing Complexity: Biosimilars are derived from living cells and possess intricate molecular structures, distinguishing them from traditional

generic drugs. Even minor deviations in the manufacturing process can influence their efficacy and safety, making consistency in production a critical challenge.

2. Immunogenicity Risks: As biologic medicines, biosimilars can elicit immune responses that may impact their effectiveness and safety. While regulatory agencies mandate comprehensive immunogenicity evaluations, uncertainties regarding long-term immune reactions in diverse patient populations persist.
3. Interchangeability and Substitution: Regulatory bodies, including the FDA, enforce strict criteria for biosimilars to be classified as "interchangeable" with their reference products. Gaining this designation often necessitates additional clinical trials. In jurisdictions where automatic substitution is limited, healthcare providers may be reluctant to transition patients from the original biologic, thereby restricting access to biosimilars.
4. Patent and Market Exclusivity Barriers: Patent protections and exclusivity durations frequently delay the market entry of biosimilars. Legal disputes over patents, for instance, have significantly postponed the availability of adalimumab biosimilars, resulting in sustained high treatment costs for patients.
5. Extrapolation of Indications:Following approval for a specific medical condition, manufacturers may pursue additional indications based on pre-existing clinical data. However, some healthcare professionals remain cautious about this strategy, particularly in oncology, where treatment responses can vary significantly.

5.ACCESSIBILITY AND AFFORDABILITY: A HUMAN RIGHTS PERSPECTIVE

Access to affordable medicines, particularly biosimilars, constitutes a fundamental human right intimately connected to the right to health. Nevertheless, patent monopolies, elevated drug prices, and regulatory obstacles frequently obstruct equitable access to essential biologics. A human rights approach, rooted in international legal frameworks and constitutional provisions, underscores the urgent necessity for policy interventions to guarantee that biosimilars are both accessible and affordable for everyone, especially in low- and middle-income nations such as India. The right to health and healthcare is universally recognized as a fundamental human right. Article 25 of the Universal Declaration of Human Rights (UDHR) affirms this right, while Article 35 of the European Charter of Fundamental Rights emphasizes universal access to healthcare as a cornerstone of European citizenship.

5.1. RIGHT TO HEALTH AND ACCESS TO MEDICINES

The right to health is universally acknowledged as a human right, as articulated in various international legal instruments. The International Covenant on Economic, Social and Cultural Rights (ICESCR), through Article 12, mandates states to undertake necessary measures for the prevention, treatment, and control of diseases while ensuring access to essential medicines. Similarly, the Universal Declaration of Human Rights (UDHR), under Article 25, affirms the right to an adequate standard of health, which encompasses access to medical care and essential social services. The World Health Organization (WHO) guidelines further emphasize the importance of equitable access to essential medicines, viewing them as integral to the right to health.In India, the right to health is inferred from Article 21 of the Constitution, which guarantees the right to life and personal liberty. The Indian judiciary has consistently interpreted the right

to health as a vital component of the right to life. Landmark rulings, such as Consumer Education and Research Centre v. Union of India (1995) and Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996), have reinforced the obligation of the state to provide affordable healthcare. Additionally, the Directive Principles of State Policy (DPSP), particularly Articles 38, 39(e), and 47, instruct the state to promote public health and ensure the welfare of its citizens. Despite these legal commitments, high drug prices—often stemming from patent monopolies—continue to impede access to essential medicines.

5.2.AFFORDABILITY CRISIS DUE TO PATENT MONOPOLIES

High costs associated with patented biologic drugs represent a significant barrier to accessing biosimilars. Patent monopolies enable pharmaceutical companies to retain exclusive rights over their innovations for extended durations, resulting in exorbitant prices that render these medicines inaccessible to a majority of the population in developing countries.

5.3 CASE STUDIES ON HIGH-PRICED BIOLOGICS IN INDIA

Instances of high biologic prices in India have significantly restricted patient access. A prominent example is trastuzumab (Herceptin), a biologic for breast cancer treatment. Initially developed by Genentech (now part of Roche), Herceptin was launched at a price of ₹1.2 lakh (approximately $1,500) per dose, making it unaffordable for many cancer patients in India. The introduction of biosimilars like Canmab (by Biocon) and Hertraz (by Mylan) has substantially decreased costs, with biosimilars priced 40–60% lower than the original biologic. However, ongoing accessibility challenges persist due to regulatory delays and insufficient awareness.Another example is adalimumab (Humira), a biologic for autoimmune diseases such as rheumatoid arthritis and psoriasis. Developed by AbbVie, Humira dominated the market due to extended patent protections and aggressive litigation strategies. In India, biosimilars like Exemptia (developed by Zydus Cadila) have emerged as more affordable options, costing nearly 70% less than the original drug. Nonetheless, the legal and commercial strategies employed by multinational pharmaceutical companies continue to stall the widespread availability of biosimilars.

5.4. BRIDGING THE HUMAN RIGHTS AND PATENT POLICY DIVIDE

To reconcile patent policies with the right to health, governments must implement robust interventions that balance intellectual property (IP) protections with public health priorities. Key measures include:

1. Price Regulation Mechanisms: Expanding the Drug Price Control Order (DPCO) in India to encompass more biologics and biosimilars can prevent excessive pricing and guarantee affordability.
2. Compulsory Licensing: Utilizing provisions under Section 84 and Section 92 of the Indian Patents Act, which permit the government to grant compulsory licenses for essential drugs, can facilitate the production of affordable biosimilars in cases of significant unmet medical need.
3. Public-Private Partnerships (PPPs): Promoting collaborations among government agencies, research institutions, and domestic pharmaceutical companies can enhance biosimilar development and affordability.
4. Subsidies and Insurance Coverage: Expanding government health schemes, such as Ayushman Bharat, to include biosimilars can improve access for economically disadvantaged patients.

5.5 POLICY RECOMMENDATIONS FOR PATENT LAW AMENDMENTS

To establish a more equitable framework, patent laws should be reformed to facilitate biosimilar access while maintaining incentives for innovation:

1. Restricting Evergreening Patents: Amending Section 3(d) of the Indian Patents Act to strictly prevent evergreening—where companies make minor modifications to prolong patent life—can expedite biosimilar market entry.
2. Expediting Regulatory Approvals: Streamlining the Biosimilar Guidelines (2012, revised in 2016) to shorten approval timelines and eliminate redundant clinical trial requirements for well-established biosimilars can enhance accessibility.
3. Strengthening Parallel Import Policies : Allowing the import of biosimilars from countries with lower pricing can foster competition and reduce costs.

6.CONCLUSION

India's journey in the biosimilar sector has been transformative, marked by early adoption, innovation, and a commitment to affordability and accessibility. As one of the first countries to approve a biosimilar in 2000, India demonstrated its pioneering spirit by developing and commercializing biosimilars even before established regulatory frameworks were in place. Over the years, Indian pharmaceutical companies such as Biocon, Dr. Reddy's Laboratories, and Zydus Cadila have emerged as global leaders, with several biosimilars gaining approval from stringent regulatory authorities like the USFDA and EMA. The biosimilar industry has significantly improved access to life-saving treatments, particularly in low- and middle-income countries (LMICs). By offering biosimilars at 20–30% lower costs than reference biologics, India has played a pivotal role in reducing healthcare disparities. This affordability has been especially impactful in addressing diseases like cancer and autoimmune disorders, where treatment costs are often prohibitive. Furthermore, biosimilars align with India's broader policy goals of inclusive growth and social inclusion, as emphasized in the 12th Five Year Plan and the National Health Policy. By prioritizing equitable access, biosimilars have become a cornerstone of India's efforts to achieve "health for all."However, the biosimilar sector is not without challenges. Policy debates surrounding intellectual property rights (IPRs), socioeconomic inequality, and gender disparities underscore the need for inclusive innovation. Patent thickets, for instance, remain a significant barrier to the entry of affordable biosimilars. To address these challenges, it is essential to refine the legal and regulatory framework for biopharmaceuticals. Key recommendations include:

1. **Legal Separation from Traditional Medicinal Products**: Biopharmaceuticals should be legally distinguished from traditional medicinal products that are based on active chemical substances. This separation is essential to reflect the complex nature of biologics and their development processes.
2. **Clear Categorization Under Pharmaceutical IP Regime**: Clear distinctions must be established for biopharmaceutical categories within the pharmaceutical intellectual property (IP) framework. This will help streamline regulatory processes and ensure appropriate protection and innovation incentives.
3. **Continued Use of the Term "Biosimilars"**: The term "biosimilars" should continue to be used for follow-on biopharmaceuticals. This ensures clarity and consistency in regulatory and market discussions.
4. **Protection of IP Exclusivity Rights**: Biopharmaceuticals should not be treated as common goods or part of the public domain, as this would undermine IP exclusivity rights. Instead, patent laws should be further adapted to meet the specific needs of the biopharmaceutical industry, balancing innovation incentives with public health goals.

5. **Introduction of New Patent Exemptions**: The optimal legal regime for intellectual property rights related to biosimilars may include the enactment of new exemptions to the scope of patent protection. Such exemptions can help address barriers to entry for biosimilars while maintaining a fair and competitive market.

Looking ahead, India's biosimilar ecosystem holds immense potential to further reduce health disparities and drive inclusive growth. Strengthening public-private partnerships, expanding insurance coverage, and streamlining regulatory processes will be critical to sustaining this momentum. By addressing challenges such as regulatory delays and lack of awareness, India can continue to lead the global biosimilar market while ensuring that the benefits of scientific advancements reach the most marginalized populations.

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