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A COMPARATIVE ANALYSIS ON PATENT LINKAGE ACROSS VARIOUS JURISDICTIONS

AUTHORED BY - SENBAGAM S

ABSTRACT:

*This research explores the legal frameworks governing **patent linkage systems** across different jurisdictions and their implications for global healthcare. Patent linkage refers to the mechanism that connects the approval of generic drugs to the patent status of reference brand-name drugs, creating a regulatory interface between patent protection and market entry of generics. This comparative study examines key jurisdictions, including the **United States**, **Canada**, **European Union**, and **India**, highlighting the diverse regulatory approaches and legal complexities involved. The study explores how various nations strike a balance between the interests of patent holders and producers of generic drugs, assessing the impact of patent linkage in promoting pharmaceutical innovation and perhaps postponing the release of reasonably priced generics. The analysis highlights the legal and regulatory gaps created by the Hatch-Waxman Act (U.S.) and the Notice of Compliance (NOC) Regulations (Canada) by comparing them to other countries that do not have formal patent linking systems. The study also looks into how patent linking affects public health, specifically with regard to access to reasonably priced medications in both developed and developing nations. It discusses the implications for global healthcare, including issues with patent ever greening, the lengthening of legal proceedings, and the purposeful exploitation of linking systems to increase market exclusivity. The research offers recommendations for harmonizing policies and enhancing access to key medications globally through this comparative analysis, which offers crucial insights into how patent linkage regimes impact the pharmaceutical landscape.*

Keywords: Patent linkage, pioneer drug, generic drug, TRIPS agreement, public health, Hatch-Waxman act, Food & Drug Administration (FDA).

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CHAPTER 1

1. OVERVIEW ON INTRODUCTION

1.1. INTRODUCTION:

Patent Linkage is the process of connecting a drug's patent status to its marketing clearance. Patent linkage is the relationship between a generic drug's permission for sale and the branded drug's patent status. In the context of intellectual property (IP) regulations, in particular, striking a careful balance between promoting innovation and guaranteeing the public's access to reasonably priced medications continues to be a very difficult task for legislators. This discourse centers on patent linkage schemes, which tie the patent status of name-brand medications to the approval of generic drugs. While fostering competition and protecting intellectual rights are their dual goals, the ways in which they are applied and what happens as a result varied greatly between areas.

The Hatch-Waxman Act, passed in the US in 1984, established a systematic procedure for the approval of generic medications while upholding the validity of current patents, and thus helped popularize the idea of patent linkage. In order to assist regulatory bodies in identifying patent status prior to authorizing clearance for generics, this legal framework developed the Orange Book, a crucial resource that includes patented medications and their authorized generic equivalents. Since then, additional countries have embraced comparable structures, each with its own set of operational procedures and legislative frameworks, such as the European Union and Canada.

However, not all countries embrace patent linkage. Some, like India, have chosen to forgo tight adherence to patent rights in favor of legislative systems that permit the independent clearance of generics, with the goal of facilitating wider access to reasonably priced medications. The efficiency of patent linking systems in fostering innovation and guaranteeing the fulfillment of public health demands is seriously called into doubt by this discrepancy[1]. Legal problems frequently cause countries with strict patent protection systems to delay the introduction of generics into the market. This can result in increased medicine prices and less access for patients, especially in low- and middle-income areas where healthcare resources are tight.

[1] Bouchard R, Empirical analysis of drug approval-drug patenting linkage for high value pharmaceuticals, Northwestern Journal of Technology & Intellectual Property, 8 (2) (2010) 174-227

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These different strategies for patent connection have significant ramifications. Not only is it important to follow the law, but access to medications is a vital part of public health policy that impacts millions of lives. The effectiveness of patent linking systems is a critical problem for global health governance, since the World Health Organization highlights the significance of access to important medications as a fundamental human right. Furthermore, in order to properly respond to public health catastrophes, the COVID-19 pandemic has highlighted the need of removing access restrictions and the necessity of reevaluating the current patent regimes.

This research aims to conduct a comparative analysis of patent linkage systems across key jurisdictions, including the United States, Canada, the European Union, and India. This study aims to determine the benefits and drawbacks of various patent linking strategies by looking at legislative frameworks, regulatory procedures, and their effects on pharmaceutical innovation and access to medications. Additionally, the study will examine how international accords, including the TRIPS Agreement, have shaped these systems and what that means for the world's health care system.

This study ultimately hopes to add to the current conversation about how to strike a compromise between the urgent need for fair access to necessary medications and the preservation of intellectual property. Through the identification of legal gaps and obstacles in patent linkage systems, this research will put forth practical policy suggestions that seek to improve global regulatory harmonization, foster pharmaceutical innovation, and increase universal access to medications. The research findings hold significance not just for legal academics and politicians, but also for public health advocates, stakeholders in the pharmaceutical sector, and global health organizations that strive to provide innovative and easily accessible healthcare.

1.2. SIGNIFICANCE OF THE STUDY:

Patent protection plays a major role in the pharmaceutical industry's ability to recover the high expenses of medication research and development (R&D) and encourage innovation. With a patent, an inventor is granted exclusive rights that, usually, last for 20 years and allow them to stop anyone from producing, using, or marketing the patented medication. On the other hand, generic drug producers may enter the market once these patents expire and provide less expensive substitutes that encourage greater access to medications.

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Patent linkage schemes, which connect the approval of generic pharmaceuticals to the patent status of reference (brand-name) drugs, have been implemented by several nations as a way to balance innovation with competition[2]. A related patent dispute or current patent protection on the branded medicine essentially prevents regulatory bodies in charge of drug approvals, such the U.S. Food and medicine Administration (FDA), from approving a generic drug application.

In the US, the Hatch-Waxman Act of 1984 established one of the most well-known patent linkage schemes, establishing a framework that permits the approval of generic drugs while upholding patent rights. In order to help regulators determine the patent status of pharmaceuticals, it also produced the Orange Book, a database listing patents in that field. The result is a disjointed global regulatory environment. Other jurisdictions, including the European Union and Canada, have created their own patent linkage systems, each with distinctive characteristics.

Conversely, countries like India have rejected formal patent linkage mechanisms, opting instead for a system where generic drug approvals are independent of patent status, emphasizing broader access to affordable medicines. This divergence in approaches creates a significant contrast in how pharmaceutical competition and public health priorities are managed globally.

International trade agreements such as the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) have impacted the global deployment of patent linking systems in addition to national legal frameworks. But patent linking is still a contentious issue, especially for low- and middle-income nations that mostly rely on reasonably priced generics to address public health demands, despite TRIPS' aim of striking a balance between intellectual property protection and public health concerns.

This research is therefore crucial in understanding the comparative legal frameworks that govern patent linkage globally. By examining how different jurisdictions regulate patent linkage and analyzing the implications for innovation, litigation, and access to medicines, the research will provide insights into the legal vacuums and challenges present in the current

[2] Anshul Mittal, Current scenario and need for deliberation. Journal of Intellectual Property Rights, Vol. 15, 2010, PP 187-196

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systems. Furthermore, it will explore the feasibility of global harmonization of patent linkage systems and how such a move might impact healthcare outcomes, particularly in developing countries.

1.3. REVIEW OF LITERATURE:

- Intellectual Property and Public Health in the Developing World, Monirul Azam, Open Book Publishers, 2016

  Here in this author clearly explains the intersection between intellectual property rights, particularly patents, and public health concerns in the developing world. It provides an analysis of the TRIPS Agreement and the challenges faced by developing countries in implementing IP provisions related to pharmaceuticals.
- Patent Law and Policy: Cases and Materials, Robert Patrick Merges, John Fitzgerald Duffy, Carolina Academic Press, 2017 (7th Edition)

  Here in this authors clearly explains that covers key cases and legal principles in patent law, this book is a valuable resource for understanding the legal frameworks governing patents, including issues related to patent linkage and pharmaceutical innovation.
- Pharmaceutical Innovation, Competition, and Patent Law Reform: A Trilateral Perspective, Jakkrit Kuanpoth, Edward Elgar Publishing, 2010

  The authors discusses the role of patents in pharmaceutical innovation, examining how patent laws in the U.S., the EU, and developing countries affect competition in the pharmaceutical industry. It also looks at reforms needed to balance innovation with access to medicines, making it a good reference for understanding comparative patent laws.
- Patent Policy and Innovation in Pharmaceuticals, Ove Granstrand, Springer, 2020

  This book focuses on the role of patents in pharmaceutical innovation, providing an in-depth look at how patent policy impacts the development and commercialization of new drugs. It also discusses how patent linkage can shape competition and access to generics.
- Pharmaceuticals, Patents, and the Law, Trevor Cook, Bloomsbury Professional, 2021

  This book provides an overview of the relationship between patents and the pharmaceutical industry, discussing legal frameworks, key cases, and the impact of patent systems on drug pricing, market access, and generic competition.
- Intellectual Property, Pharmaceuticals, and Public Health: Access to Drugs in Developing Countries, Kenneth C. Shadlen, Samira Guennif, Alenka Guzmán, N.

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Lalitha, Edward Elgar Publishing, 2011

This book focuses on the challenge of balancing intellectual property rights and public health in developing countries, providing detailed analysis and case studies on the impact of patents on access to medicines.

- Triveni Singal, Need for a patent linkage system in India, https://www.mondaq.com/india/patent/871208/patent-linkage-and-indian-laws#:~:text=India%20has%20not%20adopted%20Patent,originator%20drug%20is%20i n%20force (last visited on 22 Sep 2024)

  This article explains the concept of patent linkage is a double-edged sword. India is currently leading in the exportation of generic drugs to the world. We cannot bear to pay exorbitant prices for drugs, which are provided by generic companies for lesser amounts. As seen above, patent linkage incurs huge expenses to the consumers and governments that sponsor health care.

- Bouchard R, Empirical analysis of drug approval-drug patenting linkage for high value pharmaceuticals, Northwestern Journal of Technology & Intellectual Property, 8 (2) (2010) 174-227.

  This Journal focuses on the examination of patent linkage practices across the United States, Europe, and India reveals distinct approaches and philosophies governing the intersection of pharmaceutical patents and generic drug approvals.

- Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. (last visited on 15 sep 2024) Here in this authors clearly explain that Before a drug can be tested in people, the drug company or sponsor performs laboratory and animal tests to discover how the drug works and whether it's likely to be safe and work well in humans. Next, a series of tests in people is begun to determine whether the drug is safe when used to treat a disease and whether it provides a real health benefit.

- Manisha singh & Swati Gupta, Patent Linkage And Indian Laws, https://www.mondaq.com/india/patent/871208/patent-linkage-and-indian-laws#:~:text=India%20has%20not%20adopted%20Patent,originator%20drug%20is%20i n%20force Here in this authors clearly explain that India has not adopted Patent linkage yet. A generic manufacturing company can apply forth marketing approval of a generic product even if the patent status of the originator reference product is valid. However, the approved generic drug cannot be brought to the market if the patent of the originator drug is in force.

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1.4. RESEARCH GAP:

A thorough comparative analysis that considers the ways in which the variations in patent linkage frameworks across major international jurisdictions affect innovation, the global pharmaceutical market, and the availability of reasonably priced medications is lacking, despite the fact that patent linkage systems have been extensively researched within individual jurisdictions. The Hatch-Waxman Act in the United States and the Notice of Compliance laws in Canada are two examples of single jurisdiction patent linking systems that are the subject of most of the research now in publication. Just a little amount of study, nevertheless, offers a comparative analysis across several countries, particularly when it comes to looking at how these disparate systems as a whole affect public health and the worldwide pharmaceutical industry. A lack of formal patent linkage systems in developing countries (like India) can have an impact on global healthcare goals like access to affordable medicines.

1.5. RESEARCH PROBLEM

What is the impact of differing national patent linking schemes on the prompt release of generic medications?

What legal flaws or loopholes exist in the present systems of patent linkage, and how may they be fixed to better strike a balance between the protection of intellectual property and the general public's access to healthcare?

1.6. OBJECTIVES OF STUDY:

This study aims to perform a comparative analysis of patent linkage systems in different international jurisdictions. Specifically, it will examine the legal frameworks, regulatory mechanisms, and their broader implications for pharmaceutical innovation, the entry of generic drugs into the market, and global healthcare.

Examine the Legal and Regulatory Frameworks: The patent linking frameworks of important legal countries, including the US, Canada, EU, and India, to learn how they function and how they strike a balance between patent protection and generic competition.

Identify Legal and Regulatory Vacuums: Point out the flaws and contradictions in the various patent linking schemes, such as legal hold-ups, regulatory gaps, and patent ever greening, which impede timely access to reasonably priced medications.

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1.7. HYPOTHESIS:

In comparison to various jurisdiction lacking such laws, patent linking system cause a considerable delay in the entrance of generic drugs into the market.

1.8. METHODOLOGY:

This research is based on the doctrinal method or it can be known as non-empirical method so the sources are from secondary sources like books, article, journals and various online database materials.

This research is done by the comparative analysis method to acquire the intricate details of the respective topic.

1.9. SCOPE AND LIMITATION:

The main goal of the study is to compare patent linking systems in depth across important countries, such as the US, Canada, EU, and India. These nations were picked for their varied perspectives on the effects of patent linkage on their pharmaceutical markets, as well as their differing legislative frameworks. The examination will encompass the legislative structures, oversight procedures, and past case studies that illustrate the practical applications of patent linking in various areas. The research will look at how international agreements such as the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) impact the regulatory environment around patent protection in various nations and how they shape patent linkage systems.

The study is restricted to analyzing a few major jurisdictions, mainly the United States, Canada, the European Union, and India. Although a wide range of regulatory procedures are represented by these locations, other significant jurisdictions (such as South Africa, Brazil, and Japan) will not be thoroughly covered, which will restrict the findings' applicability to a worldwide setting. he study focuses on public health and ethical concerns, such as the moral consequences of delayed access to inexpensive medications. The ethical aspect, however, could not be as thoroughly examined as it might be in a public health or ethics-focused study because of the research's legal focus.

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CHAPTER-2

2. CONCEPT AND STRUCTURE OF PATENT LINKAGE SYSTEMS

2.1. PATENT LINKAGE:

The process of linking the patent status of brand-name medications to the regulatory approval of generic drugs is known as "patent linkage." To put it another way, think of it as a generic medication traffic light system where the green light to enter the market is dependent on the validity or expiration of pertinent patents. Patent linkage's main goal is to stop generic medications that could violate already-existing patents from receiving regulatory approval. In addition to guaranteeing that creative firms may profit from their R&D investments, it creates a clear path for generic producers to join the market when patents expire.

A drug is produced using one of the two methods listed below:
By a global or domestic multinational pharmaceutical corporation following the approval of the patent covering all phases of the research and development process, including clinical trials, or by manufacturers of generic medications (The chemical makeup of a generic medication is identical to that of the brand-name medication).

All drugs, regardless of how they are made, must go through a procedure called drug marketing approvals and gain the national drug authority's permission before they can be sold. The process by which a nation links the status of the patents pertaining to the original drug that is for sale to the drug marketing approval of a generic medicine is known as patent linkage. This approach prevents any generic medication from being granted marketing permission unless the patent owner agrees, or until the original drug's patent expires or the appropriate authority determines that the patent will not be infringed upon or is invalid[3]. This makes it much more important for the generic medication producer to demonstrate to the FDA that the medicine it produces is not protected by a legitimate patent. The registration and marketing of the generic medication must be stopped by the national regulatory bodies if the same cannot be conclusively demonstrated. Consequently, the regulatory body becomes a tool for patent enforcement.

[3] European Generic Medicines Association (2009). https://www.medicinesforeurope.com/wpcontent/uploads/2016/03/Market_Barriers_Report_FINAL_update_How_to_Increase_Patient_Access_to_Generic_Medicines.pdf

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The idea of "TRIPS Plus" was created, encompassing acts aimed at enhancing the level of protection afforded to right holders beyond what is currently stipulated in the TRIPS Agreement.

The TRIPS Agreement's Article 28 protects a patentee's rights with relation to product patents, including the ability to stop third parties from using the product for profit without the patentee's consent. Confidential information on pharmaceutical or agro-based chemical products or pharmaceuticals is protected against unfair commercial use under Article 39 of the Agreement. The legal stance on patent linking differs widely and is not consistent in many jurisdictions. To comprehend the necessity of patent linkage in India, one must first examine the patent linkage systems of other jurisdictions.

2.2. PIONEER DRUG:

The first medication that a pharmaceutical firm develops and releases onto the market is referred to as a pioneer drug, innovator drug, or both. A brand-new, never-before-approved active component is included. Regulatory agencies such as the FDA approve pioneering treatments after they go through rigorous clinical testing and research, and they are patent protected. For the duration of the patent's expiration, these patents provide the manufacturer the only authority to market the medication. In systems where generic medicine approval is dependent on the original drug's patent status, pioneer pharmaceuticals are essential.

A unique chemical compound or biological entity is introduced by pioneer pharmaceuticals and is utilized to treat a particular illness or condition. Following the discovery, the pharmaceutical business requests a patent that would give them exclusive rights to commercialize the product. There isn't another business that can make or market a generic version of the medication during this time. Pioneer medications must pass a rigorous approval procedure that includes preclinical research and Phase I, II, and III clinical trials in order to guarantee the drug's quality, safety, and efficacy[4]. Regulatory bodies that assess the data and approve its use for public consumption include the European Medicines Agency (EMA), the Food and Drug Administration (FDA) of the United States, and other national health authorities. A pioneer drug's development frequently necessitates a large financial, time, and resource commitment. A groundbreaking drug's development and commercialization can cost

[4] Pharmaceutical Innovation, Competition, and Patent Law Reform: A Trilateral Perspective, Jakkrit Kuanpoth, Edward Elgar Publishing.

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billions of dollars and take ten to fifteen years. After being authorized, the pioneer medication usually has market exclusivity, which prevents the production of generic equivalents until the patent expires. This exclusivity allows the original business to recoup its R&D expenditures and benefit from the drug's sales.

2.3. GENERIC DRUG:

A generic medicine is one that is manufactured to have all the same qualities, performance characteristics, dosage form, strength, mode of administration, and intended use as an authorized brand-name drug (also known as an innovator or pioneer drug). It must adhere to the same safety, effectiveness, and quality requirements as the brand-name version and has the same active components. A generic medication differs greatly in price from its brand-name equivalent, which is the main distinction between the two. This is so that generic manufacturers won't have to bear the expense of duplicating the clinical studies and expensive research that the original manufacturer carried out to demonstrate the efficacy and safety of the medicine.

The active component of generic medications must be the same as that of the original (pioneer) medication, and they must function, dose, and use in the same manner. This indicates that generic medications are bioequivalent to name-brand medications, meaning they provide the body with the same quantity of active ingredient in the same period of time. Generic medications may vary in terms of color, shape, size, packaging, and non-active components (excipients), but the active substance must always be the same. However, these variances do not influence the safety or efficacy of the medicine. The cost of generic medications is far lower than that of brand-name medications[5]. This is mainly due to the fact that generic manufacturers are exempt from paying for the marketing expenses related to introducing a new medicine to the market as well as the research and development (R&D) expenses necessary for new pharmaceuticals. Rather, they depend on the information gathered from the initial clinical studies carried out by the well-known producer. Prices decrease as a result of increased competition brought about by lower production costs and the ability of numerous businesses to make the same generic medication. Brand-name pharmaceuticals are covered by patents for a period of time (usually 20 years from the date of filing). The drug's development firm is the only one allowed to market it throughout this patent term. Other businesses can produce and market generic copies of the medication when the patent and any related exclusive rights expire.

[5] Pharmaceutical Innovation, Competition, and Patent Law Reform: A Trilateral Perspective, Jakkrit Kuanpoth, Edward Elgar Publishing.

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The major event that facilitates the entry of generics into the market and lowers the cost and increases the accessibility of essential medications is the expiry of patents. A regulatory agency such as the Food and medication Administration (FDA) in the United States, the European Medicines Agency (EMA), or other national regulatory bodies must approve a generic medication before it may be sold. A generic medicine maker needs to file an Abbreviated New medicine Application (ANDA) proving the medication is bioequivalent to the brand-name counterpart in order to get approval. Since the drug's safety and efficacy have already been determined by the initial studies, the ANDA procedure is less expensive and quicker than the New Drug Application (NDA) process needed for pioneer medications.

2.4. TRIPS AGREEMENT:

The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) plays a significant role in the patent linkage system and the broader topic of pioneer and generic drugs in your research. The agreement, established under the World Trade Organization (WTO) in 1995, sets minimum standards for intellectual property (IP) protection, including patents, across all member countries. It has direct implications for how pharmaceutical patents are handled globally and influences the availability of generic drugs. WTO member nations are required by the TRIPS Agreement to issue patents for pharmaceutical items and methods for a minimum of 20 years after the patent's filing date. This guarantees the protection of the pioneering (innovator) pharmaceuticals and permits the original producer to market their product solely for the duration of this time[6]. This is consistent with the patent linkage system as generic manufacturers are unable to make or market the identical medication until the patent expires. TRIPS has an impact on patent linking because it creates a legal framework that prevents drug regulatory bodies from approving a generic medication if the pioneering medicine still has an active patent. This connection delays the release of less expensive alternatives by increasing the amount of time that a pioneering medication is the sole one on the market.

While patent linking systems are not required by TRIPS, member nations are free to implement them. This allows nations to experiment with diverse strategies for striking a balance between the demands of public health and intellectual property rights. Some nations like India do not have explicit patent linkage systems and instead prioritize the quicker clearance of

[6] Patent Law and Policy: Cases and Materials,Robert Patrick Merges, John Fitzgerald Duffy, Carolina Academic Press, 2017 (7th Edition).

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generic pharmaceuticals[7]. Other nations, including the United States and Canada, have formal patent linkage systems in place that relate drug approval to patent status. One TRIPS flexibility is allowed for under Article 31 of the TRIPS Agreement: forced licensing. A government may, by forced licensing, permit a generic medication producer to create a patented medicine without the patent holder's approval, typically in response to an emergency involving public health. By encouraging innovation, this clause can mitigate the limiting consequences of patent linkage.

The Doha Declaration on TRIPS and Public Health was ratified in 2001 in response to worries about drug availability, particularly in poor nations. It was reiterated that WTO countries are entitled to apply TRIPS flexibilities, such as compulsory licensing, to make sure that, in cases when it is required, the public health takes precedence over patent rights[8]. Because it highlights that intellectual property protection shouldn't stand in the way of access to reasonably priced medications, particularly in instances of public health emergency, this declaration is significant when it comes to talks about patent linkage. In order to combine protecting patents (and encouraging innovation) with advancing access to generics, it allows nations greater flexibility to evade some of their TRIPS responsibilities when they encounter public health issues.

[7] Anshul Mittal, Current scenario and need for deliberation. Journal of Intellectual Property Rights, Vol. 15, 2010, PP 187-19
[8] Public health and intellectual property in developing nations Open Book Publishers, Monirul Azam (2016)

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CHAPTER-3

3. GLOBAL PERSPECTIVES ON PATENT LINKAGE:

3.1. PATENT LINKAGE IN US:

In the US, the approval of generic marketing is contingent upon the expiration of the patent for the original medicine. Patents are awarded by the USPTO at any point during the lifespan of medication development, while exclusivity refers to the exclusive marketing rights granted by the FDA upon drug approval, which can occur simultaneously with or independently from a patent. The Drug Price Competition and Patent Term Restoration Act of 1984, sometimes referred to as the Hatch Waxman Act, legally acknowledges patent linkage in the United States.

In the US, the Orange Book, officially titled "Approved Drug Products with Therapeutic Equivalence Evaluations," serves as a comprehensive reference for FDA-approved drugs, offering critical information on their safety and efficacy evaluations. This publication plays a crucial role in the pharmaceutical landscape by documenting details about approved drugs, those that have been discontinued, and the associated patents. The Orange Book not only lists the approved and discontinued drugs but also provides essential information regarding patents and exclusivity. There are two types of applications filed under the Hatch Waxman Act that become relevant here. A New Drug Application (NDA) is typically submitted by the innovator or brand- name drug manufacturer seeking approval for a new drug and is filed before the marketing of a new drug begins. An Abbreviated New Drug Application (ANDA) is filed by a generic drug manufacturer seeking approval to market a generic version of an already approved innovator drug. The ANDA applicant must demonstrate the bioequivalence of the generic drug to the reference-listed drug (RLD) by referring to the safety and efficacy data of the RLD.

3.1.1. ABBREVIATED NDAs:

The process of marketing of generic drugs was statutorily enacted in the United States as part of the Drug Price Competition and Patent Term Restoration Act 1984 (as amended) (commonly called the "Hatch-Waxman Amendments"). The system of generic approval provided by this statute is similar to legislation enacted in Canada and Europe and has largely been harmonized internationally. Prior to the Hatch-Waxman Amendments, an original generic application, called a "paper" new drug application (NDA), had approval parameters that were subjectively determined by the US Food and Drug Administration (FDA) on a product by-product basis and the efficacy and safety were based on the review of publicly available information. Further,

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there were no provisions for data exclusivity nor, in particular, bars to product approval based on a patent filed with the FDA.(1) As a result of the enactment of the Hatch-Waxman Amendments, an additional "abbreviated" process for approval of competitive generics after expiry of the originator product's patent and data exclusivity was created.

To give an idea of the scope of "abbreviation", a typical full NDA is composed of:

- two adequate and well controlled clinical trials;
- formal statistical planning and analysis;
- human dose-ranging, pharmacokinetic and pharmacodynamic studies;
- absorption, distribution, metabolism and excretion studies;
- non-clinical safety pharmacology, pharmacology, pharmacokinetic, pharmacodynamic, genotoxicity, fertility and toxicology studies; and
- a full description of the chemistry, manufacturing and controls (CMC).

Additional clinical safety or efficacy studies that develop information on drug-drug interactions, human safety pharmacology and special populations may also be required.
In contrast, an abbreviated NDA (ANDA) is composed only of:

- a pharmacokinetic comparison of the generic to the innovator/branded drug product or other FDA-designated reference drug that demonstrates bioequivalence;
- a copy of the innovator labeling revised to reflect changes in manufacturer and contact information; and
- The CMC section.

Said differently, an ANDA application is not required to repeat preclinical and clinical safety and efficacy research so long as it can be demonstrated that the generic product performs in the same manner as the innovator drug (ie, that the generic product is bioequivalent to the innovator drug). The innovator/branded drug is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication (known as the "Orange Book") and is known as the "reference listed drug" (RLD).

Occasionally, especially with older drugs, the innovator may withdraw from the market, thereby effectively eliminating an RLD for new generics to reference in their ANDA submission. In that event, the FDA may designate another drug – typically one of the earlier

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generic drugs – as the reference standard (RS) so that additional generics may enter the market and use the RS in place of the RLD. New generics may then enter on comparison to that RS.

To support the successful development of generic drug products, the FDA issues product-specific guidance for generic drug development. This guidance helps generic drug applicants understand the data the FDA recommends providing within the ANDA to establish bioequivalence for pharmaceutically equivalent drug products[9].

In the United States, the current average review time from submission to final approval for ANDAs is approximately 39 months (29 months to tentative approval). The recently enacted Generic Drug User Fee Act and its successor, the FDA User Fee Reauthorization Act 2017, provide for fee revenue to increase the Office of Generic Drug's resources. The FDA has committed to assessing and acting on ANDAs within 10 months (or eight months for priority track) of submission.

3.1.2. *ORANGE BOOK PATENT LISTING:*

By law, to take advantage of a bar to FDA approval of an ANDA during the patent term, an NDA holder must list each patent that claims the drug or a method of using the drug that is the subject of the NDA (or amendment or supplement to it) and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use or sale of the drug product.

FDA regulations further provide that, when filing an NDA, the applicant should include:
patent that claim the drug or a method of using the drug which consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents.

The applicant should exclude process patents [and] patents claiming packaging under 21 Code of Federal Regulations section 314.53(b)(l).

The statute also separately provides for periods of data exclusivity – for example, new chemical entity exclusivity which may expire before or after the Orange Book patents. The period of data

[9] Public health and intellectual property in developing nations Open Book Publishers, Monirul Azam (2016)

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exclusivity is largely impervious to third-party legal challenges.

3.1.3. *CHALLENGING PATENTS LISTED IN ORANGE BOOK:*

For an ANDA to be accepted for review, the ANDA applicant must certify against each of the patents then-listed in the Orange Book. If the ANDA applicant intends to launch its generic product before an Orange Book patent has expired, it must certify to the FDA and notify the patentee and NDA holder, that the patent is invalid, unenforceable and/or that the ANDA product does not infringe any valid and enforceable claim. Under the statute, the patent holder is then authorised to seek a judgment of infringement. Generally, if the patent holder files a complaint within 45 days of receiving the notice, a 30-month stay of regulatory approval is automatically applied, although FDA review may progress and tentative approval may be obtained.

Another avenue to challenge a patent involves requesting that the FDA ask an NDA holder to confirm the patent information in the Orange Book. When patent information is submitted to the FDA for publication in the Orange Book, the NDA applicant attests to the accuracy of the information[10]. The FDA does not evaluate the accuracy of any information related to the patent listing. A challenger may write to ask that that the FDA request the NDA holder to confirm the information listed in the Orange Book. However, the FDA is unable to force delisting of the patent.

An improper listing was recently successfully challenged in the First Circuit as outside the scope of authorisation for listing and improper conduct that could serve as the basis of an antitrust violation of section 2 of the Sherman Act. Here, the patent claimed a part of the device used to administer the drug. The First Circuit found that this was too tenuous a connection and that Sanofi had improperly listed patent claims that "do not mention the drug for which the sNDA was submitted" and therefore it could not have claimed "the drug".

Another potential avenue for challenging Orange Book listings involves a counterclaim in response to a patent infringement suit filed by the patent holder as part of a declaratory judgment following the certification of non-infringement notice. In one such case, a generic applicant filed a counterclaim seeking to delist a patent on the basis that the patent did not claim

[10] Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. (last visited on 15 sep 2024)

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or disclose either the drug substance, drug product or method of use. The case was dismissed pursuant to a settlement agreement before the court ruled substantively. In 2012, the US Supreme Court permitted a generic drug manufacturer to assert a counterclaim alleging an improper use code listed in the Orange Book, in response to allegations that the generic manufacturer's product infringed method-of-use claim.

Since these rulings, the Orange Book Transparency Act 2020 was passed, which requires the FDA to list and publish drug patent and exclusivity information. The FDA has created an internal working group to improve the transparency of the Orange Book.

3.1.4. *PURPLE BOOK FOR BIOLOGICS:*

The Purple Book for biologics lists licensed biologics and their approved corresponding licensed biosimilars. In particular, the Purple Book enables users to see whether biologics licensed under section 35l(k) of the Public Health Service Act (the PHS Act) have been determined to be biosimilar to or interchangeable with a brand-name product (also known as a "reference biological product"). Additionally, the Purple Book provides information on existing reference biological product exclusivity. Although the Purple Book includes exclusivity information, it does not include an expiration date for all biologics, and the lack of an expiration date does not mean a product is not eligible for statutory exclusivity. Moreover, the Purple Book does not list patents for biologics or include manufacture or process patents. In contrast to the Orange Book and the statutory requirements under the Hatch-Waxman Amendments, the PHS Act does not prohibit the FDA from receipt, review or approval of a biologic application that relies on a reference biologic product with unexpired patent listings in the Purple Book.

3.1.5. *DISCLOSURES TO BRANDED COMPANY AND OPPORTUNITY TO SUE:*

An ANDA applicant seeking FDA approval of a generic RLD must make certain disclosures related to patents for the RLD. If an ANDA applicant seeks approval before a patent has expired on the basis that the patent is invalid, unenforceable or not infringed, the applicant must submit a paragraph IV certification to the FDA. When doing so, the applicant must also provide the NDA holder and the patent holder(s) notice of the paragraph IV certification. The notice must describe the factual and legal basis for the ANDA applicant's claim that the patent is invalid,

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unenforceable or not infringed.

The patent owner then has an opportunity to sue the ANDA applicant for patent infringement. As noted previously, if the patent holder initiates a patent infringement lawsuit against the ANDA applicant within 45 days of receiving notice, ANDA final approval will be stayed for 30 months from the later of when the NDA holder or patent owner(s) receives the paragraph IV certification, unless the NDA has new chemical entity exclusivity. In this case, ANDA final approval will be extended to seven-and-a-half years from the date of NDA approval.(7)

3.1.6. *ANDA FIRST-TO-FILE 180-DAY EXCLUSIVITY PERIOD:*

The first ANDA applicant to file a paragraph IV certification is awarded exclusivity vis-a-vis other ANDA applicants for a 180-day exclusivity period. This exclusivity period is given to the first ANDA applicant in exchange for the ANDA applicant risking exposure to patent litigation by filing a paragraph IV certification and giving the requisite notice to the NDA holder and patent owner(s). An ANDA applicant does not need to win a patent infringement suit to retain eligibility for the 180-day exclusivity period.(8)

3.1.7. *CHALLENGING PATENTS USING USP TO IPR PROCEEDINGS:*

An inter partes review (IPR) is a type of post-grant proceeding before the Patent Trial and Appeal Board (PTAB) that allows parties to challenge claims in a patent based on prior art and printed publications. Introduced in 2012 under the America Invents Act, IPRs are now the most utilised mechanism for challenging patents in postgrant proceedings at the PTAB. Adjudicated by a three-administrative judge panel of the PTAB, IPRs have a resolution deadline of just 18 months, requiring careful preparation by the challenger and swift responses from the patent owner.

According to statistics provided by the US Patent and Trademark Office (USPTO), the institution rate of IPRs has been decreasing from year to year. The rate was historically higher than 60%, most recently in 2019, and has now fallen to about 57% in 2021. However, drug patents continue to have a high institution rate. As of June 2021, in IPRs involving Orange Book patents, 62% were instituted, only 15% resulted in final written decisions finding all instituted claims invalid.

This means that a well-drafted petition will more likely than not result in an institution of at

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least one ground asserted in the petition. Importantly, of the instituted petitions that resulted in final written decisions, 50% of the final written decisions found at least one instituted claim to be invalid, while 44% found all of the instituted claims to be invalid. This means that if a petition is instituted, at least one asserted claim will more likely than not be invalidated, if not all of the asserted claims. Therefore, an institution will put a heavy burden on the patent owner as to whether a district court case should proceed to trial.

3.1.8. *PATENT TERM OF ORANGE BOOK PATENTS:*

For patents granted by the USPTO after 8 June 1995, in general, there is a 20-year patent life term from the date of the first effective patent application filing. Having said this, the practical term of protection of the marketed product is often less than 20 years because patents are often granted well before a product's actual commercial marketing.

Many factors affect the effective patent term length, including the pre-market approval requirements applied to certain products regulated under the Federal Food, Drug and Cosmetic Act (FD&C Act). Frequently, these products must undergo extensive testing in humans (and possibly animals) to demonstrate their safety and efficacy to the FDA before the agency will approve the product for commercial marketing.

As a result, to promote product development and innovation, in 1984, Congress chose to enact legislation affording the opportunity to extend patent terms under certain circumstances to compensate patent holders for patent time lost while developing a product and awaiting FDA premarket approval. The legislation allows these patent holders to gain back some of the lost patent time.

While there is much focus given to patent term restoration issues for pharmaceuticals, often little attention is given to medical devices in this regard. However, a subset of medical devices, class Ill devices subject to pre-market approval under section 515 of the FD&C Act can qualify for patent term restoration based on the development and pre-approval process requirements established by the FDA for them.

In the relevant part, under the patent term extension statute at 35 US Code section 156, the owner of record of a patent (or its agent) must submit to the PTO an extension request within the 60-day period beginning on the date the class Ill medical device received approval for

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commercial marketing. For the purposes of an extension request for a class Ill device subject to pre-market approval, the "regulatory review period" that can be recouped is defined as the sum of the following:

- the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date a premarket approval application was initially submitted with respect to the device to the FDA; or
- the period beginning on the date the application was initially submitted with respect to the device to the FDA and ending on the date such application was approved by the FDA.

3.2. PATENT LINKAGE IN EUROPE:

No patent linkage is practiced by the European Union (EU). It asserts that manipulating bolar provisions via patent linkage will surely delay the release of generic medications. Any patented product may be tested and its test findings produced; these can then be submitted to the registration body for marketing permission without breach of EU law. A medicine's patent status is not taken into consideration when the European Medicines Agency (EMEA) makes decisions about drug approval in the EU. Drug clearance may only be refused for the reasons specified in Regulation EC 726/2004 and Directive EC 2001/83. The absence of a relationship exists because patent status is not one of the grounds.

However, to encourage the companies that create new drugs, the EU gives them special rights to control who can make generic versions. For a brand-new kind of drug, they get exclusive rights for a very long time, up to 10 or 11 years. Out of the 10 years, 8 years is the standard data exclusivity period with an additional 2-year marketing exclusivity period. If there is a significant improvement in the existing drug during the first 8 years, an additional 1 year can be added to the 10 years exclusivity period[11]. During this time, no one else can make and sell a generic version. Some countries in the EU, like Hungary, Italy, Portugal, and the Slovak Republic, still use a system where generic drug companies have to declare related patents and not market their products before the expiry of existing patents.

[11] Patent Law and Policy: Cases and Materials,Robert Patrick Merges, John Fitzgerald Duffy, Carolina Academic Press, 2017 (7th Edition).

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3.3. PATENT LINKAGE IN CANADA:

Major changes to the Patented Medicines (Notice of Compliance) Regulations (Regulations), the patent linkage structure that serves as the foundation for Canadian pharmaceutical and biologics patent litigation, were proposed by the Government of Canada on July 15, 2017. Key modifications included in the proposed adjustments are as follows:

1. Actions rather than applications will henceforth be the mode of procedure under the Regulations.
2. Proceedings under the Regulations will now ultimately establish whether alleged patent claims are invalid or non-infringed by a prospective drug submission.
3. First individuals may, under certain conditions, assert inventions and patent claims that are not registered on the Patent Register.
4. First people will no longer be liable for section 8 damages if they choose to forgo the 24- month regulatory stay, enabling quicker competitive market entrance.
5. Compensation to a second party for a permanent loss of market share may now be included in section 8 damages, if any.

   It is anticipated that these suggested changes will be approved in September 2017 after a brief 15-day comment period.

3.3.1. *AN OVERVIEW OF THE PROPOSED MODIFICATIONS AND THEIR BACKGROUND:*

The Canadian version of the Hatch-Waxman Act, known as the Regulations, was enacted in 1993 with the goal of striking a balance between the rights of patent holders and generic businesses to request the Minister of Health for expedited medication clearance. Nevertheless, the Regulations' shortcomings became apparent over time, chief among them being the necessity for patent holders to apply for an injunction barring the Minister of Health from authorizing a generic medication. Because cases under the Regulations did not definitively resolve the issues between the parties, patents were frequently re-litigated in follow-on infringement or impeachment actions. These unfavorable consequences of the scheme for litigants included the fact that patentees frequently could not appeal the dismissal of applications for orders of prohibition against the Minister of Health. This resulted in a lack of certainty for the parties and “at risk” launches for generic companies. The proposed amendments seek to address these, and other, perceived shortcomings.

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The fundamental framework of the Regulations will not alter, notwithstanding the magnitude of the proposed modifications. The range of patents that can be included will not change. The Patent Register will stay frozen, meaning that applicants for generic or biosimilar drugs (referred to as "second persons") only need to mention patents that were present on the Patent Register when they submitted their drug applications. In addition to section 8 damages remaining available for generic or biosimilar firms kept off the market because of the 24-month stay, the approval stay for generic or biosimilar products will continue to last for 24 months. But it's also suggested that the Regulations be altered substantially in the following ways:

1. Modifications to the Patent Register: The Patent Register will now include "certificates of supplementary protection" (CSPs), which were incorporated into Canadian law by the CETA Implementation Act, which was enacted following the signing of the Comprehensive Economic and Trade Agreement between Canada and the European Union. The Minister of Health will be granted extensive authority to actively manage the Patent Register.
2. Requirements for new notices of allegations (NOAs): Generic and biosimilar producers (second persons) will still have to serve a Notice of Availability (NOA) even if the procedures will be conducted through an action. Only in regards to the claims of invalidity will the NOA need to be specified. The parties will now have some flexibility under the Regulations to submit restricted non-infringement material prior to the start of an action. There's no doubt that future lawsuits will focus on the practical implications of the revisions and what constitutes sufficient information in the NOA.
3. papers/information to be included with NOAs: NOAs must contain copies of any papers cited to substantiate invalidity claims, as well as a searchable electronic copy of the pertinent sections of the second person's drug submission. For the duration of the lawsuit under the Regulations, the second party will be required to provide information about its medication submission continuously. The first person may ask to have these reasonable secrecy duties altered, or the second person may impose them on them.
4. Nature of the action: First persons will no longer seek a prohibition order against the Minister of Health, but rather declarations that making, using, selling or constructing a drug in accordance with the second person’s drug submission will infringe the patent or CSP, along with other available remedies. Counterclaims may be filed by second parties in an attempt to invalidate a patent or CSP or to get a non-infringement declaration. In the event that a second party's regulatory submission potentially leads to

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infringement of these collateral patents, first persons/patentees may claim unlisted patents or patents not subject to the NOA upon receipt of the NOA.

5. 24-month stay: The right to renounce the 24-month stay, without affecting one's rights under the Patent Act, shall be granted to the first person to file an action under the Regulations. With this tactic, a first party will be able to minimize the possibility of section 8 damages and have more control over the extent of the action.
6. Section 8 damages: A second party may sue all previous plaintiffs for section 8 damages in the event that a patent infringement case initiated under the Regulations is unsuccessful. The first party, the patent holder, or any other party making a claim under the patent might all be plaintiffs. By the conclusion of the process conducted under the Regulations, the section 8 damages.

3.3.2. *NEW CHALLENGES:*

The purpose of the new Regulations is to provide finality for litigants and grant patentees complete rights of appeal, two goals that are thought to be lacking in the present Regulations. But there will be additional difficulties as a result of the new regulations, such as the following:

New strategic flexibility: First persons and patentees will have to make novel and maybe challenging decisions to manage their legal and commercial risks in light of new rules that allow them to assert claims that were previously irrelevant or to abandon the 24-month stay.

Application of current case law: Regarding a number of problems impacted by these amendments to the Regulations, litigants will be unsure for a number of years as to the applicability of current case law. These concerns will involve the standard of patent listing evaluation as well as the sufficiency of NOAs.

Effect on biologics: There are no special rules for biosimilars or other non-generic goods under the modified regulations. In contrast to the US, the Canadian government did not establish a patent linkage system or regulatory pathway to meet the special patent, regulatory, and commercial characteristics of biosimilars. Whether the Regulations framework will operate effectively with this new product class is still up in the air.

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3.4. PATENT LINKAGE IN INDIA:

There is no provision for patent linking in India. Two different Acts address different facets of novel medications. The 1940 Drugs and Cosmetics Act (DCA) governs the import, manufacturing, sale, distribution, and marketing approval of pharmaceuticals, agricultural chemicals, and cosmetics. In order to receive marketing clearance, new medications must demonstrate their safety and efficacy through test data that is submitted to the Drug Regulatory Authority, also known as the Drugs Controller General of India (DCGI). The DCA Rules of 1945 specify the need for test data for new drugs. A new medicine is one that has not received Indian approval before. The bio-availability/bioequivalence research must be submitted for later marketing clearance.

The Patent Act of 1970 addresses pharmaceutical medication patenting. The Act's Bolar type provision permits generic medicine producers in India to conduct trials using any patented medication in order to gather information that may subsequently be submitted to a drug regulatory body[12]. The purpose of this Bolar-type provision is to expedite the introduction of generic drugs into the market, hence facilitating public access to more affordable generic medications.

There is no provision for protection of undisclosed test data submitted to the regulatory authorities in either of the above acts and also no separate legislation for the same. By not giving exclusive protection to undisclosed test data the Indian government has used TRIPS flexibility.

The Declaration of TRIPS agreement on public health (14 November 2001) states that the TRIPS provisions should not prevent member countries from taking measures for protecting public health rather it’s provisions should be interpreted to support protection of public health and access to medicines.

The Satwant Reddy Committee was established in 2004 to address the matter of Article 39.3 of the TRIPS Agreement. The committee turned in its findings in 2007. The committee believes there is no need for separate test data protection laws, although it does recommend adding a "data exclusivity"-like mechanism to DCA and DCA guidelines to stop others from unfairly

[12] The patent act,1970, India,

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using the patent owner's unreported test data for commercial purposes. It recommended a model to be used during the TRIPS Agreement's transition phase in order to safeguard pharmaceutical companies' and traditional medicine companies' unreported test data. It was advised that, in the case of patented medications, the duration of data protection should never exceed India's 20-year patent protection period. Additionally, the new drug's validity will expire if it is not promoted for twelve consecutive months or within six months of the marketing approval being granted.

Even the Ranjit Roy Committee suggested doing bioequivalence (BE) studies on people and bridging Phase III trials for first-time producers in India. Pre-clinical development and bridging Phase III clinical trials are recommended for comparable biologics, or biosimilars, in accordance with the criteria provided by the Department of Biotechnology (DBT) and the Central Drugs Standard Control Organization (CDSCO).

The Satwant Reddy Committee's recommendations were addressed in the Syngenta case. Syngenta said that in this instance, test data submitted for market approval by the agrochemical and pharmaceutical sectors had to be protected under Article 39.3 of TRIPS. In the absence of a protection framework, the petitioner raises concerns over vulnerability arising from data leak and its use by applicants for the same product to support their registration claim. The petitioner also makes reference to a study by the "Reddy Committee," which concluded that changes should be made to the Act and the Rules to prevent others from unfairly using the originator's test results for commercial purposes without disclosure. The court dismissed Syngenta's argument, ruling that it was not within its authority to declare policy since it had been invited to do so.

In 2007, the Satwant Reddy Committee made the recommendation that giving India data exclusivity would not be in its best interests. Similar to the Satwant Reddy Committee's stance, a legislative study has affirmed that data exclusivity should not be provided at this time. In addition to actively advocating for the same cause, foreign pharmaceutical corporations are also at the center of the FTAs India is negotiating with the European Union (EU).

3.4.1. *CASE LAWS:*

In the case, **Bristol-Myers Squibb Co. vs. Hetero Drugs Ltd (CS (OS) No. 2680/2008):**
The disputes in India about patent linking began with this case.

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The medication, "Sprycel," which was prescribed for chronic myeloid leukemia, was patented by the plaintiff in India. Their application was for an ex-parte injunction, which would prevent the medication Controller from granting access to the defendants' generic medication, Dasatinib. The court had placed the defendant's application for marketing clearance of its medication on hold. This ruling was criticized and viewed as cancerous since it placed additional duties on the Drugs Controller to oversee patent rights and decide their validity—issues that belong in the hands of the patent officer or the court.

Bayer Corporation & Ors vs. Cipla, Union of India & Ors (2009 (41) PTC 634(Del)):

In this case, Cipla applied for a marketing license for its drug “Soranib” to the Drug Controller, following which Bayer filed a writ petition seeking a restraint on the grant of license to Cipla.

The supreme court ruled that patent linking was invalid and refused its admission in India, stating the following grounds:

The Patents Act does not govern the Drug Controller's authority or jurisdiction, and he is not qualified to handle matters concerning the validity of patents. Instead, the DCA's regulations govern these matters.

Since India is a party to the TRIPS Agreement, it is not required to embrace the idea of the patent linking system, which is a component of "TRIPS Plus."

The courts are unable to recognize the patent linkage system by any pronouncements as the notion of patent linkage could not be included into the current Indian legal laws.

Bayer Corporation and Anr. v Union of India and Ors:

In this case, the court made the following important observations-

The government is not required to take proactive steps to enforce and safeguard patents under Section 156 of the Indian Patents Act, 1970. It just places a negative duty on the government to refrain from violating the patent. The Drug Controller cannot be held responsible for encouraging the violation of any patent when he approves a generic medication for commercialization.

The control of the import, production, distribution, and sale of pharmaceuticals and cosmetics is the only goal of the DCA. It doesn't go so far as to uphold a patent awarded under the Patents

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Act and then prevent a generic version of a patented medicine from being approved for sale. When requesting market approval, the maker of generic drugs need merely prove to the Drug Controller that their product is bioavailable and bioequivalent to the patented one. The DCA makes no mention of the problem of prohibiting the medicine Controller from approving the generic version of the original patented medicine for marketing use for the first three years (or until a mandatory license may be granted).

The court also pointed out the following drawbacks which could arise if the patent linkage system was given recognition in India:
As long as the original patented drug's period of protection does not expire, the Drug Controller will be forced to reject the application of any maker of generic drugs, which goes against both the Patents Act and the DCA's rules.

Rather than verifying the patent's validity, the Drug Controller will need to assume it. He will then have to decide whether to fully reject the applicant's request for marketing permission or to "hold" the application until the applicant resolves the patent's validity via legal procedures before an appropriate body. The Drug Controller is not qualified to handle issues pertaining to the legitimacy of drugs, and such a procedure is outside the purview of their authority.

Any generic producers who would have been able to get the medication into the market at a reasonable price would be blocked by the patent holder. Therefore, until the patent holder chooses differently, the patented medicine will essentially stay inaccessible in India even if they choose not to seek for marketing permission.

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CHAPTER – 4

1. IMPACT OF PATENT LINKAGE:

Legal voids in patent linking system have a profound and wide-ranging effect on public access to reasonably priced medications as well as pharmaceutical innovation. Different jurisdictions have different standards since there is no universal agreement. In certain countries, the introduction of generic drugs is delayed because there are unclear frameworks for patent linking. This keeps brand-name medicine monopolies in place longer, which raises drug prices and restricts access, especially in poor countries. These delays are made worse by actions like patent evergreening, in which new patents are applied for in order to prolong market exclusivity. Furthermore, it is challenging for generic manufacturers to contest patents because to the opaque nature of patent listings, which prolongs monopolies and reduces the availability of reasonably priced alternatives.

The inconsistent application of TRIPS flexibilities, such as compulsory licensing, especially in response to public health emergencies, prevents countries from using legal tools to address high drug prices[13]. Litigation delays, such as the U.S. 30-month stay when a patent is challenged, extend market exclusivity for brand-name drugs, which impedes the entry of generics. For biologics, the unclear patent linkage framework and the patent dance process further complicate the introduction of biosimilars, reducing competition in this crucial segment of healthcare.

Because TRIPS-plus clauses lengthen exclusivity periods and limit the use of TRIPS flexibilities, they disproportionately harm low- and middle-income nations by strengthening patent protections through regional trade agreements. Lastly, by limiting competition from other generics, market exclusivity periods such as the 180-day exclusivity granted to the first generic to challenge a patent can keep costs higher for longer. These gaps raise the expense of healthcare worldwide and put major obstacles in the way of access to inexpensive, life-saving medications.

[13] Public health and intellectual property in developing nations Open Book Publishers, Monirul Azam (2016)

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CHAPTER - 5

2. SUGGESTION & CONCLUSION:

a. SUGGESTION:

Engaging stakeholders through surveys or interviews to give practical insights, such as legislators, representatives from the pharmaceutical business, and legal experts, helps deepen the analysis. It is possible to provide empirical evidence for your results by including case studies of particular pharmaceuticals and quantitative analysis of generic drug entry timetables and lawsuit outcomes. Assessing the effects on public health, especially in low- and middle-income nations, and investigating alternative models such as flexible patent regimes or open-access licensing will enhance the analysis even further. Aim to include ethical viewpoints about the consequences of patent linkage schemes for public health and access to necessary medications, and stay abreast of new developments in the fields of biosimilars and digital health technology. Examine possible opportunities for regional collaboration and how regional trade agreements may unify patent linking systems to enhance access to healthcare globally. In order to involve the larger academic and policy community, provide concrete policy suggestions and arrange for the dissemination of your results through conferences, papers, or workshops.

b. CONCLUSION:

There are notable differences in the legislative frameworks and their effects on the pharmaceutical industry among the major jurisdictions when patent linkage systems are compared, such as the US, Canada, the EU, and India. Strong patent protection can encourage innovation in nations with strong patent linking systems, but it can also unintentionally delay the introduction of generic treatments, limiting patients' access to reasonably priced medications. Conversely, nations without rigorous patent linking procedures frequently enjoy speedier market entry for generics, benefiting public health outcomes but potentially eroding incentives for pharmaceutical development.

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CHAPTER - 6

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