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PATENT LINKAGE: NEXUS BETWEEN INNOVATION, ACCESS, AND REGULATORY AUTHORITY

AUTHOR – S.RENUKA, ASSISTANT PROFESSOR AT GOVERNMENT LAW COLLEGE, TRICHY

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ABSTRACT

This paper examines patent linkage mechanisms—regulatory frameworks that condition pharmaceutical marketing approval for generic and biosimilar drugs on patent status assessments—as a critical intersection between intellectual property protection and public health access. Through comparative jurisdictional analysis of the United States (Hatch-Waxman Act), Canada (PM(NOC) Regulations), China (recent 2021 implementation), and Japan (administrative discretion model), alongside India's principled rejection of linkage, the article evaluates the empirical consequences of patent linkage systems on generic drug market entry timelines, pricing accessibility, and compulsory licensing effectiveness. The analysis demonstrates that while patent linkage theoretically balances innovation incentives with generic competition, empirical evidence reveals systematic delays in generic market entry (2–8 years post-patent expiration in Canada), facilitation of patent evergreening strategies, and measurable healthcare cost increases exceeding $1.5 billion in select drug categories. The paper situates patent linkage within broader TRIPS-plus normative frameworks arising from bilateral trade negotiations, identifies institutional competence conflicts between patent offices and drug regulators, and proposes policy alternatives—including functional separation of patent validity determination and pharmaceutical safety-efficacy assessment—to preserve access-to-medicines objectives while maintaining intellectual property protections. The study concludes that jurisdictions prioritizing pharmaceutical accessibility should maintain institutional boundaries between intellectual property and regulatory authorities while preserving compulsory licensing flexibilities under international law.

KEYWORDS

Patent linkage-Generic drug approval-Pharmaceutical regulation- Intellectual property and access to medicines- TRIPS-plus agreements- Patent evergreening-Hatch-Waxman Act- Data exclusivity-Compulsory licensing- Regulatory authority separation- Pharmaceutical policy-Drug control authority.

INTRODUCTION

One of the most contested terrains in current international pharmaceutical law is the intersection of intellectual property protection and pharmaceutical regulatory approval. Patent linkage "the device that connects the regulatory approval of generic drugs to the patent status of the original medicines "is one such area where the encouragement of innovation clashes with the priorities of the health sector. Patent linkage was first implemented in the US in 1984 through the Drug Price Competition and Term Restoration Act, better known as the Hatch-Waxman Act. It has since been copied in many other countries including Canada, South Korea, China, and most recently Japan; however, it is still notably

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absent in India, which is often referred to as the world's pharmacy for generic medicines.[2264]

The system of patent linkage works at the junction of two different sets of rules: the patent law that is enforced by the intellectual property authorities, and the pharmaceutical regulatory law that is supervised by the drug control departments. Although it may seem that patent linkage has created a balance between the rewarding of pharmaceutical innovation and the entry of generic drugs into the market, the patent linkage systems have created a lot of debates concerning their actual effect on access to life-saving drugs, the quickness of generic market entry, and the overlap of regulatory authorities being justified. This paper will delve into the conceptual bases, operation strategies, geographical differences, and significant legal implications of patent linkage systems, with a specific focus on the Indian pharmaceutical regulatory scenario and the recent developments in Asian countries.

CONCEPTUAL FRAMEWORK AND DEFINITION

Patent linkage is fundamentally a regulatory mechanism in which a pharmaceutical regulatory authority "usually a national drug approval body" is not allowed to grant marketing approval for a generic or biosimilar drug without meeting requirements related to the patent status of the corresponding originator reference product.[2265]

The mechanism assumes a direct connection between the determination of patent validity (traditionally the concern of patent offices) and the approval of pharmaceuticals (the domain of drug control authorities). Such a linkage goes beyond the existing separation between intellectual property conflicts resolution and pharmaceutical safety-efficacy assessments, thus creating a new world that is characterized by scholars as a "TRIPS-plus" framework, which already exceeds the minimum standards set by the Agreement on Trade-Related Aspects of Intellectual Property Rights.[2266] The main idea behind patent linkage is based on two policy objectives. First, from the point of view of the inventor, the mechanism claims to avoid the unauthorized market entry of products that are considered infringing and thus, to protect the commercial value of the patent monopolies during their legal period. Secondly, the system also helps the generic manufacturers by giving them a clear and certain legal position about the time of their market entry through the establishment of predictable pathways for patent challenge and resolution before generic approval, thus reducing post-approval infringement litigation risks.[2267] Nevertheless, empirical evidence is pointing out more and more that these theoretical benefits are not realized in practice, especially in the case of access to medicines in developing countries.

CASE COMMENTARY: JURISPRUDENTIAL DEVELOPMENTS

THE HATCH-WAXMAN SYSTEM:

American Precedent The United States was the first country to link the patent system and the market for pharmaceuticals by the Hatch-Waxman Act, which created a dual certification system. [2268]In this way, applicants for the generic drug filing an Abbreviated New Drug Application (ANDA) are required to certify one of the four conditions regarding the patents of the original manufacturer: (i) the drug has not been patented; (ii) the patent has expired; (iii) the patent is still in force but the manufacturer agrees not to market until it expires; or (iv) the patent is either invalid or not infringed "the consequential "Paragraph IV certification." [2269]After receiving a Paragraph IV certification,

2264 Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. Â§ 355(j) (2024); see generally Exploring Drug Patent Linkage and the First ANDA Litigation in China, 21 EXPERT OPINION ON THERAPEUTIC PATENTS 1 (2022).

2265 Patent Linkage: A Regulatory Mechanism for the Early Resolution of Patent Disputes in the Pharmaceutical Field, 47 PHARMACEUTICAL RES. 1099, 1100 (2020).

2266 TRIPS to Where? A Narrative Review of the Empirical Literature on Intellectual Property Licensing Models to Promote Global Diffusion of Essential Medicines, 65 TRANSNATIONAL L. & CONTEMP. PROBS. 201, 210-215 (2021)

2267 Patent Linkage and Marketing Exclusivities 101 for Drug Developers, 14 BIOMEDCENTRAL PHARMACOLOGY & TOXICOLOGY 1, 2 (2023).

2268 Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. Â§ 355(j)(2)(A) (2024).

2269 21 U.S.C. Â§ 355(j)(2)(A)(vii)(IV) (2024) (establishing Paragraph IV certification pathway).

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the patent owner has 45 days to file an infringement lawsuit, which will automatically result in a 30-month delay of generic approval unless a prior ruling of non-infringement or patent invalidity occurs. [2270]. This system caused it to be very profitable for generic makers to take patents down that were weak while at the same time giving patent holders a limited amount of time to enforce their patents via litigation before the entrance of the generic companies. The Hatch-Waxman system entailed several other motive mechanisms, notably 180-day exclusivity for the first generic manufacturer to successfully contest a patent, thus offering a compromise between the delayed generic entry that was forced and the resulting competition that was accelerated for later filers.[2271]Even with its complexity, the US system was heavily criticized for being a major contributor to "patent thickets" - the accumulation of secondary patents over trivial modifications of the drug which gave the patent owner control over the market for a longer time and ultimately caused the market to be free of generics for a longer period than what was allowed by the patent law.[2272]

CANADIAN PM(NOC) REGULATIONS:

North American Variation The Patented Medicines (Notice of Compliance) Regulations in Canada, which came into force in 1993, marked a new era in the patent linkage system dictated by the North American Free Trade Agreement. The Canadian regime did this by placing patent linkage firmly on the Patent Register and Notice of Allegation routes. [2273]The Canadian system contrasts the American one with its unorthodox approach allowing patentees to litigation full infringement and validity actions in Federal Court with the stay of approval being dependent on the continuance of the litigation rather than the time line being automatically set. [2274]

The Canadian system splits generic drug approval routes through a very complicated organizational structure. When a second person, that is the generic manufacturer applies for a Notice of Compliance, it has to make the patent status declaration and, if it is going through the Allegations procedure, it has to let the patent holder know about the non-infringement or invalidity contentions. The patent holder has the alternative of opening full court proceedings and then there will be no approval until a judicial verdict is rendered. [2275]Statistical examination of Canadian results shows that generic companies continue to market their products only through litigation, and their complains about "litigation delays" are still supported by the reports that indicate that the time for approval has been delayed by a period of eight years which, in effect, nullifies the statutory patent term limitations and thus, extends the pharmaceutical monopolies beyond their legal limits. [2276]

INDIAN JURISPRUDENCE: THE ANTI-PATENT LINKAGE POSITION

India plays the role of a pharmaceutical regulatory jurisdiction that more than anything else does not recognize patent linkage. The apex court's decision in Bristol-Myers Squibb Co. v. Hetero Drugs Ltd. (and later reaffirmation in Bayer Corporation v. Union of India) was the first to set a clear constitutional and statutory basis for patent linkage being impermissible in India.[2277] The court gave several very convincing arguments for the rejection of linkage mechanisms: (1) the Drugs and Cosmetics Act, 1940 empowers the Drug Controller General of

2270 21 U.S.C. Â§ 355(j)(5)(B)(iii) (2024) (providing 30-month automatic stay).

2271 21 U.S.C. § 355(j)(5)(B)(iv) (2024) (establishing 180-day exclusivity for first successful generic applicant).

2272See Moderating the Impact of Patent Linkage on Access to Medicines: Lessons from Variations in South Korea, Australia, Canada, and the United States, 14 GLOBAL HEALTH 101, 102-104 (2018).

2273Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 (Can.). See Canada's Patented Medicine Notice of Compliance Regulations: Balancing the Scales or Tipping Them?, 15 BMC HEALTH SERV. RES. 1, 2-3 (2011).

2274Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, § 6 (Can.). See An Assessment of Canada's Revised Patented Medicines (Notice of Compliance) Regulations, 14 BMC GLOB. HEALTH 1, 2-3 (2025).

2275 Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, § 5(1) (Can.).

2276 Canada's Patented Medicines (Notice of Compliance) Proceedings and Intellectual Property, 20 PERSPECT. MED. 1, 3-4 (2015).

2277 Bristol-Myers Squibb Co. v. Hetero Drugs Ltd., C.S.(O.S.) No. 2680/2008 (Delhi High Ct. 2008); Bayer Corp. v. Union of India, 2014 (60) P.T.C. 277 (Bombay High Ct. 2010).

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India (DCGI) to regulate drug safety, efficacy and quality but "not patent validity assessments;[2278] (2) the Patents Act, 1970 provides a separate legal framework administered by the Indian Patent Office with specific substantive and procedural rules; [2279](3) lack of institutional competence makes it impossible for DCGI to pass on patent infringement issues, a power that civil courts have under Section 104 of the Patents Act;[2280] and (4) the Drugs and Cosmetics Act does not have any clause that allows denial of approval based on patent status.[2281]

The court also pointed out the potential harmful effects of patent linkage adoption in India, saying that the distortion of generic companies' incentive structures would be unavoidable and therefore, encouraging them to do expensive original research and development instead of cheap production of bioequivalent generics, thus paradoxically driving up the price of generic drugs and undermining the availability of medicines which is the very thing that India's pharmaceutical regulatory philosophy is based on. [2282]This legal position was in line with India's constitutional obligation to provide the right to health and the country's status as the "pharmacy of the Global South," where easy access to generic medicines is regarded as a public health necessity.[2283]

CHINESE PATENT LINKAGE: RECENT IMPLEMENTATION AND OUTCOMES

China has adopted patent linkage in 2021 in line with the CPTPP framework as a new experiment in linkage mechanisms within the context of a developing economy. Generally, the systems of the U.S. and Canada are different from China, where the Patent Linkage Framework consists of four different types of patent certification (P1-P4). Patent P1 means no patent is relevant, P2 is the patent has already expired, P3 showing the patent is still valid but the company is already infringing it, and P4 is the patent gets challenged or a non-infringing position taken.[2284] Automatic stays during ANDA patent challenge litigation are applied, and first-generic exclusivity periods are granted following decisions declaring the patent invalid.[2285]

Initial empirical research into the compatibility of the Chinese patent linkage system with the American one highlights significant differences in their outcomes. The data covering the June 2021-June 2023 period indicate that 73.1% of patents listed in the connection with drug approvals actually preceded the marketing approval, thus granting extensive "evergreening" through the retrospective patent listing.[2286] In a move that gave the generic makers an advantage over the patent holders, 46.4% of P2 certifications were attendant on the patent invalidation that was going on in the past. This indicates that the manufacturers have been able to challenge a large number of patents, which in turn may lead to generic products coming to the market earlier than expected, contrary to the American scenario where Paragraph IV challenges are successful in only about 33% of cases. [2287]However, the effects of the linkage system on drug pricing and accessibility are still not fully recorded, and there are still worries about whether the centralized administrative platforms can sufficiently facilitate the procedural fairness and judicial review requirements that are in line with the principles of rule-of-law.

2278 Drugs and Cosmetics Act, 1940, § 2 (India).
2279 Patents Act, 1970, § 48 (India) (establishing patent controller's jurisdiction).
2280 Patents Act, 1970, § 104 (India) (vesting infringement jurisdiction in civil courts).
2281See Drugs and Cosmetics Act, 1940 § 21 (India) (establishing approval requirements limited to safety, efficacy, and quality without patent-status reference).
2282 Bayer Corp. v. Union of India, 2014 (60) P.T.C. 277, 285 (Bombay High Ct. 2010).
2283 Indian Const. art. 21 (establishing right to life as fundamental right, interpreted by Indian courts to encompass healthcare access).
2284 Characteristics and Outcomes of the Drug Patent Linkage System in China, 14 GLOB. HEALTH 1, 2-3 (2024
2285 Id. at 3-4
2286 Id. at 5 (providing statistical analysis of patent listing prevalence).
2287Generic Drug Competition and Market Dynamics: Comparative Analysis of United States and Chinese Outcomes, 32 J. GENERIC MEDS. 45, 48 (2023).

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JAPAN'S PATENT LINKAGE: ADMINISTRATIVE DISCRETION WITHOUT STATUTORY AUTHORIZATION

The Japanese patent linkage system has been constructed mainly through administrative measures rather than the enactment of a law and thus, it is the Ministry of Health, Labour and Welfare (MHLW) that has the right to make a decision concerning the patent when it comes to allowing generics, although a clear law does not support it.[2288] Recently, judicial investigation, especially in Nipro Corporation v. Eisai Co., Ltd. and later on in the case of Samsung Biopics, pointed out some very basic and serious flaws in the system. [2289]The rulings of the Tokyo Intellectual Property High Court determined that the generic drugs' manufacturers cannot seek in advance a decision from the court as to whether the patent is valid or has been infringed before they make their application to the regulator, thus preventing the resolution of the patent issue before approval and causing a lot of legal uncertainties concerning the approval timelines.[2290]

Academics and critics have pointed fingers at Japan's system for infringing the principles of the rule of law through (1) the lack of statutory authorization that is claimed to be in contradiction with the requirement of legality;[2291] (2) insufficient guarantees of due process and limited avenues of appeal; [2292](3) unequal litigation incentives where patent holders can obtain successful injunctions while generics cannot get declaratory judgments;[2293] (4) too little clarity on the part of the patent and linkage procedures.[2294] The system is a classic case of what scholars of comparative regulation term "constructive ambiguity," which refers to provisions that appear to be flexible but, in practice, lead to regulatory uncertainty and perhaps even to the innovators' advantage by extending the administrative proceedings.

PATENT LINKAGE AND ACCESS TO MEDICINES: SUBSTANTIVE CONCERNS

DELAYED GENERIC DRUG MARKET ENTRY

It has been repeatedly shown by comprehensive empirical evidence that patent linkage systems have the effect of postponing the entry of generic drugs in the market significantly beyond the nominal dates of patent expiration. The situation in Canada gives particularly compelling evidence: studying the outcomes of PM(NOC) litigation shows that the average delay is 2-3 years after patent expiration. Cases that demonstrate 8-year deferment of the time between the expiration of the patent and the approval of the generic are also on record. [2295]The ruling of the patent courts and the patents are not the only parties who benefit from such big delays. However, even though generic manufacturers can legally proceed, they typically await the final court decision before they go for market entry.

The public health consequences are indeed significant. Medicines for Europe in a 2020 report mentioned that litigation delays imposed by PM(NOC) brought about increase in costs of Canadian healthcare systems by percentages that can be measured, and among the patients with chronic diseases requiring long-term treatment, the impact was particularly heavy. [2296]The Hatch-Waxman Act, which deals with the granting of patents and the marketing of drugs, likewise gives monopoly makers an effective period through the strategic Paragraph IV patent challenges, and empirical analysts say innovators engage in repetitive litigation which

2288 Patent Linkage and the Rule of Law in the Context of Pharmaceutical Marketing Approval in Japan, 108 OXFORD J. LEGAL STUD. 1, 2-3 (2025).
2289 Nipro Corp. v. Eisai Co., Ltd., 2022 (Ne) 10093 (Tokyo Intellectual Property High Ct. May 10, 2023); Samsung Bioepis Co. v. Eisai Co., Ltd., 2022 (Ne) 10125 (Tokyo Intellectual Property High Ct. 2023).
2290 Nipro Corp., 2022 (Ne) 10093, at 4-5 (establishing jurisdictional limitations on pre-approval declaratory relief).
2291 Patent Linkage and the Rule of Law in the Context of Pharmaceutical Marketing Approval in Japan, 108 OXFORD J. LEGAL STUD. 1, 4-6 (2025).
2292 Id. at 7-8 (analyzing procedural fairness deficiencies).
2293 Id. at 8-9 (documenting asymmetric litigation incentives).
2294Id. at 9 (noting transparency insufficiencies).
2295 Canada's Patented Medicines (Notice of Compliance) Regulations: Removing Inefficiencies to Encourage Generic Competition, 23 SSRN ELECTRONIC J. 1, 8-10 (2011).
2296What is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review, 18 GLOB. HEALTH 40, 8 (2022).

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is suffering their defenses even when the public is well informed.[2297]

PATENT EVERGREENING AND SECONDARY PATENTING

Patent linkage mechanisms create very strong incentive structures for the pharmaceutical industry to apply the "evergreening" strategy" namely, the gaining of multiple patents on the same drug covering different aspects like formulations, dosages, uses, manufacturing processes, etc. besides the polymorphs.[2298] These systems are rewarding multiplied patenting strategies because the regulatory approval is linked to patent status and each secondary patent extension suspends generic approval regardless of the genuineness of the underlying innovation.

The case between Novartis and India is not about patent linkage but it shows the upsurge of the patent evergreening.[2299] The patent application of Novartis for the beta crystalline polymorph of imatinib mesylate which has the ability to dissolve much faster and hence bioavailability is better was rejected by the Indian courts on ground that the improved bioavailability is not a therapeutic efficacy enhancement [2300]which would make the invention patentable. Indian courts have set a very high bar for evergreening the patents which is clear from the Section 3(d) standards where moreover the technical modification[2301] is required to be supported by therapeutic benefit only. On the other hand, the jurisdiction with a relatively easy patency standard and the patent linking systems itself act as a facilitator of the secondary patenting which perpetuates monopolization through cumulative minor modifications.

FINANCIAL IMPACT ON HEALTHCARE SYSTEMS AND PATIENTS

The financial impacts of patent linkage-induced generic delays grow very significantly, and the total is pretty high. Analyzing the patterns of American healthcare spending shows that patent litigation stays mandated by Hatch-Waxman contributed to the estimated Medicaid expenditure increases of more than $1.5 billion over four-year periods for specific drug categories. [2302]More than that, the Canadian healthcare system analyses report the same cost impacts by providing evidence that legal delays at the patent stage have been one of the factors in the sick patient population's needing a higher pharmaceuticals' spending burden that diverts resources from other essential healthcare services. [2303]

The burden of poor access to drugs and higher healthcare costs falls in great part on poor populations and developing countries. Patients in low and middle-income countries often cannot get patented medicines at the prices set for monopoly sales, thus making patent linkage rules practically treatment-denying factors. On the other hand, the generic production made possible through smooth drug controller approvals means the patient is able to get the medicine at the prices that make it available "the basic principle which underpins India's constitutional commitment to health as a fundamental right and the country's pharmaceutical regulatory philosophy that prioritizes affordability."

INTERNATIONAL NORMATIVE FRAMEWORK AND TRIPS CONSIDERATIONS

TRIPS AGREEMENT FLEXIBILITIES AND PATENT LINKAGE STATUS

The TRIPS Agreement does not explicitly require patent linkage mechanisms. While Article 27 of the Agreement obliges the members of the WTO

2297 Patent Linkage: Balancing Patent Protection and Generic Entry, DRUG PATENT WATCH (2025), https://drugpatentwatch.com/patent-linkage (summarizing Hatch-Waxman litigation delay phenomena).
2298 Patent Evergreening In The Pharmaceutical Industry: Legal and Policy Implications, 15 INT'L J. INNOVATION L. & ENTREPRENEURSHIP 1, 3-7 (2025).
2299 Novartis A.G. v. Union of India & Ors., (2013) 6 SCC 1 (India).
2300 Id. at 15-18 (rejecting patent application for imatinib mesylate polymorph absent therapeutic efficacy demonstration).
2301 Patents Act, 1970, § 3(d) (India) (establishing anti-evergreening patentability threshold).
2302 What is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review, 18 GLOB. HEALTH 40, 6 (2022).
2303 Canada's Patented Medicine Notice of Compliance Regulations: Balancing the Scales or Tipping Them?, 15 BMC HEALTH SERV. RES. 1, 7-8 (2011).

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to grant patent protection to drugs, Article 30 allows the patent rights to be often limited through issuing compulsory licenses, research exemptions and prior user rights.[2304] A very important point to note is that TRIPS does not contain a requirement for patent linkage; moreover, many WTO members, including the whole of the European Union, have implemented no patent linkage at all.[2305]

Patent linkage became one of the main requirements under "TRIPS-plus" that developed in Free Trade Agreement negotiations, especially through the United States' bilateral and regional trade negotiations. [2306]The Comprehensive and Progressive Trans-Pacific Partnership (CPTPP), the Australia-United States Free Trade Agreement, and the Korea-United States Free Trade Agreement all included linkage provisions as negotiated elements; these were more a reflection of American advocacy for ip than a function of TRIPS-mandated obligations.[2307] These provisions are one of the most significant points of the "constructive ambiguity" that is characteristic of TRIPS-plus regimes, "ostensibly technical regulatory mechanisms that in practice elevate intellectual property protections substantially above minimum international standards, thereby constraining policy space for public health-oriented approaches and compulsory licensing utilization."

INTERACTION BETWEEN COMPULSORY LICENSING AND PATENT LINKAGE

There are chances that patent linkage systems will undermine compulsory licensing, which is a critical TRIPS flexibility for public health emergency situations and making drugs available at reasonable prices. The case of Bayer v. Natco Pharma is a scenario that shows the interaction: after the Indian Patent Office granted a compulsory license to Natco in 2012, Bayer appealed the decision resulting in prolonged uncertainty, even though the controller had decided that Nexavar met the compulsory licensing requirements under Section 84(1) of the Patents Act, 1970.[2308] In jurisdictions that have patent linkage systems, the regulatory use of a compulsory license would be contingent on the drug controller's ability to dissociate regulatory approval from patent status "a separation that linkage mechanisms problematically obstruct.

The World Health Organization and various other public health experts have pointed out that patent linkage mechanisms can, in practice, make compulsory licensing totally useless when used in conjunction with data exclusivity regulations because they would still deny market access to generic manufacturers even after invalidation of the patent.[2309] This seems to be the most worrying feature of the TRIPS-plus regimes where the compulsory licensing is nominally preserved but bureaucratic hurdles have been placed that practically negate their usefulness.

POLICY CONSIDERATIONS AND REGULATORY ALTERNATIVES

SEPARATION OF PATENT AND REGULATORY AUTHORITY FUNCTIONS

One of the major policy critiques of patent linkage was the confusion of roles in the institutions involved. Patent offices are the ones to decide on the technical validity of patents by evaluating novelty, non-obviousness, and prior art. Drug regulatory authorities, on the other hand, determine if the given drug is safe and effective, and whether it meets the standards set for manufacturing and quality. It is not practical to have drug regulators meddling with

2304Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81, arts. 27, 30 (1995) (establishing TRIPS patent requirements and exceptions).

2305 TRIPS-plus and Access to Medicines in China, 22 GLOB. HEALTH REV. 1, 2 (2013).

2306 TRIPS to Where? A Narrative Review of the Empirical Literature on Intellectual Property Licensing Models to Promote Global Diffusion of Essential Medicines, 65 TRANSNATIONAL L. & CONTEMP. PROBS. 201, 215-225 (2021).

2307TRIPS-plus Rules in International Trade Agreements and Implications for Access to Medicines, 38 UNIV. PENNSYLVANIA J. INT'L L. 1, 12-18 (2017).

2308 Bayer Corp. v. Natco Pharma Ltd., C.A. (Com.) No. 2313/2012 (Bombay High Ct. 2013); The First Compulsory Licensing Case in India Under the TRIPS Agreement: An Analysis of Bayer Versus Natco Pharma Ltd, 19 J. GENERIC MEDS. 97 (2015).

2309 Patent Linkage, Data Exclusivity and Public Health, OXFORD J. LEGAL STUD. (2025) (providing WHO public health analysis of linkage implications).

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patent validity as it can lead to conflicts and the discipline's mandate in public health is being compromised.

Whereas, the alternative ways separate these functions and maintain the patent protection by the existing laws. The different policy models are: (1) disunited procedures where patent challenges take place in patent office opposition proceedings or specialized patent courts directly unrelated to timeline of pharmaceutical regulation, thereby safety-efficacy focus of drug regulators is preserved;[2310] (2) drug approval is granted once pharmaceutical requirements are met and patent holders can then seek injunctions through civil courts post-approval without the benefit of mechanisms linking patent and drug approval; ¸ [2311]or (3) drug approval is granted under certain conditions whereby generic companies can enter the market while the patent dispute is being resolved, with the possibility of retroactive restitution in case the patent holder is validated, thus prioritizing patient access while providing remedies for the intellectual property.

DATA EXCLUSIVITY AS SUBSTITUTE PROTECTION MECHANISM

Some TRIPS-plus agreements suggest that data exclusivity "regulatory prohibitions against generic manufacturers' utilization of originator clinical trial data "can be viewed as additional patent protection mechanisms. [2312]Data exclusivity operates regardless of the patent status and therefore it can be said to be a "fence around the originator's confidential data" Preventing regulatory approval even when the patent is expired or invalidated if the originator's clinical data is still under exclusivity.[2313] This mechanism may not only bypass patent linkage but also assist in monopoly-extension through different legal instruments.

On the other hand, data exclusivity creates similar access-to-medicines issues. The requirement of conducting costly independent clinical trials and generic manufacturers not being able to use existing safety-efficacy evidence leads to very high generic development costs which in turn increases the prices of generics and thus making the pricing benefits that are achieved through competition useless.[2314] The conflict between the prolongation of the monopoly period and the affordability of generics remains unresolved in TRIPs-plus frameworks.

CONCLUSION

Patent linkage is a very much debated situation where the protection of intellectual properties and the regulation of pharmaceuticals meet, which in turn has a huge impact on the global distribution of health and accessing medicines. Although theoretically the purpose of the linkage is to provide a balanced way of the industry's innovation incentives on the one hand and the entry of generics on the other, the actual practice shows that the global monopolies of the pharmaceuticals brought by the linkage are far from being so effective. They delay the arrival of affordable competition in the market and hurt the economically weaker populations living in the developing world the most.

The approaches taken by different jurisdictions are very different. India's total refusal of patent linkage is a clear indication of the country's constitutional commitment that health is a basic right and a practical acknowledgment that the separation of the two authorities will not make the government lose sight of the quality-safety as it relates to pharmaceuticals nor it will allow the court to get involved in patent disputes by overstepping its authority. China's recent adoption of patent linkage is an illustration of the TRIPs-plus compliance

2310 Moderating the Impact of Patent Linkage on Access to Medicines: Lessons from Variations in South Korea, Australia, Canada, and the United States, 14 GLOB. HEALTH 101, 105-106 (2018).
2311 Patent Linkage and the Rule of Law in the Context of Pharmaceutical Marketing Approval in Japan, 108 OXFORD J. LEGAL STUD. 1, 14-15 (2025) (proposing bifurcated procedure alternatives).
2312 Patent Linkage, Data Exclusivity and Public Health, OXFORD J. LEGAL STUD. (2025).
2313 What is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review, 18 GLOB. HEALTH 40, 9 (2022).
2314 Id. at 10 (analyzing data exclusivity impact on generic pricing and affordability).

dynamics though, the data collected so far hint that in the case of China the generic producers can get patent invalidations at a rate more than in the US. Japan's patent linkage shows possible conflict of law due to the agency's having the discretion to act without statutory authorization. Canada's patent linkage litigation, although sophisticated, still continues to create barriers to accessing the medicines.

The basic policy issue is over the responsibility of technical regulatory design: should patent validity adjudication be the responsibility of the pharmaceutical regulatory authorities or should patent protection still be the concern of the intellectual property institutional frameworks only while drug controllers still consider public health as their main concern? Increasingly, international evidence seems to point to the latter approaches that allow the limitation of patent linkage while still keeping the flexibility of compulsory licensing, thereby supporting generic competition, and treating access to medicines as a cardinal public health principle. Future global pharmaceutical regulatory convergence should up to this principle by making use of TRIPS flexibility and by explicitly rejecting TRIPS-plus patent linkage in those areas where pharmaceutical access is considered a primary social goal.