Journal of Intellectual Property Rights
Vol 31, November 2026, pp. 1017-1027
DOI: 10.56042/jipr.v31i6.23396

Patent Linkage Mechanisms: Legal Shields or Market Barriers?

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Received: 3rd December 2025; revised: 16th March 2026

Patent linkage the legal establishment of drug marketing authorization on the patent position of an originator product- the so-called patent linkage- is at a controversial crossroads between intellectual property law and trade policy and public health. The paper evaluates the legal implications, regulatory framework, and health impact of patent linkage by conducting a narrow comparative case study of three jurisdictions, namely the United States, India, and South Korea. These three countries lie at the extremes of the pendulum on the scale of adoption of the patent linkage: on one end, the United States is the creator and most belligerent advocate of the mechanism; on the middle-ground, South Korea is an implementation actor, which remains under bilateral trade pressure; and on the opposite extreme is India, an implementation opponent, who is rooted in the jurisprudence of the health of the population. The main argument that will be proposed in this paper is that patent linkage, purportedly aimed to ensure alignment of intellectual property protection with the drug regulatory procedures, actively prolongs the exclusivity of originators of medicines beyond the reasonable scope of a true innovation and, as a consequence, limits the entry of generic drugs, overcharges pharmaceutical markets, and overstretches the financial means of national health services - the extent of which effects is defined by the leniency of the jurisdictional design itself. Based on cross-national legal evidence, empirical pricing evidence and evidence-based costs in the health-system, this paper maps the institutional asymmetries and judicial dilemmas that erode equitable access to medicines. It ends with progressive suggestions to redesign the regulations, autonomous validation of patents, and health-focused policy security.

Keywords: Patent Linkage, TRIPS-plus, Generic Drug Access, Hatch-Waxman Act, Evergreening, Drug Price Inflation, Intellectual Property Law, KORUS FTA, Pharmaceutical Regulation

Patent linkage refers to a regulatory policy whereby a regulatory drug authority (DRA) would be obliged or practically compelled to grant a marketing approval to a generic medicine on the basis that it will not infringe any patent owned by the originator firm.[1,2] Patent linkage is a policy that binds two types of regulatory questions, which a regulatory authority should not be institutionally better qualified to address, to a generic medicine, rather than handling two separate processes with two separate sets of competencies: patent validity and market authorisation. The mechanism is said to have its modern legal roots in the Hatch-Waxman Act of 1984, the United States Drug Price Competition and Patent Term Restoration Act of 1984. This design which was to create a structured system of patent listings by the FDA and a 30-month regulatory stay which is mandatory whenever an originator company is engaging an infringement action against a generic applicant has in effect become a tool of delaying the generic market entry, frequently far beyond the duration which the underlying patent protection merits.[3]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) does not mandate patent connection. A TRIPS-plus obligation - an assortment of IP standards that go beyond TRIPS minimums - that the United States and, to a smaller degree, the European Union have actively interred in bilateral and plurilateral Free Trade Agreements (FTAs) is the reason why, despite its protectionist features, TRIPS emphasizes flexibility in interpretation by member states to serve the cause of protecting public health and promoting access to medicines. The after-effects are quantifiable and documented.[3] A 2022 systematic review of 55 empirical studies by Tenni *et al.* concluded that TRIPS-plus intellectual property restrictions systematically increase the cost of medicines, slow the entry of generic competitors, and increase the amount of money consumers and governments spend, both in high-income and middle-income countries that opt to link on an FTA pressure without the institutional capacity to deal with the outcomeant litigation or the regulatory savvy to curtail procedural abuse. [4]

This paper explores patent linkage by using a three country comparative case study; the United States,

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South Korea, and India, which were chosen due to the three main regulatory postures that a jurisdiction can take, which include aggressive implementation, negotiated adaptation, and principled resistance. By so doing, it fills a gap in the current literature, which has the weakness of reviewing the linkage of patents across numerous countries in general without adequately questioning the structural design decisions that define whether a linkage functions as its said purpose or as a market-exclusivity extension mechanism.

The hypothesis of this paper is as follows: Patent linkage mechanisms in its prevailing dominant design have a systematic effect on the balance between the incentives to innovate in the pharmaceutical sector and equitable access to drugs. In cases where the procedural architecture of linkage (such as automatic stays, eligibility of broad patent listing, weak and restricted sanctions against vexatious litigation and the lack of generic exclusivity) are not adequately restricted, patent linkage operates not as a procedural gateway to protect the legitimate intellectual property, but as a barrier to market access that helps to privilege the interests of originators against the interests of the public health. This hypothesis is supported and operationalised by the three-country comparison introduced here using legal, the empirical, and the institutional evidence.

The three research objectives in this article are inter-related:

(i) To examine the legal underpinnings and structural form of patent linkage in the United States, South Korea, and India, by exploring the impact of lawmaking decisions, judicial precedent and regulatory provisions on the effectiveness of linkage in each location.

(ii) To determine the empirical data regarding the connection between patent linkage design and quantifiable outcomes, such as generic entry delays, drug price patterns, and cost to the health system to support or qualify the main hypothesis.

(iii) To determine the presence of structural regulatory lapses and research gaps in the literature on patent linkage, and to come up with evidence-based suggestions to reform.

Patent Linkage as a Legal Matter: Hatch-Waxman Act in the US

The legislative basis of patent linkage in its senses of acceptance and export is the Drug Price Competition and Patent Term Restoration Act of 1984, the Hatch-Waxman Act. The Act established a new drug application (ANDA) pathway that was abbreviated to allow generic manufacturers to use the safety and efficacy data of a previously approved originator drug provided that the bi-equivalence was established. As a condition to such regulatory concessions, generic applicants are required to establish the connection to every patent contained within the FDA orange book.[3]

The Orange Book lists patents related to approved drug products, comprising active ingredients, drug formulations and compositions, and approved method of use. It acts as a public database of patent claims which generic entrants have to respond to before they can be granted marketing clearance. The FDA does not itself evaluate the validity or breadth of listed patents; it depends upon self-tagging by the companies that are the originators, which provides a structural incentive to file patents of untestable validity to prolong the listing - and, therefore, the protection in procedure that the Orange Book provides.

The 30-Month Stay and Paragraph IV Certification

In case a generic applicant submits an ANDA containing a Paragraph IV certification - that a patent listed in the Orange Book is invalid or that the generic product would not infringe its claim - the originator must commence infringement of the patent within 45 days. In the event that it does, the FDA is automatically frozen in incurring the ANDA 30 months, no matter how meritorious the substantive soundness of the patent claim.[3]

Empirical research establishes that the 30-month stay can often be abused by originator firms by so-called defensive patenting - putting up another patent on a reformulation, dosage form, metabolite, or polymorph of an active ingredient to stuff the Orange Book with new entries before a generic challenge under Paragraph IV can be filed. DiMasi and Grabowski (2007) discovered that, in the years before the expiry of patents, originator-companies had registered three to five new secondary patents on an average, each of which could attract a new 30-month stay. In America, of all new Orange Book listings (1995-2000), 78% of those were secondary patents on previously approved drugs rather than new molecular entities.[4]

A generic applicant who first to successfully submit a Paragraph IV certification and win in patent

litigation grants 180 days of generic market exclusivity a reward that is meant to encourage patent challenges. Nevertheless, the originator firms have come up with the habit of authorised generic which is the introduction of their own generic products in the period of exclusivity; this cuts the revenue of the hardworking generic by a half, which decreases the economic motivation of new challenges.

Provisions of TRIPS and TRIPS-Plus

TRIPS Agreement came into force in 1995 and it provides the global standards that are minimum in protecting intellectual property such as patents of pharmaceuticals. It obliges the members of WTO to grant 20-year terms of protection on pharmaceutical products, but does not mandate patent linkage, exclusivity in data past the safety of unfair commercial use, or extension of patent terms.[2]

TRIPS article 27 stipulates that inventions in all domains of technology should have access to a patent, however it does not specify the manner in which regulatory approval and a granted patent position should be connected. Article 39.3 safeguards unpublished test data provided in support of the marketing approval of new chemical entities against unfair commercial use, but does not specify that data exclusivity is the only available form of protection - a loophole that India has used to frustrate data protection exclusivity claims.[2]

Article 31 (compulsory licensing), Article 30 (limited exceptions to exclusive rights and the Bolar exception allowing pre-expiry bioequivalence testing), and Article 6 (exhaustion principles, allowing parallel imports) are the flexibilities of TRIPS of special interest to patent linkage. Doha Declaration strengthened these flexibilities and established that TRIPS should be construed in a way that favours the rights of member states to safeguard their populations on matters touching on health. Linkage of patents, providing barriers to entry in the form of regulatory level binding that are not dependent on judicial review, effectively nullifies the Bolar exception and may make obligatory licensing a hard-to-implement reality.

Comparison of the USA, South Korea and India

The three countries considered here have been chosen based on the fact that each of them is structurally different in regards to the regulatory stance in patent linkage. The mechanism is designed by the United States and most aggressively implemented; adopted by South Korea under negotiated FTA coercion, and gradually adjusted since then; and opposed by India as legislatively, judicially interpreted, and analyzed. Put collectively, they offer a comparative prism, in which the structural determinants of linkage outcomes, such as generic delay, pricing impacts, and institutional capacity can be evaluated (Fig. 1).

United States: The Template Jurisdiction

The United States patent linkage regime of the Hatch Waxman Act is the world standard model and reference point of all the systems. Its fundamental structure the Orange book listing, Paragraph IV certification, automatic 30 month stay and 180 day first generic exclusivity has been partially duplicated, with some modifications, in South Korea, Canada, China, Australia and some other countries via negotiations conducted with the United States Trade Representative (USTR).[3]

The system has produced both evidenced mixed results. On one hand, a successful patent invalidation due to the Paragraph IV challenge mechanism has introduced much generic competition on the market sooner than it would otherwise have taken place. In the period between 2001 and 2019 out of 73 percent

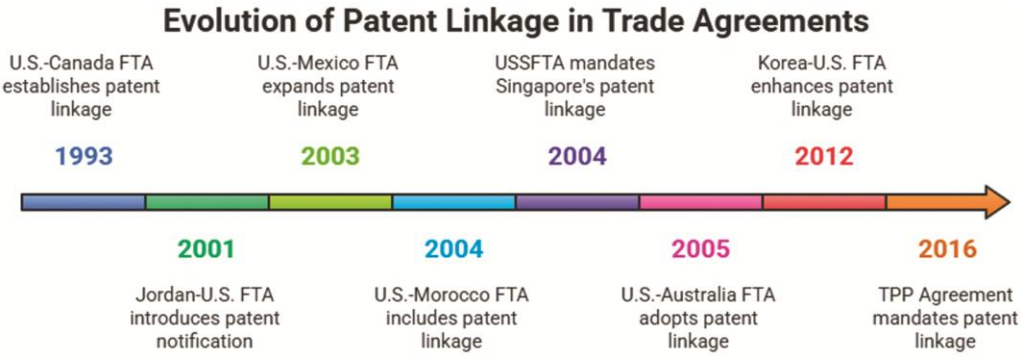


Fig. 1 — Evolution of patent linkage in trade agreements

of paragraph IV challenges were decided in favor of finding a patent invalid or not infringed indicating that a significant part of Orange Book-patents is of dubious quality.

The procedural abuse, on the other hand, has large economic costs. Tenni et al. discovered that in the United States, extensions of data exclusivity and delayed generic entry of three drug classes cost Medicaid state programmes an average of USD 1.5 billion between 2000 and 2004, with the national costs estimated to be USD 430 million.[4] A notable example is the case of Colchicine, an ancient anti-gout drug: extension of data exclusivity rights to a new formulation resulted in the price per pill rising by USD 0.09 to USD 4.85, a fifty- fold increase attributable entirely to exclusivity manipulation, not pharmaceutical innovation.[4]

These effects are further enhanced by the treatment of the U.S. legal system to evergreening. The court, in Pfizer Inc. v Teva Pharmaceuticals USA Inc., had upheld a secondary patent on a crystalline structure of atorvastatin (Lipitor) to bar generic entry and maintain the monopoly of a USD 12 billion annual revenue product where the original compound patent had expired. In Abbott Laboratories v. The court affirmed a formulation patent on Omnicef, allowing the company, Sandoz, Inc. to remain in the market despite the expiry of the original active-ingredient patent. Patentability restriction of section 3(d) type - the type of patent legislation that India employs to prevent such incremental secondary patents - lack any analogous protection in U.S. patent law, where the broadest interpretation of patentable subject matter is permitted.[15]

South Korea: Reform by Negotiation and Halfway Covenant

The introduction of patent linkage in South Korea was done in two phases after the expiry of Korea-United States Free Trade Agreement (KORUS FTA). The patent list and notification system came into effect in 2012; followed by the regulatory stay and first-generic exclusivity provisions in 2015.[3] The system loosely follows the U.S. model, but introduces various structural changes based on the different market conditions and institutional capability of South Korea.

The South Korean K-Orange Book is regulated by the Ministry of Food and Drug Safety (MFDS) which still holds the power to remove irrelevant patents off the listing, a feature the U.S. Orange Book model does not have, where listing decisions are mostly self-regulated by their originators. The notification procedure is similar to the U.S. Paragraph IV procedure with a regulatory stay of up to nine months, including, unlike the U.S., 180 days.[9] Although more exclusivity period is applied, Korean domestic generic manufacturers comment that the economic incentive to seek a patent challenge is inadequate. In a survey-based research, Choi et al. (2022) have discovered that the majority of domestic manufacturers perceive the linkage system to be a logistical burden: the challenges are operationally challenging, penetrating the market with Korean generics is difficult compared to the U.S., and litigation expenses are disproportionate to the projected exclusivity revenues. The 73% success rate in U.S. Paragraph IV challenge has no parallel published Korean counterpart in part due to the lower frequency of challenge.

An analysis of patent issues and their results under the KORUS-era system by Son *et al.* (2021) revealed that some guiding questions on patenting therapeutics and realizing innovations, such as the lack of a distinct provisional invalidation mechanism, in which a generic drug could be launched on the market until a final decision on the validity of the patent was reached, and then damages were paid, was a significant structural gap of the Korean system, compared with the best-practice models.[9]

Quantified economic effects of the provisions of the KORUS patent linkage are high. Son *et al.* estimated the total welfare loss that can be attributed to being linked to a patent under KORUS as about USD 40.03 million per annum, based on a modelling whereas the Ministry of Health and Welfare has estimated an increase in pharmaceutical expenditure on a long-term basis, but again methodologically the contribution of any new cost increase by the presence of a patent linkage rather than data exclusivity or data term extension is challenging.[1,3]

The system of South Korea has such a measure as the penalty provisions, according to which the owners of patents have to compensate the generic companies in relation to losses occurring due to stays caused by vexatious or misleading claims on infringement, however, in the years since such measures were fully adopted, no successful application of the system has been reported.[3,9]

India: The Principled Resistance via Legislative and Judicial structure

India has not just chosen not to adopt patent linkage as a policy choice, but it is entrenched in the

legal frameworks governing drug regulation as well as the patent law, and has been upheld in the courts not only in its specific statutory interpretation, but in a coherent constitutional and institutional justification. The most basic legislative framework includes the Drugs and Cosmetics Act of 1940 (DCA) governing marketing approval and using only the terms of quality, safety, and efficacy, and the Patents Act of 1970 as amended in 2005, in line with the requirements of TRIPS. The two laws are implemented by various institutions namely Central Drugs Standard Control Organisation (CDSCO) and Indian Patent Office respectively, which have varying mandates and institutional competencies. Neither of the Acts has a statutory commitment that the CDSCO needs to condition its marketing approval to clearance of the patent, nor does it have a mechanism by which the holder of the patent can invoke a regulatory stay.

A case of the highest judicial authority on patent linkage in India was the decision of the Delhi High Court in the case of *Bayer Corporation and Others* v *Cipla*and *others* v *Union of India (UOI).* The court concluded beyond any doubt that no linkage of patents can be made in Indian law. Its logic worked in several ways. To begin with, the court found that the DCA and Patents Act have different and contradictory statutory purposes of regulating public safety and entitlement to commercial monopoly respectively, and cannot be construed in a manner that obligates one institution based on the mandate of another. Second, it believed that the Drug Controller General of India (DCGI) does not have institutional capacity, resources and legal powers to test the validity of patents - a role of the Patent Office and the courts. Third, the court described the effort by Bayer to suggest the establishment of a patent linkage under Section 2 of the DCA and the establishment of a patent linkage under Section 48 of the Patents Act as an impermissible attempt of judicial legislation: where the legislature has decided not to provide a mechanism of patent linkage, the courts could not provide the omission by innovative statutory interpretation.[1]This court also determined that generic medicines, although they technically might infringe a patent, could not be considered spurious drugs under the meaning of Section 17B of the Drugs Act because spuriousness means deception as to origin, or composition and not patent infringement. The ruling also observed that the linkage of patents would effectively serve to invalidate Section 107A of the Patents Act (the Bolar provision), which expressly enables generic manufacturers to use patented products in order to get regulatory approval before the patent expires which was specifically intended to facilitate market-available entry of generic products on the first day of patent expiry. Introduction of linkage obligations would effectively nullify this condition through the fact that regulatory clearance would then be conditional, itself on the status of the patent.[1]

Section 3(d) of the Patents Act which has no international counterpart supports the resistance of India to the linkage of patents, which has the effect of disallowing the grant of patents in respect of new forms of known substances unless the new form is shown to have significantly improved efficacy compared to the known substance. This was the subject of a long constitutional challenge by Novartis AG whose request that it be permitted to patent a beta-crystalline form of imatinib (Gleevec/Glivec) be denied by the Supreme Court in *Novartis AG* v *Union of India* (2013). The Court found that Section 3(d) does not conflict with the Indian TRIPS commitments but fulfills the lawful public interest in avoiding evergreening - filing a series of incremental patents aimed at extending exclusivity but not substantial innovation.[15]

The real-world implications of the policy on non-linkage in India regarding access to medicine in the world are enormous. In India, the largest generic drug producer, the heterogeneous competition of price-reducing Indian generic manufacturers in the market has been associated with exports of over 200 countries and provision of more than 80 percent of antiretroviral (ARV) drugs to governments of developing nations and donor-sponsored international governments tried by lowering the costs of certain regimens by over 99 percent, as concluded in a 2006 analysis of this policy direction, supporting the view that Article 39.3 of TRIPS should be used to protect undisclosed test data by trade.[2-4]

Procedural Abuse and Strategic Use of Patent Linkage: Evergreening

Secondary Patent Filings and Evergreening

Evergreening is the act whereby pharmaceutical firms apply secondary patents on minor alterations to an original compound - new polymorphs, salts, esters, metabolites, formulations, dosage forms, delivery mechanisms, or modes of use - to extend the useful

market life of a compound past the expiration date of the original compound patent. Every secondary patent can be eligible to be listed in the Orange Book and in the event that it is challenged, it can result in a new 30-month stay.

The U.S. situation is well-quantified because of the phenomenon. A 2005 survey of Orange Book revealed that about two-thirds of new patent listings between 1995 and 2000 were of drugs already in the market, with most having a series of three to seven secondary patents able to support an automatic stay in case of infringement.[4] When summed up over the entire secondary patent portfolio, the average useful life of a successful pharmaceutical is statistically significantly longer than the nominal 20-year term.

Product-line extensions are related to evergreening: these are re-formulations of an already existing product, where the property of extended-release, delayed-release, or fixed-dose combination is added to form a new product. A study conducted by Hong et al. (2005) on drugs that lost their primary patent protection 1987 to 1992 again found that line extensions had their products in the market prior to the introduction of the generic product, and original brand increased its price at the rate of about 0.78 annually following the entry of the generic product, and prices dropped by between 20 and 60 percent after the introduction of the generic product. In 2004, the basic compound was genericised, but the sales of the extended-release version of bupropion (Wellbutrin XL) reached USD 1.5 billion, a few years after the introduction of the compound, demonstrating the commercial scale of strategic line extension.[16]

The Section 3(d) of the Indian Patents Act is a direct structural opposing force to evergreening. India sets a high level of patentability of the category of incremental innovation that produces the greatest number of secondary Orange Book listings in the United States, by making the novel forms of known substances more efficacious in order to be patented. The Novartis case affirmed that this standard is used even on innovations that could be found to be patentable in the United States or the European Union under the expanded patentable subject matter criteria.[15]

Regulatory Capture and Procedural Abuse

Patent linkage provides structural preconditions that favour regulatory capture - or, in other words, the process through which private interests of originators appropriate or capture public regulatory procedures to benefit themselves in their private competitive advantage. Linkage systems make regulatory bodies vulnerable to systemic pressure by originator firms to deliver patent-related rulings, and this opens the regulatory body to systematic pressure to retrench listing systems that go beyond, and does not scrutinize, patent protection.

Orange book listing system in the United States is founded on the principle of originator self-certification and FDA does not play any independent gate keeping role over listing eligibility. This structure has been abused by listing patents of uncertain validity and patents of uncertain relevance as method-of-use patent on drug products in generic formulations, and patent on a device or a packaging which is associated with a drug product. In 2003, the Medicare Prescription Drug, Improvement and Modernization Act brought about some changes which include certain specifications such as the preciseness of listing patent declarations by the declarants which is a requirement, however, little has been done regarding enforcement measures.

The design feature that is crucial in facilitating procedural abuse is the automaticity of the 30-month stay. Since the stay is achieved only by the commencement of litigation, and not by any judicial determination of the merits of the patent claim, originators are given a structural incentive to sue on each patent listed, even those to which they know the outcome of litigation will be a loss, as the stay itself provides 30 months of continued exclusivity of the patent, whether the initiation of litigation succeeds.[3,9] In South Korea, regulatory provisions provide financial penalties against stay on the occasion of vexatious infringement, but the MFDS has had little experience with enforcing such penalties, and market entry is not blocked by a stay because of a listed patent: the Therapeutic Goods Administration may register a generics product, and the originator needs to proceed to court to obtain an injunction.[3]

World Reports on Aids, Patent Linkage and Access to medicines

In the last ten years, several authoritative multilateral institutions have made evaluations based on which the interdependence of intellectual property mechanisms such as patent linkage and access to medicines has been documented. All these reports are an empirical record which is used to support the hypothesis that is put forward in this paper. TRIPS-

plus provisions, such as the linkage of patents, data exclusivity, and extension of the term of the patents, were expressly recognized by the High-Level Panel on Access to Medicines (2016) of the United Nations Secretary-General as systemic barriers to fair access to health technologies in low-income and middle-income countries. The Panel recommended that governments must not agree to take TRIPS-plus policies when such would be detrimental to the population health, and urged governments to create coherence between intellectual property regulations, trade agreements, and international human rights commitments. The analysis of patent linkage by the Panel found that it puts regulatory barriers to generic market entry that prolong the effective monopoly of originator companies beyond the reasonable claim of genuine innovation.[12]

A report by the World Health Organization on the improvement of access to novel COVID-19 treatments in 2022 recorded the impact of intellectual property mechanisms on access to pandemic medicines, including finding that TRIPS flexibilities, such as compulsory licensing and technology transfer pools such as the Medicines Patent Pool and the C-TAP, were systematically not exercised, partly due to the fact that bilateral FTAs commitments created institutional and legal obstacles to their use. The report discovered that the framework of patent linkage provisions in some bilateral trade agreements had caused confusion between national regulatory bodies as to whether they could lawfully grant approval to generic versions of COVID-19 therapeutics even where compulsory licences had been granted.[11]

The report Intellectual Property, Human rights and Access to Medicines, released by the South Centre (2020, third edition) offered a systematic analysis of the operation of TRIPS-plus measures, catalogue of their functioning in 30 jurisdictions. The report established that, on average, patent linkage provisions added 24 to 36 months (not allowed by patent law) to generic entry, and that the overall impact of linkage and data exclusivity and extension of patent term were to extend effective pharmaceutical monopolies by 5 to 12 years in linked markets. The report has reported the disproportional effects on low and middle-income nations where increased medicine costs are directly converted into disparities in treatment access and avoidable deaths.[13]

Incorporating intellectual property language in a pandemic preparedness pact is the subject of ongoing negotiations at the World Health Organization, with Health Policy Watch (2023) documenting the advocacy of the European Union government that IP enforcement mechanisms actually remain part of the WTO framework instead of being embedded into health regulation tools, which is a view that reveals an apprehension that regulatory approval-based IP enforcement, such as linkage-type provisions, would limit the capacity to respond to future health crises.[14]

Combined with such other reports these reports create a convergent evidentiary pool: the provisions of patent linkage as implemented, up to now, in markets where it has been adopted, have demonstrable negative implications on access to generic drugs, pharmaceutical pricing, and the costs of the health system, in particular in markets where the institutional capacity to limit procedural abuse is less developed.

Economic and Public Health Impact

Inflation of Drug Prices and Late Savings on Generics

The effect of the linkage on pharmaceutical expenditure is always characterized by the economic literature on patent linkage effects that delayed generic entry is the leading mechanism of transmission. The generic drug usually enters the market at 20-80 percent of the price of the originator; as soon as several generics enter the market, the prices can drop to 6-20 percent of the position before the competition, and in a three-five-year period, this can be seen as a direct loss of consumer welfare, government drug spending, and health system sustainability.[17]

Under the CUSMA and CETA combined frameworks in Canada, the TRIPS-plus extends of the Comprehensive Economic and Trade Agreement (CETA) terms on data protection and supplementary protection certificate (SPC), which extended the period of generic entry and pharmaceutical spending, were projected by Health Canada analysts to add up to CAD 410 million/year, or about five months, to the average brand-name market exclusivity period, increased to an average of 152 days, or about five months, to generic approvals.[10]

The estimated welfare loss that can be attributed to patent linkage under KORUS in South Korea with the help of the model would be USD 40.03 million per year at most, excluding the indirect costs of sustaining high-price prescription throughout the period of exclusivity.[1] The application of the data exclusivity provisions in the US-Jordan FTA in Jordan was

estimated to have raised pharmaceutical prices to approximately USD 18 million to the private consumer in 2004 alone and that government procurement costs were also estimated to have increased as a result of exclusivity-enforced pricing.[1] The Thailand compulsory licensing programme of seven drugs between 2006 and 2008 including ARVs and cardiovascular drugs offered a natural comparator of the cost of linkage-induced exclusivity. It is estimated that the programme has had the effect of extending the treatment to further 84,158 patients and saving the government USD 370 million in five years time -savings that would not have been possible under a patent linkage regime that prevented the entry of generic products.[4]

A systematic review of 40 empirical studies on the effects of patent expiry on the price of drugs by Vondeling et al. (2018) revealed that price reductions following the generic entry occurred at a higher level of this range at a faster rate in countries with more effective competitive frameworks and regulatory frameworks, such as the lack of linkage barriers.[17]

Health System Burden

The overall health system cost of the patent linkage and other related TRIPS-plus actions are not limited to pharmaceutical spending but also includes opportunity costs: health services abstinence, less coverage, and worse outcomes due to resource being tied up in premium-priced originator products instead of existing generic alternatives.

The models used in the United States showed that between 2000 and 2004, market exclusivity deals on specific drugs cost Medicaid USD 1.5 billion, high generic prices due to first-generic exclusivity manipulation, and delayed generic penetration during 30-month hospitalization.[4]

The economic modelling by Lanjouw (2005) in India showed that an introduction of the patent on pharmaceutical products in 2005, as mandated under the TRIPS, would cause an increase in the price of the relevant patented medicines by between 26% (that of a linearly demand-related economy) and 242% (that of a constant elasticity economy).[4]

It was estimated by the Australian government that the effect of patent term extension provisions introduced in AUSFTA will raise pharmaceutical spending, by an extra AUD 240 million in the short run and by an extra AUD 480 million in the long run, as a result of promoting entry of biosimilars into the Pharmaceutical Benefits Scheme (PBS).[4] Conversely, the policy design option aimed at maximizing fiscal returns by encouraging generic competition in the pharmaceutical sector, has been estimated to generate savings of up to 24% of the AUD.

Regulatory Lapses and Research Oversights

Despite the comprehensiveness of the current patent connection literature, there are a number of structural lapses that limit the generation of detailed evidence-based policy in the area.

The greatest disparity is the almost complete lack of patient-centred health outcome data tying regulatory stay periods to clinical outcomes. Although the cost of delayed generic entry is quantified in monetary terms in economic literature, no associated literature follows through with morphing the delays into morbidity, mortality, treatment interruption or disease progression outcome at the patient or population level. The relationship between a 30-month regulatory stay and a subsequent delay in patient still access to affordable care is implicit in the pricing literature but has not been quantified in a systematic manner.

The geographical area covered by the literature is also limited. Empirical evidence on the effects of patent linkage is concentrated in the high-income and upper-middle-income countries of the United States, Canada, South Korea, and Australia that implemented the linkage mechanisms mostly in the 1990s and 2000s. Little primary empirical research on domestic linkage effects has been generated in African, Southeast Asian and South Asian countries that are increasingly coming under TRIPS-plus FTA pressure due in part to the fact that their systems are more recently adopted and in part because these markets lack research capacity. This is especially important considering that these are the nations where the social health impact of the restrictions on access is the most critical.

Another gap has to do with the strategic behaviour amongst generic manufacturers within linkages. The behavior of originator companies has been modeled under linkage (in most studies) such as patent listing strategy, evergreening, authorised generics, but comparatively little empirical research has investigated how generic firms modify their litigation strategy, targeting of a therapeutic class, and portfolio diversification to linkage restrictions. One cannot create effective first- generic exclusivity and patent challenge incentive systems without an understanding of generic-sector strategy.

Lastly, there is a chronic disciplinary fragmentation of the literature. The economic modelling of patents is not taken into account in legal studies of patent linkage; the institutional and constitutional aspects of judicial supervision are not addressed in the health economic literature. Actually interdisciplinary research models, that is a combination of legal study, health system economics, patent analytics, and public health epidemiology, are required to give policymakers the entire evidence base needed to make effective reforms.

Future Directions and Recommendations

The above discussion results in a number of practical suggestions on patent linkage frameworks to be considered or reviewed by jurisdictions (Fig. 2).

To start with, automatic regulatory stays must be eliminated or substituted with preliminary injunctions that would be approved by a judiciary. The most abusive feature of procedures in the U.S. and U.S.-inspired systems, the automatic stay gives originator companies an extension of exclusivity guaranteed regardless of the quality of its patent claims. Substituting it with a judicial preliminary injunction test, and requiring the patent holder to satisfy that he/she has a serious question to be tried and that the balance of convenience favours a stay, would remove the incentive to engage in litigation to solely invoke the stay. The diluted model of Australia that entails originators to initiate judicial injunctions as opposed to automatic administrative stays is a viable template.

Secondly, the eligibility of patent listing must be confirmed. Self-certification of the originator companies in Orange Book, makes an unchecked pipeline of listing claims, most of which do not receive adjudication but add delay to procedures. Proposed listings should be evaluated by an independent administrative review mechanism who may be either the patent office, the regulatory authority or in a special panel, before they are admitted to the register to establish their relevance and credibility. The MFDS de-listing authority of South Korea is a weak form of this reform; a stronger system would be more proactive in reviewing listing, instead of being reactive.

Third, there should be stronger generic incentive frameworks made by jurisdictions. The first-generic exclusivity of 180 days in the United States and nine months in South Korea has caused certain volume of patent challenges but has been too little to encourage the systematic challenge of secondary and evergreening patents. Increasing exclusivity terms, banning authorised generics within the exclusivity term and giving subsidies to litigation costs to challengers of secondary patents would even out the incentive balance.

Fourth, the legislative safeguarding against the erosion of the flexibility of TRIPS and especially its

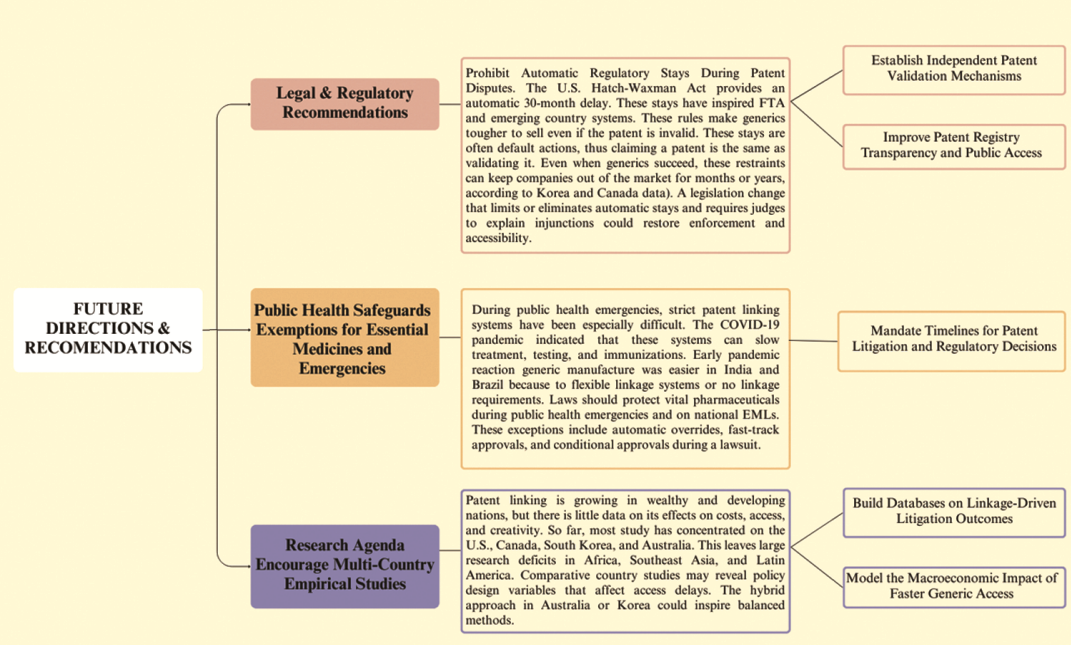


Fig. 2 — Future directions and recommendations[1–4,6–9,16,18–23]

Bolar exception must be preserved against linkage. Countries that are forced to patent linkage frameworks by FTA must, at the same time, enact statutory safeguards that guarantee the Bolar infusion to work: that generic producers are allowed to finish bioequivalence evaluations, manufacturing validation, and regulatory submissions until patent expiry and that patent linkage duties are imposed on full approval granting of the product and not on the pre-approval regulatory measures.

Fifth, poor and middle-income nations must not be induced to adopt patent linkage through FTA without sufficient credible evidences of net benefit due to their particular institutional settings. The indicators here: the non-linkage policy of India, the role of countries in the non-linkage policy in the supply of generic drugs to the world, the signs of cost associated with the mechanism of countries that did adopt the TRIPS-plus provisions in FTAs and the results of the UN High-Level Panel all confirm the conclusion that implementation of U.S.-style patent linkage in those markets that did not develop the institutional capacity to limit procedural abuse create health system costs greater than any innovation-incentive benefits that can be attributed to the mechanism.

Conclusion

In the comparative analysis of patent linkage through the prism of the United States, South Korea and India, the phenomenon turns out to be an instrument in which the legal structure defines whether the linkage fulfils its objective of matching patent protection with drug regulatory procedures to safeguard the true intellectual property rights or whether it is an instrument of the commercialisation of pharmaceutical monopolies at the cost of the health of the population.

The US system, with automatic stays, self-certified Orange Book listings and lack of any required penalties against vexatious litigation, has proven to be able to facilitate procedural abuse, with known costs to public health systems running into billions of dollars per year. The hybrid approach that is adopted in South Korea; shorter stay, penalty, MFDS de-listing power, is a partial success but still has structural features that are not sufficiently stimulative to the generic manufacturers to generate enough patent challenges and competitive entry as the design of the system would suggest. The systematic, legally-based Indian refusal to embrace patent linkage has maintained institutional integrity of the Indian drug regulatory process, facilitated the greatest generic pharmaceutical industry in the world to provide inexpensive medicines to the world, and offered a paradigm of TRIPS compliant public health protection by legal architecture and not political adjustment.

The overall pattern of patent linkage in its dominant systematically distorts the balance between innovation incentive and access to medicines, as argued in the central hypothesis of the present paper, was proven in the comparative legal analysis, the quantitative evidence on price and expenditure effects, and the institutional analysis of regulating capture dynamics across all the three jurisdictions that are considered in the present paper. The implication is also very straightforward: the fact that jurisdictional design is lenient, in its own right, through the means of automatic stays, lax validation, minimal application of anti-abuse clauses, etc. is what matters most in terms of the extent to which the mechanism can be deviated out of its intent.

The way ahead does not lie in abolishing of all means of connection between intellectual property and regulation of drugs, but redesign of patent connection on conditions that involve judicial verification, independent validation of patents, real innovation as the qualification of listing eligibility, and substantial incentives on generic patent challenge. These reforms would maintain the valid role of patent linkage and deprive the procedure structure that turns it into a legal protection rather than a market defense. As the evidence considered in this paper shows, these reforms are possible in the current structure of TRIPS and they are so needed in the face of the public health costs of the status quo.

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