Patent Linkages and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries

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Abstract Linking patent protection to generics' regulatory approvals is a heated topic of discussions and a friction point among countries proposing higher protection for patented drugs. Patent linkage has been pushed through bilateral and regional agreements outside of the WTO system. It is widely understood that patent linkage is implemented to delay the market entry of generic medicines. It is argued here that developing countries are not obliged to take up TRIPs plus patent-linkage obligations.

A list of approved drugs and their therapeutic equivalence can be published by every country. The patent information can also be published to be made known to everybody. Regulatory mechanisms and patent protection should be kept in separate parallel tracks. Any attempt to link the two streams to prevent the registration of generics based solely on alleged patent infringement would negatively affect access to medicines worldwide.

Patent linkage provisions are TRIPS-plus commitments, as there is no such obligation under the WTO TRIPS Agreement. The analysis of 16 countries which provide for patent linkage shows that it is, in most cases, a resulting commitment from regional trade agreements or bilateral agreements. Patent linkage provisions are not acceptable to the developing world, and any attempt to introduce these will affect the accessibility and affordability of generic medicines in the developing world.

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1 Introduction

Access to essential medicines is a developmental challenge to developing countries under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).¹ Accessibility, affordability, and availability of medicines (medicines and drugs are interchangeably used in this paper hereinafter) are the prime objectives of any developing country's public health policy.² Access to drugs is vital in the background that, after food, the second-largest household expenditure is on medication, and this is paid out of pocket in these countries due to a lack of sufficient public health programs. Many countries drafted their medicines policies keeping this issue in mind. The challenging problem is that pandemics' growing burden in developing and least developed countries raised a high demand for cost-effective medicines. Countries like India have previously met this increased demand by providing low-cost generic drugs to the world and helping them fight pandemics.³

Developing and developed countries alike have realized the importance of generic drugs in healthcare.⁴ The European Generics Medicines Association (EGA) formed "Medicines for Europe" in the year 2000 to support the generic and biosimilar industry, which supplies 67% of all medicines in Europe.⁵

Developing countries face challenges in the form of TRIPs-plus obligations imposed on them through various means, mainly bilateral and regional trade agreements. The availability and accessibility of medicines will be affected by policy choices, such as adopting a patent linkage. Patent linkage refers to the system or process by which a country links drug-marketing approval to the status of the patent (s) corresponding to the originator's patented product.⁶

¹WHO (2011–2016), available at https://apps.who.int/iris/bitstream/handle/10665/207519/9789290615705_eng.pdf.

²Ravikant et al. (2013), pp. 316–322.

³India recently sent an anti-malarial drug, Hydroxychloroquine, to 55 countries hit with Coronavirus. This drug is identified by the US Food and Drug Administration as a possible drug to treat Covid-19 disease, though its safety and efficacy are not yet established. See India Today, New Delhi, April 17, 2020, <https://www.indiatoday.in/india/story/india-sending-hydroxychloroquine-55-coronavirus-hit-countries-1667786-2020-04-17>. Later the accepted the Solidarity Trial's International Steering Committee recommendation to discontinue the trial's hydroxychloroquine and lopinavir from the treatment of COVID-19 patients. See WHO (2020). https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters?gclid=EAIaIqobChMIjoGlrH06wIVhzMqCh3ISAVnEAAYASABEgKMz_D_BwE.

⁴European Generic Medicines Association (2009). https://www.medicinesforeurope.com/wp-content/uploads/2016/03/Market_Barriers_Report_FINAL_update_How_to_Increase_Patient_Access_to_Generic_Medicines.pdf.

⁵Medicines for Europe, <https://www.medicinesforeurope.com/medicines-for-europe/>.

⁶https://www.wipo.int/export/sites/www/meetings/en/2007/lifesciences/sym_regulation/lss3_ge_07_ferrite.pdf.

The present IP regime in 164 countries are under the WTO's⁷ TRIPs Agreement concluded in 1995. Every WTO member country has to implement minimum standard of intellectual property at the domestic level according to TRIPs provisions. Article 1 of the Agreement stipulates, "Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement."⁸ Hence, it is clear that members are not obliged to implement higher standards than prescribed in the TRIPs agreement.⁹

The basic concept of patent protection is that once the patent term is over (presently 20 years under the TRIPs agreement), the product would be in the public domain and freely used, including for commercial purposes.¹⁰ This eclipse of patent protection is supposed to increase consumer welfare, and society would be better off from evergreening protection. Pharmaceutical regulatory approval is entirely different from patent protection. Moreover, it differs from country to country based on domestic legislation. Linking such regulatory and marketing approval to the originator's patent status would affect the generic drug industry at large and accessibility and affordability.

Patent linkage involves linking the marketing approval of generic drugs with the originator drug's patent status and refusing to allow marketing approval until the patent is expired.¹¹ The United States (US) first introduced the concept through the Hatch Waxman Act, 1984.¹² This law provides for protecting the interest of patent holders through linking patent status of originators' drugs and their regulatory approval in the "Orange Book."¹³ Thus, a generic drug would not get marketing approval if it would potentially infringe one or more patents listed in the Orange Book. The US patent linkage system can be seen as a ploy by the patent holder to delay the entry of generic drugs in the market.¹⁴ However, the originator industry argues that this will help them prevent anticipated patent infringement and promote innovation and investment by giving inventors more certainty over their patent rights.¹⁵ However, generic manufacturers argue that TRIPs plus commitment undermines the rapid approval of generic medicines. Besides, most countries' drug regulatory authorities need not inform the inventors about the application for marketing approval or the actual approval of a generic version of patented drugs. Early working allows immediate marketing at the end of the patent period, equips the

⁷ Presently, the World Trade Organization has 164 member countries, which constitute 99 percent of the world trade.

⁸ Article 1 of the TRIPs Agreement. https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

⁹ Ibid.

¹⁰ Correa (2016).

¹¹ Mirandah (2012), p. 50.

¹² <https://www.congress.gov/bill/98th-congress/senate-bill/01538>.

¹³ Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>.

¹⁴ Son et al. (2018), p. 101. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6201583/>.

¹⁵ Ellis (2019). <https://geneva-network.com/article/patent-linkage/>.

generic companies to provide cheap drugs in developing countries without delay.¹⁶ This early working limited exception under Article 30 of the TRIPs Agreement does not infringe patented drug owners' rights. Nonetheless, there is a concerted effort to introduce a link between the patent status of drugs and the regulatory approval of generic medicines in the recent past through regional and bilateral trade agreements.

This paper argues that linking a generic drug's market approval to its branded equivalent's patent status is detrimental to access to medicines in developing countries and least developed countries. It is argued that India and other developing countries should not statutorily link patent protection with marketing approvals of generic drugs, which is well beyond the TRIPs obligations. The backdoor entry of these provisions through regional trade agreements should be prevented to allow the production of cheap drugs for the developing world.

This paper analyses the legal regimes adopted to implement drug-related patent-linkage provisions, enforcement, and standard practices of 21 jurisdictions.¹⁷ The legal system of patent linkage countries (15 in number) and non-patent linkage countries (6 countries) is analyzed mainly in South-east Asian countries to understand these countries' legal obligations and its implications in access to medicines. The Indian experience is examined carefully, along with compulsory licensing practice. Important judicial decisions are also analyzed to understand its effect on access to drugs. The paper concludes that linking patent rights with marketing approvals for generic medicines has far-reaching adverse consequences in developing countries' access to drugs. Patent linkage has an incentive for extending monopoly rights beyond 20 years of the patent term and will negatively affect generic drugs' entry after the expiry of patent rights. It is relevant to note that only 15 countries implemented patent linkage directly among the WTO Members,¹⁸ but regional trade agreements have patent linkage provisions, and their adoption will increase the number.¹⁹ All the countries with direct patent linkage provisions are included for a better understanding of the provisions.

¹⁶See Chapter 5.

¹⁷This include the US, EU, Canada, Australia, Japan, South Korea, China, Taiwan, Russia, Ukraine, Thailand, Philippines, Singapore, Malaysia, Indonesia, Vietnam, Thailand, Jordan, UAE, Peru and India.

¹⁸US, Canada, Japan, Australia, South Korea, China, Taiwan, Russia, Ukraine, Philippines, Singapore, Jordan, Mexico, UAE and Peru.

¹⁹Townsend et al. <https://www.bilaterals.org/IMG/pdf/ssm-id2850294.pdf>.

2 Perspectives on Patent Linkage

2.1 US

In the US, patent linkage is included in the Drug Price Competition and Patent Term Restoration Act, 1984 (Hatch Waxman Act) to regulate the generic industry. Patent extensions are also allowed in the US for up to five years for qualifying patents.²⁰ The patented drug must not have been infringed until expired or held invalid. However, the legislation also provides some benefits for the generic industry.²¹

The Act has passed with an objective of hassle-free approvals to generic drugs and unnecessary disputes with branded and patented drugs. Unfortunately, the multinational drug companies exploit the loopholes in the Act in favor of them to extend the patent protection.

In the US, the generic drug approval is linked to pioneer drug patents under the Hatch Waxman Act, 1984 through Orange Book, certification process, and a limited 180-day generic market exclusivity period for first generic applicants who challenge the validity of the patent or claim it would not be infringed under the Act's Paragraph IV certificate system. Under the "patent linkage" provisions, the new drug application should include patent details, and the FDA reflects the existence of patents as part of the approval process for specific drug applications. If a valid patent exists, marketing approval will not be granted to a generic drug until the patent has expired or declared invalid by competent authorities. This generic marketing approval is "linked" to the expiration of the patented drug. Such patent information can be published in "Orange Book." This Book lists approved drugs, discontinued drugs, and patent and exclusivity information. It is argued that the patent linkage system

²⁰West and Allison Hoppert. <https://www.oblon.com/A11960/assets/files/News/125.pdf>.

²¹They can be summarized as follows:

- Generic drugs need not prove their safety and efficacy but must demonstrate the product's bioequivalence to the original patented drug. This will reduce the cost and delay of clinical trials of generic medicines.
- Generic drugs are granted 180 days of exclusivity limited to the first generic entrant who files a paragraph IV certification and thereby challenges the patent's validity or claims that it will not be infringed.
- Abbreviated New Drug Application (ANDA) applicant is not required to produce independent evidence of the generic drug's safety and effectiveness. He has to prove also that the generic drug is bio-equivalent to reference listed drug (RLD).
- If the applicant submits a paragraph I or II certification, the patent in question will not delay ANDA approval.
- If the applicant submits a paragraph III certification, the applicant agrees to wait until the relevant patent has expired before seeking the ANDA's final approval.
- Paragraph IV certification does not survive the expiry of a listed patent. In making paragraph IV certification, the generic drug maker says he believes that the patented drug is invalid, not infringed, or unenforceable.
- If the NDA holder brings a suit for infringement, the FDA can't approve it for 30 months or whenever the court determines the issue.

increased the efficiency and productivity of the research and development sector of a generic company and patent holder company. However, generic drug approvals are vital for developing countries in curing pandemics.

Studies have revealed that generic drug approval applications were late by 30 months due to patent linkage provisions and the infringement litigation.²² These infringement cases increase the cost of drugs, and the generics lost the right to enter the market during the stay period. S.156 provides for patent term extension up to five years if certain conditions are met like any patent term adjustment granted under section 154(b).²³

The Act's misuse includes "reverse payments" from originator companies to generic companies during the 180 days exclusive period not to enter the market. This is popularly known as the "pay-for-delay" program adopted by the originator companies. The FTC has taken a strong exception to this anti-competitive practice and believes that such practices are per-se illegal. To stop this practice, Congress passed the Medicare Prescription Drug Improvement Modernization Act, 2003. This Act stipulates that within ten days of reverse settlements, companies to register such settlements with FTC.²⁴ As per the FTC estimate, consumers lost \$3.5 billion higher drug cost every year due to this "pay-for-delay" tactics of the originator companies.²⁵ But in some cases like in *In re Tamoxifen Citrate Antitrust Litig.*,²⁶ the Second Circuit rejected the *per se* rule and held that reverse payment settlements do not violate anti-trust laws if they fall within the exclusionary zone of the patent. But the US Supreme Court, in a landmark judgment, *FTC v. Actavis*,²⁷ held that the pay-for-delay practice of originator companies for settling patent disputes with generics and delay in entering the market could have significant anti-competitive effects and violate anti-trust laws.²⁸

Patent linkage is similar to that of the branded drug companies' pay-for-delay program to delay the entry of generics into the market. Thus access to cheaper medicines is denied in developed and developing countries if patent linkage or similar provisions are implemented.

Other tactics used by the originator companies, including asking the FDA to take action on any ANDA application under "Citizen Petition" provision, will likely delay the generic version of drugs. FDA has to take a decision not longer than 150 days. Again, this will delay the generic entry for another 150 days, and

²²Winkler et al. (2018). <https://www.finnegan.com/en/insights/requirements-benefits-and-possible-consequences-of-listing-patents-in-fdas-orange-book.html>.

²³*Merc & Co. Inc v. High Tech Pharmaceuticals Inc.*, US Court of Appeals No. 2006-1401, decided on March 29, 2007.

²⁴Meagher (2017), p. 589. Available at: <https://brooklynworks.brooklaw.edu/bjcfcl/vol11/iss2/12>.

²⁵Pay for Delay, Federal Trade Commission. <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay>.

²⁶466 F.3d 187, 228 (2d Cir. 2006).

²⁷570 US. 136, 2013.

²⁸Decided on June 17, 2013, https://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf.

originators can file multiple, successive petitions. Another methodology adopted by the branded companies is “product hopping” or “forced Switch schemes.” These are branded companies’ strategies to come up with alternative versions of the medicine shortly before the patent expiry with the effect of withdrawing the existing product registration, which might be thwarted registration of the generic equivalent. A patient who is using a particular branded medicine has the least possibility of switching to a new generic drug; instead, continue with the altered version of the branded drug. Thus, they were compelled to use essentially the same medicine with the same company for a higher price; this maintains the originator company’s monopoly for a more extended period than prescribed. Since the decision in *Actavis* by the US Supreme Court, the number of pay-for-delay cases has been decreased.²⁹

2.2 EU

The EU does not follow the patent linkage system. But at any time, the patent holder can get an injunction against any infringement throughout Europe. EU believes that any tinkering with the bolar provision through patent linkage will delay the entry of generic drugs into the European market.³⁰ EU directives do not prohibit experimenting with any patented drug during the patent term and generating test data, which can be submitted to the regulatory authorities for marketing approval.³¹ EU’s Pharmaceutical Sector Inquiry preliminary report of November 28, 2008, accounts that 700 patent litigations were filed to prevent or delay the entry of registered generic drugs into the market.³²

The European Medicines Agency is responsible for the marketing approvals of a generic drug in the EU.³³ Article 81, Regulation No.EC726/2004³⁴ and Article 126 of Directive EC 2001/83 laying down community procedures for authorization of medicinal products.³⁵ EU believes that patent linkage provisions are beyond the TRIPs obligations and not desirable in the EU. The bolar rule is strictly implemented

²⁹Michael Carrier *FTC v. Actavis: Where We Stand After 5 Years*, 18 June 2018.

³⁰Article 10.6. of Directive 2001/83/EC as amended).

³¹Data Exclusivity/Patent Linkage in the Context of EU Generic and Biosimilar Applications. Presentation by Suzette Kox at the WIPO Life Sciences Symposium: Intellectual Property and Life Sciences Regulation, 16 November 2017. https://www.wipo.int/export/sites/www/meetings/en/2007/lifesciences/sym_regulation/lss3_ge_07_kox.pdf.

³²European Commission (2008). https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

³³European Medicines Agency Generic and Hybrid Medicines. <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/generic-hybrid-medicines>.

³⁴https://ec.europa.eu/competition/sectors/pharmaceuticals/archive/4_Regulator_framework.pdf.

³⁵https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf.

in the EU through Article 10.6 of Directive 2001/83/EC as amended.³⁶ Generic companies are applying for marketing approval to demonstrate that it is bioequivalent to the originator product. For that, the generic companies can refer to the test data submitted by the originator companies. The test data provided by the originator firms will get data exclusivity period for eight years, but during the additional two-year market exclusivity provision, generic producers can early work and apply for marketing approval.³⁷ Moreover, the EU practices a maximum of five years of extension based on the Supplementary Protection Certificate (SPC). Submission of generic biosimilar applications only possible after the data exclusivity period.³⁸

In 2012, the European Commission³⁹ formally asked Italy to remove patent linkage provisions outlined in Law No 30 of 2005 (the IP Code), namely paragraph 1-bis of Article 68 containing a clear patent linkage., which harm and delay the entry of generic medicines in the market.⁴⁰ The provision allows generic drug manufacturers to start the drug registration process only during the “last year” of the patent or supplementary protection certificate’s validity. The Italian provision violated Article 10 of Directive 2001/83/EC in the community code relating to medicinal products. In 2012, Law No. 27/2012 made the Italian law in compliance with the EU Regulation. Now the marketing authorization application for a generic drug can be filed more than one year before the patent or supplementary protection certificate expiry. But manufacture, import, or sale of the drug would be considered as an infringement. But Law No. 189/2012 excluded generic drugs from the National Health Care Service. It means that generic drugs cannot be listed for reimbursement until the patent is expired. But in the name of secondary patents, the generics have to wait until its expiry as well.⁴¹

On 1 July 2019, Regulation UE 2019/933 introduced some amendments to the previous Regulation (EC) 469/2009 concerning the SPC, setting forth a waiver

³⁶ https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf.

³⁷ Medicines and Law Policy (2019). <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf>.

³⁸ Data Exclusivity/Patent Linkage in the Context of EU Generic and Biosimilar Applications. Presentation by Suzette Kox at the WIPO Life Sciences Symposium: Intellectual Property and Life Sciences Regulation, 16 November 2017. https://www.wipo.int/export/sites/www/meetings/en/2007/lifesciences/sym_regulation/lss3_ge_07_kox.pdf.

³⁹ Daniela Ampollini (Trevisan & Cuonzo) (2011). <http://patentblog.kluweriplaw.com/2011/04/08/patent-linkage-infringement-proceedings-by-the-european-commission-against-italy/>.

⁴⁰ Intellectual Property Watch (2012). <https://www.ip-watch.org/2012/01/31/european-commission-orders-italy-to-drop-patent-linkage-delaying-generics/>.

⁴¹ Decision of the Regional Administrative Court of Rome on January 2018 (T.A.R. Lazio, sez. III, - Roma, 19 January 2018, No 662).

under certain conditions to export such manufactured drugs outside the EU jurisdictions.⁴²

Other EU countries like Hungary, Portugal, and Czech are trying to establish different kinds of linkages with patents.⁴³ Italy and Belgium have restrictions on the reimbursement by National Health Service on drugs that infringe third-party patents. In Hungary and Egypt, declarations of non-infringement are sought by applicants at the time of filing.

The introduction of patent linkage would increase litigation frequency in patent enforcement and delay generics' entry in the EU market.⁴⁴ The EU Council of Ministers expressed concern over very high, unsustainable drug prices in the EU.⁴⁵ The FDA style patent linkage cannot be implemented in the EU because there is no single patent in the entire EU jurisdiction. Instead, it is a bundle of patents filed in the European Patent Office (EPO). However, in the Italy case, the European Commission made it clear that patent linkage delays the entry of generic medicines and a clear abuse of the EU regulatory system.⁴⁶ Patent linkage is considered illegal in the EU under Regulation (EC) No 726/2004 and Directive (EC) No 2001/83).⁴⁷

2.3 *Canada*

In 1993 Canada first adopted a patent linkage system closely patterned on US law. These regulations were adopted to ensure that the early exception is not abused by generic drug applicants seeking to sell their products during the patent term. Notice of compliance provisions is similar to that of the Hatch – Waxman Act. Canada also keeps a Patent Book like Orange Book. Notice of allegation (NOA) and notice under Paragraph IV of the HW Act are similar. The statutory stay of approval in Canada is 24 months, and it is 30 months in the US. In 2017, significant amendments were made to the Patented Medicines (Notice of Compliance) Regulations 1993 (PM-NOC-amended) to align with Canada's obligations under the

⁴² <https://practiceguides.chambers.com/practice-guides/patent-litigation-2020/italy/trends-and-developments#:~:text=The%20European%20Union%20does%20not,advance%20of%20the%20patent%20expiration.>

⁴³ Research Report on Establishing System of Linking New Drug Application and Patent Protection, BIPI Research (2016) No. 002. <http://www.theglobalipcenter.com/wp-content/uploads/2017/03/full-report-E.pdf>.

⁴⁴ European Generic Medicines Association (2008).

⁴⁵ Catherine Drew (2017). <https://www.pinsentmasons.com/out-law/analysis/eu-unlikely-to-follow-us-with-patent-linkage-system-says-expert>.

⁴⁶ Intellectual Property Watch (2012).

⁴⁷ Pharmaceutical Sector Inquiry – Preliminary Report, Fact Sheet “Regulatory Framework”. https://ec.europa.eu/competition/sectors/pharmaceuticals/archive/4_Regulator_framework.pdf.

Canada-European Union Comprehensive Economic and Trade Agreement (CETA).⁴⁸ The changes in the amendments can be summarized below:

1. The Minister of Health was given the power to maintain the Patent Register.
2. Generic or bio-similar manufacturers are required to serve a notice of allegation (NOA).
3. All NOAs need to include a searchable electronic copy of the second person's drug submissions and copies of documents to be submitted.
4. First-person cannot seek a prohibition order against the Minister of Health.
5. First-person, who brings an action under the law, will be able to renounce the 24-month stay.
6. An unsuccessful action for patent infringement under the law, the second person will be able to sue all the plaintiffs for section 8 damages.⁴⁹

It is worth noting that Canada introduced a Bolar exception provision in 1991.⁵⁰ Section 55.2 of the Act provides for two exceptions to patent infringement. These are "early working" and "stockpiling" exceptions. EU filed a case in the WTO dispute settlement against this provision. In the year 2000, the Panel held that the early working provision did not violate the TRIPs agreement.⁵¹ However, the Panel held that the manufacturing and stockpiling of drugs in the last six months of the patent expiry term violate the Agreement. Later on, the stockpiling provision was repealed.

2.4 *Australia*

Australia effectively implemented patent linkage through Section 26B of the Therapeutic Goods Act 1989 and AUSFTA and consequent legislation, the US Free Trade Agreement Act, 2004. The generic companies seeking marketing approval must provide a patent certificate stating that the generic did not infringe any originator drug patents and notice the patentee.

If the generic drug infringes, no marketing approval will be granted. Moreover, an injunction will be issued, which will delay generic entry for another three years.⁵² The Australian courts are generally in favor of patentees, and permanent injunctions are usually granted to the originators.⁵³

⁴⁸<https://laws-lois.justice.gc.ca/eng/regulations/sor-93-133/index.html>.

⁴⁹White et al. (2017). <https://www.osler.com/en/resources/regulations/2017/canada-s-patent-linkage-regulations-get-long-await>.

⁵⁰Correa (2016).

⁵¹WT/DS114/R.

⁵²Palombi (2014). <http://theconversation.com/its-time-to-fix-the-free-trade-bungle-on-the-cost-of-medicines-32574>.

⁵³Managing IP (2019). <https://www.managingip.com/Article/3865388/Australia-Protecting-pharmaceutical-market-share-in-Australia.html>.

The patent linkage provision is included under Section 26B of the Therapeutic Goods Act 1989.⁵⁴ An applicant seeking marketing approval of a generic or biosimilar medicine must certify either that:

- (i) it will not market the drug in a manner that would infringe a valid patent *or*;
- (ii) It has notified the rights holder of their intention to market the drug before the patent term expiry.⁵⁵

However, Australia claims that there is no administrative patent linkage in the country—after the potentially infringing applicant's notice, the patent holder must sue to protect its rights.⁵⁶ Permanent injunctions are an effective way for originators to prevent generics from entering the market. The Australian High Court considered the question in *Aktiebolaget Hassle v. Alphapharm Pty. Ltd.*⁵⁷ Evergreening and linkage of the patent were discussed by the Court in this case and discussed how the patent owners use a regulatory process to extend their blockbuster drugs patent term for rent-seeking. The linkage-form of evergreening is the new method developed by the drug companies following the US Hatch – Waxman legislation. The companies try their luck in other jurisdictions even though there are no patent linkage provisions in Australia.⁵⁸ The Astra group filed a patent infringement case against a generic drug manufacturer, Alphapharm, who started importing the drug to the Australian market at the end of the patent term. Justice Kirby, in his judgment, observed the tactics of the originators to delay the generic entry even after the patent term, in its most persuasive words:

The strategies that large pharmaceutical manufacturers have employed to avoid such generic competition, which include the use of intellectual property law, have been detailed elsewhere. They are attracted to the attention and response of the Federal Trade Commission in the United States. Such battles have had their counterparts in many other countries. They present serious issues for the developing world. . . in its interpretation of the legislation, and in identifying the proper approach to the ultimate factual determination of obviousness called for by that statute, this Court should avoid creating fail-safe opportunities for unwarranted extensions of monopoly protection that are not sustained by law.⁵⁹

AUSFTA, Article 17.10.04, provides that the branded drug manufacturer would be informed of an anticipated product.⁶⁰ The regulatory process and marketing approval for generic pharmaceuticals would be connected with patent infringement status through this provision. It is also required to notify the patent holder of any

⁵⁴ Australian Government, About the Australian therapeutic goods legislation. <https://www.tga.gov.au/about-australian-therapeutic-goods-legislation>.

⁵⁵ Son et al. (2018).

⁵⁶ DrugPatentWatch Patent linkage: Balancing patent protection and generic entry <https://www.drugpatentwatch.com/blog/patent-linkage-resolving-infringement/>.

⁵⁷ (2062) HCA 59, 12 December 2002.

⁵⁸ Faunce and Lexchin (2007). <https://anzhealthpolicy.biomedcentral.com/articles/10.1186/1743-8462-4-8>.

⁵⁹ *Aktiebolaget Hassle v. Alphapharm Pty Ltd*, 212 CLR 411, para 101 2002.

⁶⁰ Faunce and Lexchin (2007).

generic marketing approval application.⁶¹ Originators have used the preliminary injunction route for successfully stalling the entry of generics in the market. The high degree of proof is with the generic industry to prove that they are not violating any patents. Besides, AUSFTA provision 17.10.4(b) required that the patent holder be notified of a generic marketing approval application. This provision is criticized as an attempt to delay the entry of generic medicines in the Australian market.⁶²

2.5 Japan

Even though Japan directly did not implement the patent linkage system, the de-facto patent linkage system was implemented through a government regulation to approve generic drugs.⁶³ During the active patent validity period, no generic approval will be granted.⁶⁴ The patent linkages are secured in two stages of regulatory approval and drug price listing.⁶⁵ If there is a delay in getting marketing approval of the patented drug, the duration can be stretched for a period of up to five years.⁶⁶

After an amendment to the Patent Act in 2018, the patentee can claim patent extension if it is granted after five years of application. The patent extension term will mostly depend upon the period in which the originator is unable to use the patented drug during a marketing approval process. Japan also keeps a US-style Orange Book⁶⁷ and patent linkage.⁶⁸ The Minister will not approve any generic drug when a patent right prevents the generic drug from being marketed.⁶⁹ However, under the price regulation system, the drug prices in Japan are determined by the state.

Any dispute between originator drug manufacturers and generic manufacturers must be reported to the Ministry of Health, Labor and Welfare.

⁶¹ AUSFTA Article 17.10.4(b).

⁶² Faunce and Lexchin (2007).

⁶³ IP Litigation in Life Sciences – Costs, Duration and Enforceability in Japan. Presentation by Yoichi Okumura, Global Head of IP, Takeda Pharmaceutical Company Limited. WIPO Conference on IP Dispute Resolution in Life Science, 22 May 2015. https://www.wipo.int/export/sites/www/amc/en/docs/basel2015_okumura.pdf.

⁶⁴ Abe (2019). <https://www.managingip.com/Article/3888280/Japan-What-impact-do-generic-drugs-have-on-the-Japanese-market.html>.

⁶⁵ <https://system.jpaa.or.jp/patent/viewPdf/3066>.

⁶⁶ Law No. 145 of 1960.

⁶⁷ Approved Drug Products with Therapeutic Equivalence Evaluations.

⁶⁸ Notification No. 0605001 of the Economic Affairs Division, Health Policy Bureau of 2009 and Notification No. 0605014 of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau of the Ministry of Health, Welfare and Labour of 2009.

⁶⁹ Koizumi et al. (2011). https://www.amt-law.com/asset/res/news_2011en_pdf/110225_2055.pdf.

Japan allows experimentation exemption under the Patent Act 2006 (Amended).⁷⁰ Tests conducted during the patent term for submission to the regulatory approval is not an infringement under the Japan patent law.⁷¹

Price competition between originator drug and generic drug is significantly less in Japan due to state price control. Reverse payments are considered as an anti-competitive activity in Japan. Unlike the US, the ANDA 180-day exclusivity to the first filer is not available in Japan. All these measures show that patent linkage is not so intense that compared to the US. Nevertheless, Japan is a party to the RCEP Agreement and may be forced entirely to implement patent linkages if these are included in the final agreement.

2.6 South Korea

South Korea is another country that implemented the patent linkage system, in line with the US Hatch-Waxman Act of 1984. This was done through a back door of the US – Korea Bilateral Free Trade Agreement signed in 2007,⁷² entered into force in 2012 (Article 18.9.5 – IP Chapter).⁷³ The amendment introduced the patent list and the notification system. In addition to that, the government implemented a nine-month stay on marketing approval and nine-month first generic exclusivity in 2015. It was reported that the amendment increased the number of patent challenges as well as marketing approvals related litigations.⁷⁴ According to the Agreement, Korea agreed to the following additional commitments over and above the TRIPS agreement:

- Extended patent term to compensate for the patent prosecution delays from the Korean Intellectual Property Office and other regulatory review delays.
- Data exclusivity should be granted for efficacy information submitted to support a prior approved drug (three years) or newly approved drug (five years).
- Patent linkage provision informing patentees of an applicant's identity before granting marketing approval of a generic drug.
- Marketing approval will not be granted for a generic drug without the original patent owner's consent during the valid patent period.

The South Korean Pharmaceutical Affairs Act permits clinical test data submitted by originators to be used by generic drug manufactures seeking marketing approval. Korean patent listing is also strictly policed by MFDS, and it allows Korean generic

⁷⁰ www.japaneselawtranslation.go.jp.

⁷¹ *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceuticals Industries, Ltd.* Judgment dated 16 April 1999.

⁷² Son et al. (2019).

⁷³ See Raley (2019a), pp. 459–492.

⁷⁴ Son and Lee (2017), pp. 1169–1178.

manufacturers to institute administrative hearings before the patent hearing. The branded companies must petition MFDS for the stay of generic drug sales, and the stay lasts for nine months, but the branded manufacturers to obtain a stay of generic drug FDA approval for up to 30 months like in the US.⁷⁵ South Korea also provides patent term extension up to five years for pharmaceuticals and agrochemicals. South Korea is a part of RCEP negotiations. The leaked Korean RCEP draft on IP provides for patent term extension for unreasonable delays in granting patents. Unreasonable delay is defined as the delay for more than four years from the date of filing of the application or three years after the request for examination of the application, whichever is later [Article X.D.1.4(a)].⁷⁶

2.7 China

The Administrative Measures for Drug Registration 2002 provides for the protection of patent rights related to drugs. The applicant has to prove the patent status and declare that it did not infringe on any patents. Attempts were made in 2005 and 2007 to include patent linkage provisions but are never happened until 2017.

In 2017, the Chinese Communist Party proposed reforms in the medical device approval system and issued Reform Opinion (Order No. 55) to implement the US model patent linkage system in drug regulation.⁷⁷ China implemented “bolar exemption” provisions through patent amendments laws in 2008, known as the “Naked Bolar Exemption.”⁷⁸ Article 16 of “Opinion on Deepening Approval and Review System Reform and Encouraging Innovation of Drug and Medical Apparatus” of 2017 describes the patent linkage system in China. It includes notifying the relevant patentee of the generic drug and patent term adjustment system’s marketing approval process. The long term review process and delays will be compensated through a reasonable extension of the patent period. However, the Chinese new Drug Administration Law, 2019, took effect from December 1, has a patent linkage provision.⁷⁹ The new law provides for a nationwide drug marketing authorization holder system.⁸⁰ The Chinese model of Orange book now has more than 131 drugs as well.⁸¹

Order 55 provides for the following:

⁷⁵Raley (2019b).

⁷⁶Townsend et al. <https://www.bilaterals.org/IMG/pdf/ssm-id2850294.pdf>.

⁷⁷Chen and Shi (2017), pp. 1484–1487.

⁷⁸Article 69.

⁷⁹China IPR (2021). <https://chinaipr.com/category/patent-linkage/>.

⁸⁰Global Legal Monitor (2019). <https://www.loc.gov/law/foreign-news/article/china-drug-administration-law-revised/>.

⁸¹Zhang et al. (2018). <http://patentblog.kluweriplaw.com/2018/04/03/china-establish-patent-linkage/>.

1. A generic drug applicant shall notify the known patents at the time of drug filing.
2. If the drug applicant challenges a patent, it should declare that his drug does not infringe on any patent.
3. The patent owner should start patent infringement proceeding within 20 days after the drug filing.
4. The CFDA has the discretion to make the application pending for 24 months before drug approval.
5. If there is no judicial remedy within the waiting period of 24 months, CFSA can approve the generic drug.
6. If there is any infringement suit after the generic drug's approval, it will be subject to the judicial decision's outcome.

On 15th January 2020, China and the US signed an Economic and Trade Agreement to ease trade between the countries required to build a patent linkage and patent term restoration system in China.⁸² Article 1.12 of the agreement provides for patent extensions in case of unreasonable delays while examining the patent application and delays in marketing approvals. The excessive delay means more than four years from filing or three years from requesting examination. The patent validity can be extended by a maximum of five years in case of marketing approval delays.⁸³ China was an active participant in the RCEP negotiations on patent linkage.⁸⁴

2.8 Taiwan

Taiwan has implemented a patent linkage system from 20 August 2019 following the amended Pharmaceutical Affairs Act. A new chapter of "Patent Linkage of Western Pharmaceuticals" was added to the law.⁸⁵ The new generic drug manufacturers seeking marketing approval of generic drugs has to submit a declaration that the new drug is not patented, or the patent has expired, or the approval must be given after the expiry of the patent, or the patent on the new drug is not valid or not infringed by the generic drug. Patent listing has to be made through online systems under the Taiwan Food and Drug Administration (TFDA). Patentees to upload information about originator drugs within 45 days from the approval of the TFDA.

⁸²BRIEF—China progressing drug-related patent laws, The Pharma Letter, 22 April 2020. <https://www.thepharmaletter.com/in-brief/brief-china-progressing-drug-related-patent-laws>.

⁸³Reddie & Grose LLP (2020) <https://www.reddie.co.uk/2020/01/23/what-does-the-us-china-trade-deal-mean-for-pharmaceutical-patent-holders/>.

⁸⁴Li and Tong (2018), pp. 270–280. See also <https://www.bilaterals.org/IMG/pdf/ssrn-id2850294.pdf>.

⁸⁵Reddie & Grose LLP (2020) <https://www.reddie.co.uk/2020/01/23/what-does-the-us-china-trade-deal-mean-for-pharmaceutical-patent-holders/>.

The originator can file infringement suits within this period and delay a generic drug's approval for up to 12 months.⁸⁶

2.9 *Russia*

Presently there is a positive trend towards the implementation of linkage in Russia. The Russian Civil Code provides a patent owner to file a claim to cease any activities that infringe the patent, including marketing approvals for the generics. Infringing activities include offering to sale, producing, storing, or distributing a general medicine. Threatening of infringement, obtaining marketing approvals, and registering maximum sales price provided that the relevant patent is used to manufacture the generic. The marketing authorization will be canceled if the generic is not presented in the Russian market for three or more years. If the generic drug is already in the market, the originators try to get a judgment from the court in their favor and refer the matter to the Ministry of Healthcare for canceling the marketing approval.

Russia is a member of the Eurasian Economic Union (EAEU) rules, which entered into force in 2017. The EAEU rules stipulate that the application for generic marketing approval must include information on patents covered and a statement to the effect that the medicine does not infringe on any parties' intellectual property rights. Submission of inaccurate information is a ground for revocation of marketing approval of the generics. From the year 2021, national legislation has to include all obligations under EAEU rules, including patent linkage. In April 2019, Russia launched state registration of drugs and pending applications before MoH.⁸⁷

In a 2018 Judgement by the Russian Intellectual Property Court dated 24 April 2018, it was held that preparations to launch a generic drug three years before the expiry of the patent constitutes a threat of patent infringement.⁸⁸ This decision overrules an earlier position that Russian law does not recognize generic drugs' registration during the patent validity term as an act of infringement (Art. 1359 (2) of the Russian Civil Code.⁸⁹

The MoH has prepared an amendment to the Law on Drugs, which states that "any company seeking to register a new drug (original or generic) shall indicate all patents and trademarks relevant for this new drug. Another obligation is to warrant that registration of this new drug would not infringe any third party's intellectual rights, under the risk of penalties."⁹⁰

⁸⁶Celebrating the Start of Patent Linkage, Taiwan Business TOPICS, 9 September 2019. <https://topics.amcham.com.tw/2019/09/celebrating-patent-linkage/>.

⁸⁷<https://grls.rosminzdrav.ru/StatementRUInfo.aspx>.

⁸⁸Case No. A41-85807/2016. <http://www.lidings.com/eng/legalupdates2?id=388>.

⁸⁹Decision of the Supreme Commercial Court in case No. A40-65668/2008, dated 06.16.2009.

⁹⁰Malakhov (2019).

2.10 Ukraine

In Ukraine, Article 9 of the Ukrainian Law on Medicines and Drugs, 1996⁹¹ provides that marketing approval of a generic drug before the expiration of the originator's drug patent may be considered a violation of the patent owner's rights. Medicinal products shall be allowed only after registration with the Ministry of Health (MoH).⁹² A generic applicant has to file a guarantee that the generic drug is not infringing any patented drugs. Patent infringement is a ground for the cancellation of marketing approval of generic drugs.

Article 34 of the Ukrainian Law on the Protection of Rights to Inventions⁹³ provides that the manufacturing and selling of generic drugs before the expiration of the originator drug's patent may be considered patent infringement. But it is not clear whether an application for marketing approval itself violates a patent or is regarded as an infringement. However, at the same time, a valid patent is not a guarantee for refusing a marketing approval for a generic drug by the MoH. As the patent linkage is not fully implemented in Ukraine, the originator patent owners have to monitor the marketing approvals and subsequently file patent infringement suits against generic drug applicants and cancel the marketing approval and issuance of an injunction.⁹⁴ It is also to note that in Ukraine, there is no bolar provision available in any legislation for the early production of the generic drug before the expiry of the patent term.

Ukrainian law provides that the applicant for marketing approval must submit a sample of medicine to state regulatory bodies as part of the marketing authorization procedure. Production of such a sample of the drug itself will also be considered as patent infringement without any difference, whether it was just a non-commercial medicine production or not.⁹⁵

The Ukrainian Supreme Court made vital observations on disputes between originator and generic drug manufacturers in *Merck Sharp & Dohme Corp v. Aurobindo Pharma Limited.*, and granted injunctions against the generic manufacturers.⁹⁶ The court of appeal clarified that state registration of the pharmaceutical, as well as any preparatory actions without the actual placing of the product on the market, are not included in the concept of "use" of a patented invention within the

⁹¹No. 123/96BP, 4 April 1996.

⁹²https://www.wto.org/english/thewto_e/acc_e/ukr_e/WTACCUKR139_LEG_8.pdf.

⁹³LAW OF UKRAINE on the Protection of Rights to Inventions and Utility Models https://ukrpatent.org/j_upload/file/law-special-1.pdf.

⁹⁴*H.Lundbeck A/S v. Farmak JSC*, <http://reyestr.court.gov.ua/Review/3683167>. In this case the patent holder, Lundbeck, brought a claim because Farmak started the procedure to prepare the launch of a generic medicine while the patent was still in force. The court issued an injunction against, inter alia, the production, sale and offering for sale and the launch of the marketing authorization process.

⁹⁵*H. Lundbeck A/S v Chemo Iberica, S.A.*, <http://www.reyestr.court.gov.ua/Review/10026637>.

⁹⁶Ukraine: Interim injunctions in pharma cases, Vasil Kisil & Partners. Lexology <https://www.lexology.com/library/detail.aspx?g=0eb0c844-233d-4988-9774-efffe9ebcabd>.

meaning of Article 28(2) of the Law of Ukrainian Law, “On Protection of Rights to Inventions and Utility Models.” The Supreme Court dismissed the Court of Appeal’s order and upheld the ruling of the court of the first instance that refused to prohibit Aurobindo pharma from placing the drug on Ukraine’s market.⁹⁷ Mostly the courts are in granting injunctions against marketing approval of generic medicines and favor originator companies.⁹⁸

2.11 Thailand

Presently there are no patent linkage laws applicable in Thailand. However, in 2017, Thailand constituted a committee to monitor various agencies, including the Food and Drug Administration (FDA) and 15 other governmental agencies. It establishes a clear linkage between agencies involved in the enforcement of IP, especially the Department of Intellectual Property (DIP) and FDA, indirectly.⁹⁹

The FDA imposed a condition that all applicants of a new drug must fill a form listing all existing patents. Section 80 is included in the draft 2018 amendment to the Drug Act 1967.¹⁰⁰ This is a mandatory requirement from generic drug manufacturers to find out possible infringement.¹⁰¹ Thailand wants to be part of the 11 member TPP agreement, but the discussions stalled due to the COVID-19 pandemic.¹⁰² The Pharmaceutical Affairs Act was amended and taken effect from 13 October 2019.¹⁰³ Amendment to Section 80 provides for a “new drug or a new traditional drug applicant would be required to include documents showing patent/petty patent rights (Patent Information) or rights related to traditional Thai medicinal wisdom for regulatory approval of a drug.”¹⁰⁴ This will formalize a system since 2008; the FDA has required that all applicants for a new drug fill out a form listing all of their

⁹⁷ Judgment dated 14 August 2018. (<http://reyestr.court.gov.ua/Review/75896089>).

⁹⁸ Polikarpov (2015). <http://patentblog.kluweriplaw.com/2015/02/19/bolar-provision-in-ukraine-fiction-or-reality/>.

⁹⁹ <https://www.tilleke.com/resources/ip-linkage-thai-government%E2%80%99s-efforts-connect-agencies>.

¹⁰⁰ Baker McKenzie, Thailand: Proposed Addition to Drug Act - Move Towards Patent Linkage Concept. <https://www.lexology.com/library/detail.aspx?g=f19da913-6e8d-4498-8d4e-8b5f53da695e>.

¹⁰¹ Bangkok Post (2017). <https://www.tilleke.com/resources/ip-linkage-thai-government%E2%80%99s-efforts-connect-agencies>.

¹⁰² Bangkok Post, February 17, 2020. <https://www.bangkokpost.com/business/1859454/thailand-to-decide-on-trade-pact-around-april-japan-minister>.

¹⁰³ Drug Act (No. 6), B.E. 2562 (AD 2019). <https://www.lexology.com/library/detail.aspx?g=8f66805c-64eb-49e1-87cc-25f6c716feb0>.

¹⁰⁴ Baker McKenzie, Thailand: Proposed Addition to Drug Act.

existing patents.¹⁰⁵ The Patent Act allows the patent owner to take criminal and civil actions against infringers. The penalty for infringement is not more than two years imprisonment or a fine up to THB 400,000.¹⁰⁶

2.12 Philippines

The Philippines removed the patent linkage system in 2006. The Government Order permits acceptance of product registration without verifying whether there is a relevant patent. However, the FDA shall comply with any court order. An originator cannot prevent a generic drug manufacturer from getting a Certificate of Product Registration (CPR). The innovator must file a civil, criminal, or administrative case and get an injunction against CPR issuance. The Intellectual Property Code provides provisions for patent infringement. Criminal action is available only for repeated infringers. Philippines will be affected by the RCEP agreement, which is pending for approval from India. Then patent linkage will be implemented throughout these countries.¹⁰⁷

2.13 Singapore

After entering a free trade agreement with the US and both countries, Singapore introduced a patent linkage system, and both countries implemented it from January 1, 2004.¹⁰⁸ The system allows the patent owners to monitor the generic drug marketing application and imposes mandatory disclosures.¹⁰⁹ Patent linkage provisions are incorporated in Regulation 23(2) of the Health Products (Therapeutic Products) Regulations 2016 ('TPR'). The Health Science Authority (HAS) of Singapore administers regulation on drug approval. Registration of any therapeutic product needs a declaration to the effect that no patent is infringed. The applicant must also declare that (1) the patent owner has given consent to the launch of the generic version; (2) the patent is invalid; or (3) the patent will not be infringed by acts relating to the therapeutic product.

¹⁰⁵ https://www.tilleke.com/sites/default/files/2017_Apr14_IP%20Linkage_The%20Thai%20Government%E2%80%99s%20Efforts%20to%20Connect%20Agencies.pdf.

¹⁰⁶ McKenzie (2019). <https://www.bakermckenzie.com/en/insight/publications/guides/global-guide-to-patent-linkage>.

¹⁰⁷ Mirandah (2012), p. 50. <https://www.lexology.com/library/detail.aspx?g=73ee9ee5-1873-457e-b24f-8af6e96721ff>.

¹⁰⁸ United States – Singapore Free Trade Agreement. <https://wits.worldbank.org/GPTAD/PDF/archive/US-Singapore.pdf>.

¹⁰⁹ <https://www.tilleke.com/resources/ip-linkage-thai-government%E2%80%99s-efforts-connect-agencies>.

Filing of the false information is an offense with a fine and imprisonment of up to 12 months. If a generic company applies for marketing approval in the last 18 months of the patent's life, to be granted after the patent period's expiry, the marketing approval process will continue. Upon notice to the patentee, the marketing approval can be stalled for 45 days (notice period). The HAS may register the therapeutic product without further notice to the patent's proprietor if no Order or Declaration has been made at the end of 30 months after the date of the application for the Order or Declaration. The patent holders get a 30-month stay of approval of any product license upon applying for the necessary Order or Declaration. This prolonged delay of up to 31.5 months in total leads to uncertainty among generic manufacturing seeking marketing approval and the patentee.¹¹⁰ A person who made a false declaration shall be liable for conviction to a fine of $\leq$ SGD 20,000 and/or imprisonment for a term $\leq$ 12 months. The result of marketing approval in such cases will depend upon the court decision.

In *AstraZeneca AB (SE) v. Sanofi-Aventis Singapore Pte. Ltd.*, the High Court discussed delaying originator drug makers' tactics.¹¹¹ This case was examined under the Medicines Act, which was replaced by the TPR, 2016. Sanofi has applied for marketing approval for film-coated tablets comprising rosuvastatin and a stabilizer. Sanofi declared that the product would not infringe AstraZeneca's Singapore Patent No.SG89993 (993), because of a different combination. AstraZeneca argued that its patents are infringed, and hence, a 30-month stay in the application process is applicable. Sanofi was forced to disclose its composition of their product under the court order. High Court observed that the 30 months' objective is to settle the dispute before the product enters the market. However, this provision may be misused for delaying the entry of drugs by the originators and, therefore, have the effect of delaying public access to competitors' products. The Court concluded that "By way of a parenthetical concluding observation, where a claim has serious consequences to the public and a defendant's legitimate business, as a matter of good practice, the plaintiff should be required to give proper particulars of its claim" to save a considerable amount of time, energy and expense.¹¹²

What kind of information could be disclosed to the patentee during marketing approval is also under discussion in *Millaneium Pharmaceuticals, Inc. v. Drug Houses of Australia Pte Ltd.*¹¹³ Millennium Pharmaceuticals owns two patents in Singapore nos. SG 151322 and SG 182998, which are the process for manufacturing bortezomib. Drug Houses of Australia (DHA) obtained marketing approval of bortezomib, an anti-cancer drug in Singapore. The declaration filed as a part of the marketing approval process was never made available, and Millenium was not

¹¹⁰30 months stay period and 45 days notice period.

¹¹¹[2013] SGHCR 7.

¹¹²*AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 <https://www.supremecourt.gov.sg/docs/default-source/module-document/judgement/2013-sghcr-7.pdf>.

¹¹³(2018) SGHC 149 (First Instance); Appeal (2019) SGCA 31.

served notice about the application and thus prevented from commencing litigation under the TPR.

Millennium argued before the High Court that failing to declare the patents and lack notice is in violation of laws, and the patents are infringed and a consequent injunction restraining DHA from infringing patents. The court held that generic companies must declare all patents which could be considered relevant to the product in question. The High Court sided with Millenium and confirmed that the defendant had made a misleading statement. In this case, generic companies would be compelled to disclose process patents formulation patents related to the generic to be granted marketing approval.¹¹⁴

Singapore provides data-exclusivity for five years from the date of the original marketing approval. HAS will not grant authorization for a generic drug based on the actual test data without the originator company's approval. Patent term extensions and adjustments are available in Singapore, similar to that of the US. Patent term adjustments are possible only due to a delay in prosecution by the Singapore Patent Office.

The patent linkage regime in Singapore is in favor of originator companies. The generic drug manufacturers have to inform the innovator of any possibility of infringing the patent, and consequent litigation prolongs the entry of generics in the market. Failure to inform about the possible patent infringement will lead to the cancellation of the marketing approval and even criminal sanctions.¹¹⁵

2.14 Malaysia

Presently, there is no patent linkage in Malaysia. The exclusive use of the patentee is protected under section 36 of the Patent Act 1983. The drug regulatory body has no power to contravene the rights of the patentee. The generic marketing approval cannot be considered as an excuse for infringement.

In March 2018, Malaysia signed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), and the agreement is entered into force on 30 December 2018. Chapter 18 of the CPTPP provides a patent linkage system. However, the CPTPP has not yet been ratified by Malaysia,¹¹⁶ and technically there is no patent linkage in Malaysia. However, the Drug Control Authority (DCA) monitors newly approved drugs when patent holders commence infringement

¹¹⁴ Khoo and Lucas (2020). <https://www.mondaq.com/patent/927960/patent-linkage-in-singapore-better-to-be-safe-than-sorry>.

¹¹⁵ Lexology (2020). <https://www.lexology.com/library/detail.aspx?g=3f5760db-39a8-47fd-8d86-95de83072e36>.

¹¹⁶ Trans-Pacific Partnership Agreement (TPP) & Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) <https://fta.miti.gov.my/index.php/pages/view/71#:~:text=Malaysia%20is%20still%20evaluating%20the,Prime%20Minister%20and%20his%20Cabinet>.

proceedings against marketers and manufacturers of generic medicines. However, according to Section 37(1A) of the Patent Act 1983, no action can be taken against the generic companies registering the drug, and no commercial activities in Malaysia before the patent expiry. Nevertheless, if the generic manufacturers manufacture the drug and stockpile, advertise, originators can file an “imminent infringement” suit against the company under Section 59(2) of the Patent Act. This provision is similar to that of the US, and the originators can sue the generic manufacturer before the expiry of the patent.

The originator companies can monitor the notifications published by the National Pharmaceutical Regulatory Agency (NPRA) related to a new drug product that has been approved. The legal proceeding can be commenced against the generic drug manufacturers those who infringe any patents. The generic companies can register their products during the validity of the patent. However, other than registration, no commercial activity is allowed. Evidence of patent infringement can be obtained through an Anton Piller Order.¹¹⁷ The court will issue such an order only when the originator producer *prima facie* case against the infringer.

There is no criminal punishment for infringements; only civil action can be initiated before the “IP High Court” bench. The remedies available are permanent injunction, impounding of the infringed products (Discovery Order), and compensation by way of damages.

In *Ranbaxy (M) Sdn. Bhd. v. El Du Pont Nemours and Co.*,¹¹⁸ the Court of Appeal of Malaysia upheld a decision of the High Court of Malaysia relating to patent infringement. The Generic manufacturer Ranbaxy argued that the regulatory approval granted by the National Pharmaceutical Control Board (NPCB) means that the manufacturing and sale of a patented pharmaceutical product are valid and not an infringement. The plaintiff obtained regulatory approval in Malaysia to manufacture and market a pharmaceutical drug known as COVANCE containing potassium losartan. The defendant alleged infringement of one of the claims. The court further held that the patent claim’s description sufficiently and adequately described or taught the invention and supported the invention, and there is sufficient disclosure to understand the patent. The Court of Appeal found that the appellant to have infringed the patent.¹¹⁹ The court rejected the argument of linking regulatory approval with the patent rights of originators in this case.¹²⁰ A study on the impact

¹¹⁷ An Anton Piller Order is a form of civil search warrant which allows the plaintiff to enter the defendant’s premises and conduct a search. It takes the name from the famous case of *Anton Piller KG v. Manufacturing Processes Ltd.*, [1976] 1 All. E.R. 779, [1976] Ch. 55, [1976] 2 W.L.R. 162, [1975] EWCA Civ 12.

¹¹⁸ 2011, 1 AMCR 857.

¹¹⁹ Court of Appeal upholds a drug-related patent infringement claim, International Law Office, 12 November 2012

<https://www.internationallawoffice.com/Newsletters/Intellectual-Property/Malaysia/Shook-Lin-Bok-Kuala-Lumpur/Court-of-Appeal-upholds-a-drug-related-patent-infringement-claim>.

¹²⁰ Pharmaceutical Association of Malaysia www.phama.org.my.

of patent linkage on Malaysia by Rafiq Idris reveals that patent linkage will increase Malaysia's drug cost.¹²¹

2.15 Vietnam

In Vietnam, also, there are no declared patent linkage provisions. Even though the Drug Administration of Vietnam (DAV) is notified about the potential infringement, a generic drug's marketing approval will not be stopped. The marketing approval will be withdrawn after a suit for infringement is successful. Usually, preliminary injunctions have not been granted in infringement cases.¹²² Article 126 of the Vietnam Intellectual Property Law, 2005 amended in 2009 and 2019. Using the patent for personal, non-commercial purposes, for research, evaluation, analysis, and testing, is not considered patent infringement under Article 125(2) of the IP Act. Article 13.4 of Circular 44/2014/TT-BYT, the DAV, is obligated to revoke the marketing approvals in case of any patent infringement. Drugs can be imported without any license or marketing approvals under "special import quota." A patentee can seek revocation of such quota on the strength of a conclusion of infringement from a competent body.

In 2015, the Ministry of Science and Technology (MOST) conducted a raid in a generic manufacturers facility in South Vietnam, on a complaint from an American patentee. The patentee was aware of the generic drug's entry in 2014 for treating diabetes and filed a possible patent infringement against the manufacturer who got a marketing approval. MOST seized hundreds of finished tablets and raw materials. A cease and desist order was also passed against the manufacturer, along with revoking marketing approvals. This case shows an effective administrative action from originator drug manufacturers during a valid patent period.¹²³

2.16 Indonesia

Presently there is no patent linkage system in Indonesia. In Indonesia, BPOM Regulation No. 3/2011 deals with the registration of drugs. It allows registration of generic drugs and issues distribution licenses, which will take effect only after the patent period expires. Criminal actions can be taken against the infringers, including search, seizure, and closing infringers' business. Infringement is punishable with

¹²¹Idris (2016), pp. 1672–1676.

¹²²Managing IP (2017). <https://www.managingip.com/article/b1kbpj5jsl30y6/vietnam-improving-pharmaceutical-ip-protection>.

¹²³Le and Mai (2015), pp. 57–58. https://www.tilleke.com/sites/default/files/2015_Apr_Pharma_Maze_Patent_Enforcement_Vietnam.pdf.

four years of imprisonment and a fine up to IDR 1 billion. The patent holder may file civil proceedings as well for damages.

2.17 *Jordan*

Marketing approval is not provided for pharmaceutical products during the period of patent validity. Since the WTO accession in 1999 was amended in 2001,¹²⁴ Jordan maintained a patent linkage system and prevented generics' registration corresponding to a patent. Before enacting the patent law in 1999, consistent with the TRIPs agreement, Jordan was a heaven of copycat drugs infringing patents.¹²⁵ In 2002, the Minister of Health clarified that there would be no acceptance of dossiers for generics' marketing approval during the patent period. An application for a new drug marketing approval will be accepted by the Ministry only if the new drug produced by the domestic manufacturer is "similar but not the same as a patented one."¹²⁶

2.18 *Mexico*

In Mexico, the Mexican Institute of Industrial Property (IMPI)¹²⁷ and the Federal Commission for Protection against Health Risks (COFEPRIS)¹²⁸ work together to avoid granting marketing approvals for allopathic drugs which may infringe a patent in force. IMPI established a system of publication of patents through special Gazette listing patents and their non-proprietary names (INN). The linkage system is established under Article 167 bis of the Health Supplies Regulation and Article 47 bis of the Industrial Property Regulations in 2003. An application for marketing approval to COFEPRIS relating to "substances or active ingredients" are obligated to indicate whether they are the patent holder or licensee of the existing patent.¹²⁹ If the applicant is not the patentee or the licensee, they must provide a declaration, under oath, that the application for marketing approval does not infringe the patent holder's rights. The COFEPRIS works with IMPI for ten days to determine the product's

¹²⁴ Jordan, Patents of Invention Law, Law No. 32 for the Year 19991 (and its amendment by: Temporary Law No. 71 for the Year 2001). <https://www.sabaip.com/wp-content/uploads/2018/04/Jordan-Patent-Law.pdf>.

¹²⁵ Armouti and Nsour (2018). <http://www.hjil.org/wp-content/uploads/Nsour-FINAL.pdf>.

¹²⁶ report.nat.gov.tw.

¹²⁷ <https://www.gob.mx/impi/>, accessed on September 30, 2020.

¹²⁸ <https://www.gob.mx/cofepris/>, accessed on September 30, 2020.

¹²⁹ By Jorge (2019).

https://www.southcentre.int/wp-content/uploads/2019/07/PB64_The-USMCA-must-be-amended-to-ensure-access-to-affordable-drugs-in-Mexico_EN-1.pdf.

patent status for a pending marketing application. If a patent is listed in the Gazette, the Ministry of Health has not provided marketing approval for a new product that would infringe the patent.¹³⁰

2.19 United Arab Emirates (UAE)

In UAE, Pharmaceutical patent registration is governed by Federal Law No. 17 of 2002 (as amended by Federal Law No. 31 of 2006) (Patent Law) and Ministry of Health Decree No. 404 of 2000 (Patent Resolution). The Drug Control Department (DCD) of the Ministry of Health (MOH) reviews applications for pharmaceuticals' marketing exclusivity under the Patent Resolution.¹³¹

Applications for generic drugs will be accepted 12 months before the expiry of UAE patent protection provided that the application does not contain any information relating to the patentee, which is protected under Article 36 of the TRIPS agreement.¹³²

The UAE Ministry of Health¹³³ Resolution provides that the Ministry deny marketing approval for a product that would infringe an existing patent in UAE or the country of import of that drug. The Ministry will either reject the application or keep abeyance of the application until the patent term expires. This system provided patent infringements by generic drugs infringing patents.¹³⁴

3 Patent Linkage Provisions in Regional and Bilateral Trade Agreements

3.1 CPTPP

The Trans-Pacific Partnership (TPP) agreement was dropped after the US refused to participate in the negotiations in 2017. TPP minus the US lead to the Comprehensive and Progressive Agreement for Trans-Pacific Agreement (CPTPP) agreement, a free trade agreement between 11 countries in the Asia-Pacific Region. The countries involved are New Zealand, Australia, Brunei Darussalam, Canada, Chile, Japan,

¹³⁰ Moeller IP, Patent Linkage in Mexico. <https://www.moellerip.com/patent-linkage-in-mexico/>.

¹³¹ <https://www.firstconsulting.com>.

¹³² Aljurf and Murray (2018). [https://content.next.westlaw.com/Document/I81997321b69811e698dc8b09b4f043e0/View/FullText.html?contextData=\(sc.Default\)&transitionType=Default](https://content.next.westlaw.com/Document/I81997321b69811e698dc8b09b4f043e0/View/FullText.html?contextData=(sc.Default)&transitionType=Default).

¹³³ United Arab Emirates Ministry of Health and Prevention, Health Legislation. <https://www.mohap.gov.ae/en/Aboutus/Pages/PublicHealthPolicies.aspx>.

¹³⁴ http://www.theglobalipcenter.com/wp-content/uploads/2018/02/United_Arab_Emirates.pdf.

Malaysia, Mexico, Peru, Singapore, and Viet Nam. Article 18.53 requires that the generic manufacturer notify the patent holder about the marketing of such a pharmaceutical product. The provision allows patent owners to intervene to prevent the marketing approval issuing and avoids the chance of infringing their patents.¹³⁵ CPTPP came into force for the first six countries, Canada, New Zealand, Australia, Japan, Mexico, and Singapore, on December 30, 2018. On January 14, 2019, it came to force for Viet Nam.¹³⁶ Canada, Australia, Japan, and Singapore have patent linkage provisions; others have to include provisions once they ratify the agreement. Peru signed the CPTPP in 2018 and agreed to implement the patent linkage provisions.

3.2 US – Peru FTA

The US-Peru Free Trade Agreement, which entered into force in 2009, Article 16.10.4, provides patent linkage. The generic drug will undergo a bioequivalence test before getting marketing approval. Notice to the patent holder is mandatory for getting marketing approval for the generic drug. The marketing approval will be deferred until the patent has expired, or sufficient time has to be given for adjudicating the dispute on the status of the patent. Un-authorized marketing of the product is prohibited before the expiry of the patent. Legislative decree of Peru 1075 imposed penalties and sanctions on a party deliberately provide false information to the regulatory authorities.¹³⁷

3.3 AUSFTA

The Australia-US Free Trade Agreement (AUSFTA) 2005 provides for patent linkage (Article 17.10.4 – IP Chapter). There are measures in the marketing approval process to prevent others from marketing a product during the patent term without the patent owner's consent. The owner will be informed of a marketing approval application.¹³⁸ In *Aktiebolaget Hassle v. Alphapharm Pty Limited.*, the High Court

¹³⁵ <https://www.mfat.govt.nz/assets/Trans-Pacific-Partnership/Text/18.-Intellectual-Property-Chapter.pdf>.

¹³⁶ <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/index.aspx?lang=eng>.

¹³⁷ Kiliç and Maybarduk (2011). https://www.citizen.org/wp-content/uploads/comparative_analysis_of_the_u.s._intellectual_property_proposal_and_peruvian_law.pdf.

¹³⁸ Australian Government, Australia–United States Free Trade Agreement, Chapter Seventeen – Intellectual Property Rights. <https://www.dfat.gov.au/about-us/publications/trade-investment/australia-united-states-free-trade-agreement/Pages/chapter-seventeen-intellectual-property-rights>.

of Australia observed that pharmaceutical manufacturers had employed many ways to delay the generic competition. It held that “the court should avoid creating fail-safe opportunities for unwarranted extensions of monopoly protection that are not sustained by law.”¹³⁹

3.4 RCEP

Negotiations for a Regional Comprehensive Economic Partnership (RCEP), as launched in 2013, involved ASEAN member states and six of its trading partners, including; China, India, Japan, Australia, New Zealand, and South Korea. In November 2019, India decided to pull out of the negotiations citing its internal economic concerns, mainly the trade deficit with China. The RCEP was signed in November 2020. The IP chapter does not provide for patent linkage. An earlier leaked draft of the RCEP agreement¹⁴⁰ had patent linkage provisions for “prevention of marketing pharmaceutical products infringing effective patent.”¹⁴¹ This provision sought to tie the marketing approval process to the patent validity, originators extension of the patent, and delay in the entry of generics. It would create a burden on the regulatory authorities to look into the validity of the patent. Presently, most of the countries do not have patent term extension provisions. But the draft included a patent extension provision both in Japan and South Korea’s drafts.¹⁴²

3.5 KOREA - US FTA

The U.S.-Korea Free Trade Agreement (KORUS FTA) entered into force on March 15, 2012.¹⁴³ Under Article 18.9.5 of the agreement provides that when a non-originator of a pharmaceutical product applies for marketing approval, the patent owner must be notified of the identity of the person making such a request. The government must make administrative arrangements to see that no marketing approvals will be granted without the patent owner’s consent. Patent linkage for biologics and generics was included in the Korean Pharmaceutical Affairs Act, amended in 2015 following obligations under the KORUS FTA. It is similar to that of the US provisions, provides for notice to the patent owner not less than

¹³⁹ *Aktiebolaget Hassle v Alphapharm Pty Ltd.*, 212 CLR 411, para 101. 2002.

¹⁴⁰ Weatherall (2016).

¹⁴¹ <https://www.bilaterals.org/IMG/pdf/ssm-id2850294.pdf>.

¹⁴² Bouchard et al. (2010), pp. 174–227.

¹⁴³ U.S. - Korea Free Trade Agreement. <https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta>.

180 days before the first marketing date of the bio-similar. Korea followed the US system as it is and is severely criticized in Korea.¹⁴⁴

4 Indian Scenario

India does not presently provide for patent linkage under its patent law. The Indian drug industry is one of the largest in the world, with 20 percent (value)¹⁴⁵ in all generics and accounts for 75 percent of the Indian market share.¹⁴⁶ The US is the prime destination of Indian generic exports. In 2008, the Department of Pharmaceuticals started a program in the name of “Jan Aushadhi” (medicine for people) shops to made available unbranded generic drugs available to the poor people in the country at a reasonable and affordable price. Until June 30, 2019, 5300+ “Pradhan Mantri Bhartiya Janaushadhi Kendras” are functional spread over 35 States/UTs of our country.¹⁴⁷ Under the umbrella of “Bureau of Pharma PSUs of India,” more than 900 drugs and 154 surgical & consumables covering almost all major therapeutic groups have been supplying.

The prime objective of Draft Pharmaceutical Policy, 2017¹⁴⁸ of India, declares, “making essential drugs accessible at affordable prices to the common masses.” To fulfill the policy objective, the Government has come out with a price regulation mechanism through the National List of Essential Medicines. The National Health Policy, 2017 also emphasizes affordability as one of the fundamental principles.¹⁴⁹ The policy’s goal is to “achieve the highest possible level of good health and well-being for all Indians through a preventive and promotive healthcare orientation in all developmental policies.” These policy objectives cannot be achieved without a vibrant generic drug industry.

The Government of India’s Pharma Vision 2020¹⁵⁰ aims to make India a global leader in end-to-end- drug manufacturing. The export of pharma products is expected to reach \$20 billion by 2020 and the total market to the tune of USD\$55 billion.¹⁵¹ India supplies 20 percent of the global generic drug demand.¹⁵² It is more

¹⁴⁴Laurenza (2015), pp. 439–442.

¹⁴⁵<http://www.uniindia.com/generic-drugs-holds-70-pc-market-share-in-pharmaceutical-sector-in-india/south/news/1512004.html>.

¹⁴⁶Indian Generic Drug Market Outlook 2020, September 2015. <https://www.ncos.com/Market-Analysis-Reports/Indian-Generic-Drug-Market-Outlook-2020-IM779.htm>.

¹⁴⁷<http://janaushadhi.gov.in/mesgceo.aspx>.

¹⁴⁸<http://www.indiaenvironmentportal.org.in/files/file/draft%20pharmaceutical%20policy%202017.pdf>.

¹⁴⁹<https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf>.

¹⁵⁰India Pharma 2020: Propelling access and acceptance, realising true potential <https://online.wsj.com/public/resources/documents/McKinseyPharma2020ExecutiveSummary.pdf>.

¹⁵¹Ibid.

¹⁵²Press Information Bureau (2018). <https://pib.gov.in/newsite/PrintRelease.aspx?relid=186696>.

important to note that Indian pharmaceutical firms supply over 80 percent of the antiretroviral drugs used internationally to combat AIDS (Acquired Immune Deficiency Syndrome). The Indian industry provides even 30 percent of the US generic drug market.¹⁵³ Any changes in the global and regional policies will severely affect the Indian generic industry. There is a direct correlation between generic drugs and price affordability. However, there is a conflict of interest between patented drug manufacturers and the generic drug industry, and allegation of patent infringements are common in many cases. It is alleged that the originator drug industry is charging exorbitant prices on their patented drugs, which is no match to their investments. In India, the Madras High Court in the famous *Novartis* case discussed this issue.¹⁵⁴

4.1 *Drugs and Cosmetics Act, 1940*

Rule 122E (Drugs & Cosmetics Rules) 1945 defines “new drug”. A generic drug has not been defined in the Act nor Rules. The Central Drugs Standards Control Organization (CDSCO) under the Directorate General of Health Services is responsible for the approval of drugs in India. The objective of the Act is to examine the safety and security of drugs that are manufactured and imported. There is no interlinkage between the Drugs and Cosmetics Act and Patent Act 2005. Grant of a patent by the Patent Controller General of India has no impact on whether or not marketing approval should be granted. Patents can be opposed by pre-grant [section 25(1)], and post-grant [section 25(1) (t)] opportunities, or even it can be canceled (Section 64). The Drugs Controller of India (DCGI) under the Drugs and Cosmetics Act, 1940, is the statutory authority to grant manufacturing and marketing approval. However, none of the legislations in India neither permits nor intends to provide patent linkage.

4.2 *Bristol Myers Squibb v. Hetero Drugs Ltd. – 2008*

The petitioner successfully got an ex-parte injunction against the Hyderabad-based Hetero Drugs, which effectively linked patent status with marketing approval of the generic version of the originator drug, in this case, Dasatinib, a cancer drug. The Delhi High Court granted an injunction against the defendant and restrained generic company from “manufacturing, selling, distributing advertising, exporting, offering for sale or in any manner dealing directly or indirectly in any product infringing the plaintiff’s patent...” The court also observed that the DCGI must see that such approvals are not infringing any patent. The court held that “It is expected that the

¹⁵³ <https://www.ibef.org/industry/pharmaceutical-india.aspx>.

¹⁵⁴ Raju (2009), pp. 7–32.

Drugs Controller while performing statutory functions will not allow any party to infringe any laws and if the drug for which the defendants have sought approval is in breach of the patent of the plaintiffs, the approval ought not to be granted to the defendant.” This judgment created unrest and concerns in the generic industry. Unfortunately, this is far beyond the court’s jurisdiction without adequately examining the Drugs and Cosmetics Act’s provisions about the mandate of the DCGI. It is not the duty of the DCGI to enforce the patent rights in India. Its mandate is to ensure the safety and quality of the drugs sold or imported into India. This will automatically stall India’s generics’ approval process during the patent term, which is a derogation from the bolar provision contained in Section 107A of the Patent Act.

There is no linkage in India, and neither the Patent Act nor the Drugs and Cosmetics Act has provisions for connecting this. The court tried to implement patent linkage, which is not envisaged, nor the legislature intended to include in the concerned laws during its drafting. The court has attempted to fill the gap, which is never existed. The costly originator medicines are a severe threat to needy patients in India. On one side, the foreign companies argue for patent linkage, and on the other hand, the generic companies and non-governmental organizations working in access to medicines are objecting to the patent linkage. This decision caused unrest in the well established generic industry in India. The court had delivered this judgment when the DCGI was not even a party to the dispute. Effectively this judgment made patent policing by the court without any legislative sanctions.

4.3 *Bayer - Cipla Case*

In *Bayer v. Cipla, Union of India and Others*, 2009,¹⁵⁵ the Supreme Court held that submission of clinical data for getting marketing approval is not an infringement of the originator. Bayer has filed a case against Cipla, an Indian generic manufacturer in the High Court of Delhi, alleging that “sorafenib,” is a spurious drug, which is an imitation of the originator patented drug “Sorafenib tosylate.” A single Judge of the court dismissed the petition in August 2009, rejecting Bayer’s argument that interfering drug agencies’ role in patent policing or enforcement is unacceptable. Bayer appealed before the Division Bench of the High Court, and the judgment was delivered by the court in February 2010,¹⁵⁶ upholding the position of the single judge in this case and refused to issue a restraint order against the grant of marketing approval to Cipla for its generic drug “Sorafenib.” Bayer filed a Special Leave Petition (SLP)¹⁵⁷ before the Supreme Court, which decides the case in December 2010, upholding the decision of the Delhi High Court.

¹⁵⁵ WP(C) No. 7833/2008.

¹⁵⁶ LPA 443/2009-9 February 2010.

¹⁵⁷ Special Leave to Appeal (CIVIL) No. 6540/2010.

It is interesting to know that Bayer argued that S.2 of the Drugs and Cosmetics Act (DCA) read with S.48 of the Patent Act provides for inbuilt provision for “patent linkage.” The marketing approval granted under S.2 shall not derogate any other legislation, i.e., Patent law S.48, patentee’s rights. Bayer argued that patent linkage could be inferred from the joint reading of Section 2 of the Drugs and Cosmetic Act and Section 48 of the Patent Act. On the other hand, Cipla clearly said that submitting information to the drug regulatory is not an infringement of the patent. The Drugs Controller, given the regulatory approval to Cipla based on the drug, was safe, effective, and not an act of “making, using, offering for sale, selling or importing” the petitioner’s patented product.¹⁵⁸ Section 107A(a) is known as the Indian “Bolar” provision, permits any drug manufacturer to experiment with any patented drug to generate data that could then be submitted to a drug control authority. The aim of the rule is that ensuring the immediate entry of generic drugs on patent expiration. “Spurious drug” is defined under section 17B of the Drugs Act, which does not include a generic version of any medicines. The court rejected Bayer’s argument that Rule 122B(1)(b) of the Drugs Rules, read with Form 44, and the data required (Appendix 1 to Schedule Y) intends patent linkage.

To suggest that patent linkage is established only because an entry in Form 44 asks the applicant to indicate the drug’s patent status is to misconstrue the provisions as they stand. A form in an appendix to a statutory rule (in this case, the DCR) cannot be understood contrary to the statute’s scheme. Court agreed with the respondent’s contention that the Drug Controller General of India’s (DCGI) office is not equipped to deal with patents’ validity. The office and functions of DCGI are governed under the Drugs and Cosmetics Act (DCA) and not under the Patents Act. The court observed that “spurious drugs” and “generic drugs” are two different concepts. The court found that patent linkage is a “TRIPs plus” obligation, and TRIPs do not deal with the concept of patent linkage.

The court concluded that patent linkage could not be read into the provisions of the Drugs and Cosmetics Act and Patent Act, and such systems are undesirable for the Indian context. Some of the other observations are very pertinent, as follows:

- Policing of patent rights is not the duty of the regulators.
- Patent rights are private rights, and they cannot be mix with public rights.
- Patent linkage will undermine the “Bolar” provision.
- Article 27 of the TRIPs Agreement requires that patents are made available without discrimination by the field of technology, patent linkage only specific to the pharmaceutical industry alone.

The Court elaborately discussed the objectives of the two legislations. Delhi High Court when dismissing the petition and imposed a cost of Rs. 6,75,000/- payable in equal shares to the Union of India and Cipla for vexatious and luxury litigation. The Supreme Court held that there is no room for patent linkage in India, and no such system could be encompassed into the existing Indian laws. Some scholars argue

¹⁵⁸ Mittal (2010), pp. 187–196.

that denial of patent linkage in India is a negative development, and the availability of life-saving drugs must be ensured through compulsory licenses, not through giving parallel approval to generic drug manufacturing by DCGI.

Access to life-saving drugs in developing countries is essential and an essential public interest topic in India. Adopting patent linkage, either legislatively or judicially, would severely affect the generic drug industry in India.

5 Conclusions

The objective of patent rights is to give incentives to the innovator for further research and development. This protection is for a limited period, 20 years, as fixed under the TRIPs agreement. Presently, 164 WTO members are subscribed to this agreement and obliged to implement at the domestic level since 1995. The protection of patent rights is inevitable to promote innovation in the pharmaceutical sector. At the same time, generic medicines also play a crucial role in pharmaceutical innovation, especially affordability and accessibility in developing and developed countries. But an inappropriate extension of the monopoly rights beyond the permitted period of 20 years must be considered an abuse of the patent system. Patent linkage is how the country allows linking marketing approval of the generic drug with the originator drug's patent status. The practice requires that generic companies applying for marketing approval must prove that they are not violating any valid patent. Under the arrangement, national regulatory authorities should prevent the registration and marketing of generic pharmaceuticals.

Originally, patent linkage introduced through the Hatch-Waxman Act 1984 in the US intended to encourage the manufacture of generic drugs without infringing any patents and to promote innovation in the pharmaceutical industry. However, there were no many takers of patent linkage provisions in other countries. The declared objective of the law is to facilitate the entry of generic drugs in the US market. But it is turned out to be a barrier for the generic companies to get regulatory approvals by filing an ANDA.

For the last 36 years, since the introduction of the patent linkage in the US, approximately 15 countries have adopted patent linkage provisions. Precisely, these provisions are pushed through regional or bilateral trade agreements by the US. There is no obligation under the TRIPs agreement to implement patent linkage. Originator companies argue that patent linkage is a rational means of ensuring patent rights and regulatory agencies not helping patent infringement. However, the objective of patent law and regulatory approvals are different, and their functions are dissimilar. Patent linkage is not mentioned in the TRIPs agreement at all. The US has made the patent linkage provision to create a second tier of protection for a patent monopoly. Patent rights are private rights and have to be enforced privately, and it cannot be implemented through government regulatory authorities.

The passive approach to free trade agreements and IP standard setting is evident. Most of the bilateral trade agreements include IP chapters. The TRIPs flexibilities are

breathing space for many developing and least developed countries, including India. Eroding these flexibilities will kill the golden goose who produces a significant chunk of the generic medicines for the developing world. Patent law requires enforcement of patent rights, but linkage inappropriately uses regulatory authorities to prevent infringement. These authorities may not be competent enough to determine patents' validity, and their mandates are different. Marketing regulatory procedures should not be subject to patent law. Only the courts can decide if the patent is infringed or not after adducing sufficient evidence, and it is not the duty nor expertise of the regulators to do it.

EU does not support the idea of patent linkage because it will adversely affect the implementation of the bolar provision to manufacture generics and biosimilars in advance of patent expiry. However, Patent term extension is already granted in the EU in the form of supplementary protection certificates (SPC) on a national basis. It is alleged that patent linkage's main objective is to extend the patent term by delaying generic medicines' entry. A centralized "Orange book" also is missing in the EU. In the *Italian* patent linkage provision case, the European Commission made it clear that patent linkage delays generic medicines' entry and a clear abuse of the EU regulatory system. It is also noticed that the originators are misusing the system by filing frivolous litigations against the generic industry. In 2007, 20 such cases were filed by the originators against generics and regulators in Portugal.¹⁵⁹

Canada amended the Patent Act in 2017 and introduced patent linkage provisions. The patent register is available similar to that of the "orange book" in the US. However, 180 days exclusivity period is absent for the generic manufacturers to challenge the patent. The statutory stay of generic is for 24 months less than the US period of 30 months.

Japan also implemented patent linkage in the country. The patent linkages are secured in two stages of regulatory approval and drug price listing. During the active patent period, no generic approvals will be granted. Patent extension up to five years is available.

Australia implemented a patent linkage through AUSFTA and consequent domestic legislation. South Korea also implemented patent linkage through the US – Korea Bilateral Free Trade Agreement. China effectively implemented linkage through the Chinese new Drug Administration Law in 2019. On 15th January 2020, China and the US signed an Economic and Trade Agreement to effectively implement patent linkage provisions. These provisions are similar to that of the US provisions under 35 U.S.C.§.154(b). Chinese Taipei (Taiwan) also added patent linkage provisions to the Pharmaceutical Affairs Act in 2019. The linkage provisions have close similarities with Chinese provisions.

Thailand effectively implemented patent linkage through "Drug Patent Approval Linkage" in 2019. Brunei, Singapore, New Zealand, and Chile signed the Trans-Pacific Partnership (TPP) in 2006, and patent linkage is introduced through this

¹⁵⁹ https://www.medicinesforeurope.com/wp-content/uploads/2009/06/EGA-IP_Barriers_web.pdf.

agreement. Singapore's judicial decisions made it clear that the courts favor more excellent protection to the patentees and already implemented patent linkage.

Even though Malaysia claims there is no patent linkage system, but it effectively implemented the CPTPP. The High Court and Court of Appeal of Malaysia held that the regulatory approval is nothing to do with any authorization to work on the patent. It means that in Malaysia, there is still room for the generic industry to get marketing approval.

It is interesting to note that regional trade agreements are taking the main stage in implementing the patent linkage provisions. AUSFTA and US-Peru FTA also have patent linkage provisions. Patent linkage provisions were also proposed in RCEP. These TRIPs-plus provisions could substantially increase generic medicines' costs in the countries and threaten access to essential drugs in most states.

There is no patent linkage in India so far, and the courts are made it clear that these two systems cannot be connected. Indian courts actively prevented patent linkage successfully. The Satwant Reddy Committee Report in 2006 suggested the gradual adoption of patent linkage in India. However, the Indian scenario is unique, and it is the warehouse of generic medicines. Nevertheless, the jurisprudence from India gives mixed feelings. In the *Bristol Myers Squibb* dispute, Delhi High Court held that the Drug Controller General, when granting marketing approval to the generic drug, must see that no valid patent is infringed.

On the other hand, in *Bayer v. Cipla*, the same Delhi High Court (another bench) held that patent rights are private rights, and patent rights policing is not the regulators' duty. Court also observed that linkage would undermine the bolar exemption granted under the TRIPs agreement. The dispute has gone to the Division Bench of the High Court and Supreme Court of India but confirmed the first ruling in favor of generic drugs in India.

However, the story in *Roche Ltd. & Anr. v. Cipla* is protracted litigation for almost a decade. Initially, the case was in favor of Cipla and lost the dispute up to the Supreme Court. Nevertheless, the second phase of the dispute was absolutely in favor of Roche. The case reached the Supreme Court in 2017 again and finally settled out of court.

Later, Roche filed a series of suits against Indian generic pharmaceutical companies like Glenmark Pharma, Reddy's Lab, Natco Pharma, Innova Pharma, Cipla, Aureate Healthcare, BDR Pharma, Oncare Lifesciences, Accuracare Pharmaceuticals, and Metrix. This shows the ill intentions of the originator companies for using litigation as a coercive measure in India.

Linking patent rights with regulatory and marketing approvals will have undesirable results in developing countries and have a negative effect on access to medicines in developing and least developed countries. Patent linkage introduces a significant obstacle to the timely availability of generic medicines. With this analysis of many countries' linkage provisions, it is clear that while some developed countries adopt these provisions, many do not, and imposing this in the developing countries like SAARC has an everlasting negative impact on the availability and accessibility of generic drugs. The comparative analysis of the patent regimes of different jurisdictions reveals no unanimity about patent linkage's importance or

utility. Enforcement of regional trade agreements with patent linkage provisions will change this scenario. Patent linkage provisions will be used as a restrictive measure upon drug development in the developing nations. This provision favors multinational pharmaceutical companies those who want to extend their patent term for maximum exploitation.

5.1 Suggestions

- TRIPS-plus obligations such as patent linkage should not be imposed on developing countries.
- Pre-emptive patent infringement suits only delay the entry of generic drugs, and such infringement suits may not be entertained by courts when public interest is involved.
- The role of licensing or regulatory authority and patent granting authority has to be separated. Regulatory officers cannot make an informed decision about the applicability of the patented drug and generic drugs. It must leave it to the court to decide the status.
- TRIPs plus patent linkage obligations should not be imposed on developing countries through regional trade agreements.
- Originator companies can very well file patent infringement suits even without patent linkage provisions and seek to enforce their private rights through courts.
- Patent infringement suits must be based on good faith. Hefty fines should be imposed on companies who file frivolous litigations to delay marketing approvals of generics.
- Administrative procedures may be simplified, transparent, and a national registry should list all new drug applications.
- Declaration of non-infringement can be taken for generic approvals to avoid unnecessary litigations.
- The originator company should disclose all its patent registrations for products/process while filing the regulatory approval.
- The patent application status should not be a ground for refusal, suspension, or prevention of marketing approvals.
- Patent linkage is an administrative procedure and nothing to do with the concept of patent protection. But some of the countries like Hungary made a provision for declaring the patent status when applying for marketing approval of the generic.
- Reject all efforts to introduce patent linkage in any form in developing countries.

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