Patent Linkage

7.1 Introduction

Patent linkage refers to the practice of national pharmaceutical registration authorities “linking” the granting of marketing approval – that is, the right to market a drug – with the patent status of an originator drug. The most common form of patent linkage prevents the relevant registration authority from granting marketing approval (i.e., registration of a generic drug for sale on the market) while there is a valid patent in place covering the drug. Without patent linkage, the registration authority confines its assessment to ascertaining whether the pharmaceutical under investigation is safe and effective. Simply stated, without patent linkage the patent status of a drug is irrelevant to the marketing approval process. The registration authority ensures the safety and efficacy of the drug at issue while the patent act sets out the rights of the patent holder.¹ Of course, the granting of marketing approval does not in any way override patent rights, and a generic pharmaceutical company would infringe those rights by bringing the drug to market while a valid patent remains in force.

¹ The Canadian Supreme Court noted the inherent tension between the regimes in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560, 2006 SCC 49 (Can.) at 12:

The [patent linkage regulations] lie at the intersection of two regulatory systems with sometimes conflicting objectives. First, is the law governing approval of new drugs, which seeks to ensure the safety and efficacy of new medications before they can be put on the market . . . [This] process culminates (if successful) in the issuance of [marketing approval] to an applicant manufacturer by the Minister of Health on the advice of his officials in the Therapeutic Products Directorate. The . . . objective is to encourage bringing safe and effective medicines to market to advance the nation’s health. The achievement of this objective is tempered by a second and to some extent overlapping regulatory system created by the Patent Act . . . Under that system, in exchange for disclosure to the public of an invention, including the invention of a medication, the innovator is given the exclusive right to its exploitation for a period of 20 years.
Patent linkage extends the monopoly selling period of an originator’s pharmaceutical in the market by a period equal to the time it takes for a generic manufacturer to gain regulatory approval, usually between six and twenty-four months in developed markets. This extension of monopoly protection beyond the statutory period of the patent is unique to pharmaceutical products (and agrochemicals), where the additional step of gaining approval from a regulatory authority is necessary prior to marketing the product.

The TRIPS Agreement does not mandate, prohibit or even mention patent linkage. This is not because the topic was unknown during the Uruguay Round. To the contrary, the negotiating parties were aware of but chose not to include such protection in the international agreement. By not mentioning the subject, TRIPS neither requires nor prohibits patent linkage. Patent linkage is therefore a “TRIPS-Plus” provision that is beyond the mandate and scope of the WTO. The one caveat to this is that certain newly acceded Members of the WTO agreed to patent linkage (and test data exclusivity) as part of their WTO accession package.

While the purpose of patent linkage is “to provide monopoly rights to private firms in exchange for new and innovative drugs while at the same time facilitating the timely entry of generic drugs,” public health advocates view it as simply a means for extending monopoly pricing, delaying access to more affordable medicines and extending market exclusivity.

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beyond that of the originating patent. Regardless of position, it is clear that patent linkage is representative of a novel evolution of the protective framework for pharmaceutical products that impacts on the availability and cost of medicines and related products.

The chapter proceeds as follows: Section 7.2 reviews the historical development of patent linkage in the United States and its spread to other jurisdictions. The section also analyses the situation in Hong Kong, which does not provide for patent linkage but has faced attempts by the industry to provide for the protection via judicial interpretation. Section 7.3 critically evaluates both the reasons why Hong Kong should not adopt patent linkage and considerations to take in case the jurisdiction ever contemplates its adoption. Section 7.4 concludes.

### 7.2 International Framework and Effect of Patent Linkage

#### 7.2.1 Domestic Legislation: The Beginnings

Patent linkage first appeared in the United States as part of the Hatch-Waxman Act (1984) as and part of a “grand bargain” intended to stimulate the development of innovation and availability of new medicines while at the same time facilitate the timely entry of generic competition into the market. Until the introduction of the Hatch-Waxman Act, the FDA essentially treated undisclosed clinical trial and other data submitted by a pharmaceutical company/originator in an application for marketing approval as a trade secret. With the FDA considering such information confidential, competitors did not have access to and therefore could not rely on the


data when seeking to obtain marketing approval for generic versions of the patented pharmaceutical. While this did not bar generic applicants from conducting their own clinical trials, the time and expense of conducting such duplicative trials as well as the unlikelihood of recouping the R&D costs (not to mention the ethical concerns of repeating trials to achieve an already established result) meant in reality that competitors could not apply for marketing approval during the term of patent protection. With undisclosed data submitted to the FDA treated as a trade secret, the originator received monopoly power not only for the life of the patent, but also for a period of time thereafter as generic competitors prepare and apply for marketing approval.

The Hatch-Waxman Act allowed for quicker and easier entry into the market as generic companies can “use” a patented drug in order to seek marketing approval from the FDA before the expiration of patent protection⁹ and without having to conduct clinical trials; instead, generic companies merely have to prove the bioequivalence – that is, potency and availability in the body – of their version of the pharmaceutical with the originator product.¹⁰ While the Act does not allow generic competition on the market during the term of patent protection, it does provide a financial sweetener to facilitate early entry of generics into the market by granting a generic company that successfully challenges the validity of a patent with its own six-month period of market exclusivity.¹¹

The Hatch-Waxman Act thus “linked” the patent status of a pharmaceutical (under the Patent Act) to marketing approval (under the Food, Drug, and Cosmetic Act).¹² Consequently, the FDA is now prohibited from granting marketing approval to a generic product so long as the originator company filing a New Drug Application (NDA) “listed” or “registered” at least one patent contained in the approved drug in the “Approved Drug Products with Therapeutic Equivalence” (commonly referred to as the “Orange Book”).¹³ While the FDA must now consider matters outside

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¹⁰ Generic manufacturers also have to demonstrate that the product was manufactured according to good manufacturing practice (GMP). See 21 CFR pt. 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals (2007).


the scope of the safety and efficacy of a pharmaceutical product, the burden is not great as the agency simply relies on the information provided in the NDA to restrain approval of generic drugs.

Under the Hatch-Waxman Act, an Abbreviated New Drug Application (ANDA) facilitates the entry of generics into the market. However, ANDA applicants must certify that (1) the drug has not been patented; (2) the patent has expired; (3) the generic drug will not be placed on the market until the patent expires or (4) the patent is not infringed on or is invalid. Referred to as paragraph I, II, III and IV certifications, the first three are straightforward, whereas a paragraph IV certification is more complex. In a paragraph IV certification the ANDA applicant must notify the innovator company of its filing and describe the reasons why the patent will not be infringed or is invalid or unenforceable. Following receipt of the notice, the originator is given forty-five days to file a lawsuit for infringement (submission of a paragraph IV certificate to the FDA triggers an infringement for purposes of the Federal Court). If the originator begins proceedings, FDA approval is stayed for thirty months. Thus, the mere claim that a valid patent exists on the drug triggers an automatic thirty-month injunction. When this period expires, the FDA can issue tentative marketing approval allowing an ANDA applicant to enter the market, yet most do not actually market the product until resolution of the litigation in order to avoid what could be significant liability for damages if the court ultimately finds a patent infringement.

The Hatch-Waxman Act undoubtedly facilitated the entry of generic pharmaceuticals into the market – generics accounted for 18.6 percent of drugs sold in the United States in 1984 and 86 percent in 2015. At the same time, the Act has allowed for gaming and anticompetitive behavior, and serious questions have been raised in regard to both the economic and health benefits of the “grand bargain.” Foremost among the concerns are the delayed introduction of generic competition resulting from multiple patents over one drug and the resulting evergreening strategies of the branded industry as well as agreements whereby potential generic applicants agree not to compete with the branded drug in exchange for monetary remuneration.14

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7.2.2 The Spread of Patent Linkage

In recent years, patent linkage has spread throughout the world. While most countries have introduced provisions as part of FTAs with the United States, some have adopted patent linkage without any external pressure. Patent linkage now exists in a diverse range of countries, including China, Japan, Mexico, South Korea, Singapore and Canada. In contrast, the EU considers patent linkage to be unlawful.\(^{15}\)

Patent linkage provisions are not uniformly drafted and implemented. While a simple version of patent linkage could merely require that an applicant for marketing approval notify the patent owner of the application or limit the filing of applications to a specific time period prior to the expiration of the relevant patent (i.e., within two years of the expiration of the patent), the more common version not only includes a notification requirement, but also precludes the granting of marketing approval for a generic drug while the relevant patent remains in force (i.e., until it expires


or is invalidated) or even outright prohibits a registration authority from reviewing an application while a patent remains in force. In some countries (including the United States), patent linkage requires the registration authority to maintain a registrar of patents and essentially verify the patent status of any drug during the registration process.

It also must be stressed that while patent linkage may have made sense in the US context as part of a “grand bargain,” most countries do not share the same legal and political framework. That is, context matters and what may be beneficial for one jurisdiction may be harmful for another with a different legal and social starting point. Perhaps the starkest contrast was the introduction of patent linkage in Canada. Canada adopted a model largely based on the US template in 1993 in anticipation of the coming into force of the NAFTA. In Canada, patent linkage did not facilitate the entry of generics into the market but rather effectively killed one of the most pro-generic regimes in the developed world. Until the introduction of patent linkage, Canada was home to a number of successful generic manufacturers and Canadians enjoyed some of the most affordable drug prices among the developed countries. While Canada’s

16 For instance, generic applicants will not receive marketing approval until all listed patents have expired or a generic manufacturer challenges the validity of the patents via a Notice of Allegation (NOA). If the generic manufacturer issues an NOA, the originator has forty-five days to apply for judicial review and request an “order of prohibition” preventing the Minister from issuing the NOC until the expiration of the patent expiry. This act triggers an automatic injunction of twenty-four months. See Patented Medicines (Notice of Compliance) Regulations SOR/1993–133, (Can) at §5(1)(a), (b), §5(3)(a) and §6(1).


18 Generic manufacturers also benefited from the establishment of provincial programs to reimburse the cost of medicines for certain groups of individuals and legislation that required the purchase of generic-equivalent medicines where available. See Smith, above n. 17.

19 Harrison, above n. 17, 547. See generally Thomas K. Fulda and Paul F. Dickens III, “Controlling the Cost of Drugs: The Canadian Experience” (1979) 1(2) Health Care Finance Review 55. It should be noted that Canada fundamentally altered the scheme in 1987 to
pharmaceutical patent regime had to be revised in light of the international obligations undertaken in the TRIPS Agreement – in that rules discriminating on the basis of field of technology and country of invention/manufacture needed to be revised – it was not required to introduce patent linkage. That requirement came from a commitment in the NAFTA.

It is therefore important to look at a number of jurisdictional-specific factors when evaluating the merits of patent linkage, including the policy intent that underpins the potential implementation of patent linkage, public health and economic policy, clarity of the relevant laws and regulations as well as the potential for judicial interpretation and other developments to influence or change the balance of competing health-related interests. Such factors apply equally when evaluating the success of existing regimes or desirability of patent linkage for jurisdictions where patent linkage does not currently exist.

7.2.3 Patent Linkage in Hong Kong

Hong Kong does not provide for patent linkage. In this regard, the authorities responsible for the granting of patents (Hong Kong Intellectual Property Department) are separate from the authorities responsible for the distribution and supply of pharmaceutical products (Hong Kong Pharmacy and Poisons Board). Moreover, the Drug Office of the Department of Health does not maintain a registrar of patented pharmaceuticals nor does it require applications for marketing approval to declare noninfringement of third parties’ patent rights. In fact, the Department of Health’s “Guidance Notes on Registration of Pharmaceutical Products/Substances” explicitly states that “the Pharmacy and introduce, inter alia, a ten-year period of protection against compulsory licenses to import a generic medicine and seven years’ protection against a compulsory license when the generic medicine would be manufactured in Canada. See Bill C-22 (1987) 35–36 Eliz. 2, ch. 41 (1987) amending the Patent Act, R.S.C. ch. P-4 (1970). See also Chromecek, above n. 17, 526–34; Brian W. Gray, “New Changes to the Patent System” (1988) 43 Food Drug Cosmetic Law Journal 641, 645–46. The changes came in the form of Bill C-91 (June 1992), which became law in February 1993.

20 Bouchard et al., above n. 6, 8.

Poisons Board does not take the factor of ‘patent right’ into consideration while deciding on an application for registration of a pharmaceutical product/substance.”

Hong Kong has considered and decided against the adoption of patent linkage on a number of occasions. In some instances, the government’s rejection of patent linkage is strongly worded:

The Administration does not consider that registration of pharmaceutical products should be linked to the issue of patent. The drug registration system is established for protection of public health. As there is already a well-established patent protection system in Hong Kong, the drug registration system should focus on the safety, efficacy and quality aspects. In this regard, it is noted that . . . patent linkage could delay the process of drug registration purely because of patent reasons, and hence affect the availability of drugs.

From the patent protection perspective, the proposed patent linkage would in effect give an extra patent protection for pharmaceutical products vis-à-vis other products which are equally protected under our Patents Ordinance. We see no strong reasons to provide for this given that the drug registration system has not deprived patent holders of any protection under the Patents Ordinance.


Despite such statements, the branded pharmaceutical industry continues to push for patent linkage through the courts. One strategy that has been used is to claim that while the application for marketing approval is not in itself an infringement, the fact that the applicant will have had to “work” or “use” the patent in formulating the application is an infringement. As the law regarding experimental use is vaguely drafted and legislation lacks an explicit “Bolar” provision, this argument has at times found favor with the courts. Another strategy that has found some success is arguing that an application for marketing approval during the period of patent protection indicates an intention to bring the drug to market – which would indeed result in an infringement. The patent holder will thus ask the court to require a declaration (under penalty of contempt of court) from the applicant that it will not to bring the drug to market until the expiration of the patent, the effect of which is to remove the ability of the applicant to challenge the validity of the patent through use.

A more direct attempt to introduce patent linkage through the courts was made in Abbott v. Pharmareg, where the court extended the period of patent protection beyond twenty years through an injunction and in doing so “linked” the period of injunction to the period of time taken to obtain regulatory approval. The dispute arose over a process patent for using the substance sibutramine in the manufacturing of a drug to treat obesity. In 2009, the court agreed with Abbott that the importation, stockpiling and sale of Obirax (a product that also contained sibutramine)

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25 For more discussion of the Bolar provision, see Chapter 5.
26 A similar attempt occurred in India, where Bristol-Myers Squibb secured an ex parte injunction; see Bristol-Myers Squibb Company & Ors v. Dr BPS Reddy & Ors, High Court of Delhi (19 December 2008) prohibiting the Drug Comptroller General of India (DCGI) from granting marketing approval for a generic version of Sprycel (dasatinib, used to treat chronic myeloid leukemia) before being overturned in Bayer Corporation and Ors v. Cipla of India (UCI) and Ors, High Court of Delhi (18 August 2009). The court cited several reasons for its decision: (i) the differing objectives between the Drugs Act (public health/safety) and Patents Act (private monopoly right), and the DCGI’s lack of expertise in adjudging patent validity; (ii) that it is not within the DCGI’s legislative mandate to determine patent status and validity; (iii) the negative health effects of reading patent linkage into the legislation, including on existing exceptions to patent rights and access to medicines; and (iv) the reticence in extending the boundaries of patents in the absence of clear parliamentary intent.
27 The decisions are: (1) the decision of the Court of First Instance of March 27, 2009, Abbott Gmbh & Co. Kg & Abbott Laboratories Limited v. Pharmareg Consulting Company Limited & Yin’s Trading Company Limited, HCA 166/2009; and (2) the decision of the Hong Kong High Court in Abbott Gmbh & Co. Kg & Anor v. Pharmareg Consulting Company Limited & Ors, HKCU 88, 8 January 2010.
infringed the patent and granted a pretrial injunction for the period until the patent expired (that is, until 21 November 2009).\(^\text{28}\)

Shortly before the expiration of the patent, Abbott sought an extension of the interlocutory injunction for an additional nine months beyond the expiry of the patent claiming that: “[s]ince the defendants have imported and used the infringing Obirax capsules to apply for registration...and the application process took nine months, such acts constituted infringement of the Hong Kong Patent.”\(^\text{29}\) In so doing, Abbott claimed the infringers derived an unfair benefit and were able to “steal a headstart by importing or causing to be imported into Hong Kong OBIRAX thus allowing it to register same with the Department of Health even before the Hong Kong Patent had expired.”\(^\text{30}\) Thus, despite the clear statements from the government in 2006 and 2007 that the law does not link marketing approval to the patent status of the pharmaceutical, Abbott requested in 2010 that registration while a patent was in place amounted to an unfair abuse of the system.

While the 2010 court extended the injunction, it did not consider whether using the patent in preparation for an application for marketing approval or even if the act of application for marketing approval itself amounted to patent infringement.\(^\text{31}\) Likewise, the 2009 decision only considered patent infringement by making, importing and stockpiling Obirax, but not its use for the purpose of obtaining marketing approval. Despite neither decision authoritatively rejecting the existence of patent linkage in Hong Kong, neither did the decisions create such a link. Thus, the situation remains somewhat unclear and uncertainty will persist until the government provides clear guidelines and legislative direction.

\(^{28}\) See Abbott v. Pharmareg, HCA 166/2009, above n. 27, paras. 41–65. The defendants questioned whether the patent at issue for the second medical use met the novelty requirement, but the court ultimately confirmed the “permissibility” of the “Swiss type” claim for a subsequent second medical use of sibutramine. See ibid., para. 37. See also Abbott v. Pharmareg, HKCU 88 (2010) above n. 27, para. 40(4).

\(^{29}\) Abbott v. Pharmareg, HKCU 88 (2010) above n. 27, para. 20. The complainants relied on the decisions in Dyson Appliances Ltd v. Hoover Ltd (No. 2) [2001] RPC 544 at 558–68 and in Generics BV v. Smith Kline & French Laboratories Ltd. [1997] RPC 801 for the proposition that the court will grant an injunction that extends beyond the patent expiration date in order to prevent an infringer from unfairly benefiting from any advantage sought to be obtained from acts of infringement committed during the term of the patent. Ibid., para. 19.

\(^{30}\) Ibid., para. 14.

\(^{31}\) The judge in the 2010 case stated: “[I] am of the view that it would not be proper for the court at this interlocutory stage to make any decision as the merits or otherwise of the case.” Ibid., para. 48.
7.3 Assessing the Merits and Options

The issues involving patent linkage are many, but revolve around two larger questions: first, whether patent linkage should be adopted, and second, if so, what form of patent linkage should be adopted.

7.3.1 Should Patent Linkage Be Adopted?

There are many reasons to oppose the adoption of patent linkage. Chief among them is that it delays the introduction of generic medicines onto the marketplace. Such delays bring about economic rents to the industry but do so at the expense of the government and consumer, both of whom are forced to pay higher prices for pharmaceuticals beyond the normal patent period. Patent linkage has been found to delay the entry of generic competition by three to five years in some markets, whereas the European Commission found delays of generic competition to the market in the EU of only seven months. Importantly, the European Commission also found the extended delay in generic competition occurs even when litigation determines the patent is invalid, which in many jurisdictions happens in the majority of instances.

Another reason to oppose patent linkage is that the potential economic and health benefits advocates claim it brings are questionable. On the contrary, studies in the United States and elsewhere often find patent linkage encourages firms to engage in anticompetitive behavior. One Canadian study led by Bouchard concludes that “rent-seeking behavior by brand-name pharmaceutical firms to leverage loopholes in the regime is passed on in the form of continued monopoly costs to the public.”

Moreover, while it is true that originators deserve and society relies on their ability to innovate, the simple fact is that there is no evidence that patent linkage boosts innovation. As pointed out throughout this book, the reality is that the branded-pharmaceutical industry is using multiple tools to delay generic competition in the marketplace, including by focusing on incremental inventions and marginally useful second use.

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32 Bouchard et al., above n. 6, 30. 33 EC Final Report, above n. 14, 8.
34 Ibid. 35 See above n. 14.
assessing the merits and options 195

Thus, far from stimulating innovation it appears that TRIPS-Plus provisions such as patent linkage discourage innovation while at the same time encourage market distortions and gamesmanship in an effort to maintain monopoly rights.

Yet another reason to oppose patent linkage is that it changes the nature of the regulatory regime by reversing the burden of proof. With patent linkage it is the generic applicant who must prove that it does not infringe on a patent, not for the owner of the private right to enforce the patent once infringement has occurred. This transforms a private property right that would normally depend on the owners’ willingness and desire to enforce into a public right that will be enforced by a governmental authority, a significant departure from traditional IP norms. That IPRs are private rights, not rights that are enforced by government, is often lost, if not obfuscated, by the branded pharmaceutical industry. For instance, AstraZeneca stated in the context of Canadian law that patent linkage – including presumably the need for an automatic injunction – was needed to “prevent infringement” from occurring and attempted to reiterate its point by stating that in Canada it was difficult to obtain an interlocutory injunction after the product has been placed on the market. These statements are an astonishing reversal of the traditional view of IP protection and enforcement and a brazen attempt at institutionalizing the burden shift to generic applicants and governmental authorities.

The “prevention of infringement” severely curtails the scope of activities of generic manufacturers and completely removes the right and opportunity for generic manufacturers to willingly and knowingly take the calculated risk of making and placing a product on the market without authorization from the patent owner either in the belief that the patent is invalid (and thus unenforceable) or because they have found a way to circumvent the claims set out in the patent. Such action is one of the cornerstones of the patent system, whereby a competitor can bring the product to market and, if sued for patent infringement, directly challenge the validity of the patent. Taking away this right of action, without a corresponding move making it easier to challenge a patent by administrative means, transforms the challengeable presumption of validity of the patent into a much more secure property right.

Finally, there does not appear to be any need for patent linkage in Hong Kong. With generic manufacturers usually not applying for marketing approval until well after the expiration of the patents on pharmaceuticals, it is unsurprising that a study conducted by Hollis and
Grootendorst found that the average period of market exclusivity for the branded drug in Hong Kong is greater than that in the United States, Canada and other markets. This information is valuable for the branded pharmaceutical industry, which has consistently lobbied the government for the introduction of patent linkage. Such efforts may be unnecessary, and political capital and resources are better directed to other issues. Of course, the economic losses to the public health system as a result of initiating patent linkage would also be more limited than elsewhere, as patent linkage would only delay marketing approval of generics applied for during the patent period and not affect the majority of generic entrants who only seek approval following the expiration of the patent term.

Hong Kong has thus far resisted the trend to adopt patent linkage. This should be maintained for the reasons outlined above. Moreover, given the judicial challenges outlined above, Hong Kong should strengthen the wording of the relevant regulations to ensure and make even clearer that an application for marketing approval does not amount to a patent infringement. This will send a strong signal that patent linkage is not part of the laws of Hong Kong.

7.3.2 If so, What Model?

While essentially all forms of patent linkage could possibly delay the introduction of generic competition into the marketplace, the differences between and among regimes matter. Some forms are particularly onerous, however, while others more balanced. But all of the regimes are based on the original US template. This seems oddly misplaced, as the policy intent and context of patent linkage in the United States may (and likely would) not be appropriate in another jurisdiction.

The policy intent in the United States was to stimulate the development of innovative drugs while at the same time facilitate the timely entry of generic competition to the marketplace. This purpose has been confirmed in the jurisprudence and also encompassed in a statement by Senator Orrin Hatch when the Hatch-Waxman Act came into force: “The public

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38 See, e.g., Mylan Pharmaceutical v. Bristol-Myers Squibb. 268 F.3 1323, at 1326.
receives the best of both worlds – cheaper drugs today and better drugs tomorrow.”

In 1993, Canada relied on essentially the same justification for introducing patent linkage. Likewise, throughout the AUSFTA negotiations patent linkage was promoted to Australians as necessary in order to stimulate investment into pharmaceutical R&D. Using the same justification for every jurisdiction seems rather bizarre – the formula used to encourage innovation and the development of drugs, or even to adequately secure an appropriate level of pharmaceutical patent enforcement or facilitate the entry of generic competition into the market, differs in every jurisdiction. Simply stated, what is missing from the sweeping justification for patent linkage is the appropriate comparator, or baseline legislation, from which each proposed measure should be judged. For instance, the pre-1984 law in the United States treated test data as a trade secret and clearly hampered the entry of generic competition into the market by providing a de facto extension of monopoly sales. The bargain reached to provide additional forms of protection in exchange for providing an easier pathway for generics to enter the market seemed appropriate to the United States.

In contrast, Canada historically encouraged generic competition and local production through a compulsory licensing regime for pharmaceuticals. Far from facilitating the timely entry of generic competition into the market, patent linkage has harmed the once-thriving domestic generic industry and led to an increase in the price of drugs. Moreover, with Canada’s limited domestic market (with a population of slightly more than 30 million) it is unlikely that patent linkage has increased innovation or R&D in the pharmaceutical sector. While the specifics of legislation in Australia, Mexico, South Korea and elsewhere differ, the broader point

39 Congressional Record – Senate at 23764 (10 August 1984), as cited in Bouchard et al., above n. 6, 10.
40 This can be seen in several reports and Regulatory Impact Analysis Statements. See, e.g., Canada Gazette vol. 140, no. 24, 17 June 2006: “The Government’s pharmaceutical patent policy seeks to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors.” See also Bouchard et al., above n. 6, 10–11 at note 48.
is that the baselines in these jurisdictions were more similar to Canada than the United States and therefore it is unlikely that patent linkage has stimulated R&D and innovation or even promoted quicker or easier entry of generic competition. Simply stated, the policy justification for patent linkage in the United States is not relevant to jurisdictions with different baselines.

That differences between jurisdictions matter is often lost on governments. With the cost of litigation high in every country, it is questionable whether patent linkage is beneficial to most nations. More specifically, patent linkage (in addition to other laws and regulations that attempt to balance enhanced protections for the rights holder with encouraging generic entry into the market) may work in larger markets – and in particular the United States, with approximately 40 percent of the worldwide market – where the value of entry into the marketplace is high. In smaller jurisdictions, the benefits of entry into the market are more limited, and the costs of litigating a patent claim mean the benefits are marginal or negative, even with exclusivity on offer for the first generic entrant (as offered in the United States and Korea). In such jurisdictions, the net result of patent linkage is to delay generic entry into the market, with higher overall costs to the healthcare system.

What this means is that jurisdictions seeking to adopt patent linkage should be careful in planning and operationalizing the regime. Decisions taken at this stage will determine the ultimate effect of patent linkage on the health system. For instance, which “patent(s)” should be “linked” – in other words, should the regime link only the first/“main” patent or should multiple patents be linked (and placed on the register if a registration system is in place)? Another pertinent question is what type of patent should qualify for linkage? These issues may be technical but are fundamental to the scope of patent linkage. To date governments have responded in very different ways, seemingly without any empirical data or justification for their decisions.

Governments do not seem to recognize the importance of the issue as it relates to health and economics – the allowance of multiple patents for inventions beyond the chemical entity and follow-on patents could lead to

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43 For instance, Singapore’s Medicines Act, 1975, Section 12A, is strikingly similar both procedurally and substantively to that of the United States, even including the thirty-month automatic injunction period. Singapore does not, however, maintain a patent register nor does it provide an incentive to generics to challenge the validity of the patent with a period of exclusivity granted to the first successful generic challenger.
patent holders gaming the system so as to delay the introduction of generic competition. Legislators in the United States recognized the potential negative effects of multiple patents, but nevertheless allowed multiple patents to be registered in the belief that delay to generic entry would be limited. This belief seems mistaken, as the Federal Trade Commission in 2002 found significant evidence of gaming to delay market entry of generic competition. In hindsight, it is not difficult to see how this occurred. In the United States (and Canada), courts have struggled to determine the appropriate threshold for what is a patent relevant to the marketed drug, and therefore eligible for registration, and when forced to do so have taken a broad approach to the term “relevance.” Meanwhile, marketing authorities (such as the FDA) are not experts in patent law and likewise take a broad approach to listing. The result is multiple patents registered for each drug. More worrying is the trend of pharmaceutical companies to produce a large amount of follow-on drugs, each with their own registerable patents, which have the effect of delaying entry of generic competition. For these reasons, allowing only the “main” patent(s) to be registered/linked is perhaps the single most important decision a jurisdiction can take to prevent the balance being tilted too far in favor of the originator and against entry of generic competition.

Limiting linkage to the “main” patent(s) is also a critical factor in determining the suitability of a patent register. With pharmaceutical patents being complex in nature, and with dozens of patents of some high-value drugs, it is questionable whether health authorities are qualified to determine the applicability of a patent to the product of a generic applicant. With courts even having difficulty in distinguishing true innovation worthy of patent protection from nonpatentable discoveries, it seems

47 Bouchard et al., above n. 6, 18; Bouchard et al., above n. 4; Hemphill and Lemley, above n. 14.
48 This point has been analyzed at length in the literature. See, e.g., Bouchard et al., above n. 6, 18; Bouchard, above n. 4.
49 See Hore, above n. 14; Avery, above n. 14. Alternatively, the Korean approach does not simply list all claimed patents but instead reviews the substance of the “Patent Listing Applications” to ensure that the relationship between the patent claims and approved product is legitimate. Such an approach could be a worthwhile model for others to follow in order to stem the flow of listings and litigation.
unrealistic to expect the health and marketing authorities to authenticate
the claims of the patentee. Hence, most jurisdictions maintaining a reg-
ister simply list all patents asserted by the original applicant. But such a
practice has been susceptible to gaming by the branded industry, which
constantly adds new patents and engages in “evergreening” so as to fore-
stall competition. For this reason, some public health advocates heavily
criticize the patent register.50

On the other hand, while a system that does not maintain a patent reg-
ister eases the burden on the authority responsible for granting market-
ing approval, it does make the verification process more difficult for the
generic applicant. A report commissioned by the Australian government
recommended the addition of a “transparency register” that would include
all patents owned by, or licensed to, the originator and relevant to the re-
levant drug so as to provide certainty for the generic applicant (who can
better identify which patents are registered) and limit infringement pro-
cedings to a finite number of patents per product (i.e., those registered).51
In this regard, the use of a patent register would discourage excessive liti-
gation, not only against generic applicants, but also against the marketing
authorities, so long as the patent owner was precluded from litigating over
patents not listed in the register. The intention behind the call for the cre-
ation of a register is therefore one of reducing costs and increasing trans-
parency and certainty to generic companies seeking to apply for marketing
approval, not a way to increase evergreening and delay the introduction
of generics onto the market.52

The Korean regime offers an innovative safeguard and perhaps can
serve as a model for others. While Korea makes use of a patent regis-
ter called the “Green List” whereby patent holders can list patents per-
taining to the substance, formulation, composition or medical use that

50 Brook Baker, “Ending Drug Registration Apartheid – Taming Data Exclusivity and
Bouchard et al., above n. 4, 174. See, contra, Commonwealth of Australia, “Pharmaceuti-
cal Patents Review Report 2013,” 149–54 (recommending the addition of a “transparency”
register in order to ease the burden on generic manufacturers in searching for relevant
patents on pharmaceutical products).

52 For instance, the report did not support several features common in other linkage regimes,
including “the introduction of the features . . . that provide for an automatic stay on generic
applications for regulatory approval, should an originator commence court proceedings,
nor those that prevent generic manufacturers from undertaking all the steps necessary to
prepare to enter the market upon expiry of the relevant patent, which includes obtaining
regulatory approval.” Ibid., 152–53.
assessing the merits and options 201
are “directly relevant” to the approved medical product,\textsuperscript{53} patents must be listed on the Green List \textit{before} the granting of regulatory approval. In this way, the system does not allow patent holders to add patents to the register in an attempt to forestall generic marketing approval or facilitate infringement claims.\textsuperscript{54} The Korean regime also adds an additional layer of protection in that its authorities vet applications instead of simply listing all patents identified by the originator. More specifically, the Korean Ministry of Food and Drug Safety reviews the substance of the “Patent Listing Applications” to ensure the relationship between the patent claims and approved product are legitimate and has the authority to change, narrow, edit and delist patent claims for failing to meet the requisite standard.\textsuperscript{55} While this increases complexity, it also serves to improve the quality of the register and limit litigation expenses. In contrast, a register that simply lists all patents identified by the originator and also allows litigation involving patents not listed in the register casts doubt on the usefulness of the register and begs the question of its purpose.

Another issue is whether and to what extent the right holder should be granted an automatic injunction on the initiation of infringement litigation. While automatic injunctions feature in US, Canadian and Singaporean regulations, they do not appear in other jurisdictions.\textsuperscript{56} Unsurprisingly, automatic injunctions have been shown to increase both the number of patents per high-value product and litigation. More specifically, pharmaceutical companies regularly abuse the registration process by listing a substantial number of patents not entirely related to the drug in the Orange Book, or even listing additional patents subsequent to an ANDA application from a generic company. Furthermore, the evidence points not only to increased litigation following the introduction of patent linkage, but also to an increase in the time it takes a generic to come to market.\textsuperscript{57} To this end, the EC Pharmaceutical Sector Final Report found

\textsuperscript{53} Enforcement Regulations of Korea Pharmaceutical Affairs Act, Decree No. 162 (18 October 2012), Article 30\textit{ter}, para. 3.

\textsuperscript{54} Ibid., at Article 30\textit{ter}.

\textsuperscript{55} Ibid., at Article 24, Paragraph 10; Article 30\textit{ter}, para. 5. The Korean scheme also applies to biologic medicines, whereas in the United States biologics are separately regulated.

\textsuperscript{56} For instance, in Canada the mere assertion of the originator that its patent is valid triggers an automatic injunction for a period of twenty-four months, or until the court has determined the issues (i.e., whether the generic applicant is “justified”) or the patent expired, whichever is earliest. Patented Medicines (Notice of Compliance) Regulations SOR/1993–133, (Can) at 7.

\textsuperscript{57} The Federal Court of Canada summarized the situation as follows: “by merely commencing the proceeding, the applicant obtains what is tantamount to an interlocutory injunction
that the mere threat of automatic injunctions sends a strong chilling effect to generic competitors, with data “illustrat[ing] the strength of the link between patent-related exchanges and patent litigation.”

The Korean and Australian regimes may be model approaches in that both limit the anticompetitive effects of the injunction. For instance, Korea does not issue automatic injunctions but rather will grant injunctions only where there is a “need to prevent significant damage.” Where granted, injunctions are limited to a twelve-month period from the date of notice (as opposed to thirty months in the United States). Moreover, and importantly, the injunction applies to generic sales, not to the granting of marketing approval. Likewise, Australia does provide for automatic injunctions but requires a patent holder seeking an interlocutory injunction to prevent the marketing of the generic pharmaceutical product to first notify the Australian Attorney-General (who shall be deemed a party in the proceedings) and obtain leave from a court. Where the application for an interlocutory injunction is unsuccessful, the court has the authority to order the originator to pay compensation to the applicant as well as to the federal and/or state/territory government in order to recoup losses to the Pharmaceutical Benefits Scheme (the government system for purchasing and distributing subsidized prescription medicines to Australians). Moreover, Australia has adopted rather progressive “anti-evergreening” measures that attempt to safeguard the system by providing that following a certification by a generic manufacturer the patent holder must certify that any infringement proceedings it initiates are being commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay, with penalties for a false or misleading certification of up to AU$10 million.

for up to 30 months without having satisfied any of the criteria a court would require before enjoining issuance of an NOC.” Bayer AG v. Canada (Minister of National Health and Welfare) (1993), 163 N.R. 183, at 189. See also Eli Lilly & Company v. Apotex Inc., 1997 CanLII 6216 (FCA); Merck Frosst Canada Inc. v. Apotex Inc., [1997] 2 FCR 561, 1997 CanLII 4806 (FCA). In the United States, issues can be resolved in one step and without the threat of damages. This is not the case in Canada, where summary proceedings under linkage regulations are often followed by infringement litigation. But automatic injunctions are not solely to blame for the increased delays. Perhaps more damaging to consumers are settlements between branded and generic firms that delay the introduction of generics into the market.

58 EC Final Report, above n. 14, para. 575.
60 Australia’s Therapeutic Goods Act 1989 (Cth), Section 26D.
61 See ibid., Section 26C. The term “reasonable prospects of success” is defined in s26C(4) as follows: “(a) the second person had reasonable grounds in all the circumstances known to
Yet another choice is whether to encourage generics to challenge patent validity by providing them incentives to do so. The United States provides such an inducement in the form of a 180-day period of exclusivity to the first generic to successfully challenge the validity of a patent.\(^\text{62}\) This serves to stimulate generic competition and effectively balances the automatic injunction provided to originators.\(^\text{63}\) Unlike the United States, most adherents to patent linkage do not balance the automatic injunction with any market-based incentives to generics. This may not matter, however, as the high cost of litigation may not warrant the potential returns on offer for generic applicants. Simply stated, few markets would be large enough to serve as an incentive for a generic to challenge a patent – and this is certainly the case in Hong Kong, where most generic manufacturers do not even apply for marketing approval until well after the expiration of the patents of the originator drug. For this reason, most do not provide the inducement to encourage generics to bring claims – yet the lack of this inducement coupled with an automatic injunction changes the balance originally struck in the US legislation in a manner that is against competition. Such is the case in Canada, which offers a twenty-four-month injunction without the corresponding benefit to generics.

Australia’s regulations could serve as a useful model to others seeking to balance the rights of the patent holder with larger societal benefits. Australia does not provide for automatic injunctions but instead requires the originator to seek an injunction through a court order, with penalties for failing to act in good faith.\(^\text{64}\)

Another, more systemic, issue is how patent linkage fits with experimental use provisions, particularly where a Bolar or regulatory review exception is written into legislation that expressly allows a generic to

\(^{62}\) By contrast, Korea provides for a twelve-month period of exclusivity to the first generic company to successfully challenge the validity of a patent if litigation commences before filing for marketing approval. See Korean FDA, above n. 59.

\(^{63}\) There is, however, some evidence to suggest that the exclusivity period is not working as designed. See Federal Trade Commission, above n. 14.

\(^{64}\) See also the approach taken by Korea, above nn. 53–55.
“use” the patented pharmaceutical for the purpose of preparing an application for marketing approval. In Canada – Pharmaceutical Patents, a WTO panel held that such practice fit within the perimeters of the exception clause (Article 30) of the TRIPS Agreement. To some commentators, linkage acts as a barrier to countries wishing to resort to the regulatory exception to Article 30. This may be an overstatement, as even in most patent linkage regimes a regulatory review exception allows a generic manufacturer to prepare and submit an application for marketing approval during the patent term; even if such application cannot be approved until the expiration of the patent, it can be approved immediately upon the expiration of the patent, and thus generic drugs would come to market several months before they would if no regulatory review exception was in place.

That being the case, many jurisdictions suffer from having vaguely worded and opaque regulatory review exceptions. For instance, Section 75(b) of the Hong Kong Patents Ordinance reads: “The rights conferred by a patent shall not extend to acts done for experimental purposes relating to the subject-matter of the relevant patented invention.” The lack of clarity and precision in the language could be interpreted narrowly or broadly and in this sense it is unclear whether, for instance, the term “experimental purposes” covers conducting tests using a patented subject matter as part of an application for the pharmaceutical regulatory approval. Thus, and despite the fact that a regulatory review exception is entirely consistent with the TRIPS Agreement, it remains unclear whether such conduct is consistent with Hong Kong patent law. The vagueness and undetermined nature of legislation such as this illuminates the need for patent linkage to be introduced in conjunction with a clearer and more tailored research exemption that specifically includes patent use to facilitate an application for regulatory review in order to minimize delays to the introduction of generic competition on expiration of the patent.

Even though the EU does not maintain a patent linkage regime, its Bolar exception can serve as a model in providing generic manufacturers with

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the comfort that “[c]onducting the necessary studies and trials with a view to the application [for marketing approval] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.” Such a statement would explicitly allow generic manufacturers to “use” the patent in conducting the necessary studies, tests and trials before making an application for marketing approval and, in certain jurisdictions, challenging the validity of the patent via certification (e.g., paragraph 4 certification in the US).

As importantly, care must be taken to ensure that patent linkage does not conflict with or impede compulsory licensing provisions and the right of countries to take measures to protect public health. This would seem to necessitate legislation that suspends patent linkage in the event that the government issues a compulsory license (for either domestic use or export under the waiver of Article 31 of the TRIPS Agreement). Failing to legislate in such a manner could result in a situation where an importer or local manufacturer cannot obtain marketing approval to sell the drug subject to the compulsory license in the jurisdiction. Somewhat surprisingly, such legislative protections are virtually unknown to this author in any jurisdiction.

67 See, e.g., European Directive 2004/27/EC (amending Directive 2001/83/EC) on the EU code relating to medicinal products for human use. The scope of the clause, however, remains unclear “due to the use of ambiguous, vague and broad terminology [and] diverging implementation in the various EU Member States.” See European Generic Medicines Association, above n. 15, at 23–24. One important area of divergent interpretation is whether the Bolar exception extends to the filing of an application for price and reimbursement listings. In one case, a Swedish court refused to find the Swedish Medical Products Agency liable for contributory infringement for its determination that a generic medicine (risperidone) was interchangeable with Risperdal, holding that the Medical Products Agency cannot determine the validity of patent rights and can only decide whether the medical demands for interchangeability have been met. See European Generic Medicines Association, above n. 15 at 24–25. In this regard, the “EC Pharmaceutical Sector Preliminary Report” stated: “As long as these activities are strictly necessary to prepare for [a marketing approval] application, they are not deemed to infringe patents rights . . . in view of the so-called Bolar provision [which] creates a safe harbor for certain tests and studies while the reference product is still patent-protected so as to enable the generic producer to apply for marketing authorisation once the eight-year period of data exclusivity granted to the [patent] holder . . . has elapsed.” See “EC Preliminary Report,” above n. 15, 260.


69 Of course, a manufacturer will in most countries not need marketing approval to produce a generic for export as the drug will not be released onto the domestic market.
A final issue to note is how to essentially engage in legal transplantation without oversights or mistakes. The legal transplantation process is not always entirely smooth. Most notably, Singapore faced issues regarding the cause of action in litigation. More specifically, while the US Patent Code statutorily provides that an ANDA submission is an infringement, Singapore simply added Section 12A to the Medicines Act in lieu of introducing an amendment to the Singapore Patents Act for the filing of an application for marketing approval as a new cause of action. This led to some confusion, and required the court in *AstraZeneca v. Sanofi-Aventis* to get slightly creative in holding that Section 12A of the Singapore Medicines Act, read together with the accompanying regulations, constitutes a cause of action separate and independent from a patent infringement action under the Patents Act.

In the case, Sanofi-Aventis applied to the Health Sciences Authority under Section 12A of the Singapore Medicines Act for marketing/licensing approval to import a cholesterol-reducing drug into Singapore despite the fact that at least one patent on the drug was held by AstraZeneca. Sanofi-Aventis served a Notice to Proprietor of Patent on AstraZeneca stating the reasons why it did not believe its drug infringed AstraZeneca’s patent. AstraZeneca duly commenced an action against Sanofi for a declaration of patent infringement if Sanofi were to import the products into Singapore. Sanofi-Aventis responded by seeking to strike out AstraZeneca’s action for a declaration of infringement on the ground that the action was frivolous, vexatious or an abuse of process of the court, since AstraZeneca failed to allege any instance of a past act of infringement in its claim. The court agreed with AstraZeneca that the responsive action is infringement not pursuant not to the Patents Act, but rather to Section 12A of the Medicines Act, which when read with other regulations forms a separate cause of action for which a patent holder can seek a declaration of infringement. Thus, the court did not agree with Sanofi-Aventis that Section 12A of the Medicines Act merely provides notification

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71 Ibid., at 35 (stating that “section 12A of the Medicines Act, read with its accompanying subsidiary legislation, contemplates a cause of action separate and independent from a patent infringement action under the Patents Act”). In so doing, the court rejected the arguments from Sanofi-Aventis (1) that Section 12A did not provide for a cause of action separate and independent from a patent infringement action under the Patents Act, and (2) correspondingly, that the Patents Act only deals with actual infringements and there is no separate mechanism provided for threatened infringements.
to inform the patent holder of an application for marketing/licensing approval relating to a patented product, but does not provide the patent holder with a right or cause of action to commence infringement proceedings.

The merits of patent linkage for most jurisdictions remain questionable – this is especially so for countries without any significant pharmaceutical industry. In every case, countries considering the adoption of patent linkage should take these general principles and “best practices” guidelines into consideration:

- Patent linkage should not forestall the development of generic competition or unduly delay an application for marketing approval.
- Patent linkage should not prohibit a generic manufacturer from challenging the validity of a pharmaceutical patent. Likewise, the grant of marketing approval should not be a defense to any action for infringement. Where patent linkage does delay the registration of a generic product, marketing approval should take effect on the day the patent expires or is invalidated.
- Patent linkage should apply only to patents involving the primary active ingredient(s) and not to compositions, dosage, new use and process patents.
- When a country uses a patent register, patent claims attempting to halt generic marketing approval should be limited to patents listed on the register at the time of the application for marketing approval.
- Regulations should not allow for automatic injunctions following a claim for patent infringement, but rather should only be granted after the plaintiff has made a prima facie case that the patent in question is valid. In any event, requiring a mandatory notice provision whereby a generic applicant must inform the patent holder of its application should provide enough time to allow the latter to determine whether it should initiate an infringement proceeding (as opposed to presuming the validity of the patent).
- Where automatic injunctions are granted, an exclusivity prize should exist for the first generic to successfully challenge the validity of the patent.
- As a matter of expediency, efficiency and legal harmonization, all claims involving marketing approval and patent infringement should be heard in a single forum, so far as possible.
- Attempts to prevent or delay generic competition through payments and other inducements from the innovator company should be illegal, whether through competition law or otherwise.
7.4 Conclusion

This chapter reviewed the historical development of patent linkage, questioned the necessity and desirability of patent linkage and highlighted the fact that the context, contours and effects of patent linkage differ between jurisdictions.

Patent linkage is not required by the international IP framework. Jurisdictions that choose to adopt patent linkage do so voluntarily, even if it is included as an FTA obligation. While patent linkage regimes have presumably all been designed to suit the particulars of the differing jurisdictions, there is little evidence that any of the systems reduces costs, increases access to medicines or promotes innovation. Perhaps the most worrying part of patent linkage is that despite almost all the empirical evidence suggesting it has negative health and economic effects on a country, only one country is considering its removal and more countries are adopting it as law. As more countries adopt patent linkage, empirical evidence on the effect of the various forms of patent linkage should also grow. If used wisely, such evidence can form the basis of a tardy but informed debate on the benefits and detriments of patent linkage.

To this end, Hong Kong and other governments must think carefully before adopting a regime of patent linkage, and ensure its introduction follows a systemic review that takes into account policy priorities and objectives and fully accounts for all potential costs. This is, of course, what occurred when the United States introduced patent linkage in 1984 as part of a broad law aimed at balancing promotion of innovation and safeguarding public interests, including through the early introduction of generic competition in the marketplace.

Any review of patent linkage would necessitate an evaluation not only of the economic benefits/costs and potential models and choices (e.g., a patent registry, automatic injunctions, exclusive marketing periods for the first generic to challenge, penalties for frivolous claims, etc.), but also of the basic framework, including how patent linkage intersects with other patent and relevant regulatory laws. Foremost among such issues is the relationship between patent linkage and the regulatory review exception. In Hong Kong and a number of other jurisdictions, the regulatory review exception is vaguely worded and ill-defined. Introduction of patent linkage without a more precisely worded research exemption could create disharmony within the law, as would provisions that conflict with or impede compulsory licensing.

If Hong Kong does consider the adoption of patent linkage – or, more likely, agrees to do so in an FTA – the patent linkage regimes in Australia
and South Korea should serve as a model. Both regimes adopted patent linkage as part of FTAs with the United States but tailored the regime to their own needs – and while it is premature to call these systems a success, at first instance the systems appear to have more effectively balanced the interests of the branded industry, generic interests and consumer interests than other jurisdictions. Unfortunately, these countries are in the minority. Most regimes adopt patent linkage on the basis of no evidence and implement a version that closely resembles the US regime.

Hong Kong should resist temptation to adopt patent linkage, but if it does it should learn from the experiences of others and ensure better and more precise drafting to negate some of the more undesirable aspects of patent linkage.