4.1 Introduction

The availability of patent protection is essential to the innovative pharmaceutical industry as it provides incentives to engage in the R&D of new products. In order to encourage and reward innovation and the advancement of science, patents provide the inventor with the exclusive right to prevent third parties from making, using, offering for sale, selling or importing for these purposes the patented product or process. Such rights are fundamental to the proper functioning of a patent regime and are entrenched in Article 28 of the TRIPS Agreement. To safeguard these rights, Article 33 of the TRIPS Agreement requires that Members grant patent protection for a period of at least twenty years from the date of the patent application, this being generally in line with the term of protection granted by large industrialized countries prior to the advent of the Agreement.\(^1\) The idea behind the set period of market exclusivity is obviously to allow inventors to recoup R&D costs and profit from the invention – thereby giving the incentive for continued creation and scientific advancement. While the patent term is ordinarily twenty years from the date of filing a patent application, in regard to pharmaceuticals the effective patent term\(^2\) is significantly shorter due to delay resulting in the granting of the patent and/or from the health authorities in granting marketing approval for the pharmaceutical product. In fact, it takes on average between eight and twelve years to fulfill the requirements

\(^1\) The TRIPS Agreement uses wording similar to that of Article 63.1 of the EPC. Other countries, including the United States and Canada, previously had provided protection for a period of seventeen years from the date of the grant.

\(^2\) “Effective patent term” means the period from the date of approval of the product until the original expiration date of the patent.
necessary to gain marketing approval, meaning the effective patent term is on average eight to twelve years.³

The system of patent term extension (PTE) serves to compensate pharmaceutical companies/inventors for the loss during the period of regulatory delay. The PTE system is not explicitly recognized in the multilateral treaties such as the TRIPS Agreement or the Paris Convention;⁴ instead, countries have introduced PTE on their own accord, and, more recently, PTEs have been included as part of IP obligations in FTAs. The most notable proponents of PTEs are the United States and the EU, both of which were earlier adopters of the system (United States in 1984 and the EU in 1992) and now export it to other counties via trade agreements.⁵ Regionally, most of the more advanced economies have introduced PTE, including Australia,⁶ Japan,⁷ Singapore,⁸ South Korea⁹ and Taiwan.¹⁰ The

⁴ It should be noted that Article 5 bis of Paris Convention contains a provision on patent restoration; however, it merely addresses the failure of the timely payment of fees for the maintenance of patent rights. Likewise, Article 11 of the WIPO Patent Law Treaty of 2000 provides relief in respect of time limits regarding an application for a patent. See WIPO, Patent Law Treaty, www.wipo.int/treaties/en/ip/plt/.
⁶ Australia attempts to provide pharmaceutical patents with an effective term of fifteen years. More specifically, Section 70 of Patent Act allows for applications for one PTE (to be made within six months of the date of the patent or marketing approval, whichever is later) where at least five years has elapsed between the period beginning on the date the patent was granted and ending on the first regulatory approval date for the substance and for those products where the term of patent has not been previously extended. The term of extension is equal to the period beginning on the date of the patent and ending on the first regulatory approval date of said pharmaceutical, reduced by five years, and not exceeding five years. See Articles 70, 71 and 77 of the Patent Act 1990 No. 83, 1990 (amended as of 2017), available from the Australian Government's Federal Register of legislation, www.legislation.gov.au/Details/C2017C00045, accessed 8 March 2017.
structure of PTE differs among its adherents, but the intention behind PTE is shared – to counteract patent term erosion owing to regulatory delays as well as the expensive, complicated and lengthy premarketing approval testing necessary in order to bring a new pharmaceutical product to market.

On the one hand, this makes sense as the precious twenty-year patent clock begins not with the grant of the patent or of marketing approval but on the filing of the patent. Delays in the granting of a patent or marketing approval can significantly undercut the profits of a pharmaceutical product and reduce the incentive of the industry to invest in new medicines. On the other hand, issues involving affordability and accessibility to medicines mean that granting a PTE raises public health concerns. This tension between industry and wider community health concerns leads to the inevitable problem regarding how to reconcile the private or commercial interests of pharmaceutical industry with the public interests of consumers and patients. For this reason, the PTE system is not without criticism.

Hong Kong does not currently provide for PTE. This chapter seeks to ascertain whether Hong Kong should adopt PTE as it moves to a patent examination system. The chapter first briefly reviews the patent term restoration system in the United States and the supplementary protection certificate (SPC) in the EU and the incorporation of PTE into FTAs. The

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8 In line with the US-Singapore FTA, Singapore introduced PTE in June 2004, with Article 36A of the Singapore Patent Act granting a PTE for not more than five years where (a) there was an unreasonable delay in granting the patent; (b) where the patent was granted on the basis of prescribed information relating to a corresponding application, there was an unreasonable delay in the issuance/grant of the corresponding application, and the term of the corresponding application has been extended as a result of the delay; and (c) for a pharmaceutical product, there was an unreasonable curtailment of the opportunity to exploit the patent due to the process of obtaining marketing approval for a pioneering pharmaceutical product, and the term of the patent has not previously been extended because of the aforementioned delays. See Patent Act (Chapter 221) (Original Enactment: Act 21 of 1994), revised edition of 2005, https://goo.gl/FEj45a, accessed 8 March 2017.

9 South Korea allows for a PTE for up to five years for delays in marketing approval as well as an extension for delays in the patent registration of over four years from the date of filing or three years from the examination request. See Patent Act, Act No. 950, 31 December 1961, Art. 89(1), amended by Act No. 11117, Dec. 2, 2011; Patent Act, Art. 92–2, added by Act No. 11117, 2 December 2011, respectively.

US and EU systems have been selected for review as both reflect typical systems of PTE for pharmaceutical products currently in operation and have served as a model in FTAs. Next, the chapter will review how the United States and EU have incorporated PTE provisions into FTAs. Having surveyed the current framework, Section 4.3 then discusses whether Hong Kong should adopt PTE and, if so, recommends some general principles for the jurisdiction to follow when crafting its PTE regime. Section 4.4 concludes.

4.2 Patent Term Extensions for Pharmaceutical Products: The United States and the EU

This section will briefly describe the rules and mechanism established in the United States and EU for the extension of patent term beyond the normal twenty-year period. The United States and EU are used as examples here as they represent the most widely disseminated models of PTEs for pharmaceutical products and have been replicated by numerous other countries.

4.2.1 The US Regime for Patent Term Extensions

The US patent system has several mechanisms available for adjusting the patent term. Most prominent among them are an adjustment due to delays in the review process by the Patent and Trademark Office (PTO) and for delays in the regulatory review process for marketing approval by the Food and Drug Administration (FDA). The United States provides for different and separate provisions regulating these two types of PTE.

Patent Term Extension for Delays at the Patent Office

Prior to the TRIPS Agreement, the United States granted a term of patent protection for a period of seventeen years from the date of the issuance of the patent. With the enactment of the Uruguay Round Agreement Act, the United States amended the patent term to twenty years from the date of filing in order to comply with obligations under the TRIPS Agreement. As the exact period of patent protection is not preset, but rather depends on the length of time taken by the PTO in examining the patent, patent

owners are uncertain about the exact periods of effective patent term. This concern is exacerbated in relation to pharmaceuticals, where a patent must be applied for early in the R&D process, and often before stage 2 and stage 3 clinical trials.

In response to industry concern regarding the unpredictability of effective patent term, the Patent Term Guarantee Act (1999) provides for an adjustment of patent term in order to compensate the rights holder for delays caused by the PTO’s review of patent application. More specifically, Section 154(b) provides for three types of delays that could trigger an adjustment of patent term.\(^\text{12}\) The first delay is the failure of the PTO to take certain actions by specified deadlines, such as failure to notify or respond to a reply within specific periods of time.\(^\text{13}\) When such delay occurs, Section 154(b) provides that the term of the patent shall be extended one day for each day after the end of specified period until the action prescribed is taken. Second, if the PTO fails to issue a patent within three years of the actual filing date of the application, the term of the patent shall be extended one day for each day after the end of that three-year period until the patent is issued.\(^\text{14}\) Third, a one-day adjustment is added to the patent term for each day that the patent application is delayed due to the pendency of derivation proceedings, secrecy orders and successful appeals.\(^\text{15}\)

The adjustment periods are cumulative, and the law does not provide a ceiling on the maximum amount of time that can be added to the patent term.\(^\text{16}\) Moreover, the periods of adjustment are automatically determined by the PTO – meaning the patent owner need not request an extension,\(^\text{17}\) but the applicant does have the opportunity to request reconsideration of


\(^{13}\) 35 USC 154 (b)(1)(A), above n. 11. \(^{14}\) 35 USC 154 (b)(1)(B), above n. 11.

\(^{15}\) 35 USC 154 (b)(1)(C), above n. 11.

\(^{16}\) However, the periods of adjustment shall be reduced by a period equal to the time during which the applicant failed to engage in reasonable efforts to conclude the prosecution of the application. See 35 USC 154(2)(C)(i). With respect to the three-year pendency delay (second type), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude prosecution or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice was given or mailed to the applicant. See 35 USC 154(2)(C)(ii), above n. 11.

\(^{17}\) See 35 USC 154(3)(B)(i), above n. 11.
the adjusted patent term and even to appeal the PTO’s adjustment determination to the federal court.18

Patent Term Extensions for Delays in Marketing Approval

The United States provides an alternative avenue for PTE available only to pharmaceutical products, medical devices and other products subject to regulatory review by the FDA under the Drug Price Competition and Patent Term Restoration Act of 1984 (also called the “Hatch-Waxman Act”). The Hatch-Waxman Act aims to balance the incentive for pharmaceutical innovations with access to new drugs. In essence, the Hatch-Waxman Act resulted from a “grand bargain” that facilitated the early introduction of generic pharmaceuticals into the marketplace in exchange for providing, inter alia, inventor pharmaceutical companies with the possibility of a PTE to compensate for the time taken by clinical trials and the regulatory review process necessary in order to obtain marketing approval.

Patents eligible for PTE include patents for products as well as methods for using or manufacturing products.19 The PTO has set out clear regulations regarding an extension for a pharmaceutical patent, which include:

(a) the patent must be eligible to extension, namely, the patent claims a product or a method of using or manufacturing a product;

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18 See 35 USC 154(3)(B)(ii) and 35 USC 154(4), above n. 11.
19 The term “product” includes a drug product, any medical device, food additive or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act. See 35 USC 156 – Extension of Patent Term, www.gpo.gov/fdsys/granule/USCODE-2011-title35/USCODE-2011-title35-partII-chap14-sec156, accessed 8 March 2017, at (f)(1). The term “drug product” means the active ingredient of a new human drug, antibiotic drug, or human biological product including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient, or the active ingredient of a new animal drug or veterinary biological product that is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site-specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. See 37 CFR 1.710 – Patents subject to extension of the patent term, www.gpo.gov/fdsys/pkg/CFR-2016-title37-vol1/pdf/CFR-2016-title37-vol1-sec1-710.pdf, accessed 8 March 2017. See also 35 USC 156 (f)(1)–(2). The interpretation of “product” has led to inconsistent decisions at the Federal Court, although recent decisions attempt to provide clarity. See, e.g., Ortho–McNeil Pharm., Inc. v. Lupin Pharm., Inc., 603 F.3d 1377, 1380–81 (Fed. Cir. 2010); PhotoCure ASA v. Kappos, 603 F.3d 1372, 1374–76 (Fed. Cir. 2010). These decisions adopt a narrow interpretation of “product” and in doing so arguably expand the range of pharmaceuticals that can benefit from the PTE. For critical analysis of the decisions, see Ann Kotze, “Reining in Patent Term Extensions for Related Pharmaceutical Products Post-Photocure and Ortho-McNeil” (2012) 106 Northwestern University Law Review 1419.
(b) the term of the patent has not been previously extended except for interim extensions or extensions due to the delay of the PTO’s review process;
(c) an application for extension is submitted by the patent owner of agent;
(d) the product has been subject to a regulatory review period before its commercial marketing or use;
(e) the product has received permission for commercial marketing or use and such permission is the first received permission for commercial marketing or use;
(f) the application is submitted within sixty-day period beginning on the date the product first received permission for commercial marketing or use;
(g) the term of the patent has not expired before the submission of an application; and
(h) no other patent term has been extended for the same regulatory review period for the product.20

For a patented pharmaceutical eligible for extension, the patent term can be extended on application by the patent holder by the time equal to the regulatory review period for the approved product.21 However, the duration of an extended patent is subject to limitations, which include:

(1) the duration of the extension can be reduced if it is determined that the applicant did not act with due diligence during regulatory review period;
(2) after any reduction due to the failure of the applicant to act with due diligence, the period of extension shall include only one-half of the time remaining in the periods of regulatory review;
(3) subject to the above time-period limitations, if the patent term remaining after the date of the FDA approval exceeds fourteen years, the extension shall be reduced so that the total of effective patent term, including original and extended periods, does not exceed fourteen years;22 and
(4) in no event shall more than one patent be for the same regulatory review period for any product.23

20 See 37 CFR 1.720 and 35 USC 156(a), above n. 19.
21 The “regulatory review period” for a new drug, antibiotic or human biological product refers to the duration of the Investigational New Drug regulatory review period and the New Drug Application regulatory review period. See 35 USC 156(g)(1)(B), above n. 19.
For patents issued after the enactment of the Hatch-Waxman Act on 24 September 1984 (and those issued before this date but where clinical trials had not commenced), the maximum period of extension is available for five years.24 If a patent was issued and clinical trials of such drug began prior to 24 September 1984, the maximum extension available is two years.25

Thus, the US system offers a maximum of a five-year extension as a result of delays in the marketing approval process, with the effective patent term capped at fourteen years. In practice, marketing approval times in the United States are now relatively quick and the extension provisions are accordingly rarely applied.

4.2.2 Supplementary Protection Certificate System in the EU

Unlike the United States, the EU has adopted a sui generis system of term extension, called a supplementary protection certificate (SPC), which blends IP protection with drug regulation. SPC protection is available to any patented product that must undergo an administrative authorization procedure prior to marketing as a “medical product” for human or veterinary use and operates by combining the two types of PTEs detailed above into a unified system. The system therefore addresses both regulatory delays due to review of the patent application and those relating to the marketing approval process for medical products.26 The “certificate” takes effect at the end of the regular patent term and extends the same rights to the approved new medical product as conferred by the “basic patent” (and is subject to the same limitations and obligations).27

As with the US system, the purpose of an SPC is to compensate the patent owner for the time elapsed after the date of the patent application until the date the product is authorized for sale in the EU market. By granting an SPC, patents for medical products can effectively be extended

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24 See 35 USC 156(g)(6)(A)–(B), above n. 19.
25 See 35 USC 156(g)(6)(C), above n. 19.
27 “Basic patent” is defined as “a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate.”
beyond the statutory twenty-year term by up to five years.\textsuperscript{28} Again, and unlike the PTE system in the United States, the EU’s SPC legislation extends not the patent term but the period of market exclusivity of the medical products. Thus, the SPC offers similar protection for the patent owner through the denial of marketing approval to generic competitors while the SPC is in force.

Under the regulations, an applicant that applies within six months from the date the product received marketing authorization (or the patent was granted, if later in time) shall be granted a certificate if the medical product for which it was requested meets the following conditions at the time when the application was filed in a Member State where the basic patent has been issued and where the authorization to place the medical product on the market was obtained:

(a) the product is protected by a “basic patent” in force;
(b) the product, as a medicinal product, has been granted a valid marketing authorization;
(c) the product has not already been the subject of a certificate; and
(d) the marketing authorization is the first authorization to place the product on the market as a medicinal product.\textsuperscript{29}

Unlike the US system, the duration of certificate is determined by combining regulatory delays due to the patent review process \textit{and} the marketing approval for medical products. In essence, the duration of certificate – and thus the PTE – is equal to the period elapsed between the date of the patent application and the date of the first authorization to place the


\textsuperscript{29} Regulation (EC) 469/2009, above n. 26, Article 3. Applications to extend the duration of the SPC must be filed no later than two years before the expiration of the certificate. See also Article 7(4).
product on the market, reduced by a period of five years.\textsuperscript{30} Importantly, as a safeguard against overprotection, the duration of the certificate may not exceed five years from the date on which it takes effect.\textsuperscript{31} This means that the holder of the patent and SPC will benefit from an overall maximum of period of fifteen years’ protection from the date at which the pharmaceutical first gains the authorization to be placed on the EU market.

\textbf{4.2.3 Patent Term Extension in Free Trade Agreements}

Despite not being required under the TRIPS Agreement, FTAs have for some time addressed PTE for pharmaceuticals. As highlighted above, both the United States and the EU attempt to export their respective models of PTE via trade agreements. Despite some differences among these FTAs, some trends regarding PTE can be noted and warrant further discussion.

\textbf{From a Hortatory Norm to Mandatory Obligation}

Until its incorporation into the NAFTA in 1993, PTEs had never been included as a mandatory obligation in an international agreement. Even in the NAFTA, Article 1709(12) simply provides a hortatory norm regarding the implementation of PTE as the parties find appropriate: “[The parties] may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.” The parties to the NAFTA therefore retain the discretion to decide whether or how to implement the PTE system in their respective jurisdictions.

The United States only maintained this approach in the early years of its FTA strategy,\textsuperscript{32} with subsequent FTAs almost always imposing a mandatory obligation on partner countries to implement PTE with little room for policy space. With the Trade Promotion Agreements (TPAs) negotiated

\textsuperscript{30} Ibid., Article 13(1). The certificate can expire early if the certificate holder surrenders it; the annual fee is not paid on time; or the product covered by the certificate is no longer to be placed on the market. See ibid., at Article 14.

\textsuperscript{31} Ibid., Article 13(2). In cases where the medical products meet the requirements of pediatric use, an extra six months can be added to original certificate, but the duration of the period may be extended only once. See also Article 13(3), referencing Article 36 of Regulation (EC) No. 1901/2006, above n. 28.

\textsuperscript{32} See the list of the US FTAs on the website of the Office of the United States Trade Representative, https://ustr.gov/trade-agreements/free-trade-agreements. For instance, the US FTA with Jordan, Article 4.23.
in the late 2000s with Panama, Peru and Colombia as the exceptions, mandatory PTE provisions have become a fixture in US trade agreements (whether concluded with developed or developing partners) and in relation to delays in the marketing approval process are also included in the ill-fated mega-regional TPP. Likewise, while the EU has in the past negotiated FTAs with developing countries that make PTE optional, its normal practice is to include a system based on the SPC to be in its FTAs with partner countries.

The Template Approach to PTE for Delays Relating to the Granting of a Patent or Marketing Approval

The US FTA model requires PTEs to compensate the patent holder in the case of an “unreasonable delay” in the issuance of a patent, at the request of the patent owner. The phrase “unreasonable delay” is often accompanied with a definition of what would constitute an unreasonable as opposed to reasonable delay. The exact periods of delay vary among different agreements. Most often, an unreasonable delay is defined as the lapse of four years from the date of filing of the patent application or two years after a request for examination of the application, whichever is later. In other agreements, the periods of unreasonable delay are five years from the date of filing or three years after the request, whichever is later. The Korea-United States Free Trade Agreement (KORUS), however, contains a different definition where a delay is considered as unreasonable if there is a

33 In US TPAs with Peru, Panama and Colombia, PTE is optional for unreasonable curtailment of patent term caused by delays in the marketing approval process. However, PTE remains mandatory for unreasonable delays in the issuance of the patent.


35 The standardized wording is as follows: “Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent.” See, e.g., KORUS, Article 18.8.8(a); US-Bahrain FTA, Article 14.8.6(a); US-Oman FTA, Article 15.8.6(a). Article 17.9.8(a) of the AUSFTA contains a slight variation: “If there are unreasonable delays in a Party’s issuance of patents, that Party shall provide the means to, and at the request of a patent owner, shall, adjust the term of the patent to compensate for such delays.”

36 See AUSFTA, Article 17.9.8(a); US-Bahrain FTA, Article 14.8.6(a); US-Oman FTA, Article 15.8.6(a); US-Morocco FTA, Article 15.9.7; and US-Singapore FTA, Article 16.7.7.

37 See Article 15.9.6(a) of the US-CAFTA-DR FTA; Article 17.9.6 of the US-Chile FTA; Article 16.9.6(a) of the US-Peru TPA; and Article 15.9.6(a) of the US-Panama TPA.
lapse of four years from the date of filing the application or three years after a request for examination, whichever is later. Another provision frequently incorporated into US FTAs requires a country that relies on the examination and prior grant of patent in another jurisdiction to extend the patent term by a period equal to the period of extension granted by the authority in the original granting jurisdiction.

In addition, US FTAs provide that where a pharmaceutical product is covered by a patent, each party shall make available an adjustment/extension/restoration of the patent term to compensate for the patent owner for “unreasonable curtailment” of the effective patent term as a result of the marketing approval process. Unlike the first ground of extension, most FTAs do not provide clear guidance on the definition of “unreasonable curtailment” of the patent term. Such lack of clarity could lead to interpretive difficulties. For instance, is any delay automatically considered as unreasonable curtailment, or are delays resulting from clinical trials or where the regulator requests additional information an unreasonable curtailment of the “effective patent term”? Or is the definition of what constitutes an unreasonable curtailment decided by each party at its own discretion? These questions, and many others, are simply left unaddressed.

Yet another area of slight concern is that most US FTAs do not address whether the adjustment/extension/restoration applies to delays in the country where the marketing approval is sought or whether delays in the

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38 Time may be subtracted from the calculation of delay if the delay is attributable to actions of the patent applicant. In other words, if the delay of the issuance of patent was caused by the applicant, it will not be counted in determining the unreasonableness of such delay.

39 See, e.g., US-Bahrain FTA, Article 14.8.7; US-Oman FTA, Article 15.8.7. See, contra, the US-Singapore FTA, which states that an extension of up to five years due to unreasonable delay for prior grant in another jurisdiction “may” be granted; there is thus no legally binding obligation to extend the patent term due to the unreasonable delay for prior grant of patent in another jurisdiction. US-Singapore FTA, Article 16.7.8.

40 Unlike the first ground of extension, which applies to patents in all kinds of fields and any products or process, this extension applies only to pharmaceutical products subject to patent protection.

41 The terms “adjustment,” “extension” and “restoration” have all been used in US FTAs.

42 For example, Article 17.9.8(b) of the AUSFTA provides: “With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.” See, e.g., US-Bahrain FTA, Article 14.8.6(b)(i) (which substitutes the word “extension” for “adjustment” but is otherwise a replica of the other texts), and TPP, Article 18.48(2) (repeating the wording of the AUSFTA).
country where the first approval was obtained should also be taken into account. While the former interpretation would seem to be the most reasonable, the US FTA with Bahrain obliges the parties to take into account delays in the foreign country. Curiously, US FTAs do not set out the maximum time period for the adjustment/extension/restoration. This is in contradistinction to US law, which sets out a time limit of not more than five years, with the additional safeguard of a maximum exclusivity period of fourteen years from the date of FDA approval. Finally, while US law limits this extension to one patent per product, its FTAs provide no such limitation. While US partner countries can of course legislate for a similar restriction, the point here is simply that while US law provides safeguards, these provisions are lacking in the text of FTAs.

Using its own system as a template, the EU has been not only later to negotiate for PTE in its FTAs but also not as consistent. That being said, it is clear that the EU provisions are closely modeled on the concept of the SPC and in general seek an additional protection for a period of five years. For instance, Article 10–35.2 of the EU-Korea FTA provides an example of typical EU drafting:

The Parties shall provide, at the request of the patent owner, for the extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the first authorization to place the product on their respective markets. The extension of the duration of the rights conferred by the patent protection may not exceed five years. [emphasis added]

The approach negotiated with Canada in the Canada-European Union Comprehensive Economic and Trade Agreement (CETA) is more nuanced and calls for sui generis protection equal to the period that elapsed between the date on which the application for a patent was filed and the date of the first authorization to place the product on the market of that party as a pharmaceutical product, reduced by a period of five years.

43 More specifically, where a party approves the marketing of a new pharmaceutical product on the basis of information concerning the safety or efficacy of a same or a similar product in another territory, such as evidence of prior marketing approval, the party shall make available a PTE to compensate the patent owner for unreasonable curtailment of the effective patent term in the party as a result of the marketing approval process in the other territory and in the party. See, e.g., US-Bahrain FTA, Art. 14.8.6(b)(ii).

44 See 35 USC 156, above n. 19.

Moreover, and despite the aforementioned requirement, “the duration of the sui generis protection may not exceed a period of two to five years, to be established by each Party.”\textsuperscript{46} While the EU will undoubtedly opt for five years’ protection in line with domestic law, it has been reported that Canada will limit the extension to a period of two years.\textsuperscript{47} Having never before legislated domestically for or negotiated PTE into FTAs, Canada is obviously attempting to limit the effects of the extension. The CETA is also more comprehensive than other EU FTAs, with Article 9.2(2) providing safeguards such as explicitly limiting the PTE provision to the first application for authorization to place the product on their market and to one extension per product. Moreover, and quite exceptionally, Article 9.2(5) contains an exception for generic drugs that are produced for export.

With certain developing countries, the EU has made PTE optional. This is the case in Article 223.4 of the EU-Columbia-Peru FTA:

\begin{quote}
With respect to any pharmaceutical product that is covered by a patent, each Party \textit{may}, in accordance with its domestic legislation, make available a mechanism to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the first marketing approval of that product in that Party. Such mechanism under this subparagraph shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent. [emphasis added]
\end{quote}

Here again, the EU practice is not standardized. For example, Article 17 of the proposed (and long delayed) EU-India FTA requires a PTE to be granted for a period equaling the time “between the filing of the application for a patent and the first authorization to place the product on their respective markets . . . reduced by a period of five years.” While this is similar to the wording used in the CETA, it does not provide for the possibility of limiting protection to between two and five years.

\textbf{4.3 Patent Term Extension in Hong Kong}

Hong Kong does not grant PTEs for delays in either granting a patent or in the marketing approval process. With the coming shift to an examination patent system, the time is ripe for the territory to reconsider the

\textsuperscript{46} Ibid.

Patent Term Extension in Hong Kong

The issue has in fact been raised in Hong Kong, with both the American Chamber of Commerce and the Hong Kong Association of the Pharmaceutical Association calling for the government to introduce PTE for pharmaceuticals, substantiating their calls with the familiar reasoning of compensation to inventors, promotion of innovation and as a way to encourage investment and R&D in the jurisdiction. On the other hand, critics would argue that PTE would bring few if any benefits to Hong Kong while costing the government (via the Hospital Authority) millions of dollars per year.

The actual impact of PTE will largely depend on the content of specific rules and is difficult to evaluate without a holistic overview of the system. Nonetheless, it is obvious that the adoption of PTE could affect the various stakeholders – including patent holders, innovative pharmaceutical companies, generic pharmaceutical companies and patients – differently. While it is clear that innovative pharmaceutical companies and their licensees will benefit from any extension of the patent or monopoly selling period, conversely, generic pharmaceutical companies will suffer as they are delayed entry into the market. As the Hospital Authority purchases the vast majority of pharmaceuticals for the Hong Kong market, PTE will at first instance increase its costs as competition will be delayed. How much this will cost is debatable, as at present generic pharmaceutical companies do not usually apply for marketing authority until after the expiration of the patent, despite there being no barrier to submitting an application and gaining marketing approval during the life of the patent. The practical effect of this is that the introduction of generics into the market is delayed for a period regardless of any patent or associated legislation or regulations.

Another relevant point to consider is that at present both the registration of a patent and the granting of marketing approval are fairly quick in Hong Kong. Neither the granting of a pharmaceutical patent nor

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the marketing approval process takes anywhere near as long a time period to trigger an “unreasonable delay” of the granting of the patent or “unreasonable curtailment” of the effective patent term due to the marketing approval process. The move to an examination system in Hong Kong will undoubtedly add time to the process, and it remains to be seen whether the Intellectual Property Department (IPD) will suffer from “unreasonable delays” in the future that reduce the effective patent term beyond a period of five years so as to trigger the PTE. Regardless, the self-examination process should not impact the time it takes for the Department of Health to grant marketing approval; thus, it is not anticipated that legislation providing for PTE in this regard would have any practical effect.

In essence, there is no easy way to determine the costs and benefits of PTE for Hong Kong. This will be the case for several years, until the amount of time it takes the IPD to examine pharmaceutical patents becomes clear. As with many issues, the reality is that Hong Kong’s adoption or otherwise of PTE will have no impact on the innovative capacities and productivity of the pharmaceutical industry. Simply stated, the market is far too small and capacity for growth too limited to be of any consequence. Thus, while the US and EU adoption of PTE has arguably improved (or could improve) innovation in the industry and led to the development and marketing of drugs that would otherwise have been dormant, smaller jurisdictions are in a very different position. Even if one takes the position that in the longer term all stakeholders – including generic firms, the government and patients – benefit from a healthy and innovative pharmaceutical industry that produces a steady stream of new drugs and that if PTE leads to more innovative drugs being produced and marketed, the cost of the extra period of monopoly sales could be defrayed and significantly outweighed, no one can argue that Hong Kong’s adoption of PTE will have any meaningful effect on this outcome.

Other governments have recently struggled with this issue. For example, a report commissioned by the former Australian government (and ignored by the current government) attempted to value PTE by linking it with pharmaceutical R&D expenditures in Australia, finding that while Australia contributes around 2 percent of global revenues for pharmaceutical companies, Australia received only approximately 0.3 percent (or AU$1 billion) of global pharmaceutical R&D expenditures. Thus, while Australia is paying for pharmaceuticals – in part through extended patent terms – it is not benefiting through investment in Australian R&D. This reasoning seems wholly flawed. Australian expenditures on pharmaceuticals are far higher than the corresponding level of pharmaceutical R&D
investment in Australia, but this does not mean that Australia does not benefit from a wider array of innovative and life-saving pharmaceutical products. Nor could every single country expect to host high levels of pharmaceutical R&D. The level of R&D is tied to other factors, such as investment incentives, skilled workforce and costs. There is no evidence that supports the claim that PTE leads to greater R&D expenditures in the host country, nor quite frankly could one expect there to be a causal link.

The question then becomes one of cost and potential savings. The Australian report then finds net savings of approximately AU$50 million per year for each year of reduction in the term extension. More specifically, the report finds savings of AU$45 million from a reduction in extension from five to four years, savings of AU$95 million with a reduction to three years, up to $244 million through the elimination of PTE. With an annual expenditure of more than AU$9.25 billion for pharmaceuticals in 2012, the savings from a one-year reduction in term would represent 0.005 percent of the budget, while the complete elimination of PTE would represent only 2.6 percent of the budget. While not insignificant, the numbers demonstrate that PTE is not a significant burden nor would its reduction or elimination change the outlook of a health budget.

The percentages in Hong Kong would likely not substantially differ and could be far less depending on the rapidity with which the IPD examines the patent applications. Thus, even if Hong Kong would have some increased outlay for PTE, the cost would be minimal when put into the context of overall pharmaceutical expenditures. Moreover, while it may not be in Hong Kong’s economic interest to provide for PTEs, as it will not by itself lead to increased R&D in the territory, the international trend toward PTE is clear. As Hong Kong prides itself as a jurisdiction with a high standard of IPRs and respect for the rule of law, it may be in its (perceived) reputational interest to enact some form of PTE. Moreover, if Hong Kong continues to negotiate FTAs, it is only a matter time before a partner requests or demands that the territory provide for PTE. It would be a better public policy outcome if the issues were discussed and debated internally before being imposed from an external source. For this reason, it is worth discussing several aspects of PTE to come up with general principles that should guide Hong Kong’s potential (and perhaps eventual) adoption of the provision.

The most significant concern in PTE for Hong Kong would be that of overprotection, that is, providing extensions too easily and/or for too long a time period. Therefore, an important consideration must be protection
against the creation of a regime that would provide protection for far too long, with the cost outweighing any potential benefits. For this reason, if Hong Kong were to consider adopting PTE, it should follow some general principles to ensure a proper balance of interests. While PTE provisions have become more extensive in scope and specific in details in recently concluded FTAs, variations within existing agreements may accommodate a balance of interests. In fact, most, if not all, of the principles that should guide Hong Kong can be drawn from provisions in existing FTAs.

The first issue to be decided, however, is whether to adopt an EU-style sui generis system of protection or a US-type system. While both are designed specifically to address failures in the patent system to differentiate pharmaceutical patents (with the extra hurdle of regulatory approval) from other patents, they go about it in very different ways. That being the case, in most respects a jurisdiction can reach the same outcome with either approach. There does not appear to be much difference in substance as opposed to form between the two systems.

The more important issues are found in the substance of the additional protection. Several issues must be addressed, and in order to highlight the most important issues that need to be considered and addressed, it is best to present them separately in a list.

- The duration of the PTE: What is the optimal duration and how should the duration of the PTE be determined? In line with prevailing practice of the EU and US domestic law, Hong Kong should limit a PTE to a period not exceeding five years in order to avoid prolonging the patent term and unfairly curtailing market access for generic medicines. In addition, Hong Kong should follow the US and EU approach of setting a maximum period of postmarketing authorization exclusivity. While that period is set at fourteen years in the United States and fifteen years in the EU (and Australia), Hong Kong should thoroughly study the market before deciding on a figure for the desired effective term. It must be stated, however, that there does not appear any reason for Hong Kong

50 The members of the Australian review agreed the term should be shortened, with two members recommending a ten-year period and one member proposing a twelve-year period of effective protection. See Australia Patent Review, at 84–85. Interestingly, Israel provides an extension for both basic and related pharmaceutical patents for up to five years and at the same time ensures that patents granted in “recognized countries” (currently the United States, Britain, Italy, Germany, Spain and France) are protected for at least fourteen years from the first marketing approval in the recognized country. See Israeli Patents Law, 5727–1967, S 64J.
to provide a longer period of protection than the United States and EU, but perhaps it may want to look at providing a shorter period given that whatever period is set, it will have little effect on overall investment incentives in the market. Of course, it should also be noted that in reality reducing the effective term may result in little economic benefit as firms could simply adjust pricing in response.

- The PTE should not be automatic and should be limited: The system should make the PTE dependent on an application by the rights holder prior to the expiration of the basic patent and only on pharmaceuticals for the first marketing approval process. In addition, each new pharmaceutical product should benefit from only a single patent term adjustment/extension. While both the United States and EU limit eligibility for PTE, they do not always include such limitations in their respective FTAs. Hong Kong should ensure that such limitations form part of the domestic law.

- Eligibility for a PTE: PTE should be limited so as to apply only to patents covering a “new pharmaceutical product,” defined as a product that at least contains a new chemical entity that has not been previously approved as a pharmaceutical product in the territory of the party. The PTE should therefore be granted on the new product per se, as opposed to a process to obtain a product or the use of a product. While PTE most often normally applies to any pharmaceutical product that is covered by a patent, narrowing the eligibility is a way to achieve the policy goals of encouraging the development of truly “innovative” pharmaceutical products without sacrificing too much consumer interest or access to

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extension of patent term for pharmaceutical products. There is precedent for such a limitation, most prominently in the KORUS. Therefore, PTE should be granted only for a new pharmaceutical product containing a “new chemical entity” and on the “first marketing approval” for the pharmaceutical product in the territory.

• Further conditional eligibility: In order to promote the availability of new pharmaceutical products in the jurisdiction, as a condition of eligibility for a PTE Hong Kong should require a patent holder/applicant to commence the process of obtaining marketing approval for the new pharmaceutical product within a certain number of years from the date of the first marketing approval of the same pharmaceutical product in another country. While the optimal period of time can be debated, it would seem a two- to three-year period would be sufficient to encourage quick registration in Hong Kong, meaning early access to drugs and then to generic equivalents. Thus, if marketing approval in Hong Kong is not sought within the prescribed period, the product would not be eligible to receive the one-time PTE.

• Limitation on the grounds for an extension: The effective patent life may be curtailed by different types of regulatory delays in patent examination and drug marketing approval. Regulations should ensure that PTE is limited to particular types of delay and qualification criteria (e.g., what can constitute an “unreasonable” delay) and that time is subtracted from the extension for delays caused by the applicant themselves.

• Rights and limitations: The regulations must ensure that the rights and limitations in regard to scope and coverage of the extended patent are not greater or lesser than those of the original patent rights, with certain exceptions. One such exception, as explained above, is notion that a product is eligible for PTE only if an application for marketing approval is made within a set period of time following approval in another jurisdiction. A related exception Hong Kong should adopt is a “use it or lose it” safeguard that allows for the authorities to revoke the PTE should the pharmaceutical product not actually be marketed in the jurisdiction within a set number of years following the granting of marketing approval. Again, while the relevant time period can be debated, it would

52 See, contra, Article 18.48(2) of the TPP, which simply refers to “a pharmaceutical product.”
53 While it can be debated whether Hong Kong is a large enough market for any incentive to be effective, the point here is for Hong Kong to take proactive steps to ensure that pharmaceuticals come to market as quickly as possible and to prevent overprotection. It should also be noted that pharmaceutical companies normally apply for marketing approval in Hong Kong earlier than other Asian markets due to pricing mechanisms; in essence, Hong Kong pays more than other regional markets and guides the regional price.
seem that a period of two years would be sufficient to discourage delays. Yet another exception can be taken from Australia, where during the period of the PTE the exclusive rights of the patentee are not considered to have been infringed where another person exploits the pharmaceutical substance for a purpose other than therapeutic use, or exploits any form of the invention that does not include the substance.54

4.4 Concluding Remarks

Patent term extension is designed to address the issue of regulatory delays either in the granting of a patent or in reviewing applications for market approval for pharmaceutical products. As a result of these regulatory delays, on average between eight and twelve years of the patent term has expired before the medicine is placed on the market. To counteract the effects of the regulatory delays and loss of monopoly selling period, an extension of patent term has been generally accepted by most industrialized countries – usually for a period of up to five years and under specific conditions – in order to facilitate the continued development of the innovative pharmaceutical industry.

While PTE is predicated on the idea that the branded pharmaceutical industry needs the additional period of monopoly selling rights in order to continue producing a steady pipeline of new and innovative medicines, public health activists strongly oppose PTE on the grounds that the extension delays access to cheaper medicines and simply provides for the extension of monopoly rents. Such criticism has intensified since the United States and EU began including PTE in their FTAs with trading partners. With the proliferation of FTAs, several separate ways to operationalize PTE have developed, with the US model providing extensions for unreasonable delays in the issuance of a patent and unreasonable curtailment of the effective patent term as a result of the marketing approval process. For its part, the EU formula offers essentially the same protection through a sui generis system that blends both processes.

Given the immense commercial and public interests involved in extending the regular patent term for pharmaceutical products, Hong Kong and other countries considering the adoption of a PTE system should be cautious and carefully consider the benefits of such a system against the detriments and balance the private interests with the public interests. It is abundantly clear that Hong Kong’s adoption of PTE will

54 Australian Patents Act 1990 (Ch), s 78.
do little to nothing to encourage major multinationals to increase R&D budgets or somehow become more innovative. Likewise, it is unlikely that the adoption of PTE will lead to investment in Hong Kong for either R&D or clinical trials. At the same time, it is debatable whether PTE will significantly raise costs. Regardless, as a jurisdiction that prides itself on rule of law and strong protection of IPRs, it may be in Hong Kong’s long-term interest to consider the adoption of PTE. Looking into the future (albeit somewhat cynically, perhaps), if Hong Kong remains active in the negotiation of FTAs, it is only a matter of time before Hong Kong will as part of an FTA be required by its negotiating partner to adopt and implement PTE.

If, and perhaps when, Hong Kong does decide to adopt a system of PTE, it should look to the implementation of PTE in other jurisdictions as a guide. Such a comparative approach will offer a variety of policy options to shape the contours of the domestic PTE system. This chapter highlighted several principles and safeguards that Hong Kong should strongly consider adopting should it decide to adopt PTEs. If followed, Hong Kong will demonstrate that it is a good international citizen while at the same time guarding against overprotection.

PTEs can be implemented so as to ensure that Hong Kong pays for the innovative R&D (without risks inherent in conducting such R&D) only years after it has been undertaken and only if the drug becomes established in the market and its entry is delayed by a considerable period of time due to the patent application or marketing approval process. This seems to be in line with Hong Kong’s view of itself as a strong protector of IP and good international citizen. On the other hand, there is no reason to believe that PTE would lead to increased pharmaceutical R&D in Hong Kong; for that, other more targeted incentives are needed.