Standards of Patentability

3.1 Introduction

The positive effects of patents are well known – patents provide an incentive to invest in costly research and reward scientific progress. Patents can also have significant downsides such as distorting competition through the granting of monopoly power. In regard to pharmaceuticals, it is almost a truism to say that without the temporary monopoly rights granted by patent protection there would be little incentive for investment and pharmaceutical R&D and far fewer breakthrough and follow-on drugs. As a result, the populace would be unhealthier and less productive. Quite obviously, no individual or company would invest hundreds of millions of dollars in medical R&D without at least an opportunity for a return on investment.\(^1\) At the same time, the granting of a patent inevitably raises the cost of the product to a level that greatly exceeds the marginal production cost for as long as the patent remains in force – medicines are expensive to invent and bring to market, but inexpensive to produce. Monopoly rights granted by the patent thus allow the inventor to price the product at a rate that far exceeds the cost of production, and in so doing makes it more difficult for people to access the medicines at reasonable costs. Moreover, patents (and in particular pharmaceutical patents) could also stifle

\(^1\) Plausible estimates on the cost of inventing and bringing a drug to market vary widely, but range from USD$800 million to USD$2.6 billion. See Steve Morgan et al., “The Cost of Drug Development: A Systematic Review,” (2011) 100 Health Policy, 4 (concluding after a review of original data published between 1980 and 2009 that “[e]stimates of the cost of drug development ranged more than 9-fold, from USD$92 million cash (USD$161 million capitalized) to USD$883.6 million cash (USD$1.8 billion capitalized)”; Tufts Center for the Study of Drug Development, “Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion” (18 November 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study, accessed 21 February 2017 (estimating costs at $2.558 billion, which is comprised of average out-of-pocket cost of $1.395 billion and time costs (expected returns that investors forgo while a drug is in development) of $1.163 billion).
follow-on innovations, increase legal risk for competitors and decrease competition for periods far exceeding the original patent term.

With both industrial development and human health at stake, the patent system must act to effectively balance the objectives of securing timely access to competitively priced pharmaceuticals, fostering R&D and innovation, supporting employment and facilitating scientific and industrial progress. Of course, it must be remembered that a nation’s patent system does not operate in a vacuum. International treaty obligations serve as an umbrella guiding both the substance and procedures of domestic law.

That being the case, scope exists for countries to tailor patent laws in a manner that is both compliant with the international standard and in harmony with broader governmental objectives. In this regard, countries such as India, Brazil and Argentina have prioritized the availability of cheap medicines to the populace. Accordingly, these countries narrowly define patentability provisions in domestic law, thereby restricting the number of patents granted. It is also no coincidence that these nations (and in particular India and Brazil) have thriving generic industries, which suggests that industrial policy sits beside health policy as a relevant governmental objective behind the policy. The recent Brazilian task force on patent reform admitted as much when it stated: “With the employment of higher standards for patentability requirements, one is encouraging the capacity building and technological development in Brazil.”

On the other hand, countries such as the United States and Switzerland are home to the world leaders of the innovative/branded pharmaceutical industry and thus provide for strong and broad patent protection. Still others are stuck in the middle, with undefined or conflicting objectives. China is a good example of such a nation, having prioritized and encouraged ‘innovation’ by rewarding patent filings. Unsurprisingly, this policy has resulted in a substantial increase in the number of patents filed and granted by Chinese nationals. But such inducements have done little to encourage scientific progress or real innovation. In this regard, the fundamental objective of the patent system has been lost. Still other jurisdictions do not shape patent policy through domestic objectives but merely

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follow the path taken by others. Hong Kong appears to be in this category, with its laws shaped not through governmental objectives, planning or review but simply through a mixture of the law leftover from the former colonial government and heavy reliance on the laws of select other jurisdictions.

Regardless of how a domestic law is formed or the policies behind such formation, the shadow of the international standard as set out in the TRIPS Agreement (to continue the umbrella metaphor) is large. More specifically, Article 27.1 of the TRIPS Agreement, entitled “Patentable Subject Matter,” reads:

patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5)

(Footnote 5: For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.)

Therefore, in order to comply with the international standard, patents should be granted for “inventions” that are “new” and “inventive.” This is sensible, given the justification for providing patents as a limited term monopoly is to reward and encourage further creation – granting patents for inventions previously known or obvious would be inimical to the very reason we provide the monopoly rights. The international standard also provides that a patentable invention must be “capable of industrial application,” that is, have utility or be useful.

Similar to most jurisdictions, Hong Kong virtually repeats the TRIPS standard through Section 93(1) of the Patents Ordinance, entitled “Patentable Inventions,” which states:

An invention is patentable if it is susceptible of industrial application, is new and involves an inventive step.

Of course, jurisdictions often require more in order for an “invention” to gain patent protection. For instance, the invention defined in the claims, and thereby the scope of rights obtained, must be commensurate with what is described in the specification. Moreover, as the granting of a patent is a matter of public interest, disclosure is a fundamental principle of the patent system. One US court succulently stated that “the whole purpose of a patent specification is to disclose one’s

3 Hong Kong Patents Ordinance, S 76.
invention to the public. It is the quid pro quo for the grant of the period of exclusivity.”

More specifically, applicants must provide in the patent specification sufficient information for the invention to be repeated. In this way the public has access to useful information regarding new technologies and both the jurisdiction and future inventors can use the invention after the patent term expires or is otherwise no longer in force. At the same time, the sufficiency of the disclosure (or enablement) requirement demands that the product or process for which the patent is filed is clearly and sufficiently described so that a person skilled in the art can be fully capable of producing the patent. Complete disclosure is important in order to set and adequately define the scope of the patent. Remembering that “[p]atents, unlike blocks of land, do not come with settled boundaries” and that patent specifications “are drafted by patent attorneys in a species of legalese that mocks the values of open science and communication,” governments must set clear standards and patent examiners must be equally vigilant in ensuring the standards have been met. A related requirement directly incorporated into some legislation (but not that of Hong Kong) is “best mode,” which mandates that the applicant expressly detail “the best mode contemplated by the inventor” of execution of the invention in the filing. The best mode requirement is essentially a public interest safeguard that provides transparency and legal certainty for downstream users by disciplining applicants that attempt to obtain patent protection without making a full disclosure (as is often required by the patent legislation).

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5 In this regard, Peter Drahos states that the purpose of disclosure is “to provide search systems that would allow members of the public a meaningful exercise of their rights to access invention information, and rights that they hold by virtue of the patent social contract.” Peter Drahos, The Global Governance of Knowledge: Patent Offices and Their Clients (Cambridge University Press, 2010), at 300.
6 Hong Kong Patents Ordinance, S 77.
8 Ibid., at 5.
9 See, e.g., Title 35 of the United States Code, 35 USC. 112(a).
In other words, the best mode requirement prohibits applicants from disclosing only what they know to be their second-best embodiment, while retaining the best mode for themselves.11

This chapter reviews the key features of patentability standards. Using the international standard and comparative experience of several jurisdictions as a guide, the chapter aims to make recommendations for possible amendments to the Hong Kong Patents Ordinance so as to take advantage of the available policy space to bring the Ordinance more in line with the constructed governmental objectives and priorities developed in Chapter 2. In the following sections, discussion and analysis is followed by targeted recommendations. Section 3.2 reviews the policy considerations relevant to patentability and the examination of desired standards. Section 3.3 analyzes the substantive conditions of patentability, including novelty, inventive step/obviousness and industrial application/utility. Section 3.4 briefly discusses the boundaries of patentable subject matter. Section 3.5 provides analysis on the controversial and topical issue of second use patents. Section 3.6 offers concluding comments.

### 3.2 Policy Considerations

The TRIPS Agreement sets minimum standards and criteria of patentability, but as noted above, Members have the discretion to craft the precise contours of each of the criteria for patentability. The first choice to be made in this regard is how the standards of patentability are to be judged. Many advanced economies utilize a “positive grant” system, where the substance of applications is scrutinized and only applications that fully meet the patentability standards are granted. There is, however, no international requirement to conduct a substantial examination of a patent application. Like Hong Kong,12 Thailand and several other countries register patents without a substantive examination and on the basis of examination and registration elsewhere. Still others, such as South Africa13 and until recently Singapore, simply grant a patent for any subject matter that is not explicitly excluded from patentability under the Patents Act (intrinsic

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11 For a more detailed explanation, see In re Nelson, 280 F.2d 172, 126 USPQ 242 (CCPA 1960).
13 South African Patents Act, Section 25.
policy considerations 49

patentability) and that is in compliance with the requirements of the standards of patentability (extrinsic patentability) as per the criteria modeled after Article 27(1) of the TRIPS Agreement. Following a “self-assessment” by the applicant, the patent is granted not after an examination of intrinsic or extrinsic patentability but only following a cursory examination as to whether the applicant has complied with the formal requirements of the Patents Act within the time periods set by the Act. Under such a system, the patent specification is accepted as the subject matter is described, and, within a certain time period (e.g., three months in South Africa), the patent is granted. Other forms of limited substantive examination or supplementary substantive examination in support of a positive grant system are used by various other counties. Of course, in any system the grant of the patent is a mere presumption and opposition proceedings can subsequently be launched to invalidate the patent.

The main justification for a substantive examination system and stricter patentability standards is to improve patent quality, eliminate frivolous patents and allow for localized and tailored policy. Domestic patent law should, on the one hand, be compliant with the TRIPS Agreement and, on the other, reflect local socioeconomic factors, national objectives and priorities and arguably differences in technologies.14 As Burkt and Lemley correctly point out, in implementing TRIPS standards in relation to pharmaceutical patents Members can select from policy levers in varying combinations in order to “modulate the scope and frequency of patents” and encourage innovation beyond the mere chance of registering a patent – by increasing the value of the patent once it is granted.15

A joint publication of the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO) substantiates this claim in relation to the promotion of

14 See, e.g., Max Planck Institute for Innovation and Competition, “Declaration on Patent Protection. Regulatory Sovereignty under TRIPS” (2014), Max Planck Institute for Innovation and Competition Research Paper No. 14 19 at para. 14 (“The non-discrimination principle in Article 27(1) of the TRIPS Agreement does not prevent states from adapting the subject matter and requirements of patentability to the characteristics inherent in the technology at issue. They may, for example, apply a different demarcation line between inventions and discoveries in different fields of technology; different standards of novelty, non-obviousness and disclosure depending on the technology’s maturity and dissemination”).

access to medical technologies and innovation: “Patent application, examination and grant procedures, as well as opposition, appeal, and other review procedures allow courts and other review bodies to correct erroneous decisions and give relief where necessary, in order to ensure that the patent system as a whole functions as a public interest policy tool.”¹⁶

One of the main concerns in this respect is to counter “evergreening” – which has been defined as “the practice of making incremental, patentable innovations for medicines without corresponding benefit, particularly if patients are aggressively or forcibly transitioned to the new product.”¹⁷

Most onlookers, including three prominent NGOs engaged in the access to medicines movement, conclude that countries with registration systems are “more likely to grant multiple patents on a single medicine, and to allow evergreening to occur.”¹⁸ In this regard, Vawda states that a “major complication is that the South African patents office does not conduct substantive examinations as to the merits of each patent application, nor is there any opportunity for an interested party to oppose such applications.”¹⁹

Of course, it is not enough to merely have an examination system. The legislation must be conducive to national priorities, and, as important, the patent examiners must be properly trained to implement the legal standards. In regard to the former, it is generally accepted that “developing countries need to have lower and more flexible IPRs standards than do their developed counterparts”²⁰ – and of course, the only way for


¹⁸ Treatment Action Campaign (TAC), Médecins Sans Frontières (MSF) and Research and Information System for Developing Countries (RIS), “Why South Africa Should Examine Pharmaceutical Patents” (2013), at 3, www.msfaccess.org/content/why-south-africa-should-examine-pharmaceutical-patents, accessed 21 February 2017. As an example, the briefing uses the case of Darunavir, an antiretroviral medicine used to treat HIV/AIDS: “Although the patent on the base compound (1993) was never filed in South Africa, a number of patents have been granted on different versions of this drug that do not expire till 2028.”


developing countries to do this is to apply strict criteria for the granting of patents. Leading IP and access to medicines scholar Carlos Correa expands on this idea by stating that “low standards of patentability may lead to unnecessary limitations on competition without any significant trade-off in terms of more innovation to address society’s needs.”\textsuperscript{21} He concludes that “[t]he best policy from the perspective of public health would seem to be the application of a strict standard of inventiveness so as to promote genuine innovations and prevent unwarranted limitations to competition and access to existing drugs.”\textsuperscript{22} With public health at the core of his argument, Correa proposes national guidelines for the evaluation and assessment of pharmaceutical patent applications in a manner that is conducive to public health policy goals.

Public health is not the only argument for strict patentability standards and an examination system. The joint NGO report mentioned above recommends that South Africa adopt a strict examination system, not only for public health reasons, but also in order to aid the development of local production of pharmaceuticals in the (often dubious and unfulfilled) hopes that a domestic industry can supply drugs more cheaply than imported drugs.\textsuperscript{23}

It is also important to highlight that while an examination system could be superior to a registration system in controlling and managing standards, it cannot and should not be adopted by every country. Designing, implementing and maintaining a well-functioning patent examination system is costly in terms of both monetary and human capital. Finding, hiring, training and retaining enough qualified patent examiners capable

\begin{itemize}
  \item \textsuperscript{22} Ibid., at 4.
\end{itemize}
of examining innovations in all fields of technology would also be difficult for many countries. This cost would be borne by the host state, but also by patent applicants in the form of higher application fees. Other, non-monetary costs include a more complicated process and increased time to grant the patent. Simply stated, an examination system is not suitable for all countries. Cost and resource issues may dictate that a country maintain a registration or self-assessment system. For these reasons, a World Bank report in 2002 recommended a registration system for low-income countries, registration or limited substantive examination system for middle-income countries and a substantive examination system for high-income countries.24

Hong Kong has decided to transition from a registration to an examination system. Even though costs will rise and the move may not be entirely necessary given that currently Hong Kong registers patents from only a few select jurisdictions, from a policy perspective the arguments for a positive grant system based on a substantive examination and for the adoption of stricter/higher patentability standards are compelling. As detailed in Chapter 2, Hong Kong is a relatively wealthy jurisdiction with an aging population, rising health costs and very little innovation or manufacturing capabilities. These factors should be borne in mind with regard to both Hong Kong’s legal framework and the regulations used to guide future patent examiners.

The next section focuses on the substantive criteria used to evaluate a patent application, with particular attention paid to the international standard and comparative practice to be used as guidance in developing an examination system in Hong Kong.

### 3.3 Substantive Conditions

As mentioned above, the TRIPS Agreement does not define the criteria of novelty, inventive step and industrial applicability. Instead, the Agreement leaves Members with a certain degree of flexibility to fashion their own interpretations. While the WTO has not even attempted to harmonize standards, the WIPO’s Standing Committee of the Law of Patents (SCP) – as part of its Patent Law Treaty harmonizing regulations on patent formalities and procedures, adopted in 200025 – unsuccessfully attempted

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24 See World Bank, above n. 20, at 141.

to draft a Substantive Patent Law Treaty. The negotiations commenced in 2001 but were put on hold in 2006 following a breakdown due to the absence of consensus on the issues.26

Given that Hong Kong will soon transition to an examination system, the time is ripe for the jurisdiction to tailor its patent provisions to best suit its own needs and priorities instead of following the idiosyncratic provisions of other jurisdictions. Following the conclusions reached in Chapter 2, Hong Kong should prioritize access to cost-efficient medicines while maintaining respect for international standards and its well-earned reputation for rule of law and friendliness toward business interests. In this regard, Hong Kong should follow the advice of Correa when he stated that “[l]ess technologically advanced countries may prefer to set higher standards of novelty and inventive step in order to preserve and enhance competition without violating minimum international standards.”27 Although Correa was writing in the context of developing countries, the scenario of Hong Kong necessitates equivalent advice. With scant manufacturing abilities and limited research capacities, Hong Kong should maintain strict patentability standards that, while serving to encourage and reward innovation, do not unnecessarily overprotect inventions in a manner that would curtail access to affordable medicines or the ability of the government to provide world-class healthcare to the populace. The remainder of this section will further explain the advice and make recommendations in regard to novelty standards (Section 3.3.1), inventive step/non-obviousness (Section 3.3.2) and utility (Section 3.3.3).

3.3.1 Novelty Standards

Article 27(1) of the TRIPS Agreement requires WTO Members to protect inventions that are, among other things, “new.” There is consensus among Members that the subject matter of a patent application is “new” if it does not form part of the prior (or existing) art. However, there have been some historical differences in interpretation as to what constitutes the boundaries of prior art, and the TRIPS Agreement allows for each Member to decide the scope for themselves.


The Patent Cooperation Treaty (PCT) is equally unhelpful as a guide. While Article 33(2) of the PCT defines novelty for the purposes of the international preliminary examination – “a claimed invention shall be considered novel if it is not anticipated by the prior art” – Article 33(5) makes clear that each Member may apply additional or different criteria, and, in regard to what the standard of novelty should be applied, the PCT remains silent. Each jurisdiction can decide this important question for itself through a factual assessment.

In regard to pharmaceuticals, a novelty threshold that is too lax could grant patent protection for medicines for which the active ingredient (or otherwise) is already known, and therefore provide monopoly rights over a product that could otherwise be manufactured and sold to the populace as a generic far more cheaply.

Most jurisdictions (including Australia, the EU, India, Japan, Russia, Singapore and Taiwan) attempt to draw clear boundaries of what is referred to as “absolute” novelty – that is, an “invention [that] is not publicly known anywhere in the world” prior to the filing of the patent application or priority filing date.28 An invention is therefore novel if it does not form part of the state of the art, or prior art, anywhere in the world immediately before the priority date of that invention, which includes any disclosure of the invention made available to the public, such as written publications, sales, public oral disclosures and public demonstrations or use.29 Such is the case in Hong Kong, with Section 94 of the Patents Ordinance providing the elements that make up the state of the art, and thereby destroy novelty: “The state of the art shall be held to comprise everything made available to the public (whether in Hong Kong or elsewhere) by means of a written or oral description, by use or in any other way,” before the date of filing of an application or, if priority was claimed, before the date of priority.30 Thus, if the invention already exists in the state of the art anywhere in the world, it is not “new” or novel and would not receive a patent.

28 Review of the Patent System in Hong Kong, above n. 12, at 193.
29 See, e.g., Indian Patents Act, No. 39 of 1970, §2(1)(l) (Universal 2005) (amended 2005) (“any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art”).
30 See also Article 54(2) of the European Patent Convention: “The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.”
In certain other jurisdictions a “relative” standard of novelty is used, and only the use of the invention or public knowledge of the invention in the jurisdiction itself constitutes prior art. For example, until 2012, US Patent Code defined novelty as “[t]he invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.”

The difference in standards between countries has revealed itself in a number of instances, with perhaps the most notable being the status of neem oil. The European Patent Office (EPO) revoked a patent for lack of novelty (under Article 54(1)(2)) when evidence showed that extracts of neem oil were mixed, diluted and used to treat crops, fruits and vegetables against pests and diseases in western India prior to the filing of the patent application. In the United States, which at the time maintained a relative standard of novelty, the patent was granted.

Other interpretive issues that legislation commonly fails to address but need resolution often revolve around the concepts of absolute or relative novelty. This dichotomy is somewhat unhelpful as even the definition of “absolute” differs between and among jurisdictions. Instead of using the absolute/relative terms, it is more useful to deconstruct novelty into its constituting elements in order to understand what advantages and disadvantages each element provides.

Perhaps the most important part of novelty is the scope of the terms “use” or “public knowledge” of the invention. This is especially the case in regard to pharmaceuticals, with novelty and prior art sometimes difficult to determine when distinguishing between different types of “uses” for an invention – for example, first medical use, second and subsequent medical use and second nonmedical use. Resolution is dependent on the policy choices made within the jurisdiction, and the outcome is of great importance. If a second or further medical (or nonmedical) use is deemed to be new, such further uses will be eligible for patent protection, and thus the system is designed to stimulate follow-on innovation. On the other hand, a regime could prohibit the patenting of such further uses because it deems these practices to be a form of “evergreening,” which serves mainly if not exclusively to maintain monopoly pricing and delay competitive

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31 S 102(a)(1). Amended as a result of the Leahy–Smith America Invents Act, the current S 102(a)(1) reads: “(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”
conditions. In this case, the regime is favoring cheaper access to the product over longer-term innovative potential of follow-on drugs.

Given the importance of this issue, second and further use patents are the focus of Section 3.5 of this chapter, but brief discussion is warranted at this point. Suffice to say, opinion is divided on this issue of whether to issue second and further use patents. For instance, the UK Commission on Intellectual Property Rights (CIPR) in 2002 cautioned against regarding a product to be new, even if a new use is identified, as a safeguard against the rising costs of medicines: “[W]e caution against developing countries simply taking over from the comparatively recent European jurisprudence the counter-intuitive notion that a product may be regarded as new, if a new use is identified for it. Such an approach is not required by TRIPS.”

However, one can also make the opposite argument that humanity (and thus individual countries) should encourage the exploitation of proven drugs – a single active ingredient or medicine can yield multiple and diverse benefits. In the words of Jacob J (as he was known then), “patents are provided to encourage research. If new and non-obvious improved methods of administration of known drugs for known diseases are not patentable in principle… then there will be less of a research incentive to find such methods.”

Another important issue is whether the jurisdiction should provide a grace period for nonprejudicial disclosure to protect an inventor or their successor in title from authorized and/or unauthorized disclosure of the invention prior to the filing date. The rationale for a grace period exception is that it promotes access to knowledge and innovation while still maintaining the inventor’s right to patent the invention within the grace period. Under such an exception, inventors have the opportunity to publish their research in scientific journals, which is an important incentive for scientists, or demonstrate the marketability of the invention to potential investors in order to acquire funding for, among other things, the costly process of obtaining a patent. In some jurisdictions, the grace period applies to any disclosure, while in others the exception is limited to disclosure in certain forms. The US pre-filing grace period exception is an example of the former: “These exceptions limit the use of an inventor’s own work as prior art, when the inventor’s own work has been

33 Merck & Co Inc’s Patents [2003] FSR 298.
publicly disclosed by the inventor, a joint inventor, or another who obtained the subject matter directly or indirectly from the inventor or joint inventor not more than one year before the effective filing date of the claimed invention.” The length and language of the US provision has been accepted and essentially adopted into numerous recently negotiated FTAs, including the ill-fated Trans-Pacific Partnership (TPP). India provides an example of a more limited exception, as it only provides a twelve-month pre-filing grace period for disclosures made with the inventor’s consent in government-designated exhibitions or before learned societies.

The grace period exception seems to be a matter of common sense – the objective of the patent system is to encourage and reward innovation; the normal course of business dictates that one should acquire as much information as possible before investing and the standard in academia is to publish findings as quickly as possible for personal satisfaction, promotion and most importantly lest another scientist subsequently reach the same conclusion and get the credit because they first published the findings. Thus, while the UK CIPR stated that “[f]or those developing countries having few prospective patentees, there may therefore be little to gain from providing a grace period,” this author would caution that while such advice may be temporarily utilized by LDCs, it would not be in the long-term interests of most developing and developed economies to adopt such an approach.

As the statistics presented in Chapter 2 reveal, Hong Kong is not a highly innovative jurisdiction and may under some definitions even have “few prospective patentees.” But it does value IPRs and its place as a good international citizen. Moreover, the vast majority of local inventors in the fields of pharmaceutical and biotech are universities – exactly the type of inventor that will be looking to publish findings in journals, present at conferences and seek licensing opportunities to enable further development and bring the invention to market. For these reasons, Hong Kong should

34 America Invents Act 35 USC 102(b)(1)(A).
35 See, e.g., Australia–United States FTA, Article 17.9(9); TPP, Article 18.38.
36 India Patents Act, Sections 29–34.
37 CIPR, above n. 32, at 116.
38 For this reason, Hong Kong should not adopt a strategy like that of South Africa, where its Review recommended setting strict levels of patent criteria in order to incentivize only genuine innovation, and as an “additional motivation...to set strict patentability criteria arises where the vast majority of patent applicants are from abroad.” South African Department of Trade and Industry, “National Policy on Intellectual Property (IP) of South Africa: A Framework,” Government Gazette, 4 September 2013 (No. 36816), at 26 (2013).
not only maintain but expand its grace period exception. Modeled on Article 55 of the European Patent Convention (EPC), Hong Kong provides that a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months before the filing of the application, if (a) the disclosure resulted from an evident abuse (i.e., nonauthorized disclosure by a third party) or (b) the applicant or any proprietor of the invention displayed the invention at a prescribed exhibition or meeting.\textsuperscript{39} It would seem sensible to expand the term to a twelve-month window and, at the very least, as a regional convention and exhibition center hub, to consider expanding on its limited grace period exception of “prescribed” exhibitions and meetings beyond the officially recognized exhibitions\textsuperscript{40} in order to become even more attractive to innovation conferences, conventions and meetings. In fact, taking into account the heavy reliance in Hong Kong on university research in the pharmaceutical and biotech sector for local patenting activity, there does not seem to be any substantive reason to argue against broadening the standard to include any public disclosure by the inventor.

Hong Kong should also maintain its version of absolute novelty (subject to an expanded grace period exception) and, for reasons explained below, recognize and grant further second use patents.

### 3.3.2 Inventive Step/Non-Obviousness

The second criteria set out in Article 27(1) of the TRIPS Agreement is that an invention “involve an inventive step” or, as footnote 5 makes clear, is “non-obvious.” Article 27 does not define the terms “inventive step” or “non-obviousness.”

The rationale of the inventiveness or non-obviousness requirement is to encourage sequential innovation (follow-on innovation). Setting non-obviousness standards too low could allow companies to accumulate patents on incremental improvements, maintain patent pools and block local improvers and ultimately stymie innovation.\textsuperscript{41} This could in turn...

\textsuperscript{39} Hong Kong Patents Ordinance 1997, S 95 and 109. If making use of the convention or exhibition exception, an applicant must disclose that the invention has been displayed at the time of filing.


\textsuperscript{41} See Jerome Reichman, "Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?" (2009) 46 Houston Law Review 1115, 1134.
create formidable barriers to entry and impact on the competitive conditions within the jurisdiction. On the other hand, setting the standard too high is also dangerous, as it will not incentivize or reward R&D and could threaten the availability of advanced technology in the jurisdiction. Striking a delicate balance is therefore crucial.

As with novelty, whether a claimed invention involves an inventive step/non-obviousness is evaluated by the state of the art, excluding prior art and grace periods for nonprejudicial disclosures. Most jurisdictions set out only the general principle, which is applied to each specific case, as opposed to attempting to precisely define what is an “inventive step” or “non-obvious.” Thus, as opposed to attempting a factual comparison between a claimed invention and prior art (as is the case in determining the novelty), the assessment of an inventive step relies on a more vague, qualitative approach. The Standing Commission of the Law of Patents endorsed such an approach, considering it “suitable for the application of the patentability criteria to each invention on its merit, bearing in mind that inventions may relate to a different field of technology. It also accommodates future technological development that cannot be foreseen.”

The vast majority of advanced jurisdictions find that the threshold of an inventive step/non-obviousness has been met when the invention is not obvious to a hypothetical person having ordinary skill in the art, having regard to the prior art (the so-called person having ordinary skill in the art (PHOSITA) in the United States and also adopted in this

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43 See, e.g., Article 13 of Law No. 9.279 (14 May 1996) (Brazil Industrial Property Law).
46 See Lubrizol v. Esso [1998] RPC 727, 738 (“Patent specifications are intended to be read by persons skilled in the relevant art, but their construction is for the court. Thus the court must adopt the mantle of notional skilled addressee, and determine...what the notional skilled addressee would understand to be the ambit of the claim”). See also Pfizer’s Patent [2001] FSR 201; and Nichia Corporation v. Argos Limited [2007] EWCA Civ 741.
47 See 35 USC §103(A). The term “Phosita” appears to have first appeared in Cyril A. Soans, “Some Absurd Presumptions in Patent Cases” (1966) 10 IDEA 433, 438–39 (passionately arguing against the court’s creation of a “superhuman Frankenstein monster Mr. Phosita,” whose powers extended far beyond those of the ordinarily skilled mechanic). In time, “Mr. Phosita” became “PHOSITA” in the literature.
publication) that exists before the filing date or priority date. What constitutes an inventive step is therefore foremost a qualitative question that occurs ex post and is often done by a fact finder that lacks the skills of the art (although it should be noted that patent examiners are often specialized and grouped accordingly by the patent office).

Hong Kong, in Section 96 of the Patents Ordinance, utilizes such an approach:

(1) An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

(2) For the purpose of subsection (1), if the state of the art also includes documents within the meaning of section 94(3), these documents are not to be considered in deciding whether there has been an inventive step.

The remainder of this subsection evaluates the fictitious PHOSITA standard (3.2.1) and concludes with a review of different tests relevant for inventive step (3.2.2).

PHOSITA

As stated above, many jurisdictions explicitly state that the inventive step is determined by the PHOSITA standard. Other jurisdictions do not explicitly refer to a PHOSITA but rather an “average” person, which in practice requires a similar level of required skill. Regardless, the obvious question is who exactly is this PHOSITA, average person, or in the words of one UK judge, this “nerd”? What knowledge and ability does he or she possess?

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48 On the relevant date to be used, see Sara Lee Household & Body Care v. Johnson Wax [2001] EWCA Civ 1609.


50 See also EPC, Article 56.

51 These include Japan, Malaysia, the Republic of Korea, China, Sri Lanka, Thailand and the United States.

52 These include Argentina, Chile, Colombia, Costa Rica, Ecuador, Israel, Panama, Peru and Vietnam.

53 See Jacob LJ in Rockwater Ltd v. Technip France SA & Anor [2004] EWCA Civ 381 (01 April 2004) at 7. (“It is settled that this man, if real, would be very boring – a nerd.”)
Paragraph 13.11 of the PCT International Search and Preliminary Examination Guidelines describes some of the commonalities in PHOSITA’s interpretation across many jurisdictions:

The person skilled in the art should be presumed to be a hypothetical person having ordinary skill in the art and being aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the “prior art,” in particular, the documents cited in the international search report, and to have had at his disposal the normal means and capacity for routine experimentation. If the problem on which the invention is based and which arises from the closest prior art prompts the person skilled in the art to seek its solution in another technical field, the person skilled in the art in that field is the person qualified to solve the problem. The assessment of whether the solution involves an inventive step must therefore be based on that specialist’s knowledge and ability. There may be instances where it is more appropriate to think in terms of a group of persons, for example, a research or production team, than a single person. This may apply, for example, in certain advanced technologies such as computers or telephone systems and in highly specialized processes such as the commercial production of integrated circuits or of complex chemical substances.

Even this definition raises several questions and leaves sufficient scope for differentiation. For instance, what forms part of “common general knowledge”? In this regard, public knowledge can be distinguished from common general knowledge. Information in the public domain does not automatically become part of the common general knowledge. That said, publications such as a description in a standard textbook will provide a strong indication of common general knowledge. Singapore’s approach to this issue seems sensible – the PHOSITA is not expected to know of all the information, but rather he or she would know where to find all the relevant information.54

Moreover, and perhaps most importantly, the definition of PHOSITA is left for jurisdictional interpretation. In the United Kingdom, courts have defined the person “skilled in the art” as someone who is familiar with the background literature but is “incapable of a scintilla of invention.” For instance, the court in Technograph Printed Circuits Limited v. Mills and Rockley (Electronics) Limited stated:

54 *Nokia v. IPCom* [2009] EWHC 3482 (Pat), at 38. Likewise, in the United States the PHOSITA is expected to understand what he or she finds. See, e.g., *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The “hypothetical [PHOSITA] to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art”).
To whom must the invention be obvious? It is not disputed that the hypothetical addressee is a skilled technician who is well acquainted with workshop technique and who has carefully read the relevant literature. He is supposed to have an unlimited capacity to assimilate the contents of, it may be, scores of specifications but to be incapable of a scintilla of invention. When dealing with obviousness, unlike novelty, it is permissible to make a “mosaic” out of the relevant documents, but it must be a mosaic which can be put together by an unimaginative man with no inventive capacity.55

The South African Patent Review interprets this to mean in practice that unless the prior literature contains what often amounts to an explicit instruction or suggestion to make the invention, especially when two or more pieces of prior art need to be combined or mosaicked, the invention will be deemed sufficiently non-obvious to meet the inventive step requirement.56 The Indian Intellectual Property Appellate Board describes the PHOSITA in slightly broader terms:

We must remember that this ordinary man has skill in this art. He is not ignorant of its basics, nor is he ignorant of the activities in the particular field. He is also not ignorant of the demand on this art. “He is just an average man . . . Well . . . just an ordinary man.” But he is no dullard. He has read the prior art and knows how to proceed in the normal course of research with what he knows of the state of the art. He does not need to be guided along step by step. He can work his way through. He reads the prior arts as a whole and allows himself to be taught by what is contained therein.57

Correa also attributes some specialized knowledge to the PHOSITA as opposed to viewing that person as simply someone with very general or ordinary knowledge in the relevant technical field: “A person skilled in the art is not just an expert in his technical field but a person who should have some degree of imagination and intuition.”58 Regardless of definition, the

55 Technograph Printed Circuits Limited v. Mills and Rockley (Electronics) Limited (1972) RPC, 346 at 355. See also General Tire v. Firestone Tire & Rubber [1972] RPC 457, at 506 (“In our judgment the evidence in the instant case shows that there is far more than a ‘scintilla of invention’ in the process for which protection is claimed in the patent-in-suit”). For a similar finding in the United States, see Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985).
56 South African IP Review, above n. 38, at 32.
57 Sankalp Rehabilitation Trust v. F. Hoffmann-La Roche AG and the Asst. Controller of Patents & Designs, Intellectual Property Appellate Board, Order No. 250/2012, 2 November 2012 (India) at 42. See also KSR Int’l Co. v. Teleflex Inc., 550 US 398 (2007), at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton”).
58 Correa, above n. 21, at 4. Exceptions include Australia and Papua New Guinea, which state that common general knowledge is taken into account for the assessment of inventive step.
US Supreme Court in *KSR Int’l v. Teleflex, Inc.* warned that “[r]igid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.”

Jurisdictions have developed various tests in order to assist in identifying the PHOSITA for the purposes of determining novelty. One of the lead cases in this regard is the UK case of *Windsurfing International v. Tabur Marine*, which developed a four-step test:

1. identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;
2. identify the notional “person skilled in the art” and the relevant common general knowledge of that person;
3. identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as constructed; and
4. determine whether, viewed without any knowledge of the alleged invention as claimed, if those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention.

While this test has slightly shifted over time, it nevertheless remains a useful and illustrative guide to our discussion.

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60 *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] RPC 59 (CA) at 73–74. (“There are, we think, four steps which require to be taken in answering the jury question. The first is to identify the inventive concept embodied in the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being ‘known or used’ and the alleged invention. Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.”) This test proved influential in other jurisdictions. See, e.g., *Apothe Inc. v. Sanofi-Synthelabo Canada Inc.*, [2008] 3 R.C.S. 265, 2008 CSC 61, at 268 (“An obviousness inquiry should follow a four-step approach”). For the Court’s reasoning, see para. 67.

61 See *Pozzoli Spa v. BDMO SA & Anor* [2007] EWCA Civ 588 (22 June 2007). See also *Actavis v. Novartis* [2010] EWCA Civ 82. It should be noted that the UK’s concept of “common general knowledge” differs slightly from the traditional US test as set out in *Graham* and that of the EPC’s “problem-solution approach.” The risk of the UK approach is that too much knowledge is imparted on the skilled person and fewer inventions are deemed to be inventive. For illustration, see the decision in *Teva UK Limited & Another v. AstraZeneca AB* [2014] EWHC 2873 (Pat).
Inventive Step Tests

If the objective of the inventiveness/obvious requirement is to craft a rigorous system that rewards true innovation (such as higher-level incremental improvements but excluding small or minor improvements), a jurisdiction should use the inventive step/non-obvious standard to eradicate poor quality patents. This is easier to do in theory rather than in practice. In practice, jurisdictions have struggled to design a standard that is fair and applicable in many circumstances. For example, in *Graham v. John Deere Co.* the US Supreme Court developed a four-step test on an obviousness inquiry. First, courts must determine the scope and content of the prior art; second, courts must identify the differences between the prior art and the claims at issue; third, courts must ascertain the level of ordinary skill in the art; and fourth, courts must make use of secondary considerations as an aid.\(^{62}\)

US courts have subsequently refined the test in numerous ways. For instance, in an effort to avoid hindsight bias the Federal Circuit developed the teaching, suggestion or motivation test.\(^{63}\) Simply, if a teaching, suggestion or motivation in the prior art pointed to the invention, then it was obvious. Other supplementary, secondary consideration tests (also known as an “objective indicia of non-obviousness”\(^{64}\)) have been used in the United States since *Graham* and elsewhere in recent years. One such test is the economic significance test (also used in other jurisdictions, most notably India) and the commercial success test in South Africa.\(^{65}\) The most influential recent case is *KSR v. Teleflex World*,\(^ {66}\) which criticized the teaching, suggestion and motivation test and “identified a number of rationales to support a conclusion of obviousness which are consistent with the proper ‘functional approach’ to the determination of obviousness as laid down in *Graham*.”\(^ {67}\) This case, along with several subsequent

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\(^{64}\) See generally Thomas, above n. 49.

\(^{65}\) *Schlumberger Logelco Inc. v. Coflexip*, 2003 (1) SA 16 (SCA).

\(^{66}\) *KSR Int’l Co. v. Teleflex Inc.*, above n. 57, 415–21.

cases, led to the US Patent and Trademarks Office (USPTO) providing a nonexhaustive list of exemplary rationales that may support a conclusion of obviousness:

(A) Combining prior art elements according to known methods to yield predictable results;
(B) Substituting one known element for another to obtain predictable results;
(C) Using known technique to improve similar devices (methods, or products) in the same way;
(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
(E) Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success (so-called “obvious to try”);
(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.\(^68\)

These tests are not without controversy or problems, as they tend to favor the patent holder and could be construed to work against the interest of the public health policy goals. Then again, the advantage of the secondary consideration tests is that they are more objective than the non-obviousness test. Regardless of the chosen manner, jurisdictions would be wise to heed the caution of the US Supreme Court in *KSR Int’l v. Teleflex, Inc.* that rejecting or invalidating patents claiming obvious subject matter “must not be confined within a test or formulation too constrained to serve its purpose.”\(^69\)

The issue is even more complicated in regard to pharmaceuticals. There is a growing body of evidence that questions the inventiveness of the majority of patented drugs. While the literature is too complex and extensive to discuss at length here, the crux is that the incentive structure of the patent system at present encourages minor incremental changes to existing drugs so as to extend the term of monopoly protection in what

\(^{68}\) Ibid.  \(^{69}\) *KSR Int’l v. Teleflex, Inc.*, above n. 57, at 423.
is called “evergreening.”\(^\text{70}\) In a majority of these cases, there is little if any therapeutic benefit to such changes.\(^\text{71}\) The result is that startling few new medicines on the market can be labeled highly innovative or breakthrough drugs, defined as the first pharmaceutical product that effectively treats a given disease or promotes considerable treatment gains in comparison with existing drugs.\(^\text{72}\)

India has adopted a clear and proactive stance against evergreening through the adoption of its inventiveness standard with the specific goal of narrowing the patentability threshold. With a higher standard than most countries, which has been referred to as a “non-obviousness-plus” standard,\(^\text{73}\) India defines an inventive step not only to mean non-obvious to a person skilled in the art, but also to “involve technical advance as compared to the existing knowledge or have economic significance or both.” The burden of proof is on the applicant to show a technical advance.\(^\text{74}\)

Under such a standard, the subject matter of an extended Swiss-type or second use claim may be deemed to be a mere discovery that does not fulfill the “inventive step” requirement of patentability. Australia too has discussed setting a threshold to “inhibit the patenting of follow-on pharmaceuticals which promote evergreening with no material therapeutic benefit.”\(^\text{75}\) The difficulty in establishing such a standard is establishing the proper “size of the step” required for patentability – setting the bar too

\(^{70}\) At the same time, it is widely known that the industry abandons R&D into promising new drugs due to questions regarding the patentability of the resulting medicine.


\(^{72}\) See, e.g., CDER NDAs Approved in Calendar Years 1990–2004 by Therapeutic Potential and Chemical Type, www.fda.gov/cder/rdmt/pstable.htm, accessed 21 February 2017 (finding that only 11 percent of new drugs patented between 2000 and 2004 were considered highly innovative). See also Morris L. Barer, Patricia A. Caetano, Charlyn D. Black, Steven G. Morgan, Kenneth L. Bassett, James M. Wright and Robert G. Evans, “‘Breakthrough’ Drugs and Growth in Expenditure on Prescription Drugs in Canada” (2005) 331 British Medical Journal 815 (finding only 5.9 percent of newly patented drugs in Canada between 1990 and 2003 were labeled “breakthrough drugs”).


\(^{74}\) Indian Patents Act, Section 2(1)(j)(a).

\(^{75}\) Commonwealth of Australia, “Pharmaceutical Patents Review Report 2013,” conducted by Dr. Nicholas Gruen, Professor Dianne Nicol and Tony Harris at the request of the Parliamentary Secretary for Innovation, at xi.
high will discourage continual but incremental improvement from follow-on inventors, whereas setting the bar too low may tilt the balance too much toward such smaller increments and discourage R&D into what could be ambitious breakthroughs.\textsuperscript{76}

There is emerging consensus in a number of jurisdictions that a higher threshold for inventiveness will improve the quality of the system and lead to fewer patented pharmaceuticals, more generic competition/lower prices and perhaps a more sustainable supply of high-quality drugs given the potential for multiple manufacturers. It is also plausible that higher patentability criteria will lead to greater innovation as inventors have increased incentives to spend valuable resources on R&D, which could lead to real breakthroughs and decreased incentives to allocate R&D to incremental improvements that may not lead to patent protection. Likewise, as found in the EU Commission Pharmaceutical Sector Inquiry Report, a higher standard of inventiveness could avoid (1) the filing of numerous patents for the same medicine, leading to patent thickets or clusters; (2) excessive patent litigation, which normally revolves around “secondary” patents in order to prevent entry to the market by generic competition; and (3) life-cycle management strategies used by companies to slightly amend a formulation or dosage and orchestrate a switch away from the soon-to-be-off-patent medicines to the second-generation pharmaceutical covered by subsequent patents.\textsuperscript{77}

The recommendations of the Brazilian patent review on inventive step could be a useful model for Hong Kong to adopt:

The invention carries inventive activity when, for a person skilled in the art, it does not derive in an obvious or evident manner from the state of the art, and provided it represents a significant technical advance in regards to the state of the art.\textsuperscript{78}

It makes sense for Hong Kong to follow the burgeoning intellectual trend and define the standards for non-obviousness at a relatively high level in order both to eliminate frivolous and/or the evergreening of patents in


\textsuperscript{78} Patent report of the Brazilian Chamber of Deputies, above n. 2, at 67.
order to reduce pharmaceutical spending and to encourage local development of incremental innovations in the sector, which may be within reach of the jurisdiction’s innovative capabilities. In this regard, the adoption of the Brazilian model could limit the granting of poor-quality patents, safeguard the public health system and at the same time perhaps even assist local inventors in the market.

### 3.3.3 Industrial Applicability/Utility

In most jurisdictions, the PCT and of course in Article 27(1) of the TRIPS Agreement, industrial applicability/utility is another of the requirements for patentability. While the TRIPS Agreement does not attempt to define industrial application/utility, Article 33(4) of the PCT states:

> For the purposes of the international preliminary examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. “Industry” shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property.

In most jurisdictions there is almost an assumption that any invention is capable of industrial application. This is the case in the EU and the United States, where an applicant needs only one credible assertion of utility to satisfy the standard.\(^{79}\) Referred to as “uncontroversial” and “easily met,” the utility standard in the United States can, according to a 1998 US Patent Examination Manuel, be defeated only with “proof of total incapacity.”\(^{80}\) Mexico’s Law of Industrial Property (Ley de la Propiedad Industrial) is even more lenient, with Article 12 defining “industrial application” as “the possibility that an invention may have a practical utility or can be produced or used in any branch of economic activity, for the purposes described in the patent application.”\(^{81}\) Section 96 of Hong Kong’s Patents Ordinance is likewise broad in scope, providing that “[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.” One has to imagine that the interpretive threshold for industrial application/utility under Section 96 would likewise be exceptionally low.

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79 EPC 2000, Article 57; 35 USC 101.
81 Cited in ibid., para. 33.
In regard to pharmaceuticals, examiners and courts sometimes actively inquire into what constitutes credible utility. In the United States, any substantial, nonfrivolous use has traditionally qualified as credible activity. As such, proof of in vitro pharmacological activity has been deemed to qualify as credible utility. Likewise, the Boards of Appeal of the EPO attempted to place some threshold for the requirement when it held that there must be some “profitable use for which the substance can be employed” in order to be deemed capable of industrial application.

In recent years, additional and (slightly) more stringent standards in recent years is in large part due to the “difficulty of determining whether certain biotechnology-related inventions, such as those covering genes or proteins, really have any industrial application.” In an attempt to forestall speculative patents, the United States established guidelines requiring applicants to disclose a “specific, substantial and credible utility” for the invention. The European Patent Office (EPO) and others have followed suit with a similar requirement.

The United States has also taken the lead in setting a standard for the threshold required for pharmaceutical inventions. Recognizing the nature and realities of pharmaceutical R&D, the US Court of Appeals for the Federal Circuit stated in *In re Brana*:

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

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82 Ibid., para. 30.
84 CIPR, above n. 32, 116.
86 CIPR, above n. 32, 117.
The outlying country in terms of the industrial application/utility standard is Canada. Since 2005, the Canadian courts have diverted from the “mere scintilla of utility” doctrine and applied a so-called promise doctrine whereby a patented invention must actually do what the inventor claimed, or implied, it would do when at the time of making the patent application, backed by evidence, to satisfy the utility requirement. This is referred to in the courts as the “doctrine of sound prediction.” In Apotex Inc. v. Wellcome Foundation Ltd. the Supreme Court of Canada set out the three conditions of the doctrine of sound prediction as (a) a “factual basis” for the prediction, (b) an “articulable and sound line of reasoning from which the desired result can be inferred from the factual basis,” and (c) “proper disclosure.”

The promise doctrine most often affects the pharmaceutical industry (and medical inventions), as the specification in further and second use patents – that is, where the patent is for a new use of a known compound – must assert that the compound is useful for the claimed purpose. The promise doctrine has proven particularly difficult for the pharmaceutical industry, where patent applications are generally made at an early stage of pharmaceutical development and long before any stage 2 and 3 clinical trials (and often before stage 1 trials). It is therefore difficult for an applicant to precisely identify with any accuracy the effect of the drug at issue. This difficulty has proved fatal to numerous pharmaceutical applicants. For instance, between 2009 and 2011 the Federal Court in Canada invalidated patents that had been granted prior to 2005 – Zyprexa (olanzapine)

88 Eli Lilly quotes a 1990 Canadian Patent Office Manual, which states: “Utility [is] an essential feature of invention. If an invention is totally useless, the purposes and objects of the [patent] grant would fail and such [patent] grant would consequently be void... Utility, as related to inventions, means industrial value.” From this Eli Lilly concludes that “as long as an invention had some industrial purpose and was not inoperable, the invention satisfied the utility requirement.” Eli Lilly v. Canada, above n. 81, para. 29 (citing MOPOP §§12.02.01 and 12.03 (January 1990)).

89 Information obtained after the date of filing is irrelevant to satisfy the criteria. Apotex Inc. v. Wellcome Foundation Ltd. 2002 SCC 77 (AZT) at para. 84. Pre-filing data must be sufficiently disclosed (as opposed to merely referenced) in the patent application in order to meet the requirement. Teva Canada Ltd. v. Pfizer Canada Inc. 2012 SCC 60 (sildenafil) at para. 42.

90 Apotex Inc. v. Wellcome Foundation Ltd. 2002 SCC 77 (AZT) at para. 70.

91 Other situations requiring a promise include a selection patent claiming compounds that fall within a previously disclosed genus and where an advantage is necessary to establish inventiveness. See further Eli Lily Canada Inc. et al. v. Novopharm Limited 2010 FCA 197 (olanzapine) at para. 78; Hoffmann-La Roche Limited v. Apotex Inc. 2011 FC 875 (mycophenolate mofetil) at para. 22.
and Strattera (atomoxetine) – for failing to meet the utility threshold. In the case of Zyprexa, the Federal Court found that the drug did not meet the implied promise that the drug is “markedly superior” to other drugs for the same disease; in the case of Strattera, the Court determined that a seven-week double-blind placebo-controlled study of twenty-two patients was too small and too short in duration to provide anything more than interesting but inconclusive data.

As a result of the invalidation, pharmaceutical giant Eli Lilly brought a claim against Canada under Chapter 11 of the North American Free Trade Agreement (NAFTA) when it filed a Notice of Arbitration on 12 September 2013 claiming violations of several provisions. In its statement of defense, Canada argued that “allowing patent protection in these circumstances would permit applicants to obtain and uphold patents based on speculation, and in the absence of any adequate disclosure to the public. It would also have the effect of dissuading innovation by pre-emptively fencing off areas of research in the absence of a realized invention, undermining a primary policy goal of the Patent Act.” More directly, Canada argued that the core patent criteria must be fulfilled no later than at the time of filing: “[W]hether or not the applicant ultimately demonstrates its alleged invention to be ‘useful in fact’ (years after the filing of the invention, on the basis of wholly different research) is not the relevant inquiry.” Thus, the fact that both drugs were marketed and sold in Canada – and therefore were proven to be medically useful – is irrelevant under the Canadian doctrine.

Canada also disputed that the promise doctrine only became “good law” in 2005, instead asserting that since 1959 Canadian courts have endorsed the doctrine that inventions must be useful as specified. As evidence, Canada pointed to a 1981 case in the Supreme Court of Canada that quotes the Halsbury Laws of England as stating that an invention lacks utility

93 Eli Lilly v. Canada, above n. 81. 94 Eli Lilly v. Canada, above n. 81.
96 Ibid., at 8.
when the invention will not work, either in the sense that it will not operate at all or, “more broadly, that it will not do what the specification promises that it will do.”\textsuperscript{98} Thus, Canada asserted that although the default rule is that there is no general obligation to promise a specific utility of the invention, other than a mere scintilla of utility, this does not apply in cases where the applicant promises a particular degree of utility or selection patents – in such cases the utility must be demonstrated or “soundly predicted” as of the date of the patent application filing date.\textsuperscript{99} Canada therefore admitted that its “promise doctrine” deviates from the accepted “mere scintilla of utility” doctrine.

Canada’s view that a promise somehow raises the threshold is unorthodox. It could also be viewed as distortion and an abuse of the phrase “capable of industrial application” – whether a drug is “markedly superior” to any other drug on the market seems irrelevant to whether it is capable of industrial application or has any utility. Further, invalidating a drug that has been approved by the health authorities as being safe and effective in the treatment of a certain disease or ailment (and is currently marketed and sold in Canada) for not having utility twists the obvious meaning of the word and pushes the envelope of compliance with Article 27(1) of the TRIPS Agreement.

The novelty and inventiveness standards would seem to be better equipped to factor in the degree of inventiveness of an invention. While not a perfect substitute for the promise doctrine, these factors are far more appropriate to determine how and what a process/product does than the standard of whether the invention is capable of industrial application.

Interestingly, Canada successfully defended its approach in the investor-state dispute settlement (ISDS) decision in March 2017, but just a few months later the Supreme Court of Canada declared the promise doctrine to no longer be good law. In the ISDS dispute, the Final Award emphasized the high bar to success first in noting that the tribunal “is not


an appellate tier in respect of the decisions of national judiciaries”100 and second in setting out the customary international law minimum standard of treatment as per NAFTA Article 1105(1) as follows:

[A] violation of the customary international law minimum standard of treatment...requires an act that is sufficiently egregious and shocking – a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons – so as to fall below accepted international standards and constitute a breach of Article 1105. Such a breach may be exhibited by a “gross denial of justice or manifest arbitrariness falling below acceptable international standards”; or the creation by the State of objective expectations in order to induce investment and the subsequent repudiation of those expectations...although bad faith may often be present in such a determination and its presence certainly will be determinative of a violation, a finding of bad faith is not a requirement for a breach of Article 1105(1).101

Moreover, the tribunal made it clear that “there are distinctions to be made between conduct that may amount to a denial (or gross denial) of justice and other conduct that may also be sufficiently egregious and shocking, such as manifest arbitrariness or blatant unfairness.”102 In light of the fact that the tribunal’s task is not to act as a review mechanism over national courts, the Award stated that “considerable deference is to be accorded to the conduct and decisions of such courts [and] it will accordingly only be in very exceptional circumstances, in which there is clear evidence of egregious and shocking conduct, that it will be appropriate for a NAFTA Chapter Eleven tribunal to assess such conduct against the obligations of the respondent State under NAFTA Article 1105(1).”103

After setting out the interpretive framework, the tribunal moved to the substance of the claim and found that Eli Lilly “has not demonstrated a fundamental or dramatic change in Canadian patent law...[T]he Tribunal finds that Claimant has not demonstrated, as a factual matter, that its legitimate expectations were violated by the application of Canadian patent law to the Zyprexa and Strattera Patents.”104 This despite the fact that the tribunal accepted the point that prior to the products at issue “no commercially successful products were found to lack utility, whereas now

101 Ibid., para. 222. 102 Ibid., para. 223. 103 Ibid., para. 224. 104 Ibid., para. 387.
this is not uncommon. This is a notable fact, but Claimant has not established this to be the result of changed law.”

[T]he Tribunal recognizes that the outcome in AZT was unexpected for some practitioners and even judges who had understood the language of [a previous decision of the Court of Appeal] to mean that utility could be demonstrated through post-filing evidence (most notably commercial success). Still, having considered all of the evidence, the Tribunal cannot conclude that the Supreme Court effected a dramatic change from previously well-established law when it clarified this rule in AZT.

For these, and other, reasons the Tribunal dismissed the claim.

In regard to the Supreme Court of Canada overturning the promise doctrine on 30 June 2017, the case stems from a trial judge in the Federal Court of Canada finding AstraZeneca’s patent for its blockbuster Nexium drug (a proton pump inhibitor that decreases the amount of acid produced in the stomach) invalid for lack of utility under Section 2 of the Patent Act. While the trial judge found the patent novel and non-obvious, the patent was invalidated for lacking utility under the promise doctrine, with the judge stating that “the promise of the patent is the yardstick against which utility is measured.” In essence, while the patentee fulfilled one promise (use as a proton pump inhibitor to reduce acid in the stomach), it did not fulfil a second promise (improved metabolic properties). More specifically, the patent read:

It is desirable to obtain compounds with improved pharmacokinetic and metabolic properties which will give an improved therapeutic profile such as a lower degree of individual variation. The present invention provides such compounds, which are novel salts of single enantiomers of omeprazole.

Having determined that the promise of a “lower degree of individual variation” was not achieved by the drug, the judge concluded:

Had the patent stated that such compounds “may” or “could” give an improved therapeutic profile, then the argument that such statements referred merely to a goal would be more compelling. The same cannot be said of “will.” Will does not convey a low threshold of potential outcomes, but to the contrary, a high threshold of probable or certain outcomes that

will occur, which in turn, suggests that such outcomes are promised by the patent.\textsuperscript{110}

The decision, upheld by the Federal Court of Appeal,\textsuperscript{111} thus turns on the phrasing used in the patent application rather than the actual utility of the product.

The Supreme Court’s recent ruling in \textit{AstraZeneca} removes the promise doctrine as a basis for declaring a Canadian patent invalid, and it did so in blunt terms: “The Promise Doctrine is not the correct method of determining whether the utility requirement under [Section 2] of the Patent Act is met.”\textsuperscript{112}

The Court then attacked both the sensibility and textual support for the doctrine:

[The promise] doctrine holds that if a patentee’s patent application promises a specific utility, only if that promise is fulfilled, can the invention have the requisite utility, but where no specific utility is promised, a mere scintilla of utility will suffice. Generally, an analysis regarding issues of validity will focus on the claims alone, and only considers the disclosure where there is ambiguity in the claims. This is in accordance with the Court’s direction that claims construction precedes all considerations of validity. The Promise Doctrine, by contrast, directs courts to make determinations regarding utility by reading both the claims and the disclosure to identify potential promises, even in an absence of ambiguity in the claims. The Promise Doctrine then provides that if any one of the promises is not fulfilled, the utility requirement in [Section 2] is not met and the patent, in its entirety, is invalid.

The Promise Doctrine is incongruent with both the words and the scheme of the Patent Act. First, it conflates [Sections 2 and 22(3)] by requiring that...tosatisfytheutilityrequirementin[Section2],anyuse disclosed in accordance with [Section 27(3)] must be demonstrated or soundly predicted at the time of filing. If that is not done successfully, the entire patent is invalid, as the pre-condition for patentability – an invention under the [Section 2] of the Act – has not been fulfilled. Second, to require all multiple uses be met for the patent’s validity to be upheld, runs counter to the words of the Act and has the potential for unfair consequences. The Promise Doctrine risks, as was the case here, for an otherwise useful invention to be deprived of patent protection because not every promised use was sufficiently demonstrated or soundly predicted by the filing date.\textsuperscript{113}

\textsuperscript{110} Ibid., at para. 120.
\textsuperscript{111} \textit{AstraZeneca Canada Inc. v. Apotex Inc.}, 2017 SCC 36 (30 June 2017), para. 24. See also para. 2.
\textsuperscript{112} Ibid.
\textsuperscript{113} Ibid., at paras. 1–2
The Court continued the attack on the doctrine by stating:

_The effect of the Promise Doctrine to deprive such an invention of patent protection if even one “promised” use is not soundly predicted or demonstrated is punitive and has no basis in the Act. Furthermore, such a consequence is antagonistic to the bargain on which patent law is based wherein we ask inventors to give fulsome disclosure in exchange for a limited monopoly. To invalidate a patent solely on the basis of an unintentional overstatement of even a single use will discourage a patentee from disclosing fully, whereas such disclosure is to the advantage of the public. The Promise Doctrine in its operation is inconsistent with the purpose of s. 27(3) of the Act which calls on an inventor to “fully describe the invention and its operation or use.” Thus, the Promise Doctrine undermines a key part of the scheme of the Act; it is not good law._114

The Supreme Court then set out the correct two-step approach that Courts should take in assessing utility – that is, to first identify the subject matter of the invention as claimed in the patent and, second, to ask whether that subject matter is useful – “is it capable of a practical purpose (i.e. an actual result)?”115

As to the “degree or quantum of usefulness” required, the Supreme Court reverted to the traditional requirement that “a scintilla of utility will do,” stating:

_The Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized – a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date._116

This decision represents a rather significant reversal of the requirement for utility, and one that brings Canada back in line with international standards (and significantly lowers the threshold for defending against a challenge on the grounds of utility). While Canada successfully defended the promise doctrine against a challenge in ISDS, it is less certain whether the doctrine is compliant with the TRIPS Agreement. Canada may have been able to successfully argue that given the territorial nature of IPRs it has wide leeway in setting out the standards and perimeters for what qualifies as an “invention” and that its requirement in regard to utility was both fair and sensible; it is just as likely that a court would have seen the doctrine as counter to Article 27(1) of the TRIPS Agreement.

114 Ibid., at paras. 50–51, emphasis added, citations omitted.
115 Ibid., at para. 54. 116 Ibid., at para. 55.
Given the state of the marketplace in Hong Kong, and the legal uncertainty associated with the recent (but no longer relied on) Canadian approach, it would not seem in the interest of the territory to adopt the promise doctrine. Instead, Hong Kong should simply follow the path of the United States and EU in ensuring through interpretive guidelines that speculative inventions in the biotechnology field (or other fields) meet the traditional minimum standard of utility.

3.4 Subject Matter

This section briefly discusses the general legislation on patentable subject matter. In most jurisdictions there are a number of things that simply are not patentable or inventions “as such,” namely, discoveries, scientific theories and mathematical methods. For instance, finding a naturally occurring compound in the human body is a nonpatentable discovery. On the other hand, developing processes used to isolate or purify such a compound or producing a synthetic version of the naturally occurring compound would be a patentable invention. In many jurisdictions, aesthetic creations such as literary, dramatic, musical and artistic works are not inventions “as such.”

Jurisdictions are more divided on the granting of patents for computer programs and software-related patents as well as for business method patents. Jurisdictions also deem some inventions to simply be not patentable. These include inventions contrary to ordre public or morality, “diagnostic, therapeutic and surgical methods for the treatment of humans and animals” and “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.” These exclusions are allowable under Articles 27(2)–(3) of the TRIPS Agreement. While the exclusion for public order and morality and plants or animals needs no further explanation, the exclusion for medical techniques warrants further discussion. The rationale behind the exclusion for medical techniques is that medical practitioners should be free to use any medical method they deem necessary to treat patients. More than eighty countries currently prohibit medical method patents, including countries in the EU,

118 The exception being that Members must provide protection, whether by patents or a sui generis right, to plant varieties.
Asia, Africa, North America and South America.119 This exclusion of patentability is reached in different ways, even in Europe. For instance, some countries (including the United Kingdom, Germany and France) have incorporated provisions affirming such methods are not capable of industrial application, whereas Sweden, Italy and Denmark have declared such methods to be noninventions. For its part, Switzerland characterizes medical techniques as legal exceptions to patentability. 120

In contrast, methods of medical treatment are patentable in the United States and Australia.121 In the United States, however, medical practitioners benefit from immunity from liability. In Australia, there is no such immunity. In Section 93(4) of the Patents Ordinance, Hong Kong follows the major European countries in using industrial application to exclude patentability:

A method for treatment of the human or animal body or surgery or therapy and a diagnostic method practiced on the human or animal body shall not be regarded as an invention which is susceptible of industrial application . . . but this subsection shall not apply to a product, and in particular a substance or composition, for use in any such method.

Section 93(5) of the Hong Kong Patents Ordinance also deems that “the publication or working of which would be contrary to public order (‘ordre public’) or morality shall not be a patentable invention”; however, “the working of an invention shall not be deemed to be so contrary merely because it is prohibited by any law in force in Hong Kong” and the patenting of “plant or animal variety or an essentially biological process for the production of plants or animals, other than a microbiological process or the products of such a process.” Hong Kong drew heavily on European, UK and Irish law in formulating Section 93(5),122 and it does not appear that any modifications relating to pharmaceutical patents are required.

### 3.5 Second Use

This section revisits in greater detail second or subsequent medical use (second use) patents. Originators have long argued for the adoption of

120 Ibid., at 471.
122 See EPC Arts. 52 and 53; 1977 c. 37 ss. 1 and 4 U.K.; 1992 No. 1 ss. 9 and 10 Eire.
second use patents in order to provide for a soft landing from the patent cliff.\textsuperscript{123} Such an argument is weak, as originator companies should have taken the entirely foreseeable eventual expiration of patent protection into account and in their business models. To the contrary, some would argue that excluding second use patents will help originator companies divert attention away from less demanding research and focus on inventing new compounds.\textsuperscript{124}

That said, more compelling arguments for second use patents exist. For instance, as science progresses it becomes harder to invent completely new compounds and substances (since the lower hanging fruits of the compounds have already been harvested). Moreover, during the life-cycle of the first medical use patent, (1) beneficial effects on another disease or part of the body can sometimes be observed in a patient group suffering from more than one disease, or (2) targeted research to a second use of the drug demonstrates beneficial effects in a patient group that suffers from another disease. In addition, it has been argued that patentability of second and subsequent medical use of known compounds is crucial\textsuperscript{125} in order to reduce the cost of pharmacogenomics.\textsuperscript{126}

The development of additional medicines based on existing drugs should be encouraged, as it represents a cheaper way to expand the medicinal toolkit and benefits human health. The legal issue is how the system can encourage such innovation while at the same time discouraging second use patents that confer additional monopolies on a product that is obvious to the PHOSITA or on an old/existing product (even if it has been unexploited).\textsuperscript{127}

\textsuperscript{123} “Patent cliff” is a phenomenon caused by the expiration of a patent whereby marketing exclusivity and monopoly pricing is lost, thereby resulting in a reduction in sales and profits for the originator company.

\textsuperscript{124} Daniel Armstrong, “The Arguments of Law, Policy and Practice against Swiss-Type Patent Claims” (2001) 32 Victoria University of Wellington Law Review 201, 237 (“Even if conscious effort is required in the development of new uses, this is likely to be much less onerous than the research required in developing new compounds”).


3.5.1 The Basics of Second and Subsequent Medical Use

In principle, second use patents encourage further research and stimulate additional innovation, both of which can lead to more competition and access to more reasonably priced medicines. For this reason, advocates argue that without second use patents there is no incentive for continued R&D, and public health would suffer. Critics, on the other hand, contend that second use patents simply delay the availability of generic competition and artificially inflate prices.\textsuperscript{128}

There may well be truth in both positions, and it is also important to understand the different context among jurisdictions. A jurisdiction such as the United States, EU or Switzerland will have different considerations, and different impact on the pharmaceutical industry, from those of a lower middle income country or LDC. For Hong Kong, several considerations come into play. Hong Kong is a small pharmaceutical market, and whether Hong Kong adopts second use patents is not going to be a deciding factor in a company’s decision to conduct research into second medical uses. Moreover, given Hong Kong’s current pharmaceutical capabilities, the adoption of second use will not result in more R&D being conducted in Hong Kong. On the contrary, the adoption of second or further use patents will lead to a transfer of funds out of Hong Kong. However, this is not to say that Hong Kong should not adopt second or further use patents – it is simply to understand that this transfer of funds out of the territory is the price Hong Kong has to pay for being an internationally responsible world-class city that respects IPRs.

This context also suggests two opposing objectives that should be at the core of Hong Kong’s decision to legislate for a balanced regulation on second or further use patent protection:

1. Second or further use patents should not restrict “first use” patents. To the contrary, first use should be in the public domain allowing generic manufacturers to use and sell the resulting product – Hong Kong can then benefit from the cost savings. Care must also be taken

\textsuperscript{128} See, e.g., Patent Report of the Brazilian Chamber of Deputies, above n. 2, at 36 (“Most ‘new’ products placed in the pharmaceutical market would, in reality, be imitation products (me toos), meaning equivalent molecules to the ones already in the market that do not represent real innovation”).

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in this regard to ensure that practitioners can legally prescribe both the first and second use patented products. Legislation should therefore be mindful of and take into account potential adverse effects of second use patents on off-label use of medicines.

(2) The level of protection granted to second use patents should correspond to the level of their inventiveness: Therefore, crudely stated, more protection should be granted for pure second medical use patents, while less protection should be granted for second use claims that reside in a factor related to its efficacy, and an even lower level of protection should be granted for second use patents such as selection patents and polymorphism.

3.5.2 Hierarchy of Inventiveness

On an arguably lower level in the hierarchy of inventiveness – but of crucial importance for patients, the pharmaceutical industry and governments – are second use patents that combat the same disease or illness as the first use but demonstrate a greater efficacy by way of timing, frequency, dosage or sequence of the administration of the drug or in combination with a new compound. A growing variation of this is where the efficacy of a medicine is limited to a subset of the patients based on specific genome traits. Without such pharmacogenomic second use patents, there is simply no incentive for pharmaceutical companies to indicate the ineffectiveness of their drugs based on some genotypes or to indicate the effectiveness of a failed or expired drug for some subset of patients. Second use claims can remedy this and give pharmaceutical companies incentives to develop genetic tests and inform them about any potential adverse drug responses. This way the patent can be extended, although only for a fraction of the market, based on genotype. Pharmaceutical companies are also incentivized to improve efficacy or decrease side-effect profiles in particular patient subpopulations.

Granting such second or further use patents incentivizes pharmaceutical companies to improve efficacy or decrease side-effect profiles in particular patient subpopulations – again, this is to the benefit of human health. The proposal to use Swiss-type claims as a form of protection for pharmacogenomics inventions does not appear to have been widely considered. That being the case, the Examination Guidelines for Patent and Utility Model in Japan includes a provision that expressly approves of the application of second use claims, where novelty resides in the new
patient group, in order to provide patent protection to pharmacogenomic inventions.\textsuperscript{129}

On the same or arguably lower level of inventiveness are second use patents based on selection,\textsuperscript{130} polymorphism,\textsuperscript{131} optimal isomers,\textsuperscript{132} analogy processes,\textsuperscript{133} combinations,\textsuperscript{134} active metabolites\textsuperscript{135} and

\textsuperscript{129} Part VII: Examination Guidelines for Inventions in Specific Fields, Chapter 2.2.1.1 Method of Judging Novelty (3–3)(a): “When it becomes clear that the claimed medicinal invention intended to specify by such mode of medical treatment is effective to a patient having, for example, a particular gene, and it becomes clear that it becomes possible for those skilled in the art to clearly distinguish the target patient groups of the both, which is specified hereunder, by a fact that the target patient group of the claimed medicinal invention is different from the target patient group which is not specifically specified in the cited invention.” Medicinal Invention (Draft), Japan Patent Office Examination Guidelines for Patent and Utility Model in Japan (2005), p. 8, www.jpo.go.jp/iken_e/pdf/iken_e20050224_2/01.pdf, accessed 22 February 2017.

\textsuperscript{130} The UK Court of Appeal rejected the contention that a specific compound lacks novelty as a matter of a priori reasoning (a generalized prior description does not disclose a specific matter within it). See Dr Reddy’s Laboratories (UK) Limited v. Eli Lilly and Company Limited, Court of Appeal (Civil Division), UK, 18 December 2009, Docket No: Case No. A3/2008/2966.

\textsuperscript{131} Crystal forms of the same compound. The search for the most adequate polymorph to improve stability, solubility, bioavailability and processability of the solid form of a certain substance may already be described in the state of the art and, therefore, if this is the case will not be characterized as novel and non-obvious – one of the essential patentability requirements. See Janssen-Ortho Inc. et al. v. Novopharm et al., 2006 FC 1234. See further Joel Bernstein, Polymorphism in Molecular Crystals (Oxford University Press, 2010).

\textsuperscript{132} Optical isomers are two compounds that contain the same number and kinds of atoms and bonds and different spatial arrangements of the atoms but that have nonsuperimposable mirror images.

\textsuperscript{133} Analogy processes are noninventive processes but with a non-obvious product as a result, where the features can be derived only from an unknown and unsuspected effect (problem invention). For the EPC, see 9.17 Analogy process – envisageable product, Case Law of the Boards of Appeal (EPO), https://goo.gl/rGRBjx, accessed 4 March 2017. For the United States, see the Biotechnology Process Patents Act 1995.

\textsuperscript{134} Since 2007 the US Supreme Court held that when elements, techniques, items or devices are combined, united or arranged, and when, in combination, each item performs the function it was designed to perform, the resulting combination – “ordinary innovation” – is not patentable. This can be true even if there is no teaching, suggestion or motivation to make the combination. See KSR Int’l Co. v. Teleflex Inc., above n. 57.

\textsuperscript{135} In most countries, active metabolites that are purified or synthesized in vitro are protected, contrary to those by metabolism. Section 3(d) of India’s 2005 Patents (Amendment) Act recognizes metabolites as “new types of known substances,” in principle considered identical to known substances and thus unpatentable. Only those metabolites that differ significantly in their characteristics regarding efficacy are deemed patentable. See further Richard Li-dar Wang and Pei-Chen Huang, “Patent Protection of Pharmacologically Active Metabolites: Theoretical and Technological Analysis on the Jurisprudence of Four Regions” (2013) 29 Santa Clara Computer & High Technology Law Journal 489.
prodrugs. Thus, one can argue that the level of protection granted to such types of inventions depends on the level of inventiveness required in the jurisdiction, as well as the basic objectives of the domestic patent system.

### 3.5.3 Balance of Opposing Policy Objectives

Since Hong Kong’s standard of inventiveness is not bound by any international obligation other than the requirement to protect novel, inventive and useful inventions for products or processes under Article 27(1) of the TRIPS Agreement – and provides flexibility in how Members meet this standard – it will be able to carefully craft the regulations in such a way as to optimally balance the two objectives that should drive Hong Kong’s patent policy.

On the one hand, Hong Kong’s internal objective must be to provide access to medicines at reasonable costs to its population. Industrial policy considerations should be an afterthought, as there is little local manufacturing (of which nearly all are low-tech generics) and almost a complete absence of serious originator R&D. It is thus in Hong Kong’s interest to increase the standard of patentability such that more medicines become generic and the costs of medicines decrease. On the other hand, Hong Kong’s external objective is to uphold its reputation as a world-class, business-friendly city that respects the rule of law and property rights. Maintaining strong levels of IPRs is thus also in Hong Kong’s interest.

### 3.5.4 Methods Excluded as Subject Matter

As mentioned in Section 3.4 above, in most jurisdictions medical methods are excluded as patentable subject matter. Thus, medical practitioners are allowed to prescribe any method as they see fit. Instead, Swiss-type claims and more direct claims that reside in the use of the patented invention impose liability for infringement only on manufacturers. Moreover, the main characteristic of these second use claims is that novelty is not destroyed even though the same compound or substance is already known because of the first use of the patent. Swiss-type claims – that is, where “the

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136 Prodrugs are bioreversible, inactive derivatives of drug molecules that must undergo an enzymatic/chemical reaction in the body (in vivo) to release the active metabolite. See further Ralph Minderop, Arwed Burrichter and Nathalie Kirchhofer, "Prodrugs and Metabolites – In the Twilight of Patentability" (2013), *IP in the Life Sciences Industries 2013*, 8.
use of the known compound X in the manufacture of the medicament for the new therapeutic application Y” – are devised to avoid two obstacles to patentability: the novelty requirement and methods of medical treatment exclusion.

3.5.5 Novelty in Use

When the use in treating a medical condition might be new, novelty resides not in the subject matter of the claim but in some related use. In other words, the new use in treating a disease is included in the claim. The advantage of Swiss-type claims is that pharmaceutical companies are incentivized to continue research into new uses of known compounds and that medical practitioners’ discretion to use the method of medical treatment of their choice is guaranteed. The EPO accepted the patentability of “the (second or subsequent) use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application,” because although the exclusion of therapeutic methods from patentability provided in Article 52(4) EPC 2000 on the ground that then these are not susceptible to industrial application has the effect of excluding from patentability a claim directed to the use of a substance for therapy, this type of claim would clearly be allowable (as susceptible to industrial application) for a nonmedical use: “the use of X for treating disease A in mammals” (not allowed), with “the use of X for treating disease B in cereal crops” (allowed).137

Since the decision in Kos Life Sciences (G02/08)138 the EPO and the UKIPO no longer grant Swiss-type claims for patents covering second medical uses. Instead, patents will be granted with a more direct wording: for a pharmaceutical product with a specified (second or subsequent) medical use.

3.5.6 Options for Hong Kong

Section 94(2) of Hong Kong Patents Ordinance 1997 (“state of the art”) does not provide any room for the patentability of new uses of existing compounds since novelty would be destroyed. Likewise, Section 93(4) of Patents Ordinance 1997 excludes methods of medical treatment to be

138 Kos Life Sciences/Abbott Respiratory LLC (G 0002/08), Enlarged Board of Appeal, EPO, 19 October 2010.
patented. Therefore, should Hong Kong decide to enable second or further medical use for existing compounds, it could craft a provision that resembles Section 4A(4) of the UK Patents Act 1977, as suggested by both the HKAPI and the American Chamber of Commerce in Hong Kong (AmCham).\(^\text{139}\) Even though the new direct claims provided for under Section 54(5) EPC 2000 and Section 4A(4) of the UK Patents Act 1977 are directed to impose liability on manufacturers, there would also be a need to provide immunity against infringement liability for practitioners in order to avoid unnecessary interpretive problems. Whether the claim is phrased as a Swiss-type or more direct claim, it does not say much about novelty or obviousness. Therefore, Hong Kong can be flexible and cater to both sorts of claims, especially since Swiss-type claims are allowed in China.

Another option for Hong Kong would be to remove the method of treatment exception (Section 93(4) Patents Ordinance 1997) from the excluded subject matter for patentability. Such a model is adopted in the United States, which does not accept claims to use but instead accepts claims of method and process.\(^\text{140}\) This is also possible in Singapore, with Section 14(7) of the Patents Act providing: “In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.”\(^\text{141}\)

In addition, practitioners can be immunized against patent infringement for using the methods of medical (pharmaceutical), surgical and therapeutical treatment of their choice. If adopted, neither Swiss-type claims nor direct secondary use claims would be necessary. Next to novelty, inventiveness would be the only invalidating factor.

A survey of other jurisdictions indicates a mix of approaches and absence of international consensus. For instance, South Korea provides for wide-ranging legal protection of second medical use as long as it meets the patentability requirements normally provided by law, while Australia...

\(^{139}\) See “Review of the Patent System in Hong Kong,” above n. 12, 174. It is worth noting that the Law Society of Hong Kong also recommended updating the substantive law with regard to second medical use and Swiss-type claims. Ibid., at 176.
\(^{140}\) 35 USC Section 100(b).
provides a narrower version, with patent extensions of up to five years for claims to active ingredients or new formulations of a known active ingredient.\textsuperscript{142} In regard to the lack of novelty, “patent extension” is the correct phrase. However, Australia also uses this patent extension for new and inventive substances,\textsuperscript{143} which seems not in accord with the expression. Australia does not allow for patent extensions for new uses and methods.\textsuperscript{144} On the other end of the spectrum, several countries including the Andean Community (Peru, Bolivia, Columbia and Ecuador) exclude new use patents.\textsuperscript{145} Brazil and South Africa, meanwhile, are reportedly considering laws to remove the exception to novelty so as to prohibit second use patents in order to facilitate the entry of generic medicines in the market.\textsuperscript{146}

Another issue that would need to be addressed relates to off-label prescriptions of medicines protected by second use patents. Without special attention, the prescription of such drugs could lead to primary liability of infringement by doctors, pharmacists and patients. In addition, the generic manufacturer will need certainty that it will not be exposed to the risk of secondary liability of infringement – such a risk would be a major disincentive to manufacture the product that was subject to the first use patent, even though manufacturing, marketing and selling the medicines with the appropriate label, package and patient information leaflet is legal because the first use patent has expired.

The analysis of second use patents is not complete without mention of the 2013 decision of the Supreme Court of India in \textit{Novartis AG v. Union of India} (Glivec).\textsuperscript{147} In this decision, the Supreme Court upheld the rejection of the patent application filed by Novartis AG for Glivec in 1998 (a so-called mailbox application) with the Indian Patent Office. In so doing, the Court held that Glivec (imatinib mesylate, a beta crystalline form of

\begin{footnotesize}
\begin{enumerate}
\item[142] Australia Patents Review Report, above n. 75, at 93.
\item[143] Ibid.
\item[144] Ibid.
\item[146] South African IP Review, above n. 38, at 29. Now Section 25(9) Patents Act 1978 (amended 2002) allows it: “In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.” Patent Report of the Brazilian Chamber of Deputies, above n. 2, at 36 and 125.
\item[147] Novartis AG v. Union of India, (UOI) and Ors.; Natco Pharma Ltd. v. UoI & Ors.; M/S Cancer Patients Aid Association v. UoI & Ors., Civil Appeal Nos. 2706–2716 of 2013, decided 1 April 2013.
\end{enumerate}
\end{footnotesize}
the free base imatinib) did not meet the novelty and inventiveness require-
ments, since the beta crystalline form of imatinib mesylate was already
included in Novartis’s US patent on the free base imatinib, thereby becom-
ing part of the prior art. Section 3(d) of India’s Patent Act allows the
mere discovery of a new use for a known substance to be patented only
if the discovery can significantly improve the therapeutic efficacy of its
properties.148 This section is highly controversial and is responsible for
two-thirds of all rejected pharmaceutical patents.149

The Supreme Court of India observed that the legislature enacted the
 provision “to prevent evergreening; to provide easy access to the citizens
of this country to life saving drugs and to discharge their Constitutional
obligation of providing good health care to its citizens.”150 While India no
doubt had industrial as well as health objectives in mind when drafting
such legislation (and leaving aside the merits of the application of facts to
the law in the case), the provision and case presents a useful illustration
of a jurisdiction that allows only conditional second use in order to avoid
clear cases of evergreening of the patent, that is, the originator making
only minor changes to the patent in order to register a new one and
thereby extend protection. It would be in Hong Kong’s interest to craft a
second use provision based on India’s Section 3(d) Patent Act 2005 where
evergreening is discouraged but where the harnessing of true follow-on
innovations that lead to net benefits are allowed and encouraged. How-
ever, it is perhaps in Hong Kong’s interest to not be as strict with the
“therapeutic efficacy” component of the standard, as a switch in dosage,
form and the like could bring immense health benefits in patients.

148 Section 3 of the Patents Act 1970 (Amendment 2005) reads: “The following are not inven-
tions within the meaning of this Act, – (d) the mere discovery of a new form of a known
substance which does not result in the enhancement of the known efficacy of that sub-
stance or the mere discovery of any new property or new use for a known substance or of
the mere use of a known process, machine or apparatus unless such known process results
in a new product or employs at least one new reactant.” Explanation: For the purposes
of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers,
mixtures of isomers, complexes, combinations and other derivatives of known substance
shall be considered to be the same substance, unless they differ significantly in properties
with regard to efficacy. India reconfirmed the necessity for “therapeutic efficacy” as part of
the inventive step criteria in relation to pharmaceuticals in response to questioning from,
among others, the EU, United States, Japan, Australia and Switzerland. See Trade Policy
Review India, Minutes of the Meeting, WT/TPR/M/313/Add.1, 31 July 2015, at 102–3.
149 Peter Leung, “Most India Pharma Patent Denials Due to Single Provision,” BNA Interna-
tional Trade Daily (28 July 2016).
150 Novartis AG v. Union of India, paras. 12 and 19.
It is also in Hong Kong’s overall interest as a strong proponent of IPRs and good international citizen to promote and encourage the pharmaceutical industry to invest R&D into existing drugs leading to the creation of new and useful products that benefit human health. It would seem to be a great pity if the potential of such research remains dormant due to lack of incentives and potential financial reward. That said, second and further use patents will not directly benefit the industry in Hong Kong, nor will they lead to any strengthening of the industry. Instead, the result will be that monopolies will be extended and thus Hong Kong will pay more for pharmaceuticals. For these reasons, it is strongly recommended that in adopting second and further use patents the government think carefully about how and to what extent it provides the additional protection, and then to pay attention to the drafting of the relevant legislation. The above analysis presents several models and argues for the adoption of a model that ensures manufacturing, use and prescription of the first use is legitimate and lawful and that also sets some standards for the grant of a second or further use patents and discourages evergreening so as to reward only true innovations that benefit human health.

### 3.6 Concluding Remarks

In moving from a registration to examination patent system, Hong Kong will need to better consider how the Patents Ordinance and its interpretation can reflect the territory’s needs and developmental objectives in relation to patentability standards. Hong Kong is not an innovative pharmaceutical center, and without systemic and coordinated government efforts it will never be so. Neither is Hong Kong seeking to conflate industrial and health policy as a driver of pharmaceutical patents. Instead, Hong Kong should be concerned about its aging population and the steady rise in the costs of medicines. For this reason, Hong Kong should ensure that its transition to an examination system is accompanied by strict patentability standards that fully respect prevailing international standards while at the same time guard against overprotection and interests that run counter to those of the territory. This chapter provided comprehensive analysis of the most pressing patentability issues and made several recommendations that will assist Hong Kong in establishing a fair, predictable and efficient system based on a holistic view of health and other local priorities.