Exceptions to Exclusive Rights

5.1 Introduction

Article 28 of the TRIPS Agreement confers exclusive rights on the patent holder, including making, using, offering for sale, selling or importing the protected product. These rights, however, are subject to exceptions contained in the Agreement. In other words, while the TRIPS Agreement grants substantive rights to a patent owner, it also allows but does not oblige Members to take advantage of exceptions to these rights. The two most notable exceptions discussed in this chapter are contained in Articles 30 and 31. Article 30 is a broadly worded provision allowing Members to provide exceptions to the patent owner’s exclusive rights, provided that such exceptions are limited, do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Meanwhile, Article 31 relates to the issuance of compulsory licenses, with the mainly procedural provision permitting Members to allow third-party use of the patent without authorization of the rights holder.

Both exceptions play an important role in maintaining the balance between patent owners and broader societal interests. Both have also been the subject of controversy since the inception of the TRIPS Agreement, and the exact contours of these exceptions have yet to be fully defined. For this reason, great diversity exists in the domestic legislation of WTO Members – with some countries, most notably India and Argentina, pushing the boundaries of the exceptions while other Members take a more cautious approach. Hong Kong can generally be viewed as falling into the latter category, for reasons that appear to be more of benign neglect than design. This must change as the drafting of precise and clear provisions in domestic legislation allowing for possible exceptions to owner rights is critical in ensuring the system can properly function not only in normal
circumstances but especially in case of emergency or in times of health crisis.

The Article 30 exception is inextricably linked to the issue of access to medicines. As mentioned elsewhere in this book, stringent testing requirements apply to new pharmaceuticals, while subsequent generic applicants are subject to simplified procedures. The safety and efficacy of the drug has been established and thus the generic must only submit data evidencing that their product is the bioequivalent ("biosimilar")\(^1\) or chemical equivalent of the innovator drug, depending on the country at issue.\(^2\) While the issue is more complicated for biological drugs (i.e., pharmaceuticals made from a living organism or its products), countries are devising regulations to facilitate the entry of biosimilars.\(^3\) Owing to the abbreviated application process, the time period needed in order to secure marketing approval for a generic applicant is generally less than that of the original innovator. That said, depending on the jurisdiction and unique circumstances of each case, approval time may still be considerable.

If a generic producer must wait to apply for marketing approval until the expiration of the patent period, the time lag will delay the introduction of competitor products and result in additional monopoly rents paid to the patent owner. Simply, if a generic manufacturer cannot apply for marketing approval until the expiration of the term of patent(s) covering a pharmaceutical product, the patent owner will enjoy a prolonged period of de facto monopoly power. This de facto monopoly and corresponding monopoly rent will last for the time period it takes for the generic version of the product to gain market approval.

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\(^1\) Biosimilar products are “interchangeable” with licensed biological products, in the way that generic products are interchangeable with innovative drugs made from a chemical entity. See, for instance, the definition formulated by the US Food and Drug Administration at www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/. For a similar definition, see also Biosimilar Development, “About Biosimilar Regulations,” www.biosimilardevelopment.com/doc/about-biosimilar-regulations-0001.


The “regulatory review” or “Bolar” exception under Article 30 is designed to eliminate the de facto monopoly period by allowing a generic producer to apply for marketing approval during the life the patent, without breaching the exclusive rights of the patent owner. In this regard, the regulatory review exception reduces the time it takes for a generic to enter the market, thereby allowing competition onto the market almost immediately following the expiration of a patent. Thus, the regulatory review exception serves the purpose of reducing the price of and increasing access to affordable pharmaceuticals by allowing the generic to “use” the patent for testing and the purposes of making an application for marketing approval from the relevant governmental agency. As is discussed in greater detail below, the panel in Canada – Pharmaceutical Patents held that Canada’s regulatory review provision fell within the scope of the three-step test contained in Article 30 of the TRIPS Agreement.4

Anyone familiar with issues involving pharmaceuticals and the WTO over the last two decades would be familiar with the issue of compulsory licenses. The TRIPS Agreement allows for compulsory licenses to be issued for patented products and processes under limited circumstances and on satisfying certain conditions. These conditions have proven controversial as they limit usage of compulsory licenses. Thus, while the conditions guard against abuse, they also for example essentially prevent Members with insufficient or no manufacturing capacities from making use of the provision. The WTO addressed the issue of health and trade in the November 2001 WTO Ministerial Conference in Doha, which adopted a Ministerial Declaration on the TRIPS Agreement and Public Health reiterating and expressly stating that the TRIPS Agreement does not limit the grounds on which compulsory licenses may be granted and acknowledging the right of each Member to determine when a “national emergency” or “other circumstances of extreme urgency” exist in its territory.5 The issue of the limitation regarding compulsory licensing was not resolved until a follow-up agreement in 2003, which provided for a “waiver” of certain conditions and thus allowed Members with insufficient or no manufacturing capacities to import pharmaceuticals under compulsory license.

5 WTO, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, adopted on 14 November 2001, at 5(b) and 5(c).
This chapter proceeds as follows. Section 5.2 discusses Article 30, with particular focus on the experimental use or research exception, which includes the regulatory review exception. Section 5.3 discusses the Article 31 exception for compulsory licensing. Compulsory licenses have received considerable attention in the literature over the past two decades but are perhaps not as important in the Hong Kong context given the jurisdiction's perceived need to provide strong protection to IPRs. Nevertheless, reviewing the situation in Hong Kong and providing for adequate and effective laws should the need arise remains crucial for a properly functioning regulatory regime. Both sections will review the international framework and practice in other jurisdictions in order to formulate practical recommendations for Hong Kong.

5.2 The Exceptions

5.2.1 Article 30 – Experimental or Research Exception

The experimental use or research exception is a policy tool used by many countries in order to promote scientific research and technological development and to encourage inventive activities. In most cases, the exception “enables researchers to examine the stated effects of patented inventions and improve such patented inventions without having to fear infringing the patent.” The rationale underlying the exception is that allowing experimentation and research on existing technologies without cost or impediment leads to the development of even more technological advancement, thereby furthering the aims of the patent system. Thus, one of the justifications (if not the main one) for the exception for experimental use is to promote scientific research and innovation. The panel in Canada – Pharmaceutical Patents discussed this point when stating:

We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws – the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued

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that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a “legitimate interest” in using the patent disclosure to support the advance of science and technology.\(^8\)

The reasoning behind such an exception is in line with that of the patent system, which attempts to balance the needs of the inventors/patent holders with those of secondary innovators, end users and society at large. More specifically, the experimental use or research exemption can be traced to the ultimate aim of the patent system to provide incentives to invent in exchange for disclosure and the promotion of subsequent innovation and technological development. In this regard, free access to prior inventions and discoveries by subsequent researchers might be viewed as an effective means of promoting progress and technological development in some fields of research. Restraining this research avenue could invite peril. In a submission to an Australian report on patents and experimental use released in 2005, the Ludwig Institute for Cancer Research states:

> Curtailing the experimental use exemption could stifle innovation and slow the advance of technology. The practical effect of barring research would be to allow a patent holder to stop not only commercial competition, as is a proper right under the patent system, but also all research that might lead to such competition, as well as barring improvement, challenge or avoidance of a patented invention\(^9\)

Likewise, the World Health Assembly recommended that countries adopt an experimental use exception in order to promote “greater access to knowledge and technology relevant to meet public health needs of developing countries” and that they address public health needs in a manner fully consistent with the TRIPS Agreement.\(^10\)

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\(^8\) Panel Report, *Canada – Pharmaceutical Patents*, above n. 4, at 7.69.


In the absence of a clear experimental use exemption, it is advanced that users of the patent system incur unnecessary costs and societal costs, which include adverse effects on innovation, competition and, in regard to pharmaceutical inventions, public health. Of course, there are questions regarding the extent to which commercial interests should be able to make use of the exception or whether the exception is limited to noncommercial purposes (e.g., teaching). It is also debatable whether the exception should apply equally to all fields of technology. For instance, pharmaceutical research involves immense capital investment and concomitant commercial risks, and some commentators believe that the legal regime should guard against free-riding on the substantial efforts of the primary researchers. This, however, raises further questions regarding the distinction between the use of inventions for the intended purpose and purely experimental use. The practical reality, however, is that the distinction between basic, “pure” research with no commercial implications (which most commentators believe should be freely accessible) and applied research, which most believe should be accessible only with the authorization of the patent holder, is not as clear as one might expect. Instead, the two categories are increasingly blurred in many fields of research, including pharmaceuticals.\footnote{See Rebecca Eisenberg, “Patents and the Progress of Science: Exclusive Rights and Experimental Use” (1989) 56 University of Chicago Law Review 1017, 1018.} Despite these challenges, the aim should be for jurisdictions to draft regulations granting strong patent protection but at the same time not allowing the patent system to stifle justified scientific research activities and ultimately scientific progress.\footnote{See UK Department of Trade and Industry, “Patents for Genetic Sequences: The Competitiveness of Current UK Law” (2004), a study by the Intellectual Property Institute on behalf of the DTI, available at http://webarchive.nationalarchives.gov.uk/20060213221438/http://www.dti.gov.uk/5397_DTI_Patent_Study.pdf, at 6 (“there is evident uncertainty...about the extent of the patent research exemption, which is widely seen as problematic”).} 

The experimental exception is a recognized and legitimate flexibility in the exclusive rights of a patent holder,\footnote{See, e.g., WIPO, “Exceptions and Limitations to Patent Rights,” above n. 6.} but nevertheless remains controversial. As should be clear from the above discussion, little consensus exists among countries on the scope and parameters of the exception.\footnote{See UK Department of Trade and Industry, “Patents for Genetic Sequences: The Competitiveness of Current UK Law” (2004), a study by the Intellectual Property Institute on behalf of the DTI, available at http://webarchive.nationalarchives.gov.uk/20060213221438/http://www.dti.gov.uk/5397_DTI_Patent_Study.pdf, at 6 (“there is evident uncertainty...about the extent of the patent research exemption, which is widely seen as problematic”).} In some jurisdictions the exception is narrowly crafted, whereas in others it appears quite broad. This leads to uncertainties and thus domestic legislation is at times attacked by critics. Despite – or perhaps because of – the differences, to date there have been few attempts to systematize and
disseminate a best practices approach across countries.\textsuperscript{14} Even FTAs do not attempt to clarify or elaborate in any way on the scope of the exception, instead preferring to merely repeat the language of Article 30 of the TRIPS Agreement verbatim.\textsuperscript{15}

The laws in Hong Kong as currently drafted are vague and do not specifically provide for a number of recognized exceptions, most notably the regulatory review exception. To avoid legal uncertainty in the research sector, Hong Kong should carefully draft an experimental use provision that clarifies the extent to which research is exempted from patent infringement liability. This includes the addition of a clear provision on the consistency of generic use of a patented product for the purposes of obtaining marketing approval. In order to reach this conclusion, the section will first review the international framework, namely, through exploration of the Article 30 exception to the exclusive rights of the patent owner. The section then proceeds to examine the experimental use exception in the national laws of various countries and in FTAs with a view to finding potential sources of inspiration for Hong Kong to emulate. Finally, the section offers analysis and recommendations for Hong Kong.

International Obligations
The need to include exceptions to patent rights was generally recognized by the negotiating parties to the TRIPS Agreement. The parties differed, however, in the scope of the exceptions. While several countries supported a broad exception clause,\textsuperscript{16} the United States preferred a more limited

\textsuperscript{14} OECD, “Patents and Innovation: Trends and Policy Challenges” (DSTI/STP92003)27 13-Oct-2003 at 22, www.oecd.org/sti/sci-tech/24508541.pdf, accessed 6 March 2017. In Canada – Pharmaceutical Patents, Canada provided the panel with a list of what it deemed permitted experimental uses in accordance with Article 30: “(a) testing an invention to determine its sufficiency or to compare it to prior art; (b) tests to determine how the patented invention worked; (c) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention; (d) experimentation for the purpose of "designing around" a patented invention; (e) testing to determine whether the invention met the tester’s purposes in anticipation of requesting a licence; and (f) academic instructional experimentation with the invention.” The Panel did not engage with or comment on this list. Panel Report, Canada – Pharmaceutical Patents, above n. 4, at 75.

\textsuperscript{15} For example, Article 17.9.3 of the US-Chile FTA provides that “[e]ach Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

\textsuperscript{16} See, e.g., “Guidelines and Objectives Proposed by the European Community for the Negotiation on Trade-Related Aspects of Substantive Standards of Intellectual Property Rights,”
exception. The draft text of July 1990 included a broad, nonexhaustive list of exceptions, which included experimental purposes. The final version of the experimental use or research exception, however, is formulated more generally and without any list of exempted acts. It appears as Article 30 of the TRIPS Agreement:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

This formulation is based on Article 9(2) of the Berne Convention, with a general three-step test to determine compatibility with the provision. Article 30 is thus forever intertwined with the Berne Convention, with the negotiating history of that earlier agreement remaining relevant to the interpretation of Article 30 as per both the Vienna Convention on the Law of Treaties (VCLT) and the specific incorporation of the Berne Convention into the TRIPS Agreement. In the only WTO dispute to interpret the provision, the panel in Canada – Pharmaceutical Patents supported its interpretation of the TRIPS Agreement through explicit reference to the negotiating history of the Berne Convention.

The panel in Canada – Pharmaceutical Patents was called on to determine whether two of Canada’s pharmaceutical regulatory provisions were exceptions to patent rights covered by Article 30. The provisions were the so-called regulatory review (or Bolar) exception and the stockpiling exception, which are as follows:


17 US Submission, MTN.GNG/NGII/W/70, 11 May 1990 (proposing to limit exceptions to compulsory licenses).


19 See TRIPS Agreement, Article 2.2.

Patent Act, Section 55.2(1):
It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

Patent Act, Section 55.2(2):
It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires.

The panel determined that the three-step test contained in Article 30 is cumulative and therefore each step is independent of the others, meaning that in order to comply with Article 30, exceptions should (1) be “limited,” (2) “not unreasonably conflict with a normal exploitation of the patent” and (3) “not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.”

The panel then clarified:

The three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy. Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be “limited” and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not “unreasonably conflict with normal exploitation” could nonetheless “unreasonably prejudice the legitimate interests of the patent owner.”

The panel found that the stockpiling exception was not “limited” simply because it only applied to products that require regulatory approval (and a

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21 Ibid., para. 7.20. This finding has been criticized in the literature. See, e.g., the Max Planck Institute for Innovation and Competition, “Declaration on Patent Protection. Regulatory Sovereignty under TRIPS,” para. 8, www.mpg.de/8132986/Patent-Declaration.pdf, accessed 4 March 2017 (“Contrary to what [the panel in Canada–Pharmaceutical Patents] seemed to assume, the three conditions are not cumulative. The three-step test may be understood to require a comprehensive overall assessment rather than a separate and independent assessment of each criterion. Failure to comply with one of the three conditions need not result in the exception being disallowed”).

22 Ibid., para. 7.21.
further argument that the focus of inquiry should be on the right to “sell”). Instead, the panel found that the lack of limitations on the quantity of production and stockpiling during the six months immediately prior to the expiration of the patent resulted in a “substantial curtailment” of Article 27.1 and therefore could not fall within the meaning of “limited.” Since the stockpiling exception fell at the first hurdle, the panel did not review it under the two remaining steps of the test.

On the contrary, the panel found that the regulatory exception is consistent with Article 30 – that is, Members can use a patented invention, without the consent of the patent holder, for testing required data in order to obtain marketing approval for pharmaceutical or other products. In regard to the first step, that the exception be “limited,” the panel first had to determine the meaning of the word. In this regard, the panel stated:

7.30 The word “exception” by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term “limited exception,” the word “limited” must be given a meaning separate from the limitation implicit in the word “exception” itself. The term “limited exception” must therefore be read to connote a narrow exception – one which makes only a small diminution of the rights in question.

7.31 In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged. The term “limited exceptions” is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with.

Thus, the panel focused on the extent of the curtailment of the rights, leaving the economic effect of the rights to be evaluated under the second and third steps of the test. In addition, the panel stated that when

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23 Ibid., paras. 7.27–38. 24 Ibid., para. 7.38.
25 To some commentators, the panel’s determination that “the economic impact of the exception must be evaluated under the other conditions of Article 30 unduly narrows down the scope of admissible exceptions” and could result in a scenario where the exception may not be applicable even when the rights owner is not negatively affected in economic terms. See, e.g., Carlos Correa, “The Bolar Exception: Legislative Models and Drafting Options,” in Mercurio and Kim (eds.), Contemporary Issues in Pharmaceutical Patent Law. It should
evaluating the limiting conditions of a measure, “both the goals and the limitations stated in Articles 7 and 8.1 [as the objectives and principles of the TRIPS Agreement] must obviously be borne in mind, as well as other provisions of the TRIPS Agreement which indicate its objective and purposes.”

In regard to the second step, that the exception not unreasonably conflict with normal exploitation of the patent, the critical issues for the panel were determining what is “normal exploitation” of a patent and whether any such conflict (if any) is unreasonable. While scholars have offered several conflicting interpretations of “normal,” the panel sought guidance from the dictionary and found “normal” to be “regular, usual, typical, ordinary, conventional.” The panel considered that “normal exploitation of the patent” referred to the “commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent.” In so doing, the panel avoided having to weigh in on whether the term has empirical or normative connotations. Instead, the panel combined the two approaches and found that normal exploitation is “an empirical conclusion about what is common within a relevant community” and “a normative standard of entitlement.”

For the panel, the “protection of all normal exploitation practices is a key element reflected in all patent laws,” and the “normal practice” is for patent owners “to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity.” The panel further elaborated that patent exploitation is not static and that for “effective exploitation” a patent owner must

be noted that the panel rejected Canada’s submission for a broader interpretation of the first step. See Canada – Pharmaceutical Patents, above n. 4, para. 7.37.

26 Canada – Pharmaceutical Patents, above n. 4, para. 7.26. 27 Ibid., para. 7.54

28 Canada argued that “exploitation” involved the extraction of commercial value by “working” the patent, by selling the product in a market from which competitors are excluded, by licensing others to do so or by selling the patent rights. The European Communities largely agreed, but differed in its interpretation of the term “normal.” Ibid., para. 7.51.

29 Ibid., para. 7.54.

30 Ibid., para. 7.55. Correa strongly disagrees with the panel’s reasoning: “The panel’s reasoning is questionable. The right to exclude the use of the patented subject matter by third parties is not a form of exploitation of the patent, but a legal power established by law that may be exercised or not. The exploitation consists of the acts of making, using or commercializing the inventions without third parties’ competition. In addition, the panel went too far in considering ‘all forms of competition’ since competition may legitimately proceed through the improvement of the patented technology. The normal exploitation of a patent should be deemed limited to uses of the invention that are shielded from competition by law.” Correa, above n. 25.
“adapt to changing forms of competition due to technological development and the evolution of marketing practices.”31

Applying the law to the facts of the case, the panel concluded that the “additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization should not be considered ‘normal.’”32 The additional period of monopoly sales following the expiration of a patent during which time a generic must seek marketing approval is not a “natural or normal” consequence of enforcing patent rights, but rather an “unintended” consequence “of the conjunction of the patent laws with product regulatory laws.”33 That is, patent owners do not expect this additional period of monopoly sales, but it results by operation of the regulatory laws regarding the sales of pharmaceuticals.

As to the third criterion that the exception does “not unreasonably prejudice the legitimate interests of the patent owner,” the panel held that “legitimate interest” is not limited to “legal interests” and must instead be “defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms.”34 The panel further added that a definition equating “legitimate interests” with legal interests makes no sense at all when applied to the final phrase of Article 30 referring to the legitimate interests of third parties.35 As the last part of Article 30 – “taking account of the legitimate interests of third parties” – is not included in Article 9(2) of the Berne Convention or in Article 13 of the TRIPS Agreement, the panel concluded by stating:

Absent further explanation in the records of the TRIPS negotiations, however, the Panel was not able to attach a substantive meaning to this change other than what is already obvious in the text itself, namely that the reference to the “legitimate interests of third parties” makes sense only if the term “legitimate interests” is construed as a concept broader than legal interests.36

In the case at issue, the panel was not sympathetic that an additional period of post-patent monopoly sales was a “legitimate interest,” stating that the “interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing

31 Ibid., para. 7.55. 32 Ibid., para. 7.57. 33 Ibid. 34 Ibid., para. 7.69. 35 Ibid., para. 7.68. 36 Ibid., para. 7.71.
approval was neither so compelling nor so widely recognized that it could be regarded as a ‘legitimate interest’ within the meaning of Article 30.”

The panel therefore found the Canadian regulatory review exception consistent within the scope of Article 30 and thus the TRIPS Agreement. In so doing, the panel did not accept the argument that the patent owner should have a de facto extension of its monopoly for delays resulting from the marketing approval process for generic pharmaceuticals. This decision has played a large role in the development of experimental use exceptions in a number of countries. The panel report does not, however, settle every issue and leaves significant scope for continuing discussion and debate on the breadth of the Article 30 exception.

Experimental Use Exception in Leading Jurisdictions

As mentioned above, the experimental use exception varies under national laws in terms of the scope of coverage, definition and types of justifiable experimentation and research activities. This subsection cannot provide comprehensive coverage of the issue, but instead will canvass a variety of domestic laws so as to provide a framework from which Hong Kong can take guidance and construct a more tailored and appropriate law.

United States

The United States is one of a handful of nations that does not enshrine the experimental use exemption in statutory law. Instead, the exception is firmly established as part of the common law. The experimental use exception has a long history in the United States, with Judge Story in the 1813 case of Whittemore v. Cutter holding that “it could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described

37 Ibid., para. 7.82.
effects.”\(^39\) The court, however, limited the scope of the exception to use done “merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the [patented invention] to produce its described effects.”\(^40\) The court in *Peppenhausen v. Falke* (1861) summarized the state of the law by stating:

> It has been held, and no doubt is now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee.\(^41\)

The Federal Circuit applies the exception in a “very narrow and strictly limited” manner,\(^42\) sustaining it only when actions are performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry” and not when the infringing activities are “in keeping with the alleged infringer’s legitimate business.”\(^43\) For instance, the court in *Madey v. Duke University* held that the experimental use of a patent furthers the university’s “legitimate business” objectives, which include educating and enlightening students, faculty participating in research projects and furthering the university’s reputation and ability to attract grants, students and faculty.\(^44\) Such a narrow interpretation of the common law privilege limits the value of the exception and means that the exception is “rarely sustained.”\(^45\)

In addition to the common law, the United States has a number of statutory exceptions relating to experimental use. For the purposes of pharmaceutical research, the most relevant is the Bolar exception. This exception came about as a result of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, a 1984 case that tested the limits of the experimental use exception. In the case, Roche claimed Bolar infringed its patent on the drug Dalmane by conducting bioequivalence studies in order to apply for marketing approval from the FDA for a generic version of Dalmane (flurazepam).\(^46\)


\(^40\) Ibid., at 1121. See also *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass 1813) (No. 12, 391).

\(^41\) *Peppenhausen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861).

\(^42\) *Madey v. Duke University*, 307 F. 3d 1351 (Fed. Cir. 2002), at 1361.

\(^43\) Ibid., at 1352. 44 Ibid., at 1362.


At first instance, the US District Court for the Eastern District of New York ruled in favor of Bolar, holding no liability under the common law experimental use exemption doctrine. The US Court of Appeals for the Federal Circuit overruled the District Court primarily due to the “truly narrow” scope of the exception and the commercial nature of Bolar’s activities:

Bolar’s intended “experimental” use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar’s intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the [Roche] patent. Bolar may intend to perform “experiments,” but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use de minimis. It is no trifle in its economic effect on the parties even if the quantity used is small. It is not a dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of “scientific inquiry,” when that inquiry has definite, cognizable, and not insubstantial commercial purposes.47

In so holding, the Court also rejected Bolar’s argument that public policy considerations justify experimental use during the life of the patent in order to facilitate the availability of generic drugs immediately upon the expiration. With some sympathy, the Court stated that it should be Congress and not the courts to create exceptions and change the law.48

In response, Congress took action later that same year and passed the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act).49 Attempting to balance the protection of patented pharmaceuticals with more timely entry of generic drugs into the market, the Act reshaped the pharmaceutical market and relationship between branded and generic manufacturers in the United States. The relevant part of the Act states:

[I]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention…solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.50

48 Ibid., at Section C.
50 35 USC §271(e)(1).
Thus, Section 271(e)(1) immunizes generic drug manufacturers from liability of patent infringement for “uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.”51 In other words, a generic manufacturer will not be held liable for patent infringement when it conducts bioequivalence studies “reasonably related” to obtaining FDA approval of an Abbreviated New Drug Application (ANDA). The Act is of critical importance as it provided generic manufacturers with the right to “use” patented subject matter for the purpose of gaining regulatory approval prior to the expiration of the relevant patent(s) in exchange for the opportunity of patent owners to seek a patent term extension for delays resulting from the approval process.52 As a result, generics no longer need to conduct expensive and unnecessary clinical tests in order to apply for marketing approval, thus reducing the cost of pharmaceuticals to consumers.

The courts have interpreted the “reasonably related” component of the Bolar exception rather broadly. For instance, courts have held that Section 271(e)(1) covers medical devices, pharmaceuticals53 and pre- and even postclinical studies undertaken with the intent of making a submission to the FDA even if the product/submission never materializes.54 Moreover, courts do not look to the underlying purpose or intended consequences of a use, so long as the use is reasonably related to the FDA approval.55 Essentially, the exception will be applied where the alleged infringer – as opposed to the court – reasonably believed that there was a decent prospect that the “use” in question would contribute to the generation of

52 For discussion and analysis of patent term extension, see Chapter 4.
53 Eli Lilly and Co. v. Medtronic 496 US 661, 665–666 (1990) (Justice Scalia interpreted the phrase “a Federal law which regulates the manufacture, use, or sale of drugs” to mean the entire of Food, Drug and Cosmetic Act, which covers not only drugs but also medical devices and other products). As a result, most commentators would extend the Act to also cover such items as food and color additives. See John R. Thomas, “Scientific Research and the Experimental Use Privilege in Patent Law,” CRS Report for Congress, 28 October 2004, 16.
54 See Merck KGaA v. Integra Lifesciences I, Ltd., 545 US 193, 202 (2005); see also Momenta Pharma. v. Amphastar Pharm., 686 F.3d 1348, Section II (2012) (“the fact that Amphastar’s testing is carried out to ‘satisfy the FDA’s requirements’ means it falls within the scope of the safe harbor, even though the activity is carried out after approval”).
55 AbTox, Inc. v Exitron Corporation, 122 F.3d 1019, 1020 (Fed. Cir. 1997), modified 131 F. 3d 1009 (Fed. Cir. 1997).
information that was likely to be relevant in the FDA approval process.\textsuperscript{56} In fact, even postapproval studies that could include “materials the FDA demands in the regulatory process” have been deemed to fall within the safe harbor provision.\textsuperscript{57} Of course there are limits to the extent of the exception, and courts have held that studies with the patented compound for the purposes of developing a new patented drug are excluded from the scope of the Bolar exception.\textsuperscript{58}

**European Union**  The EU has for some time been grappling with the particularities of the experimental use exception. Attempts to add some clarity have met with limited success. One such attempt was the Community Patent Convention (CPC) 1975,\textsuperscript{59} which included the following provision for experimental use:

\begin{quote}
Article 31(b): The rights conferred by a Community Patent shall not extend to acts done for experimental purposes relating to the subject matter of the invention.
\end{quote}

The CPC, however, was not ratified by the Member States and never came into effect.\textsuperscript{60} That being the case, similarly worded provisions on experimental use can be found in the legislation of most EU Member States. However, the scope and extent of the exception is far from harmonized, with some members explicitly limiting it to noncommercial activities, whereas others allow acts that anticipate a future commercial exploitation. Legislation in some Member States is simply silent on this point.

Another point of differentiation among EU Member States is the meaning of the term “experiment” and the breadth and limits in regard to

\textsuperscript{56} See also *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. at 1280 (stating that the court should apply the exception “[w]here it would have been reasonable, objectively, for an accused infringer to believe that there was a decent prospect that the use in question would contribute (relatively directly) to the generation of information that was likely to be relevant in the processes by which the FDA would decide to approve the product”). See also *Abt ox, Inc. v. Ex tron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997); *Am gen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 106 (D. Mass. 1998).

\textsuperscript{57} *Momenta Pharm s., Inc. v. Amphast ar Pharm s.*, Inc., 686 F.3d 1348, 1359–60 (Fed. Cir. 2012).


\textsuperscript{60} An amended version of the CPC (1989) also failed to be ratified by at least four of the then-twelve EU Member States.
the exception. For instance, in the United Kingdom, Section 60(5) of the Patents Act 1977 provides for an exception for acts (a) done privately and for purposes that are not commercial and (b) for experimental purposes relating to the subject matter of the invention. However, the experimental use exception is limited to “experiments which generate genuinely new information,” thus excluding tests designed to verify existing knowledge or acts undertaken by a generic applicant in order to obtain marketing approval. Moreover, case law has also interpreted the phrase “relating to the subject matter of the invention” narrowly to mean “having a real and direct connection with that subject matter.”

In contrast, courts in Germany have given a broad interpretation to Section 11.2 of the German Patent Act 1981, which reads: “The effect of the patent shall not extend to . . . acts done for experimental purposes relating to the subject matter of the patented invention.” More specifically, the Federal Supreme Court has found the term “experiment” to include “checking of the utilisability of the subject-matter of the patented invention and checking possibilities of further development,” regardless of “whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests.” Thus, the scope of the German exception extends to commercial-oriented research as opposed to being limited to research of a purely scientific nature.

Yet another point of difference within Europe is whether the experimental use exception applies only to research on or into a patented invention or whether research with or using the patented product is also covered. While the majority of Member States limit application of the exception to the former, others follow the Belgian model, which covers

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62 Smith Kline & French Laboratories Ltd. v. Evans Medical Ltd. [1989] FSR 513

63 Klinische Versuche (Clinical Trials) I RPC 623; Klinische Versuche (Clinical Trials) II (Case XZR 68/94) R.P.C.423, 433 [1998].

64 Klinische Versuche (Clinical Trials) I RPC 623, 639 [1997], Federal Supreme Court of Germany.

65 See William Cornish, “Experimental Use of Patented Inventions in European Community States,” 29(7) IIC 735 (1998) (arguing that “[g]iven the forcefulness of the judgements . . . in Klinische Versuche I and II, there must be a strong likelihood that their outcome will be followed in courts elsewhere in the EC”).

66 See, e.g., Sean O’Connor, “Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technology Countries,” in Toshiko Takenka (ed.),
“acts accomplished for scientific purposes on and/or with the subject matter of the patented invention.”

Turning specifically to pharmaceuticals, the legality of the regulatory review exception was until recently in some doubt throughout the EU even though experimentation on an invention has generally been accepted. This is the case despite, as described above, that under certain circumstances acts done for commercial purposes in some Member States fell within the scope of the exception. The regulation of the pre-patent-expiry development was not harmonized at the EU level, and while national legislation of EU Member States commonly provided for a general research exemption for “acts done for experimental purposes relating to the subject-matter of the patented invention...legal uncertainty existed whether it covered pre-patent expiry testing in the EU,” and national courts differed in their interpretations. The EU amended Directive 2001/83/EC to provide for enhanced certainty:

Conducting the necessary studies and trials with a view to the application [for marketing approval] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Patent Law and Theory: A Handbook of Contemporary Research (Edward Elgar, 2009) (surveying exceptions in technology-oriented jurisdictions and distinguishing between commercial R&D exceptions and government or public nonprofit research exceptions as well as exceptions for research conducted “on” the patented invention (i.e., studying the drug for purposes of creating a bioequivalent version) and research “with” a patented drug (i.e., using the drug to perform other research activities)).

68 See, Clinical Trials II, above n. 63.
70 See, e.g., Monsanto v. Stauffer (1985) R.P.C. 515 (C.A.) (UK Court of Appeal holding that the experimental use provision did not exempt trials by generic companies aimed at securing regulatory approval), subsequently followed in Auchinloss v. Agricultural & Veterinary Supplies Ltd. (1999) RPC 397. But see Klinische Versuche II, above n. 63 (German Supreme Court holding that test data generation for the purpose of obtaining regulatory marketing approval can qualify for the experimental use exemption if such tests also advanced the state of art in some way).
The Directive is clearly designed to provide an exception for the use of a patented invention made to comply with the requirements for obtaining marketing approval for generic medicines.\(^72\) Unfortunately, due to vague drafting and lack of clarity surrounding the term “studies and trials,” implementation of the Directive differs widely among EU Member States.\(^73\) In essence, while some Members apply the exception narrowly to include only activities relating to marketing approval of generic medicines,\(^74\) other Members also allow uses in trials related to the development of new products,\(^75\) with some even allowing trials undertaken to comply with regulatory requirements abroad to fall within the scope of the exemption.\(^76\) Case law in the EU to establish the contours of the provision is still developing,\(^77\) and some Member States have been slow in updating the law. For instance, in the United Kingdom it was not until October 2014 that Section 60(5)(b) of the Patents Act was amended to specifically allow generic companies to use a patented product for testing or other activity for the purposes of providing information to the regulatory authorities who decide whether a drug should be given a marketing approval.

Finally, it is worth mentioning the possibility of extending the experimental use exception to cover clinical trials performed for purposes other than the approval of a generic version. The recent amendments to the UK Patents Act provide for such usage;\(^78\) meaning uses of drugs in the

\(^72\) This is confirmed through Article 27(d) of the Agreement on a Unified Patent Court (UPC), which states: “The rights conferred by a patent shall not extend to any of the following: (d) the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC 1 or Article 10(6) of Directive 2001/83/EC 2 in respect of any patent covering the product within the meaning of either of those Directives.”


\(^74\) This group includes the United Kingdom, Belgium, Cyprus, Ireland, the Netherlands and Sweden.

\(^75\) This group includes Austria, Bulgaria, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia and Spain.

\(^76\) This group includes Austria, Germany, Denmark and Italy.


\(^78\) The Legislative Reform (Patents) Order 2014 entered into force as of 1 October 2014 and amended the Patents Act 1977. Section 6(D) reads: “For the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention.” For background information, the description and assessment of the draft proposal, see Regulatory
course of clinical tests and studies carried out for the purposes of regulatory approval other than proving bioequivalence of generic drugs (e.g., as comparators for original drugs) are now explicitly exempted from patent infringement. Prior to the amendment in 2014, Section 60(5)(i) of the Patents Act exempted from infringement uses related to the regulatory approval of generic drugs; however, the Act “[did] not extend to innovative drugs.” The amendment now extends the exception in subsection (5)(b) to all acts done in or for the purposes of a medicinal product assessment (not only those for demonstrating bioequivalence to the approved drugs). Section 60(6D) now provides that “anything done in or for the purposes of a medicinal product assessment...is to be regarded as done for experimental purposes relating to the subject matter of the invention.”

The amendment thus broadens the scope of the exception and is intended to promote clinical drug development in the United Kingdom. In this regard, the UK IPO stated:

Many factors are taken into account by companies when deciding where to locate clinical trials; the risk of patent infringement being one of them... In its favour, the UK has a good healthcare and scientific infrastructure, world experts in particular conditions, specialised hospitals, good access to patients through the NHS network, and high levels of literacy and ethical standards. However, the narrow exceptions to patent infringement in UK law may put companies at a disadvantage compared to other countries with broader exceptions. Stakeholders have indicated that, everything else being equal, it is likely that trials would be located in a jurisdiction with more generous Bolar or research exceptions.

Such reasoning lacks strong empirical basis but has been persuasive to date. It will be interesting to see what effect the UK shift has on other European jurisdictions.


80 Intellectual Property Office Explanatory document, above n. 79, para. 1.13 (citations omitted).

81 Centre for Intellectual Property Policy, above n. 66, at 48. Following a study of the United States, Australia, Germany, the United Kingdom and France, this report concluded: “While the precise impact of experimental use exceptions on the vitality of health care related R&D industries remains elusive, a number of conclusions can be drawn. Most notably, ... a comparative study of the strength of research-based industries in the courtiers discussed above relative to the scope of their respective experimental use exceptions suggests that...
China  As of the latest revision to the Patent Law in 2008, China now explicitly provides for an experimental use exception and a more specific clause pertaining to the regulatory review exception. The experimental use exemption focuses on how a patented invention is used (i.e., experimentation on the patented invention per se or employing the patented invention as a means), rather than the purpose of the use (business or philosophical) as is the case in the United States.  

82 Experimental use in China has generally been considered to refer to scientific research and experimentations carried out specifically on the patented technology as such, but not those that are conducted by exploiting the patented technology. This understanding is now reflected in a directive delivered by the Beijing Higher People’s Court in 2013, entitled “Guidelines for Judgment of Patent Infringement.”  

83 Although not technically binding, the Guidelines are indicative of how courts will interpret the scope of experimental use and what is generally considered “good law” in the Chinese system.

In regard to the regulatory review provision, Article 69(5) of the Patent Law states that use “[f]or the purpose of providing the information needed for the administrative approval” shall not be deemed to be a patent infringement. While this is rather vague, China interprets the provision broadly. Such an interpretation has been confirmed by the State Intellectual Property Office (SIPO), which issued a binding directive entitled “Guidelines for Determination of Patent Infringement and Passing Off,” stating that the exception is applicable not only to patents on drugs and medical devices as such, but also to those on an active ingredient of a drug, a process for preparing a drug, a process for preparing an active ingredient of a drug, parts specifically for use in a medical device and a method
of using a medical device. Therefore, activities falling within the scope of the provision include (1) manufacture, use or import of a patented drug or patented medical apparatus by any person in order to acquire information necessary for seeking marketing approval; as well as (2) manufacture or import of the drug/apparatus by any person solely for others to acquire such information will be deemed as an exception to patent infringement.

Regulatory Review Exception – Other Jurisdictions Subsequent to the panel report in *Canada – Pharmaceutical Patents*, a number of countries adopted a regulatory review exception, which has now been widely adopted throughout the world. As expected, the scope of the provision differs between and among jurisdictions. In some jurisdictions, the experimental use exception explicitly includes acts undertaken to obtain marketing approval, while in others the regulatory review exception is contained in a separate provision. In some jurisdictions, the experimental use exception has been given a broad interpretation so as to encompass acts by third parties to obtain regulatory approval, whereas others more narrowly interpret the provision.

Ironically, perhaps, the take-up rate for the exception is lowest in Africa where increased access to medicines is most needed. For instance, review of national legislation published in 2007 revealed that only three of the thirty-nine countries included specifically provided for a regulatory review exception (Kenya, Namibia and Zimbabwe). While several countries have subsequently incorporated the exception, the take-up rate remains exceedingly low. Somewhat surprising too is the fact that several countries in Latin America and the Middle East introduced a regulatory review exception only as a result of an FTA with the United States, whose

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84 Section 7, Chapter Three, Part I Guidelines for Determination of Patent Infringement and Passing Off, www.sipo.gov.cn/tz/gz/201309/t20130925_819909.html, accessed 4 March 2017. Section 7(2) reads: “[T]he implemented medicine patents include not only the patents of the medicine itself, but also the patents of the active ingredients in the medicine, the patents of the preparation method of the medicine, and the patents of the preparation method of pharmaceutical active ingredients in the medicine; the implemented medicinal equipment patents include not only the patents of the medicinal equipment itself, but also the patents of special parts of the medical equipment, and the patents of the usage method of the medical equipment.”

85 See Tridico et al., above n. 38.

negotiating template includes a narrow form of the exception. An example of such a provision is Article 17.9.4 of the US-Chile FTA, which states:

If a Party permits the use by a third party of the subject matter of a subsisting patent to support an application for marketing approval or sanitary permit of a pharmaceutical product, the Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of the Party other than for purposes related to meeting requirements for marketing approval or the sanitary permit, and if export is permitted, the product shall only be exported outside the territory of the Party for purposes of meeting requirements for issuing marketing approval or sanitary permits in the exporting Party.

In fact, even India introduced a regulatory review exception only in 2002, taking inspiration from the US approach. The Indian exception, however, is wider of scope than the US provision, as it allows the experimental use exception to apply to the submission of information domestically or overseas, whereas the United States limits this exception for the submission of information domestically. Section 107A of the Indian Patents (Amendment) Act 2002 reads:

Certain acts not to be considered as infringement. – For the purposes of this Act:

(a) any act of making, constructing, using or selling a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product;

(b) importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.87

What this diversity of approach indicates is that while the experimental use exception is an acceptable means of achieving the balance of rights and obligations needed to promote technological innovation and dissemination, the nuances regarding scope and breadth have been left to jurisdictions. This leads to uncertainty and accusations of going beyond the parameters of Article 30 of the TRIPS Agreement. While some favor a narrow exception, others argue for a broader approach.88 For Hong Kong, the

88 See, e.g., Shamnad Basheer and Prashant Reddy, “The ‘Experimental Use’ Exception through a Developmental Lens,” (2010) 50(4) IDEA 831, 834 and 872 (“TRIPS was premised on the promise of transfer of technology. Given that there is no meaningful way of obligating developed countries to transfer technology, TRIPS should at the very least
limits may not matter as in practice it is not likely to push the boundaries of the international order. The more important issue for the jurisdiction is providing clarity to existing law.

**Policy and Legal Considerations for Hong Kong**  

Hong Kong’s experimental use exception is outdated and does not serve the purpose for which it is intended. The provision should be reviewed and updated. In so doing, Hong Kong should take a holistic approach to the experimental use exception and be mindful not to unduly limit its scope and potential importance in the community. Hong Kong should thus follow the advice of Sean O’Connor, who opined that “policymakers should be aware of the full range of research use exceptions – from exceptions for competitive commercial R&D to very narrowly tailored de facto research use exceptions for government research – and employ models that match broad research, public domain, and competition policies in their country.” At present, and like many other jurisdictions, Hong Kong’s legislation limits the scope of the exception in such a way as to curtail the usefulness of the provision. More specifically, Section 75 of the Patents Ordinance (Cap 514), entitled “Limitation of effect of patent,” sets out the experimental use exemption:

The rights conferred by a patent shall not extend to (a) acts done privately for non-commercial purposes; (b) acts done for experimental purposes relating to the subject-matter of the relevant patented invention.

Modeled after Section 42 of the Irish Patents Act 1992, the section has not been updated despite an amendment to the Irish Patents Act in 2006 implementing the EU directive on the regulatory review exception. Section 42 of the Irish Patents Act now includes subsection (g), “Limitation of effect of patent,” providing:

The rights conferred by a patent shall not extend to –

(g) acts done in relation to the subject matter of the relevant patented invention which consist of:

(i) acts done in conducting the necessary studies, tests and trials which are conducted with a view to satisfying the application requirements . . . for a marketing authorisation in respect of a medicinal product for human use.

enable countries to ramp up technological capabilities by themselves. One way of doing so is by having a robust experimental use exception, enabling such countries to work with registered patents, understand and absorb underlying technology”).

89 See O’Connor, above n. 66.
In order to avoid legal uncertainty, Hong Kong should carefully draft a regulation that makes the delineations of the experimental use exemption clear. It should also seek to draft the provision in terms as wide as possible; given its lack of domestic pharmaceutical industry, the objective should be to provide access to affordable medicines as quickly as possible. Before making further recommendations on a potential course of action, however, it is useful to review the two main issues in crafting a regulatory review exception. First, the provision should improve availability of affordable drugs by facilitating the timely entry of generic competition into the marketplace. Second, the provision should provide certainty regarding which uses (related to regulatory approval) fall within the scope of the exception and which can potentially constitute patent infringement.

With these overarching issues in mind, and with the aims and objectives of Hong Kong at the forefront, the following analysis considers specific matters relating to the regulatory review exception.

**Covered Products**: One of the first issues that must be considered is whether the exception will apply to all products subject to regulatory approval or should be more limited, such as applying only to patented pharmaceutical products or to related products and medical devices.91 There does not seem to be an overriding justification to limit the exception only to health-related or pharmaceutical products. In fact, doing so may be inconsistent with Article 27.1 of the TRIPS Agreement’s prohibition on discrimination in regard to the field of technology.92 Thus, at a minimum the regulatory review exception should cover pharmaceutical products and related medical devices.

**Permitted Acts**: Prior to seeking marketing approval from the regulatory authority, a generic applicant normally must “use” the patented product in a variety of ways. This includes working with samples of the patented product. The applicant may produce the sample or obtain it through purchase and importation. While most regulatory review provisions do not specifically allow for all such possibilities, some in fact do clearly set out which acts are permissible under the exception. An example in this regard is Section 69A of the South African Patent Act (as amended in 2002), which provides:

91 The United States, as described above in n. 55, extends the exception to related products and medical devices. Other jurisdictions limit the exception to pharmaceutical products. See, e.g., Australian Patents Act 1990, Section 119A (explicitly excluding medical and therapeutic devices from the scope of the exception).

92 But see Canada – Pharmaceutical Patents, above n. 4, para. 92.
(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

(2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.

This provides certainty to both patent owners and generic producers regarding the scope of their rights. The provision is also drafted to ensure that importation of the patented product (or active ingredient) comes within the scope of the exception. Failure to include importation in the scope of the exception would in effect mean that few if any companies manufacturing generics in Hong Kong could make use of the provision, resulting in a de facto prohibition on applications for marketing approval of generics during the life of the patent. Hong Kong should thus follow this approach and set out exactly which acts fall within the scope of the provision.

Another point worth mentioning is South Africa’s broad wording in regard to the purpose of the exception. Note here that the South African provision applies to “any law that regulates” as opposed to the more narrowly worded “acts for regulatory approval,” “acts solely for uses reasonably related to regulatory approval” or “acts exclusively aiming at regulatory approval,”93 which are used in other jurisdictions. Here again, Hong Kong would be wise to follow South Africa and draft a broad provision in order to guard against litigation and unnecessarily narrow interpretation of the exception.

Limitation to Generics or a Broader Exception: A important consideration is whether to have the regulatory review provision apply only where marketing approval for a generic product is sought or to widen the scope of the provision and have it also apply to research that could lead to the development of a new product. A number of laws do not address the issue or distinguish it based on ultimate aim of the researcher.94 This seems like

93 See WIPO, “Exceptions and Limitations to Patent Rights,” above n. 6, para. 132.
94 See, e.g., Thailand Patent Act B.E. 2522 (1979) as Amended by the Patent Act (No. 2) B.E 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999), Article 36.4 (providing the patentee's exclusive rights shall not apply to any act concerning an application for drug...
the correct approach, as a company cannot guarantee that testing will be successful or that circumstances dictate filing for marketing approval in every case. As detailed above, such a broad approach is in line with the judicial application and interpretation of US law.

Likewise, most countries do not stipulate whether the regulatory review exception applies only to preclinical studies or also applies to subsequent clinical studies (including postclinical testing). The US approach of extending the exception to all studies so long as there is a reasonable basis to believe that those studies will produce information relevant to an application to be filed with the regulatory authority seems again to be the correct approach. If the studies may be useful or required by the regulatory authority, there is no reason to distinguish between the stages of trials or when the studies are conducted.

**Temporal Limitations:** Most countries do not address the issue, but some limit the exception to a certain time frame prior to the expiration of the patent.95 There does not seem to be any justification for a temporal restriction. In fact, such a restriction limits the ability of a generic to challenge the validity of the patent by bringing a drug to market within a few years of the normal expiration of the patent.

**Submissions in Other Jurisdictions:** Some jurisdictions limit the regulatory review exception to acts undertaken with respect to an application for marketing approval in their respective country, whereas others allow the exception to cover acts undertaken for submission in another jurisdiction. An example of the latter includes India, where Section 107(a) of the Patents Act covers acts relating to the development and submission of information required by law “in India or in a country other than India.”96 Many others with similar provisions, such as Brazil, have a similar interest in encouraging generic production within their jurisdictions.97 While

registration or to the applicant intending to produce, distribute or import the product after the expiration of the patent term). See also Argentine Law 24.766 on Confidential Information of December 1996, Article 8.

95 Mexican Industrial Property Law (as amended up to 9 April 2012), www.wipo.int/wipolex/en/details.jsp?id=11711 (limiting the exception to within three years of expiration).
96 Section 107A(a) of the Patents Act 1970 (incorporating all amendments until 23 June 2017).
97 See, e.g., Brazil Law No. 9.279, May 14, 1996 (Industrial Property Law) as amended by Law 10.196 of 14 February 2001, Article 43 (VII) (applying "to acts performed by non-authorized third parties, regarding patented inventions, which aim exclusively [at] the production of information, data and test results directed to procure commerce registration, in Brazil or any other country, to allow the exploitation and commercialization of the patented product, after the termination of the terms provided in article 10").
this is not particularly relevant to Hong Kong, there are reasons to recommend that the territory allow acts undertaken for submission in another jurisdiction. Correa succinctly makes the point:

There is no solid justification for a limitation regarding submissions in foreign countries. The legitimate interests protected under a patent granted in the country where trials take place are not affected by acts made in another jurisdiction. Patents are of territorial nature. Whether the submission of information in a foreign country, before the expiry of a patent granted there, is admissible or not is a matter solely subject to the law of that country.98

Correa’s point is valid and there is no solid justification to limit the scope of the provision to within the territory. Moreover, as Hong Kong occasionally discusses becoming a pharmaceutical hub, it should ensure that its laws allow this to occur. Thus, Hong Kong should follow the Indian model of applying the exception to acts undertaken for submission in another jurisdiction.

Concluding Comments on Article 30

By paying attention to the details of its regulatory review exception, Hong Kong can benefit from the experience of other jurisdictions, and the time taken to complete the marketing approval process can potentially be reduced. Hong Kong should therefore craft a provision that is both more specific and broader than that of Ireland’s, taking into account its position as a pharmaceutical importer with little to no branded operations currently operating in the territory.

Of course, the regulatory review exception is only the starting point and does not resolve many of the important questions regarding the scope of the broader experimental use provision. For instance, it is debatable whether Hong Kong should continue with its narrow interpretation of the exception limiting its use to noncommercial purposes or broaden the interpretation (as is the case in Germany). Without an amendment specifically for a regulatory review exception, it would seem sensible for Hong Kong to broaden the scope of the general experimental use provision. However, the easier and more targeted approach would simply be to add the regulatory review amendment, such as that of the Irish provision highlighted above. In this respect, the integrity of a limited and narrow experimental use provision remains intact with clarity and explicit recognition

98 See Correa, above n. 25.
of specific necessary acts from pharmaceutical companies as a result of health and safety regulations. That being the case, limiting the exception to noncommercial use narrows the scope of the exception and does not allow users to take advantage of the full extent of Article 30 of the TRIPS Agreement. The limitation is unnecessary and not in line with the health or competition policies of the jurisdiction. Thus, Hong Kong should remove the noncommercial use limitation so as to broaden the scope of the provision while at the same time ensuring that its law remains in line with the parameters set by Article 30 of the TRIPS Agreement.

Hong Kong should also clarify whether the exception covers “experimenting with” or “experimenting on” patented inventions. In the United Kingdom, “experimenting with” inventions falls within the experimental use exception, whereas “experimenting on” inventions is outside the scope of the provision. As a net importer of patented inventions, one could argue that Hong Kong’s provision ought to be wide enough to permit entities to experiment on patented inventions with a view toward improving or even inventing around such patents. It could therefore follow Belgium in drafting a provision with wide scope. However, Hong Kong also must be mindful of the expectations of the global business community, including the pharmaceutical industry, and of its perceived place in the region as an IP hub and therefore not deviate too much from world legal standards. Moreover, the jurisdiction hosts very little pharmaceutical research and development. Given this, it does not seem appropriate for Hong Kong to push the boundaries, and thus the jurisdiction should limit the exception to “experimenting with” patented inventions.

5.2.2 Article 31 Exceptions

Compulsory licensing refers to the exploitation of a patent without the patent holder’s consent on the authorization of a national authority. Such authorization can be granted to a third party or to a government entity. In the context of pharmaceuticals, compulsory licenses are most often issued to a third party when the price and/or availability of the pharmaceutical product constrains access by citizens in the relevant market.99

The vast majority of WTO Members legislatively allow for the government and/or third parties, under certain circumstances and conditions, such

to use a patented invention without the authorization of the right holder via a compulsory license. Similar to the experimental use exception, the exact circumstances, boundaries and limits of the legislation differ among and between the jurisdictions, as the interests of various stakeholders may diverge between jurisdictions. What remains constant, however, is the core basis for the exception – that is, to prevent abuse of the monopoly power granted by a patent right and to help “ensure that the patent system contributes to the promotion of innovation in a competitive environment and to the transfer and dissemination of technology, meeting the objectives of the system and responding to the public interest at large.”

The compulsory license is also viewed as a “safeguard” ensuring that a government can adequately and effectively respond to a national security or health emergency or crisis. Compulsory licenses differ from other exceptions in that the government and/or third party is not allowed to freely exploit the patented invention. Rather, exploitation is limited to the terms of the license, and patent owners maintain the right to remuneration for such use.

While activists have for some time viewed compulsory licenses as an effective way to provide access to essential medicines throughout the developing world, the truth is that the mechanism is not a panacea. On the contrary, the value of the law as such is of more benefit as it serves to encourage voluntary licenses and price reductions. Thus it is the threat of a compulsory license that is a valuable bargaining chip to be used to extract concessions from the rights holder; whereas the use of a compulsory license is fraught with challenges. For example, while a voluntary license comes with technical knowledge and know-how, a compulsory license comes with no such assistance. Where undisclosed or technically advanced know-how is required in order to fully exploit the patented invention, the compulsory license cannot achieve the goals of reducing price and increasing access. The issuance of a compulsory license is therefore only really effective when the technology is already known and only access to it is required and the technical competence needed to exploit the technology is not advanced or difficult to replicate.

101 Ibid.
103 Ibid.
consequence of issuing a compulsory license could be reprisals from the patent owner or its home government. Reprisals can come in many forms, but to date include the delay in registration of other products by the patent owner (thus keeping them off the host country market) and the reduction of governmental aid and other assistance.

The remainder of this section introduces the international framework on compulsory licenses before reviewing how this framework has been put in place domestically in select jurisdictions. The section then reviews the current framework in Hong Kong before concluding with recommendations to update and amend the legislation in order to more fully meet the needs of the territory.

International Context

The international community has long recognized the legitimacy of compulsory licenses. Compulsory licensing features in the Paris Convention with Article 5(A)(2) explicitly granting signatories “the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.” With Article 2(2) of TRIPS importing the obligations Members have under the Paris Convention, this clause of the Paris Convention is to be read as if it is contained in the TRIPS Agreement itself. In this regard, the TRIPS Agreement builds on, rather than replaces, the earlier convention. With respect to compulsory licenses, Article 31 of the TRIPS Agreement provides for a more comprehensive procedural structure that conditions the use of compulsory licenses in a number of respects. The conditions include the following:


105 Article 2.2 of the TRIPS Agreement reads: “Nothing in Parts I to IV of this Agreement [i.e. including Part II(5) – Patents] shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.”

106 These conditions must be read together with the related provisions of Article 27.1, which require that patent rights be enjoyable without discrimination as to the field of technology or whether products are imported or produced locally. In the context of Article 30, see Canada – Pharmaceutical Patents, above n. 4, paras. 7.88–91.
(a) authorisation of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorised, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use;

(g) authorisation for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorised, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation;

(i) the legal validity of any decision relating to the authorisation of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member; [and]
(k) Members are not obliged to apply the conditions set forth in subpar-
graphs (b) and (f) where such use is permitted to remedy a prac-
tice determined after judicial or administrative process to be anti-
competitive. The need to correct anti-competitive practices may be 
taken into account in determining the amount of remuneration in 
such cases. Competent authorities shall have the authority to refuse 
termination of authorisation if and when the conditions which led to 
such authorisation are likely to recur.

It is beyond the scope of this chapter to review all the conditions, but 
it is worth singling out one subsection for special mention. Subsection 
(f) has played a major role in the controversy over patents and access 
to medicines, as it restricts the issuance of a compulsory license to that 
of “predominantly for the supply of the domestic market of the Mem-
ber authorizing such use,” meaning that a Member must have the means 
within its jurisdiction to produce the product itself or it cannot get the 
benefit of this provision. As explained below, the resolution to the prob-
lem faced by Members with insufficient or no manufacturing capacities 
came in the early 2000s.

The WTO reiterated and supplemented the TRIPS Agreement in 
November 2001 with the Doha Declaration on the TRIPs Agreement and 
Public Health (Doha Declaration), 107 and while the legal status of the 
Declaration remains undetermined, it is clearly a document that directly 
dresses the impact of the international intellectual property regime 
on the public health. 108 The Doha Declaration recognizes that “[e]ach 
member has the right to grant compulsory licenses and the freedom to 
determine the grounds upon which such licenses are granted” 109 and 
provides that the TRIPS Agreement “can and should be interpreted and

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107 WTO Declaration on the TRIPs Agreements & Public Health (WT/MIN(01)/DEC/W/2) 
min01_e/mindeci_trips_e.htm.

108 For more discussion on the legal status of the Doha Declaration, see Bryan Mercurio and 
Mitali Tyagi, “Treaty Interpretation in WTO Dispute Settlement: The Outstanding Ques-
tion of the Legality of Local Working Requirements” (2010) 19(2) Minnesota Journal of 
International Law 275, 312–13 (“the Declaration is not technically an authoritative inter-
pretation under Article IX(2) of the Marrakesh Agreement, [but] has the look and effect 
of an authoritative interpretation”); James Gathii, “The Legal Status of the Doha Declara-
tion on TRIPS and Public Health under the Vienna Convention on the Law of Treaties” 
Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law” (2009) 
43 Journal of World Trade 571, 581.

109 WTO Declaration, above n. 107, para. 5(b).
implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”\textsuperscript{110} Further, the Declaration reinforces the notion that Members can take measures to forestall or limit public health crises by stating that each has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, with the explicit understanding that public health crises, including but not limited to those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.\textsuperscript{111}

The Doha Declaration failed in one respect as agreement was not reached on how Members with insufficient or no manufacturing capacities could make use of the compulsory license provisions in Article 31 of the TRIPS Agreement. Instead, paragraph 6 of the Declaration “recognize[s] that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement...[and] instruct[s] the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”

The “paragraph 6 solution” in fact was not reached until August 2003, when Members agreed on a “waiver” to the limitation on the export of pharmaceuticals under compulsory license to LDC Members and other Members with insufficient or no manufacturing capacities. Officially the “Decision of the General Council of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” sets out a scheme to facilitate the exportation and importation of pharmaceuticals under compulsory license. The scheme is detailed and requires the importing and exporting Member to adhere to several procedural steps. For instance, the importing Member must notify the TRIPS Council of the names and expected quantities of the products needed, either confirm that it is an LDC or have established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question and confirm that, if the product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement.\textsuperscript{112}

\textsuperscript{110} Ibid., para. 4. \textsuperscript{111} Ibid., para. 5. \textsuperscript{112} See WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, WT/L/540 and Corr.1, 1 September 2003, para. 2(1).
For its part, the exporting Member must confirm that the particulars of the intended importing Member are in order and that it has granted or intends to grant a compulsory license for only the amount necessary to meet the needs of the eligible importing Member; that the product is clearly identified as being produced under this special system, such as through specific labeling or marking; that the product is distinguishable through special packaging and/or special coloring/shaping;\(^{113}\) and that prior to shipment certain required information has been posted on a website.\(^{114}\)

While the particulars of the waiver have been criticized and the system has been formally used only once since its inception,\(^{115}\) the Decision of the General Council of 6 December 2005 made the waiver a permanent amendment to the TRIPS Agreement (to replace the Decision of the General Council of 30 August 2003) on acceptance by two-thirds of the WTO membership – this occurred on 23 January 2017.\(^{116}\)

Since the establishment of the TRIPS regime, certain countries have also included provisions regarding compulsory licensing of patents in FTAs.\(^{117}\) In most cases, the FTA will restrict the issuance of a compulsory license to a limited set of circumstances. The United States is the leading proponent of such limitations, with its FTAs often providing that a compulsory license can only be issued to remedy an anticompetitive practice, for noncommercial use, in situations of national emergency or other circumstances of extreme urgency or on the grounds of failure to

\(^{113}\) There is a caveat here, being “provided that such distinction is feasible and does not have a significant impact on price.” Ibid., para. 2(b)(ii).

\(^{114}\) Ibid., para. 2(b).


\(^{117}\) It should also be noted that Article 1709.10 of the NAFTA set out conditions to the issuance of compulsory licenses, such as that the license be nonexclusive and nonassignable, predominantly to supply the domestic market; that efforts be made to obtain authorization from the right holder; that adequate remuneration be paid to the rights holder; and that the licensee is not authorized to use of the subject matter of a patent to exploit another patent except where allowed to remedy a violation of domestic competition laws.
meet working requirements, provided that importation shall constitute working.118

The Application of Compulsory License Schemes

Domestic legislation provides various grounds for granting compulsory licenses for patents and specifies factors and conditions when such provisions apply. Most of these are drawn directly from the text of Article 31 of the TRIPS Agreement. There are differences among jurisdictions, however, and as highlighted above can be (re)shaped through FTA commitments. Among the most common triggers for the issuance of a compulsory license are the following:

- Non-working or insufficient working: Domestic provisions clarify the circumstances and criteria for when a patent holder’s activities constitute “non-working” of the patent, as well as determinants of the “sufficiency” of working a patent. The issue of “non-working” is contentious, as some interpret the phrase to mean that local “working” of the patented product is required, whereas others view importation and availability of the patented product as fulfilling the requirement. This issue has been subject to a WTO claim brought by the United States against Brazil, with the complaint challenging Brazil’s legislation allowing for a compulsory license if the patent is not “worked” in the territory of Brazil as inconsistent with Articles 27 and 28 of the TRIPS Agreement and Article III of the GATT 1994.119 The parties reached a mutually agreeable solution and the claim never went to a panel. Noteworthy is the fact that Brazil did not agree to amend its legislation as part of the settlement.120

118 See Article 4.20 of the US-Jordan FTA. See also Article 17.9.7 of the US-Australia FTA; Article 16.7.6 of the US-Singapore FTA. It should be noted that a number of other FTAs – including most of those negotiated by European Free Trade Association and the EU – do not restrict compulsory licensing and explicitly recognize the principles established in the Doha Declaration. See, e.g., Article 11.5 of the Switzerland-China FTA; Article 6.2.5 of the EFTA-Peru FTA; Article 6.2.5 of the EFTA-Colombia FTA; Article 147(B) of the EU-CARIFORUM EPA; Article 10.34 of the EU-Korea FTA.

119 Brazilian legislation defined “failure to be worked” as “failure to manufacture or incomplete manufacture of the product” or “failure to make full use of the patented process.” See Brazil — Measures Affecting Patent Protection – Request for Consultations by the United States (WT/DS199/1, G/L/385, IP/D/23) (8 June 2000).

120 See Brazil — Measures Affecting Patent Protection – Notification of Mutually Agreed Solution (WT/DS199/4, G/L/454, IP/D/23/Add.1), para. 3 (19 July 2001) (“Should the U.S. withdraw the WTO panel against Brazil concerning the interpretation of Article 68, the Brazilian Government would agree, in the event it deems necessary to apply Article 68 to
• Anti-competitive practices: Domestic legislation usually allows for the issuance of a compulsory license to remedy breaches of competition law, often as a remedy in cases brought before a domestic competition authority or through judicial action in relation to an abuse of monopoly power.\textsuperscript{121}

• Public interest: Domestic legislation commonly allows for the issuance of a compulsory license in situations of emergency or crisis. Most often associated with national health emergencies, nonavailability of patented products and excessive pricing, which reduces availability in the market, these justifications are generally accepted as being compatible with Article 31 of the TRIPS Agreement.\textsuperscript{122} This is, however, not always the case and can lead to controversy and potential WTO disputes. These issues will be further explored below.

• Dependent and blocking patents: Many jurisdictions allow for the issuance of a compulsory license in situations where one patent (a so-called dependent patent) cannot be exploited without infringing another patent (“blocking” patent). Pursuant to Article 31 of the TRIPS Agreement, a compulsory license can be granted only if the second invention is an important technical advance of considerable economic significance and where a compulsory license is granted to the holder of a dependent patent.\textsuperscript{123}

There being no database or official repository, the actual number of compulsory licenses issued globally is difficult to ascertain. According to one study, between 1995 and 2011 twenty-four compulsory licenses were issued in seventeen countries covering forty pharmaceutical

grant compulsory license on patents held by the U.S. companies, to hold prior talks on the matter with the U.S. Government. These talks would be held within the scope of the U.S. – Brazil Consultative Mechanism, in a special session scheduled to discuss the subject”).

\textsuperscript{121} TRIPS Agreement, Articles 8(2) and 40(1) and (2).

\textsuperscript{122} This is not limited to pharmaceuticals. For instance, the United States has issued compulsory licenses for patents relating to pollution control devices under the Clean Air Act and those involving nuclear materials. See, e.g., the Clean Air Act, United States Code Title 42, Chapter 85, §7608.

product patents.\textsuperscript{124} The most notable compulsory license occurred in 2007 when Rwanda made use of the waiver and notified the WTO of its importation of 260,000 packs of Apo-Triavir (a generic version of a patented HIV/AIDS drug) manufactured in Canada by Apotex Inc.\textsuperscript{125} The process took some time, as both Rwanda and Canada had to comply with the procedural conditions of the waiver but ultimately allowed for the export of pharmaceuticals under compulsory license. Another notable case occurred in 2012 when Indonesia issued a compulsory license for governmental use on seven HIV and hepatitis medicines, with only a 0.5 percent royalty on generic sales payable to the rights holder.\textsuperscript{126} Likewise, in 2006 and 2007, Thailand issued compulsory licenses for governmental use on Merck’s antiretroviral efavirenz (Stocrin), Abbott’s antiretroviral lopinavir/ritonavir (Kaletra) and Sanofi-Aventis’ heart disease drug clopidogrel (Plavix) with only a 0.5 percent royalty on generic sales (while the United Nations Development Program (UNDP) recommends that rates normally be set at 4 percent).\textsuperscript{128} In response, Thailand suffered repercussions as Abbott withdrew certain products from the Thai market and it would no longer register new drugs in Thailand. Thailand responded by initiating a competition law complaint against Abbott.\textsuperscript{129} Malaysia


\textsuperscript{126} The pharmaceuticals included the HIV antiretroviral efavirenz (Sustiva) (previously subject to a compulsory license dating from 2007), abacavir (Ziagen), didanosine (Videx), combination lopinavir and ritonavir (Kaletra), tenofovir (Viread), the combination of tenofovir and emtricitabine (Truvada) and the combination of efavirenz, emtricitabine and tenofovir (Atripla). See Act Up Paris, “Indonesia Issues Compulsory Licences against Seven HIV, Hepatitis Drugs” (October 2012), www.actupparis.org/spip.php?article4984.


similarly issued compulsory licenses on three patented HIV/AIDS medicines for governmental use in 2003, purportedly importing generic versions of the patented products from India. While the price of the pharmaceuticals dropped by 81 percent (from US$315 to US$58 per month) and the number of HIV/AIDS patients treated in government hospitals and clinics increased from 1,500 to 4,000, it is debatable whether the savings of US$642,500 is worth the potential reprisals by the branded industry and other governments.

Brazil has been among the most effective countries in using the better option of threatening the issuance of compulsory license only to negotiate discounts from branded pharmaceutical companies. Most notably, in 2003 Brazil negotiated price reductions on Bristol-Myers Squibb’s atazanavir by 76 percent and Merck’s efavirenz by 25 percent, and in 2004 it negotiated with several pharmaceutical companies (Hoffmann-La Roche, Gilead and Abbott) to reduce the price of the five most expensive antiretrovirals by between 10 and 76 percent. South Africa has adopted a similar tactic and has been successful in using the threat of compulsory license together with competition law to force price reductions on branded pharmaceuticals. Notable cases include voluntary licenses following investigations in 2002–2003 by the South African Competition Commission against GlaxoSmithKline and Boehringer Ingelheim concerning excessive pricing practices for several pharmaceuticals (ritonavir, lamivudine, ritonavir/lamivudine and nevirapine).

Regardless of approach, the first step in the process is to design and draft laws that enable the issuance and use of compulsory licenses. India has taken the lead in formulating clear principles behind the patent system, and where these are not met, a compulsory license can be issued. More specifically, Article 83 of the Indian Patents Act sets out the general principles applicable to the grant of compulsory licenses and other actions under Chapter XVI of the Act:

(a) patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
(b) patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
(c) the protection and enforcement of patent rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
(d) patents granted shall not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
(e) patents granted shall not in any way prohibit the Central Government to take measures to protect public health;
(f) patent rights shall not be abused by the patentee or by persons deriving the title or interest on the patent from the patentee, and he shall not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
(g) patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

India backs this up with a broad framework that details when and under what circumstances a compulsory license can be issued, with Section 84 of the Indian Patents Act stating:

(1) At any time after the expiration of three years from the date of the [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:
   (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
   (b) that the patented invention is not available to the public at a reasonably affordable price, or
   (c) that the patented invention is not worked in the territory of India.

In 2012, and with some controversy, India issued its first post-TRIPS compulsory license. In a meticulous decision India’s Controller General issued a compulsory license in favor of Natco to manufacture and sell
a generic version of Nexavar (a kidney/liver cancer drug known by the
generic name of sorafenib tosylate) at a rate of Rs 8800 for a monthly dose
(120 tablets), with a 6 percent royalty on the net sales payable to Bayer. The
license also requires Natco to donate medicine to 600 patients in need per
year. In so deciding, the Controller found the following: (1) The reason-
able requirements of the public with respect to Nexavar were not met since
Bayer supplied the drug to only 2 percent of potential patients; (2) Bayer’s
selling price of 2,800 lakhs per month was excessive and therefore not a
“reasonably affordable price”; and (3) since Bayer did not manufacture the
Nexavar in India, it did not sufficiently “work” the patent in India.

While every aspect of the decision is controversial and can be debated,
the third criterion is of particular interest. To many commentators, Article
27 of the TRIPS Agreement would not allow Members to discriminate
between locally produced and imported products. Thus, the Controller’s
statement “that ‘worked in the territory of India’ means manufactured to
a reasonable extent in India” may not be in line with the TRIPS Agree-
ment. While I have argued elsewhere that India’s position is in fact TRIPS
compliant,133 the issue is far from settled. Another interesting aspect of
this judgment is that since approximately 90 percent of all pharmaceu-
tical patents are only imported into and not manufactured in India, the
decision leaves the vast majority of pharmaceuticals liable to the issuance
of a compulsory license. A diverse range of jurisdictions, including Brazil
and as will be detailed below Hong Kong, contain similar provisions and
reliance on imported pharmaceuticals.

Hong Kong

In Hong Kong, a compulsory license can be granted if at any time after
three years from the grant of the standard patent one or more of the
following applies:

(a) where the patented invention is capable of being commercially
worked in Hong Kong, that it is not being so worked or is not being
so worked to the fullest extent that is reasonably practicable;
(b) where the patented invention is a product, that a demand for the prod-
uct in Hong Kong is not being met on reasonable terms;

133 Mercurio and Tyagi, above n. 108, 326 (arguing that Article 5(2) of the Paris Convention
must be read together with the TRIPS Agreement as per Article 31 of the VCLT and that
the object and purpose of the TRIPs Agreement and the principles of good faith mean
that domestic legislation providing for local working requirements does not unjustifiably
discriminate against other Members in violation of Article 27 of the TRIPS Agreement).
(c) where the patented invention is capable of being commercially worked in Hong Kong by manufacture, that it is being prevented or hindered from being so worked
   (i) in the case of a product, by the importation of the product; or
   (ii) in the case of a process, by the importation of a product obtained directly by means of the process or to which the process has been applied;
(d) that by reason of the refusal by the proprietor of the patent to grant a licence or licences on reasonable terms:
   (i) the working or efficient working in Hong Kong of any other patented invention which involves an important technical advance of considerable economic significance in relation to the patent is prevented or hindered; or
   (ii) the establishment or development of commercial or industrial activities in Hong Kong is unfairly prejudiced; or
(e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent or the establishment or development of commercial or industrial activities in Hong Kong, is unfairly prejudiced.134

In addition, Section 66(1) directs the court to have the following purposes in mind when determining whether to issue a compulsory license:

(a) that inventions which can be worked on a commercial scale in Hong Kong and which should in the public interest be so worked shall be worked there without undue delay and to the fullest extent that is reasonably practicable;
(b) that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention;
(c) that the interests of any person for the time being working or developing an invention in Hong Kong under the protection of a patent shall not be unfairly prejudiced.

On its face, the compulsory license provision in Hong Kong is extremely broad and more in line with what one would expect from a developing

134 Section 64(2).
industrial country such as India and Brazil. The provision is drafted so as to explicitly allow for a compulsory license if the product is not being “commercially worked in Hong Kong” and for reasons of technology transfer. While the consistency of these provisions with Article 31 of the TRIPS Agreement is questionable, the reality is that Hong Kong will not utilize the provisions in the foreseeable future. The most applicable provision in relation to pharmaceuticals and Hong Kong is subsection (b), which allows for a compulsory license if “demand for the product in Hong Kong is not being met on reasonable terms.” This places the government in a better bargaining position with pharmaceutical companies as it can always threaten to issue a compulsory license should price demands not be reduced.

In order for a compulsory license to be granted, Hong Kong also requires several mainly procedural steps to be fulfilled. These steps are, for the most part, mandated by and set out in Article 31 of the TRIPS Agreement. For instance, Section 64(5) obliges applicants for a compulsory license to make “reasonable efforts to obtain authorization . . . on reasonable commercial terms and conditions” and the license will be granted only if “such efforts have not been successful within a reasonable period of time.” Moreover, and again in accordance with the international framework, Hong Kong law provides that the license shall be nonexclusive and nonassignable.

Likewise in line with the Doha Declaration on TRIPS and Public Health and the subsequent paragraph 6 solution and Decision of the General Council of 6 December 2005, the Patents Ordinance contains provisions relating to emergency situations and public health crises. More specifically, in regard to the former, Section 68 empowers the Chief Executive to declare an “extreme emergency” whenever he or she “considers it to be necessary or expedient in the public interest for the maintenance of [or securing sufficient] supplies and services essential to the life of the community,” and Section 69 allows the government to “do any act in Hong Kong in relation to the invention as appears . . . to be necessary or


136 See Section 64(7), with there being one minor exception to nonassignability.
expedient in connection with the urgency giving rise to the declaration under Section 68.”

In regards to the latter, amendments in 2007 gave the Chief Executive the power under Section 72B to make a “declaration of extreme urgency for public health problem” when he or she “considers it to be necessary or expedient in the public interest to do so to address any public health problem or threatened public health problem in Hong Kong.” Furthermore, under Section 72C during a period of extreme urgency a nonexclusive “import compulsory licence” allowing the marketing, stocking and using of the product may be granted if the government determines that “the pharmaceutical industry in Hong Kong has no or insufficient capacity to manufacture a patented pharmaceutical product to meet the needs for the product in Hong Kong.” Section 72D backs up this section with a list of procedural hurdles in line with the paragraph 6 solution, including notification requirements, that the scope of the exception is limited to the terms of the license, that the patented pharmaceutical product that is imported under the license shall not be exported out of Hong Kong and that the patented pharmaceutical be clearly identifiable as being imported under the license through specific labeling or marking and distinguished from the same branded product (i.e., special packaging, color or shape). Remuneration provisions are also in accordance with the paragraph 6 solution. It is worth noting that Hong Kong has declared that it “will only use the compulsory licensing system as an importer in situations of national emergency or circumstances of extreme urgency.”

137 Remuneration is to be agreed by the government and patent owner or, if necessary, by the court. Section 69(4).
138 For background, see Patents (Amendment) Bill 2007, Legislative Council Brief, Patents Ordinance (Chapter 514) CIB CR 06/08/11, including background information and the text of the Patents (Amendment) Bill (Annex A) and the Administration’s Response to the Submissions Made by Deputations to the Bills Committee on the Patents (Amendment) Bill 2007, LC Paper No. CB(1)2191/06-07(01), www.legco.gov.hk/yr06-07/english/bc/bc02/papers/bc020719cb1-2191-1-e.pdf, accessed 4 March 2017.
139 See Section 72E.
140 Report of the Bills Committee on Patents (Amendment) Bill 2007, Paper for the House Committee meeting on 2 November 2007, LC Paper No. CB(1)154/07-08, Ref: CB1/BC/2/06, www.legco.gov.hk/yr06-07/english/bc/bc02/reports/bc021121cb1-191-e.pdf, accessed 4 March 2017, see in particular para. 4. See also Hong Kong’s declaration to the WTO at the time of the paragraph 6 solution. For the complete list of Members declaring that they would use the system as importers only in situations of national emergency or other circumstances of extreme urgency as well as the list of Members declaring that they would not use the system, see WTO, Compulsory Licensing of Pharmaceuticals.
Hong Kong has also legislated to effectuate the paragraph 6 solution in the export of patented pharmaceutical products under a compulsory license. These provisions mirror to a large extent the import provisions explained above and are in line with the procedural mandate of the paragraph 6 solution.\textsuperscript{141}

Concluding Comments on Article 31

Hong Kong is unlikely to issue a compulsory license on pharmaceuticals absent a public health emergency or crisis. Moreover, if Hong Kong did issue a compulsory license, it almost inevitably would have to import the product at issue – meaning the local industry would not benefit from the issuance of the compulsory license. Therefore, questions of using compulsory licensing as a means to enable the transfer of technology, innovation and local production are essentially a nonissue in Hong Kong. At the same time, Hong Kong should be aware of the social costs to pharmaceutical patents and view the compulsory licenses as a tool to control healthcare costs and promote a coherent approach to pharmaceutical patent policy. The circumstances of Hong Kong demand that it remains vigilant and maintains policy options – Hong Kong is densely populated, and it and the region are prone to pandemics, thus necessitating that potential life-saving medicines can be easily acquired or produced in a short period of time, or even stocked and stored in large quantities before any outbreak.

The laws in Hong Kong in regard to compulsory licensing seem suitable for the purpose and are not in need of much change. The laws are broad, and the territory has put in place legislation to effectuate the importation or exportation of pharmaceuticals in line with the conditions set out in the WTO waiver/amendment. In this regard, the laws as such provide ample room for Hong Kong to negotiate for price reductions or voluntary licenses should it so desire. There is a question, however, whether Hong Kong should amend the law so as to make importation into the territory equate with “working,” as the current law may offend notions of adequate IPR protection and is arguably inconsistent with Article 27.1 of the TRIPS Agreement. This change would not reduce the ability of Hong Kong to react in times of health emergency or crisis.

\textsuperscript{141} Section 72L–72S.