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## Introduction

Questions relating to pharmaceuticals sit at the intersection of social, economic and technological issues and force policy and law makers into taking difficult decisions that balance the needs and interests of multiple (and often competing) stakeholders. The subject of this book, pharmaceutical patent law, is merely a subset of the wider field of pharmaceutical law but just as complex, and with all of the same policy considerations. Most notable among these are how to provide the populace with access to a wide range of medicines within the confines of a finite budget, promote national innovation/industry development and comply with obligations under international agreements.

Until the advent of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) in 1995,<sup>1</sup> international intellectual property (IP) law – of which pharmaceutical patent law is also a subset – could be characterized as decentralized and lacking in any meaningful and substantive harmonization. This is not to suggest that the TRIPS Agreement is the first international IP effort. To the contrary, the multilateralization of IP began in the latter part of the nineteenth century through the negotiation and adoption of two important treaties<sup>2</sup> – the Paris Convention for the Protection of Industrial Property (1883)<sup>3</sup> and the Berne Convention for the Protection of Literary and Artistic Works (1886)<sup>4</sup> – which, inter alia, introduced the principle

<sup>1</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

<sup>2</sup> It could even be suggested that the internationalization of IP law, regulation and policy began even earlier when IP-related issues appeared in Friendship, Commerce and Navigation (FCN) treaties, the first of which is reputed to be a 1778 treaty between France and the United States. See M. Sornarajah, *The International Law on Foreign Investment*, 3rd edition (Cambridge University Press, 2010) 180, note 41.

<sup>3</sup> Paris Convention for the Protection of Industrial Property of 1883, 21 UST 1583, 828 UNTS 305 (as revised at Stockholm on 14 July 1967, and as amended on 28 September 1979).

<sup>4</sup> Berne Convention for the Protection of Literary and Artistic Works, 9 September 1886, revised in Paris on 24 July 1971 and amended in 1979, S. Treaty Doc. No. 99–27 (1986)

of national treatment into international IP law. Without denigrating the advancements of these treaties, it is fair to say that they mostly focused on procedural aspects of IP law and merely serve as a structure for developing IP policy and a framework for enhanced international cooperation.

As such, signatory countries retained almost unlimited latitude to craft and shape substantive domestic norms. Even the term of patent protection varied widely, with protection in many countries ranging from fifteen to seventeen years from the date of filing or date of the grant of the patent and some countries granting protection for as little as five to seven years (Article 33 of the TRIPS Agreement now requires that patent rights be granted for a period of twenty years from the date a patent application is filed). In such a setting, experimentation became the norm and countries developed and maintained widely differing practices in almost all forms of IP. Substantive norms in relation to pharmaceutical patent law were no different, and became quite divergent. For example, while Article 27.1 of the TRIPS Agreement now requires Members to provide patent protection for both processes and products, in all fields of technology, the situation prior to the TRIPS Agreement widely varied. As many as fifty countries provided patent protection for processes but not products – meaning that while the countries protected the technology and process/method used to manufacture generic products, companies in those jurisdictions could still “reverse engineer” the product to develop a different process or method to create an equivalent product. Patents over the final products, therefore, provide for more complete protection to the patent holder and significantly weaken the position of generic pharmaceutical manufacturers.

Binding on all WTO Members and enforceable through the dispute settlement mechanism, the TRIPS Agreement became the new standard for international intellectual property law and did so by not simply mirroring the standards of the existing IP agreements but by building on them with the addition of substantive standards, rights and norms. With WTO membership at that time encompassing 127 Members (Membership now includes over 160 countries and accounts for nearly 98 percent of world trade),<sup>5</sup> the TRIPS Agreement became the first international agreement to attempt some harmonization of substantive IP law.

(the 1979 amended version does not appear in UNTS or ILM, but the 1971 Paris revision is available at 1161 UNTS 30 (1971)).

<sup>5</sup> See WTO, “Accessions,” [www.wto.org/english/thewto\\_e/acc\\_e/acc\\_e.htm](http://www.wto.org/english/thewto_e/acc_e/acc_e.htm), accessed 20 February 2017; WTO, International Trade Statistics 2014, [www.wto.org/english/res\\_e/statis\\_e/its2014\\_e/its14\\_toc\\_e.htm](http://www.wto.org/english/res_e/statis_e/its2014_e/its14_toc_e.htm), accessed 20 February 2017.

That being said, while the TRIPS Agreement is fairly prescriptive and shapes the IP laws of every WTO Member, it does not mandate complete harmonization. That is, Members retain *some* ability to tailor domestic legislation to reflect the local socioeconomic context and development priorities. For instance, even when prescriptive the TRIPS Agreement merely requires that Members meet certain minimum standards – Members retain wide latitude to exceed the standards when desirable so long as the laws and regulations remain consistent with the TRIPS Agreement.<sup>6</sup> In addition, a number of provisions contained in the TRIPS Agreement are vaguely drafted or allow for wide interpretation, thus providing Members with sufficient policy space. Moreover, the TRIPS Agreement also contains certain “flexibilities” that allow Members to tailor laws and regulations in an attempt at minimizing the negative impact of intellectual property rights (IPRs) on domestic needs and priorities. As this book will demonstrate, flexibilities are particularly relevant and readily available for pharmaceutical patent laws and regulations.

Therefore, despite setting out minimum standards in a fairly prescriptive manner, the TRIPS Agreement nevertheless affords Members some, albeit circumscribed, scope to craft laws and regulations in a manner consistent with domestic policy and in line with developmental objectives.

### 1.1 The International Framework

Before undertaking a jurisdictional analysis, as this book does, it is necessary to first understand the requirements, limits and boundaries of the international framework. It is therefore worthwhile to more fully explain the background, objectives and contours of the TRIPS Agreement before proceeding to discuss the aims and objectives of this book.

The impact of the TRIPS Agreement cannot be understated – its creation brought about a “tectonic shift” in the protection and enforcement of IPRs.<sup>7</sup> As mentioned above, the TRIPS Agreement incorporates the substantive parts of Paris and Berne but it is unlike any previous international

<sup>6</sup> TRIPS Agreement, Article 1(1), states: “Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.”

<sup>7</sup> Charles R. McManis, “Teaching Current Trends and Future Developments in Intellectual Property” (2008) 52 *Saint Louis University Law Journal* 855, 856.

IP agreement in a number of ways: It is comprehensive in scope in addressing procedural, substantive and administrative aspects of IP, broad in coverage with the addition of several new topical areas, includes most-favored nation and national treatment as cornerstone principles and provides for minimum levels of protection and enforcement.

Arriving at the same time as several new technologies (i.e., biotechnology, widespread use of the internet and e-commerce), the TRIPs Agreement changed the landscape and dramatically altered thinking about international IP. The norms established in the TRIPs Agreement are unquestionably the international standard and starting point for any further development of international IP rules (such as free trade agreements (FTAs) or stand-alone agreements administered by the World Intellectual Property Organization (WIPO)).

Negotiations for the TRIPs Agreement were long and arduous. The United States and other developed countries sought to gain multilateral backing to their unilateral efforts to enforce IPRs by directly linking IP to international trade by arguing that a country with weak or otherwise insufficient IP protection engages in unfair competition as it can benefit through the cheap production and sale of counterfeit goods and drive the costlier original goods out of the market.<sup>8</sup> These countries also argued that effective protection of IPRs would lead to increased investment, employment, technology and balance of payment issues.<sup>9</sup> In contrast, developing countries saw the proposed link as a way to transfer health from the poor to the rich and initially flatly rejected the idea of including IPRs into the multilateral trading system, arguing that WIPO was the appropriate forum to discuss IPRs.<sup>10</sup>

The United States and others ultimately convinced developing countries to negotiate for the inclusion of IPRs into the multilateral system by offering “carrots” and “sticks.” The stick came as a threat of continued unilateral action against what could be seen as “unfair trade” and implicitly a threat to the continuation of trade assistance and aid from developed

<sup>8</sup> See, e.g., Marshall A. Leaffer, “Protecting United States Intellectual Property Abroad: Toward a New Multilateralism” (1991) 76 *Iowa Law Review* 273; Max Baucus, “A New Trade Strategy: The Case for Bilateral Agreements” (1989) 22 *Cornell International Law Journal* 1; Hans Peter Kunz-Hallstein, “United States Proposal for a GATT Agreement on Intellectual Property and the Paris Convention for the Protection of Industrial Property” (1989) 22 *Vanderbilt Journal of Transnational Law* 265.

<sup>9</sup> See sources in note 8.

<sup>10</sup> Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPs Agreement* (Routledge, 2002) 33.

countries to the developing world.<sup>11</sup> The carrot came in the form of concessions in other trade areas, notably increased market access to developed countries in the areas of agriculture and textiles as well as several important TRIPs-related concessions such as promises of technology transfer, technical assistance and deferred implementation of the substantial portions of the TRIPs Agreement. After initial hesitation, the carrots and sticks proved too much to resist and developing countries agreed to negotiate measures aimed at eliminating trade in counterfeit goods. This limitation soon faded and developing countries were eventually persuaded to negotiate a more ambitious agreement regulating a broad range of IP-related interests.<sup>12</sup>

When developing the procedural and substantive standards, rules and principles of the TRIPs Agreement the drafters sought to balance several differing and at times competing interests. This balance is reflected in the objectives and principles of IPRs, represented in Articles 7 and 8 of the TRIPs Agreement, and include the promotion of the transfer of technology, the prevention of abuse of IPRs and the promotion of public health.

<sup>11</sup> The United States first began unilaterally enforcing IPRs by virtue of the authority of the US Trade Representative (USTR) under Section 301 US Trade Act of 1974 and Special 301 in 1988. More specifically, the United States initiated litigation against other countries in the US Court of International Trade (USITC) under its domestic unfair trade practices laws, even though the respondent countries had not violated any international agreement. The United States filed cases against several developing countries, most notably Brazil, Argentina, India, China and Taiwan, and extracted concessions from the respondents in a number of cases. In doing so, the United States effectively promoted the linkage of IP and international trade. See Jasper Womach, “Agriculture: A Glossary of Terms, Programs, and Laws, Congressional Research Service Report for Congress,” (2005), p. 230, available at [https://digital.library.unt.edu/ark:/67531/metacrs7246/m1/1/high\\_res\\_d/97-905\\_2005Jun16.pdf](https://digital.library.unt.edu/ark:/67531/metacrs7246/m1/1/high_res_d/97-905_2005Jun16.pdf), accessed 21 December 2017.; Alan O. Sykes, “Constructive Unilateral Threats in International Commercial Relations: The Limited Case for Section 301” (1992) 23 *Law & Policy in International Business* 263, 318–19; Michael Blakeley, *Trade-Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement* (Sweet & Maxwell, 1996) 6. See also Report of the Panel, *United States – Section 301–310 of the Trade Act of 1974*, WT/DS152/R (22 December 1999). Likewise, the European Union adopted Council Regulation 2641/84 to counter “illicit” trade practices against European exporters. For more information, see Wolfgang W. Leirer, “Retaliatory Action in United States and European Union Trade Law: A Comparison of Section 301 of the Trade Act of 1974 and Council Regulation 2641/84” (1994–95) 20 *North Carolina Journal of International Law & Commercial Regulation* 41.

<sup>12</sup> For a succinct history of the origins of the TRIPs Agreement and its negotiating process, see Matthews, *Globalising Intellectual Property Rights*, Chapter 1 (origins) and Chapter 2 (negotiations). For more detailed background on the TRIPs Agreement, see Susan K. Sell, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (State University of New York Press, 1998).

But one should not be under any illusions regarding the inclusion of IPRs into the WTO framework – the TRIPS Agreement was negotiated to promote the protection and enforcement of IPRs, and other interests (including the promotion of innovation and transfer of technology) are decidedly secondary.<sup>13</sup>

The balance struck in the TRIPS Agreement may therefore not be ideal for some (or even most) Members. However harsh this may be, in many respects the debate about the suitability of the aims, objectives and consequences of the TRIPS Agreement is academic; the TRIPS Agreement is *the* international framework and is not going to disappear (much less be amended in any meaningful manner). In some ways, for patents this is disappointing as more evidence surfaces that questions the link between ever-stronger protection and innovation.<sup>14</sup> And while most commentators view pharmaceuticals as a special industry wholly reliant on IPRs for its survival (and the continued development of medicines),<sup>15</sup> others are less enthusiastic and point out several alternative paths.

Thus, countries are left to navigate within the confines of the present system and restricted to legislating in a manner consistent with the international framework. Recently, a number of countries have attempted to

<sup>13</sup> See Bryan Mercurio, “TRIPS and innovation: a necessary reappraisal?,” paper commissioned by the International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum, November 2014, <http://e15initiative.org/publications/trips-patents-and-innovation-a-necessary-reappraisal/>, accessed 20 February 2017.

<sup>14</sup> *Ibid.*, citing numerous economic studies. See also Chamber of Deputies, Center for Strategic Studies and Debates, “Brazil’s Patent Reform: Innovation Towards National Competitiveness” (2013), p. 20, <http://infojustice.org/wp-content/uploads/2013/09/Brazilian-Patent-Reform.pdf>, accessed 20 February 2017.

<sup>15</sup> For studies evaluating the impact of patent protection on the pharmaceutical sector, see, e.g., Henry Grabowski, “Patents, Innovation and Access to New Pharmaceuticals” (2002) 5(4) *Journal of International Economic Law* 849, 851 (concluding that the “explanation for why patents are more important to pharmaceutical firms in appropriating the benefits from innovation follows directly from the characteristics of the pharmaceutical R&D process... In essence, imitation costs in pharmaceuticals are extremely low relative to the innovator’s costs for discovering and developing a new compound.”); Wesley M. Cohen et al., “Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)” 2 (National Bureau of Economic Research, Working Paper No. 7552, 2000) (stating that patent protection “is important in only a few industries, most notably pharmaceuticals”), [www.nber.org/papers/w7552](http://www.nber.org/papers/w7552), accessed 20 February 2017. See also Neel U. Sukhatme and Judd N.L. Cramer, “Who Cares about Patent Term? Cross-Industry Differences in Term Sensitivity,” 2014, [https://scholar.princeton.edu/sites/default/files/sukhatme/files/sukhatme\\_who\\_cares\\_about\\_patent\\_term\\_0.pdf](https://scholar.princeton.edu/sites/default/files/sukhatme/files/sukhatme_who_cares_about_patent_term_0.pdf), accessed 20 February 2017.

work within the system to effectuate a recalibration that ensures the proper balance between the encouragement of innovation in the form of exclusive rights and user interests and competition. The most public displays of such attempts revolve around action taken in what the country deems is in accordance with the “flexibilities” existing in the TRIPS Agreement, with the most notable of these being the issuance of compulsory licenses for a pharmaceutical products in Brazil, India, Taiwan, Thailand, Zimbabwe, Rwanda (where Canada issued a compulsory license in order to export a generic medicine to Rwanda under the 2003 Waiver of Article 31(f)) and a handful of other countries. Other countries, most notably India and more recently Argentina, have attempted to limit the influence of IPRs on the domestic pharmaceutical market, increase the availability of generic medicines and protect domestic generic producer interests by adopting stringent standards for the granting of a patent.<sup>16</sup> These efforts are in concurrence with the United Nations Human Rights Council, which in 2013 adopted a resolution reinforcing the right of WTO Members “to use [flexibilities provided in the TRIPS Agreement] to the full . . . to protect public health and, in particular, to promote access to medicines.”<sup>17</sup>

At the same time, a number of developed and developing countries have recently initiated major reviews of their pharmaceutical patent systems – including Brazil, South Africa and Australia – with a view to ensuring the system works in harmony with the needs, priorities and level of development of the jurisdiction.<sup>18</sup> Even more recently, negotiations of so-called

<sup>16</sup> While the compatibility of some of these measures with the TRIPS Agreement may be questionable, the point here is simply to illustrate attempts at rebalancing the system away from the rights holder and in favor of user interests.

<sup>17</sup> Human Rights Council, *The Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, at statement 2, A/HRC/23/L.10/Rev.1 (11 June 2013). The resolution also stressed “the responsibility of States to ensure the highest attainable level of health for all, including through access [to] essential medicines, that are affordable, safe, efficacious and of quality,” and urged governments to “promote a range of incentive schemes for research and development, including addressing, where appropriate, the delinkage of the costs of research and development and the price of health products.” *Id.* statement 3 and 5(n).

<sup>18</sup> See Brazil’s Patent Reform, above n. 14; Chan Park, Achal Prabhala, Jonathan Berger et al., “Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law,” A Study Commissioned by the United Nations Development Programme, Programme Regional Service Centre for Eastern and Southern Africa (2013), [www.undp.org/content/dam/undp/library/hiv/aids/English/using\\_law\\_to\\_accelerate\\_treatment\\_access\\_in\\_south\\_africa\\_undp\\_2013.pdf](http://www.undp.org/content/dam/undp/library/hiv/aids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf), accessed 20 February 2017; Tony Harris, Dianne Nicol and Nicholas Gruen, “2013 Pharmaceutical Patents

mega-regional FTAs awakened a skeptical public to the effects of TRIPS-plus provisions on the price and availability of medicines.

## 1.2 The Raison d'Être: Inform and Influence Public Policy in Hong Kong

Unlike other countries that have recently made use of the TRIPS flexibilities or reviewed the suitability and appropriateness of their pharmaceutical patent system, the Hong Kong Special Administrative Region is not seeking to amend its regime in order to support and promote public and industrial policy. This is curious, as Hong Kong has long viewed itself as “an innovation-led, technology-intensive economy in the 21st century... a world centre for the development of health food and pharmaceuticals... and the marketplace for technology transfer”<sup>19</sup> and continues to assert its strong belief that “sound intellectual property rights protection [is one of the] drivers for technological innovation in Hong Kong.”<sup>20</sup> One would think that a government that sees the prosperity of its jurisdiction dependent on innovation and IP would periodically review its IP system to ascertain whether it matches the needs and priorities of the jurisdiction. Instead, IP policy has focused on service-oriented and procedural considerations that could lead to the employment of highly skilled talent, such as the idea of marketing Hong Kong as an IP “Trading Hub” and the impending shift from a registration-based patent regime to an examination/original grant system.

Neither has the government elaborated any strategy of how the IP system can contribute to any desired policy goals. Factors such as stimulating local innovation and promoting local production of branded or generic pharmaceuticals, which are at the core of many other jurisdictional reviews, appear to be distinctly secondary considerations in Hong Kong. Instead, Hong Kong’s overarching interest seems to be that of controlling

Review Report” Commissioned by the Australian Government (2013), [www.ipaustralia.gov.au/pdfs/2013-05-27\\_PPR\\_Final\\_Report.pdf](http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf), accessed 20 February 2017.

<sup>19</sup> Hong Kong SAR Legislative Council, Official Record of Proceedings, 7679 (2013), (Mar. 20, 2013), [www.legco.gov.hk/yr12-13/english/counmtg/hansard/cm0320-translate-e.pdf](http://www.legco.gov.hk/yr12-13/english/counmtg/hansard/cm0320-translate-e.pdf), accessed 20 February 2017 (Council Member Ng Leung-Sing quoted the report of the Commission on Innovation and Technology (1998) and called on the government to “set forth a vision of making Hong Kong an innovation centre for the Asia Pacific Region”).

<sup>20</sup> Hong Kong SAR 2013 Policy Address: Seek Change, Maintain Stability, Serve the People with Pragmatism, The Government of the Hong Kong SAR §105 (2013), [www.policyaddress.gov.hk/2013/eng/pdf/PA2013.pdf](http://www.policyaddress.gov.hk/2013/eng/pdf/PA2013.pdf), accessed 20 February 2017.

the cost of medicines and pharmaceutical products. Even here, however, the government has not demonstrated awareness of the impact of patents on healthcare costs (or even willingness to evaluate such impact) or clearly set out a medicine procurement policy that aims to reduce costs.<sup>21</sup>

Given its reputation as a free market mecca, it is unsurprising that Hong Kong has not availed itself of flexibilities such as the issuance of compulsory licenses for medicines. More surprising, however, is that it has not attempted to tailor its pharmaceutical patent system to match its needs, interests and priorities or perceived level of development. Hong Kong's patent law effectively remains the 1997 version of its then former master, the United Kingdom<sup>22</sup> – drafted in the United Kingdom, presumably with British interests and stakeholders in mind. While sovereignty over Hong Kong passed from the United Kingdom to China in 1997, the substance of the law remained intact.<sup>23</sup> In fact, Hong Kong has not even contemplated a systemic review of the pharmaceutical patent system despite the fact that it recently initiated two “comprehensive” reviews related to the topic of this inquiry.<sup>24</sup> The most recent review, carried out by the Hong Kong Intellectual Property Department in 2011, primarily focused on the merits and implementation of an original grant patent system in Hong Kong,<sup>25</sup> while the earlier review, undertaken by the Food and Health Bureau and Department of Health in 2009, concentrated on the issue of

<sup>21</sup> See Hong Kong SAR Legislative Council, Official Record of Proceedings, at 10130, (2011), [www.legco.gov.hk/yr10-11/english/counmtg/hansard/cm0511-translate-e.pdf](http://www.legco.gov.hk/yr10-11/english/counmtg/hansard/cm0511-translate-e.pdf), accessed 20 February 2017.

<sup>22</sup> The People's Republic of China resumed sovereignty over Hong Kong in 1997 under the Joint Declaration of the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the People's Republic of China on the Question of Hong Kong, 1984.

<sup>23</sup> Hong Kong patent law comprises Patents Ordinance (Cap. 514); Patents (Designation of Patent Offices) Notices (Cap. 514A); Patents (Transitional Arrangements) Rules (Cap. 514B); Patents (General) Rules (Cap. 514C). The substantive norms are provided in Hong Kong Patents Ordinance (1997, last amended 2009) O.H.K., Cap. 514.

<sup>24</sup> See *Official Record of Proceedings* (6 July 2011), Hong Kong SAR Legislative Council 13830 (2011), [www.legco.gov.hk/yr10-11/english/counmtg/hansard/cm0706-translate-e.pdf](http://www.legco.gov.hk/yr10-11/english/counmtg/hansard/cm0706-translate-e.pdf), accessed 20 February 2017 (stating “[t]he Government considers that it is now high time to take a comprehensive review of the patent system, so as to ensure that our patent system can keep abreast of the times and promote local creative industries”).

<sup>25</sup> See generally, Hong Kong SAR, Commerce and Economic Bureau, Intellectual Property Department, Review of the Patent System in Hong Kong: Consultation Paper, (2011), [www.ipd.gov.hk/chi/pub\\_press/press\\_releases/2011/paper\\_20111004\\_c.pdf](http://www.ipd.gov.hk/chi/pub_press/press_releases/2011/paper_20111004_c.pdf), accessed 20 February 2017.

pharmaceutical product safety.<sup>26</sup> Remarkably, neither review mentioned, much less evaluated, Hong Kong's legal framework for pharmaceutical patent protection. Pharmacologist Benjamin T.Y. Chan succinctly summarized the situation: "Hong Kong is not concerned with issues of regulating the pharmaceutical industry, pharmaceutical R&D and patent protection, and state reimbursement of pharmaceutical payments which are characteristic priorities of policymaking in advanced economies."<sup>27</sup>

Perhaps even more remarkable is the near absence of scholarship on Hong Kong's pharmaceutical patent regime (or on pharmaceutical policy more generally), with no existing literature before this project analyzing linkages between pharmaceutical patents and policy areas such as public health, innovation and pharmaceutical industry development. The relevant literature is sparse, and even then barely touches on the relevant issues. For instance, in a study looking at the biotechnology sector, Professor Yahong Li found that patent laws in Hong Kong were a significant reason for Hong Kong lagging behind in patenting biotechnology.<sup>28</sup> Likewise, Professors Sharif and Baark, in a study assessing Hong Kong's innovation system and innovation policies, pointed to insufficient programs and IP laws for supporting what could be a stronger technology market in Hong Kong.<sup>29</sup> Similarly, Chib and Chan argued that Hong Kong must reconsider patent and drug registration issues in order to remain competitive.<sup>30</sup> Thus, while there is some literature criticizing the current approach, there does not seem to be any relevant literature assessing what specifically would

<sup>26</sup> See Hong Kong SAR, Food and Health Bureau and the Department of Health, *The Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong*, (2009), [www.ppbhk.org.hk/eng/files/Report\\_of\\_Review\\_Committee\\_eng.pdf](http://www.ppbhk.org.hk/eng/files/Report_of_Review_Committee_eng.pdf), accessed 20 February 2017.

<sup>27</sup> Benjamin T.Y. Chan, "Pharmaceutical Policy in Hong Kong: Defining an Evolving Area of Study" (First Conference on Pharmaceutical Policy Analysis, Zeist, Netherlands, 19–21 September 2007).

<sup>28</sup> Yahong Li, "An Overview of Patent Protection for Biotechnology in Hong Kong," in Felix Chan and Richard Wu (eds.), *Law for Practitioners Series 2003* (Sweet & Maxwell 2004).

<sup>29</sup> Naubahar Sharif and Erik Baark, "The Tamest of Tigers? Understanding Hong Kong's Innovation System and Innovation Policies" (2005) 1(3–4) *International Journal of Technology and Globalization* 462. See also Joseph Wong, "Biotechnology in Hong Kong: Prospects and Challenges," Hong Kong Innovation Project Report No. 9, [www.savantas.org/wp-content/uploads/2014/06/9\\_JWong.pdf](http://www.savantas.org/wp-content/uploads/2014/06/9_JWong.pdf), accessed 20 February 2017.

<sup>30</sup> Bindu Chib, "Hong Kong Pharmaceutical Patents: Breaking the Ranks?" (October 2004), Asia Law, [www.asialaw.com/Article/1972094/Hong-Kong-Pharmaceutical-Patents-Breaking-the-Ranks.html?Print=true&Single=true](http://www.asialaw.com/Article/1972094/Hong-Kong-Pharmaceutical-Patents-Breaking-the-Ranks.html?Print=true&Single=true), accessed 20 February 2017; Kitty Tsz Ki Chan, "Evaluation of the Drug Regulatory Systems in Hong Kong, Singapore, Taiwan, United States and European Union," submission for Master of Public Health, University of Hong Kong, February 2013 (on file with author).

need amending in the Hong Kong patent regime or otherwise providing solutions to the problems identified.<sup>31</sup>

The government's benign neglect results in outdated, vaguely drafted legislation that in places may even be contradictory. This creates uncertainties for all the major stakeholders, including both the branded and generic pharmaceutical industry, who would be better served with clear rules and regulations. The full extent of the impact of an inappropriate legislative framework on innovation, health, employment and other societal and policy interests is simply unknown, and without a comprehensive and systemic review the knowledge gap forms a lacuna and prevents informed policy deliberation and debate. With no signs of governmental movement in this regard, this research project undertook a review of the system. This monograph, the result of a three-year comprehensive review, will assist in filling the gap. Through an evaluation of the pharmaceutical patent system in Hong Kong, this monograph seeks to make recommendations that will recalibrate the legal system in order to maximize the benefits of innovation and better address the needs, priorities and interests of Hong Kong and all relevant stakeholders.

The aim of the book is chiefly to inform public policy and influence debate through a comprehensive review of Hong Kong's pharmaceutical patent law. For each substantive pharmaceutical patent issue, the international framework and current law in Hong Kong is reviewed before an assessment of whether the pharmaceutical patent law is in line with and beneficial to the needs, interests and priorities of Hong Kong and other relevant stakeholders. Unlike much of the existing literature on pharmaceutical patents and international IP, the study did not approach the topic with a preexisting view of whether IPRs and the patent system is "good" or "bad" either as a whole or for a particular sector. Instead, the starting point is that IPRs and the patent system cannot be viewed as "good" or "bad" in the abstract but rather any value, benefit, deterrent or harm entirely depends on how the systems work in a particular setting and time period. What may be beneficial or innocuous in one setting may be detrimental

<sup>31</sup> Other publications associated with this project notwithstanding, which include Bryan Mercurio and Daria Kim, "Patently Lacking: An Analysis and Call for Systemic Review of Pharmaceutical Law and Policy – A Case Study of in Hong Kong" (2014) 9 *Asian Journal of WTO & International Health Law and Policy* 63; Bryan Mercurio and Daria Kim, "Foreign Direct Investment in the Pharmaceutical Industry – What Are the Key Determinants? A Case Study of Singapore and Hong Kong" (2015) 10 *Asian Journal of Comparative Law* 235; Bryan Mercurio and Daria Kim (eds.), *Contemporary Issues in Pharmaceutical Patent Law and Policy* (Routledge, 2017).

or harmful in another setting. This book, therefore, particularly draws on comparative law and law in context methodologies to formulate feasible options suitable for Hong Kong.

To this end, this monograph will evaluate the pharmaceutical patent system in light of policy, economic and social factors relevant to Hong Kong. The ultimate aim is to use the information and data collected to recommend changes to the legal framework in order to construct a more efficient and effective system for Hong Kong. The views of the author have been shaped by information and data collected through various methods, including literature reviews, interviews and survey data. The project did not attempt to conduct a large-scale economic study,<sup>32</sup> and opinions have been shaped (and in some way limited) by available data and resources. Therefore, while the author firmly believes the recommendations made throughout this book are sound, he is nevertheless resolute in the opinion that the government must undertake a systemic review of the entire pharmaceutical patent system, including how it is affected by broader governmental initiatives such as policies on innovation, healthcare, employment and the like. As will be demonstrated in Chapter 2 and throughout the remainder of the book, governmental policy and guidance in the area of pharmaceutical law is unclear and underdeveloped. Therefore, if the government desires to improve the system, it must undertake a systemic review. Only then can it truly reshape the system in line with clear aims and objectives.

While the focus of the book is on Hong Kong and the purpose is to inform and influence domestic public policy, Hong Kong is not unique in its approach to pharmaceutical patent law. Indeed, many if not most jurisdictions have failed to undertake a systemic review of their system to ensure that it meets domestic needs and priorities and/or is in line with the state of development.<sup>33</sup> In this regard, while there is a limited jurisdictional focus of the book the underlying issues, principles and arguments are universally applicable – by contrast, domestic situations inevitably are varied and thus priorities and recommendations are jurisdictionally specific.

<sup>32</sup> But see Aidan Hollis and Paul Grootendorst, “The Cost of Potential Pharmaceutical IP Provisions in Hong Kong,” in Mercurio and Kim (eds.), *Contemporary Issues in Pharmaceutical Patent Law and Policy*, chapter 9.

<sup>33</sup> See Phil Thorpe, “Study on the Implementation of the TRIPs Agreement by Developing Countries,” Commission on Intellectual Property Rights, Study Paper 7, [www.cipr.org.uk/papers/pdfs/study\\_papers/sp7\\_thorpe\\_study.pdf](http://www.cipr.org.uk/papers/pdfs/study_papers/sp7_thorpe_study.pdf), accessed 20 February 2017.

### 1.3 Limitations and Challenges

Researching pharmaceutical patent law and policy in Hong Kong has been a challenge, and while most obstacles have been overcome (whether directly or indirectly), some difficulties proved insurmountable. Information and statistics that are widely available or easily accessible in most other advanced economies are simply not available or publicly disclosed in Hong Kong. Government databases are both sparse and opaque and industry information closely guarded. This has made economic forecasting difficult, and forced the economic portion of the research to rely on relatively small sample sizes to make projections. While easier and more complete access to statistics and data would undoubtedly have been useful, enough information was gathered to enable robust analysis, conclusions and recommendations.

### 1.4 Structure of the Book

Following this chapter, Chapter 2 introduces the array of complex considerations involved in pharmaceutical patent policy and law-making. More specifically, the chapter will introduce the “bundle” of interests and policies that influence the pharmaceutical patent regime, including interests relating to legal/IP, health, industrial and innovation policy. The chapter will also review the government’s stated policy aims and objectives in each of these areas in order to provide necessary context and insight for the remainder of book.

Although government policy direction is often unclear and underdeveloped, this in itself is useful information and assists in drawing conclusions and separating unrealistic ambition from realistic alternatives. Hong Kong is a small, relatively wealthy jurisdiction with an aging population and rising health expenditures (which are forecast to continue rising). Hong Kong views itself as a hub for economic liberalism and places great importance on the rule of law and respect for private property rights; in some ways, these make up its comparative advantage in a region replete with economic competitors for trade, finance and investment. While there is a purported push toward the cultivation of innovative research and development in Hong Kong in general, including in the pharmaceutical sector, there is little evidence to suggest this will be successful. There is also no evidence suggesting that Hong Kong’s small pharmaceutical manufacturing sector has the desire or capacity to expand. In short, while it would seem that the government would like to encourage the development of a

thriving pharmaceutical sector, it is highly unlikely to come to fruition in the near to medium term (or long term without a significant change in policy direction). The objective of any reform to the pharmaceutical patent regime must therefore be to reduce costs and increase access to medicines for the population while at the same time maintaining Hong Kong's reputation as a jurisdiction that fully respects law and order and property rights.

Chapter 3 discusses the underexplored (in Hong Kong) but extremely important topic of the standards for patentability, such as novelty, inventive step and utility, as well as exclusions from patentability and the protection for biologics. In so doing, the chapter explores the policy space available to tailor one's law around subissues such as new use of known substances. Drawing heavily on the experience of other nations, this chapter will ultimately recommend a more detailed and predictable standard than exists in the current law.

Chapter 4 relates to term extensions, which are not currently available in Hong Kong. The chapter draws on international experience and while questioning the merits of term extensions for delays in the granting of patents and delays in granting marketing approval of pharmaceutical products, the chapter recommends a course of action that provides principles and safeguards should the jurisdiction follow the trend and adopt such a mechanism.

Chapter 5 focuses on exceptions to patent rights. The chapter reviews the major flexibilities allowed under the TRIPS Agreement and explores their implementation and use in other jurisdictions before evaluating Hong Kong's legislative framework. Finding Hong Kong's laws in regard to a general exception (including a regulatory review or "bolar" exception) insufficient and opaque, the chapter recommends amendments to the current legislation that are clearer, more precise and more in line with Hong Kong's priorities. In regard to compulsory licensing, Hong Kong's laws are rather flexible and although unlikely ever to be utilized, do not require immediate attention.

Chapter 6 discusses the quasi-patent rights of protection for undisclosed test data. While not fully addressed in the TRIPS Agreement (Article 39 on undisclosed test data notwithstanding) test data exclusivity is a *sui generis* right that has become commonplace in the developed countries and spread in numerous FTAs to developing countries. Hong Kong offers a lengthy period of test data protection with minimal safeguards, which is curious given the state of the pharmaceutical industry in Hong Kong and its constructed policy objective. This chapter offers amendments to

safeguard the system through the addition of several legislative and treaty-based amendments.

Chapter 7 focuses on patent linkage – that is, the linking of marketing approval for pharmaceutical products with patent status. Hong Kong does not currently link patent status to the issuance of marketing approval, and this chapter recommends that Hong Kong maintain this position. However, given that patent linkage is spreading quickly via FTAs, the chapter recommends some ways to safeguard the system, minimize impact and avoid the most onerous aspects of patent linkage should it be implemented in Hong Kong.

Chapter 8 offers concluding comments on the need for Hong Kong (and almost every other nation) to undertake a systemic review of the pharmaceutical patent system to ensure it is operating efficiently, as intended and in line with the needs and priorities of the jurisdiction. In the case of Hong Kong, this research concludes that the law is not operating in harmony with governmental policy or in line with the needs of the population. Clearer governmental policy objectives are a necessary step toward resolving the disharmony. This research seeks to influence the public policy debate by first deducing Hong Kong's objectives and then by offering recommendations to reform the pharmaceutical patent framework.