The Contextual Framework of Hong Kong’s Pharmaceutical Patent Laws and Policy

Pharmaceutical patent laws and policy cannot be developed in the abstract. Instead, they involve an array of multifaceted policy considerations. Influenced and shaped by a multitude of sometimes contradictory interests, pharmaceutical patent laws and policy both are a product of and at the same time impact on a host of sectors, most notably health, industrial, intellectual property and innovation. The final product is policymaking at its most delicate and complex and laws that attempt to balance the competing interests.

The objective of this chapter is to provide contextual background information to the remainder of the monograph by mapping out policy areas that affect (and are affected by) the patent system. Possession of this information is critical before proceeding to evaluate and recommend changes to the current system. Stated more simply, one cannot assess the workings of the current system unless and until the policy objectives that lie behind the system are fully understood. In this regard, this chapter will seek to ascertain the objectives that drive pharmaceutical patent laws and policy in Hong Kong.

Lacking clear direction from the government, this chapter will review the government’s policy aims and objectives in the health, industrial, intellectual property and innovation sectors in order to form the basis of information from which to ascertain and/or construct the objectives that drive the government’s pharmaceutical patent policy. While clear policy direction is of course the preferred course of action, government policy in a number of areas is often unclear, underdeveloped and even conflicting. This is problematic, of course, but the lack of clear pharmaceutical policy objectives and direction is in itself useful information and plays a substantial role in drawing conclusions and separating unrealistic ambition from realistic options.

The analysis of interests and policies in this chapter reveals several important considerations that must be taken into account when shaping pharmaceutical patent policy. First, Hong Kong is a small, relatively
wealthy jurisdiction with an aging population and rising health expenditures (both of which are forecast to continue rising). Second, Hong Kong is not a leader in innovation in any sector, and the jurisdiction hosts little to no research and development (R&D) in the pharmaceutical sector and possesses limited manufacturing capacity. While the government has in recent times discussed the possibility of transforming Hong Kong into a regional pharmaceutical center, the discussions are preliminary in nature and appear rather half-hearted; there is little evidence to suggest the discussion will result in any tangible plan of action. The final consideration is that Hong Kong is a hub for economic liberalism and places great importance on its stability, friendly business climate, the rule of law and respect for private property rights (including IPRs) for its survival. In many respects, these overarching policy objectives are its comparative advantage in a region awash with competitors for trade, finance and investment opportunities.

Taking these factors into account, the chapter concludes by constructing a jurisdiction-specific policy objective for pharmaceutical patents: The objective of the pharmaceutical patent regime should 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, order and property rights.

2.1 General Landscape

This section provides necessary context through a brief description of Hong Kong’s economic and legal pharmaceutical landscape, public healthcare system and the pharmaceutical industry. Each will be addressed in turn.

2.1.1 The Economic and Legal Climate

Hong Kong is a small, technologically advanced jurisdiction that is heavily reliant on services for its economic prosperity. With over 90 percent of its gross domestic product (GDP) in the services sector, Hong Kong hosts little manufacturing, industry or agriculture. The government of Hong Kong thus actively promotes the territory as a hub for innovation and technological development with some success. For instance, *Forbes* magazine recently placed Hong Kong among the top technology hubs with a “compelling prospect in the near future” and the 2016 Global

Innovation Index Report ranks Hong Kong fourteenth among 128 countries (down from eleventh out of 142 in 2015 and fourth in 2011, it must be noted). Moreover, Ernst & Young’s 2012 Globalization Index places Hong Kong first among the sixty largest countries measured by GDP according to degree of globalization. Other estimates are slightly less complimentary or bullish, but nevertheless find Hong Kong possesses potential for innovation development.


See “Country Profiles: A Further Look into the Top 10 Performing Economies in the 2012 Globalization Index,” Ernst & Young’s Annual Globalization Index, (2012) at 4 (finding that Hong Kong “does best in cultural integration [and] its main strength lies in exchange of technology and ideas” and predicting that it will “remain on top of the Globalization Index… on the back of its forecasted increased trade and capital flows as well as improvements in technology and culture”), www.ey.com/Publication/vwLUAssets/Country_profile_of_Top_10_globalized_countries/$FILE/Country-profiles_top10_globalization.pdf. accessed 20 February 2017. It should be noted that although the report includes “technology and ideas” as one of the five main pillars and “drivers for globalization” (together with factors such as “openness to trade, capital flows, labor movements, and cultural integration”), the Index does not provide a detailed explanation of these indicators/factors or of the scoring system.


See, i.e., Naubahar Sharif and Erik Baark, “From Trade Hub to Innovation Hub: Hong Kong,” in Charles Edquist and Leif Hommen (eds.), Small Country Innovation Systems: Globalization, Change and Policy in Asia and Europe (Elgar, 2008), questioning Hong Kong’s desire to move from facilitator between China and the world to innovator. (“Hong Kong has a weak [national system of innovation], particularly if innovation is defined . . . in terms of knowledge creation through R&D inputs and patentable technology as output. This weakness is chiefly a result of Hong Kong’s historical place as a trade hub vis-à-vis China . . . In evaluating past innovation policies in Hong Kong, the most conspicuous point to be made is how ‘late’ the policies have been in their introduction.”) Although the authors find that “Hong Kong has made progress in transforming its role from that of an unrivalled trade hub
At present, however, Hong Kong has not formulated a strategy or implementation/action plan for innovation and technology. The only tangible results of the government’s interest in innovation have been the establishment of the Innovation and Technology Fund (ITF) to provide support to applied projects initiated by the industrial and R&D sectors⁶ and the recent establishment of the Innovation and Technology Bureau, which is now responsible for policy matters on the development of innovation and technology in Hong Kong.⁷

The simple point is nonetheless that Hong Kong is a globalized society that has all of the ingredients necessary to facilitate innovation and technological development. In particular, the government understands that multiple factors account for Hong Kong’s standing and readiness to embrace innovative technologies, and has consistently emphasized the rule of law and strong protection of IPRs. In this regard, the 2013 Policy Address states:

We attach great importance to the significant contribution of innovation and technology to the development of the economy and industries. There are a number of drivers for technological innovation in Hong Kong, including our rule of law, internationally acclaimed universities and sound intellectual property rights protection.⁸

This point is important because it sends a strong policy message that the rule of law and the protection of IPRs are key characteristics of Hong Kong’s business climate and play a role in the territory’s comparative advantage in the region. It is also clear that the government understands the interrelation between innovation and IPRs. For example, recognition into that of an innovation hub,” they forecast that in areas “such as automotive parts, Chinese medicine and integrated circuit design, Hong Kong is looking to exploit its ‘traditional’ role as a facilitator between China and global networks.” Ibid. at 226–31.

⁶ The ITF R&D projects for the manufacture of Western drugs and proprietary Chinese medicines are covered under the category of biotechnology. As of October 2017, the ITF has allocated more than HK$13.092 billion to support 6,709 projects – with 2,523 Innovation and Technology projects receiving funding of more than HK$10.281 billion, of which only 441 projects totaling HK$849 million went to the biotechnology sector. Biotechnology projects include funding for the development of new drugs, modernization of traditional Chinese medicines, improvement of drug formulas, development of new drug delivery systems, conduct of clinical trials, development of drug manufacturing processes and quality control methods. See “Innovation and Technology Fund Statistics” at www.itf.gov.hk/l-eng/statistic.asp, accessed 21 December 2017.


of the linkage between innovation and IPRs was behind the key objective of the patent system review in 2011, which was undertaken with a view to “develop Hong Kong into a regional innovation and technology hub.”

Beyond the basics, however, the cultivation of an innovation hub requires a deeper understanding of both the special relationship between patent protection and innovation and a thorough understanding of the sector-specific regulatory framework. Such an understanding would ideally be based on particular indicators and characteristics to measure and qualify the scale of innovation, technological capacity and expertise in local industry, including the maturity of the research infrastructure, the number of establishments in the local researched-based sector, and public and private investments into drug development activities. Thus far, the government does not seem interested in delving deeply into the issue or attempting to map the landscape of, inter alia, research capabilities, existing strengths and weaknesses.

Without such governmental action, we are forced to turn to secondary studies and anecdotal evidence. Even here, there are limited studies focusing on Hong Kong, and essentially none in the pharmaceutical sector. The only directly on-point pharmaceutical-specific study is of limited value as it is small scale and conducted by the Hong Kong Association of Pharmaceutical Industry (HKAPI), an industry association for branded companies. In this 2010 study, the HKAPI sought to evaluate Hong Kong’s potential to attract R&D for local clinical trials and to “develop into a regional hub for clinical trials.” Of note, the study found it was necessary for the government to establish a dedicated team to assist in the development of specific human resources in clinical studies and to establish a reliable patient-recruitment mechanism in relation to specific diseases in order to be successful – both of which would require coherent and sustained planning and development. The study, however, did not focus on


pharmaceutical developments as considered for the purpose of this chapter, and although many respondents positively evaluated Hong Kong’s potential for the discovery segment of the pharmaceutical value chain (including medical research infrastructure, equipment and laboratories of the clinical trial sites, expertise of local investigators and the “friendliness” of the regulatory framework), the study was based on the responses of 26 of 44 HKAPI members and conducted in response to the government’s stated desire to expand local clinical trials.\(^\text{12}\)

From a legal point of view, Hong Kong maintains a strong commitment to the protection of the rule of law and preservation of IPRs. This commitment is more than legislative with Articles 118 and 139 of the Constitution, respectively, providing that the Hong Kong government “shall provide an economic and legal environment for encouraging investments, technological progress and the development of new industries” and “shall, on its own, formulate policies on science and technology and protect by law achievements in scientific and technological research, patents, discoveries and inventions.” Additionally, Article 139 makes clear that the Hong Kong government, and not the central government in Beijing, “shall, on its own, decide on the scientific and technological standards and specifications applicable in Hong Kong.”\(^\text{13}\)

With a transparent system based on English common law that provides for predictable laws, regulations and enforcement, Hong Kong consistently ranks well in the World Bank’s Worldwide Governance Indicators Reports as well as in the World Justice Project’s Rule of Law Index. For example, the 2016 World Justice Project ranks Hong Kong sixteenth globally (among 113) and as fifth in the East Asia and Pacific region, with particularly high scores in relation to due process of law (and respect for due process), law and government data transparency and the reliability of complaint mechanisms. In all these factors, Hong Kong ranks far better than the average of regional countries and even above the average high-income countries.\(^\text{14}\)

Hong Kong is also a committed member of the international law community. Hong Kong became a member to the WIPO Paris Convention for

\(^{12}\) In particular, nineteen members of the HKAPI reported conducting 436 clinical trials in Hong Kong in 1999–2008 including in therapeutic areas such as oncology, endocrinology, gastroenterology and hepatology, cardiology and respiratory. Ibid., appendix 2.

\(^{13}\) Hong Kong 1997 Patents Ordinance Cap 514 also provides the substantive rules for an invention to be patentable. See in particular Sections 93–97.

the Protection of Industrial Property (Stockholm Act 1967) in 1985 and is bound to adhere to the Patent Cooperation Treaty (PCT). While the first two treaties are of marginal importance to the regulations on guaranteeing patent validity and the like, Hong Kong is a Member of the WTO in its own right and thus must comply with the TRIPS Agreement, which is an integral part of the WTO Agreement.

2.1.2 The Public Healthcare System

Hong Kong is in the luxurious position of being able to afford and prioritize its public healthcare system, with the government committed to “develop and maintain...a health care system which protects and promotes the health of the population, which provides lifelong holistic care to each citizen, and which is affordable and financially sustainable in the long term”. As a result, Hong Kong maintains a world-class system that rivals most in the world.

The Hong Kong healthcare system is more heavily dependent on government subvention than most other economically advanced jurisdictions, with 95 percent of the cost for across-the-board public hospital services and 97 percent for in-patient care subsidized by the government. As a result, public funding largely supports primary and specialist care, and most medicines are fully or partially subsidized through a Drug Formulary, which aims to ensure equal access to affordable medicine of proven safety and quality through standardized drug procurement and utilization policies across all public hospitals and clinics. Moreover, the public healthcare system provides an additional safety net in the form of specially allocated funding that provides financial resources to patients needing medicines that are not procured under the subsidized Drug 15


Hong Kong SAR Food and Health Bureau, ”Your Health, Your Life: Healthcare Reform Consultation Document” (2008) Annex B, at B.22 at 125, www.fhb.gov.hk/beStrong/files/consultation/Condochealth_full_eng.pdf, accessed 6 March 2017. As an illustration, a visit to the accident and emergency department costs HK$100 (equivalent to US$12.50) regardless of the reason for the visit or necessary treatment. For this reason, Hong Kong's healthcare system is skewed and wastefully dependent on public hospitals, with over 90 percent of patient care received at public hospitals compared with 92 percent of patients in England receiving care from general practitioners at private clinics. Business Monitor International, “Hong Kong Pharmaceuticals & Healthcare Report Q4,” 2015.
Formulary. At the same time, the government encourages the populace to make use of private healthcare, which offers additional medical treatment options for those willing to pay for them.

Public healthcare is delivered through the Department of Health and the Hospital Authority, the former being a government body charged with the implementation of the public health policy and the latter being a statutory body that manages all public hospitals (including resource allocation and drug procurement). In accordance with the Hospital Authority Ordinance (Cap 113), the Hospital Authority is directed to provide equitable and accessible quality public healthcare services to the population and ensure that “no one [is] denied adequate healthcare through lack of means.”

Similar to many other jurisdictions, public spending on medical and health services has been rapidly rising over recent years due to increased demand for hospital services, the implementation of measures to improve clinical care and the introduction of newer and more costly drugs to the Drug Formulary. For the reporting year of 2016–2017, the government allocated the Hospital Authority a budget of HK$57 billion (equivalent to US$7.3 billion), which is more than 90 percent higher than a decade ago and represents approximately 16.5 percent of the Hong Kong government’s general expenditures – on top of a new HK$200 billion grant provided as part of a ten-year plan to upgrade hospital facilities.

The issue of “rising health expenditure, which [is growing] at a rate faster than that of the economy” is increasingly making it more difficult for Hong Kong to maintain a world-class healthcare system. The government has long realized the growing problem, with the 2007–2008 Policy Address even stating that it would be “impossible for the Government to increase public health care expenditure indefinitely” and calling for the

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17 See 1990 Hospital Authority Ordinance (amended 2007) O.H.K., Cap 113, at 4(a)(i) (providing that the Hospital Authority is to “use hospital beds, staff, equipment and other resources efficiently to provide hospital services of the highest possible standard within the resources obtainable”).
introduction of “supplementary financing.” Following this Address, the government initiated public consultations on “comprehensive and fundamental” healthcare reform in order to address the challenges of rising costs and the substantial increase in the healthcare budget due to the rise in the demand for healthcare services. And make no mistake, demand for healthcare services in Hong Kong will rise – the population is growing and life expectancy in Hong Kong (currently at eighty-four years) is already among the highest in the world. At the same time, the incidence of chronic diseases is also on the rise, and the labor force is expected to start to decline from 2018 onward due to the rapidly aging population.

Unsurprisingly, the consultation focused on the implementation of supplementary and alternative financing options in order to combat the rising public health expenditure, with a key outcome being the adoption of the Health Protection Scheme, which shifts more of the cost burden to patients. More recently, the 2013 Policy Address stressed the further development of the private healthcare sector, finding that our rapidly ageing population has increased demand for healthcare services. The growing prevalence of certain diseases, advances in healthcare technology and public expectations for healthcare services to keep up with the latest medical practices have led to a rise in medical costs. We must tackle the root of the problem to ensure the sustainable development of our healthcare system.

The conclusions of the consultation were given a further boost when then-Hong Kong Financial Secretary John C. Tsang stated:

26 See “Hong Kong SAR 2013 Policy Address,” above n. 8, at 158.
[The population] aged 65 or above will increase from the current 0.9 million to 2.1 million in 2030. To cope with this long-term issue, both the community and the Government will have to make sustained efforts in various respects. Measures implemented in certain policy areas, such as the health-care financing reform, will help us get ready for the future. (emphasis added)\(^\text{27}\)

In the 2015–2016 Budget Speech, the Chief Executive further announced plans to “alleviate pressure on the public healthcare system due to manpower shortages and surge in demand” through a Hospital Authority fund for public-private partnership initiatives.\(^\text{28}\) Other initiatives, such as the expansion of the Elderly Health Care Voucher Scheme,\(^\text{29}\) provide stop-gap measures but are not viewed as long-term solutions.

When attempting to limit healthcare budget increases, an obvious target is the high cost of pharmaceuticals. Public procurement of medicines forms a sizable chunk of the Hong Kong healthcare budget, although as with many pharmaceutical-related issues in Hong Kong, acquiring actual figures has proven difficult. That said, it is known that drug expenditures nearly doubled between 2005 and 2015, with expenditures recently rising approximately seven percent a per annum and reaching HK$6.156 billion (US$1.7 billion) in 2017.\(^\text{30}\) This level of pharmaceutical expenditure accounts for nearly ten percent of Hong Kong’s entire health budget.\(^\text{31}\) While respect for patent rights and innovation is important, it must be understood that a central part of the balance between the maintenance


\(^{28}\) “Hong Kong SAR Budget Speech 2015–16,” above n. 25, at 142.

\(^{29}\) Used by 640,000 people, the program provides elderly residents with a HK$2,000 voucher and has an annual expenditure of some HK$600 million. See “Hong Kong SAR Budget Speech 2014–15” (2014), at 153, www.budget.gov.hk/2014/eng/budget42.html, accessed 21 December 2017.


\(^{31}\) Ibid., Hospital Authority.
of a world-class healthcare system with necessary cost containment measures occurs through the public procurement of medicines.

Unfortunately, and somewhat bizarrely, the Hong Kong government claims that it does not maintain statistics on the actual ratio between generic and branded drugs purchased by the Hospital Authority. That being the case, the Secretary for Food and Health is on the record as stating that “the annual percentage of expenditure on generic drugs procured through tenders by the [Hospital Authority] account[s] for more than 80% of the total expenditure on drugs.” Discussions with government officials confirm a policy favoring generic substitution as part of the cost-containment strategy. These figures, however, are somewhat at odds with those compiled by a leading healthcare consulting group, which found that generic pharmaceuticals currently account for 20.6 percent of the total market.

The sale and supply of pharmaceutical products in Hong Kong are regulated through a system of registration and classification. In order to market pharmaceutical products in Hong Kong the product must be registered with the Pharmacy and Poisons Board (PPB). The PPB is a statutory body that assesses applications for registration (marketing approval) on the basis of their safety, efficacy and quality through two Committees: the Registration Committee and the Poisons Committee. In order to approve any pharmaceutical product, applicants must submit to the PPB valid Certificates of Pharmaceutical Product (CPPs) issued by countries making up the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), that is, Hong Kong will not grant marketing approval to any product unless it has been approved in two ICH counties – namely, the United States,

33 Business Monitor International, Q4 2013, above n. 48 at 42 (projecting the share of generics to rise to 27 percent of the total market by 2017). The Report separates the total market into three categories: patented drugs, generic drugs and (curiously) over-the-counter medicines (which it would seem would either be patented or generic).
34 See Pharmacy and Poisons Ordinance (PPO) (Cap. 138).
35 The ICH is a grouping that “bring[s] together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration… [and whose] mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.” The ICH produces a number of guidelines, including on pharmaceutical product registration. For more information, see the ICH website at www.ich.org/products/guidelines .html, accessed 14 August 2017.
EU, Japan, Australia or Canada. The process for generic pharmaceutical products to enter the market is even more onerous and takes more time as the applicant must acquire and present a Free Sales Certificate from the country of origin, the manufacturer’s license, a Good Manufacturing Practice certificate and other documents that adequately track the manufacturing and logistics chain. Hong Kong does not treat originator products made from chemical entities differently from biological materials (i.e., products derived from living organisms). Unlike generic versions of pharmaceutical products made from chemical entities, generic versions of biological drugs are not exact copies but rather similar as a result “of the inevitable differences in molecular structures and quality attributes arising from their different manufacturing processes.” For these reasons, such generic versions are referred to as “biosimilars.” Hong Kong has a special process for the granting of marketing approval of biosimilars that is heavily based on guidelines developed by the World Health Organization (WHO) and practical experience of a number of jurisdictions, most notably the EU. In order to receive marketing approval in Hong Kong, biosimilar product applicants need to provide proof that the product has been approved in one other select market (the United States, Europe, Japan, Australia or Canada). Moreover, marketing approval will not be granted to a biosimilar until the original biological drug (called the “reference product”) has been on the Hong Kong market for a period of at least eight years. Furthermore, the biosimilar cannot rely on another biosimilar for the purposes of gaining marketing approval but must instead demonstrate similarity with the originator reference product.

Following endorsement by the PPB, the Drug Advisory Committee of the Hospital Authority will consider applications from newly registered

36 The PPB not only requires proof of registration in the other jurisdictions but also seeks to understand why the drug was registered (or, if applicable, initially rejected). That is, the PPB does not simply approve and register all applications that produce CPPs but instead uses those prior registrations to assist in its own investigation. The need for two CPPs has been criticized for delaying the registration process and limiting the availability of products for treatment of rare diseases, but is consistently defended as necessary to guard against premature and potentially dangerous drugs that are approved in only one jurisdiction before being withdrawn. See, e.g., Business Facilitation Advisory Committee, “Second Meeting of the Business Facilitation Advisory Committee,” BFAC Paper 3/06, paras. 18–19, available at www.gov.hk/en/theme/bf/pdf/2bfacpaper3–06.pdf, accessed 14 August 2017.


38 Ibid., para. 10. 39 Ibid., para. 14. 40 Ibid.
pharmaceutical products (whether chemically or biologically derived) to be included on the Drug Formulary. If successful, the product would be government-funded to the public and available at public hospitals and clinics, whereas unlisted products are available only on a user-pays, self-funded basis for patients. Approximately 70 percent of drugs sold in Hong Kong are listed on the Drug Formulary, which is revised every twelve to eighteen months to take account of the decisions of the Drug Advisory Committee.41

At the same time, Hong Kong’s Legislative Council must amend the Pharmacy and Poisons Regulations and the Poisons List Regulations before the product can be marketed in Hong Kong. The usual time for drug approval and registration in Hong Kong is on average between eight and twelve months, but can be as short as four months.42 That being said, and as mentioned above, once approval has been granted by the PPB, the manufacturer must wait for legislative approval by the Legislative Council. This process regularly adds on average an additional three to nine months to the process, and with the current state of Hong Kong politics in a state of paralysis owing to domestic political factors, routine items such as pharmaceutical approvals often get sidelined and pushed back on the agenda. The result over the recent few years has been further delays to the registration process.

The registration of pharmaceutical products is a purely scientific decision based on the safety, efficacy and quality of the submission. The PPB is qualified to make such a decision, and there does not seem to be a need for Legislative Council approval prior to approving the drug for registration. In other jurisdictions, including Australia, the EU and the United States as well as Asian neighbors Korea, Singapore and Taiwan, the process is entirely delegated to the relevant health authority and completed without legislative intervention. The need for legislation approval in Hong Kong unnecessarily delays the registration of new pharmaceutical products, to the detriment of patients and community health.

42 While Hong Kong does have a fast track approval scheme when there are “unmet needs” in the community, there are high procedural hurdles to overcome to implement the scheme and the procurement of the drug will likely have to be self-funded by the patient. Moreover, even when unmet needs have been established, the government still requires prior approval in two other jurisdictions.
Thus, on average an applicant can expect to wait eighteen to twenty-four months to receive marketing approval. This is far longer than other regional jurisdictions, which either make their own determination on the safety and efficacy or rely on only one other jurisdiction (usually being the United States or EU) as a guide. For instance, Singapore targets an approval time of forty working days for certain submissions and less than one year for all submissions. Moreover, while Singapore regularly approves between 100 and 200 new pharmaceutical products a year, Hong Kong by comparison approves only twenty to fifty new products.

While the delays ensure only high-quality pharmaceutical products are registered and that a healthcare system that is heavily reliant on public funding and subvention operates in a cost-effective manner, physicians and patients have complained that the length in processing time results in unnecessary suffering and even deaths as life-saving drugs readily available elsewhere cannot be marketed in Hong Kong. In so doing, however, quite a number of physicians conflate the marketing approval process with that of the government-funded Drug Formulary – to be clear, a drug can be approved for marketing in Hong Kong but not added to the government-funded procurement list, meaning that the patients must pay for it themselves. For instance, William Chui Chun-ming, president of the Society of Hospital Pharmacists, suggested that the long drug approval process may be due to the fact that the government subvention rate is exceedingly high in Hong Kong. Likewise, Dr. Stephen Chan, assistant

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44 These figures are sourced from the annual reports of Singapore’s Health Sciences Authority, with reports from 2001 to 2016 available at www.hsa.gov.sg/content/hsa/en/Publications/Annual_Reports/Annual_Report_FY2015_16.html, accessed 14 August 2017.

45 This figure is sourced from the annual reports of the Pharmacy and Poisons Board of Hong Kong, with reports from 2001 to 2015 available at www.ppbhk.org.hk/eng/index.html, accessed 14 August 2017.

professor of oncology at the Chinese University of Hong Kong, stated: “It is the government’s responsibility to consider the cost and benefits of certain new drugs, especially if they are very expensive, as they are managing taxpayers’ money... In Singapore, there is less concern for the government as patients are usually covered by medical insurance.”47 These may be arguments for not listing the new pharmaceutical product on the Drug Formulary, but they are irrelevant to the length of time it takes for a drug to receive market approval, or even whether the product should receive marketing approval. The statements do, however, demonstrate how the issues of the pharmaceutical approval process and funding of pharmaceuticals are misunderstood, even by those close to the system.

In Hong Kong, as in many jurisdictions, patented products are usually purchased through a single tender, while off-patent/generic drugs are procured through open tender.48 In some ways, this system serves to unwittingly delay the entry of generics into the market even further due to the tendering process, which grants access to successful tenders for a two- to three-year period. In so doing, depending on the timing of the tendering process, a monopoly on sales can be extended beyond the expiration of the patent period.

The healthcare situation in Hong Kong is thus somewhat complex and difficult to categorize. At the same time as the government attempts to reduce costs, it recently increased the cost burden of medicines on the budget in at least two ways. First, the government allocated additional funding to the Hospital Authority in order to expand the Drug Formulary so as to “introduce additional drugs of proven cost-effectiveness and efficacy as standard drugs.”49 The addition of new drugs on the Drug Formulary seems reasonable if not overdue, as medical practitioners have long complained about the restricted nature of the list and the corresponding inability to prescribe what some may deem to be more preferred medicines. Second, Hong Kong negotiated free trade agreements (FTAs) which bind the government to introduce measures that in all likelihood will increase the cost of the procurement of medicines. The most notable example of this is included in the Hong Kong–European Free Trade Association FTA (HK-EFTA FTA), which extends the period of test data

47 Ibid.
49 “Hong Kong SAR 2012–13 Budget,” above n. 27, at 426.
exclusivity in Hong Kong to eight years. More perplexing is that multiple sources have confirmed that it was Hong Kong that advocated and negotiated for the inclusion of this provision in the FTA.

The current state of public healthcare policy and pharmaceutical procurement is thus rather confusing – at the same time the government is publicly announcing its intent to contain the costs of healthcare and promoting a policy of generic substitution of medicines (presumably with cost-containment in mind), it is negotiating treaty text that delays the introduction of generic competition for medicines. The seemingly contradictory nature of the measures could be understandable if rationalized and based on solid evidence and reasoning. However, it appears that neither of the measures was accompanied by or based on any thorough study evaluating the actual role of generic and branded suppliers in drug procurement. For instance, and again rather bizarrely, the “comprehensive” consultations on public health reform completely neglected the area of pharmaceutical patent protection and did not even attempt to assess the impact of public procurement or drug pricing practices on the economics of the healthcare system. Likewise, the government did not commission or refer to any consultation or study to evaluate the effect of data exclusivity on the public healthcare system before negotiating for the extension in the HK-EFTA FTA. Thus, this author cannot avoid making the accusation that two important (and seemingly contradictory) policy developments were not taken as a result of integrated, informed and systematic decision-making but rather may be a case of one government department simply being uninformed about or ignoring what the other is doing, that is, government departments not acting in concert and in line with a clear policy directive.

2.1.3 The Pharmaceutical Industry

The importance of establishing and maintaining a domestic pharmaceutical industry is controversial. Many developing country governments believe that the sector is beneficial for economic development in that it provides foreign investment, infrastructure, technology transfer and employment opportunities as well as using it as a way to provide for “pharmaceutical security.” For more advanced economies, the sector is a worthwhile driver of innovation, source of high-quality employment for the populace and a boost to export trade terms. Still yet other

50 For more detail and discussion, see Chapter 6.
countries, both developing and advanced, do not attempt to establish or bolster a local pharmaceutical industry and are content with importing medicines.

The direction of domestic policy objectives, priorities and strategies should ideally directly shape patent laws. For instance, as the United States and Switzerland are advanced nations and home to several multinational branded pharmaceutical companies with large investments in both R&D and manufacturing and source of employment to many thousands of workers, it is not surprising that both are strong proponents of a maximalist IP regime. On the other end of the spectrum are Brazil and India, both large developing countries with large and highly advanced generic pharmaceutical industries, which seek to minimize IPRs and take advantage of all existing flexibilities built within the IP regime for both local consumption and export opportunities. Between these two extremes lie most nations, each with varying degrees of health priorities, pharmaceutical R&D, manufacturing capacity and the like.

Hong Kong is host to one of the smallest pharmaceutical markets in Asia, and given its already high level of wealth and limited capacity for population growth, it has few prospects for industry growth. Sales and profits, however, have been rising in recent years due to increased volume and price increases – which have been attributed to population increase, rising per capita pharmaceutical expenditures, geographical proximity to mainland China and other emerging markets in the region and the presence of international leading innovative pharmaceutical companies (as marketers and lobbyists). However, the overall impact of the pharmaceutical industry remains modest: In 2014, pharmaceutical sales accounted for only 0.52 percent of GDP (US$1.57 billion) and are expected to reach only 0.56 percent of GDP (US$2.14 billion) in the coming years. The sector is nevertheless a source of employment as it hosts approximately 240 importers/exporters, 720 wholesalers and 4,500 pharmaceutical retailers.

Hong Kong possesses limited manufacturing capacity. More specifically, as of 2017 Hong Kong hosts twenty-two licensed pharmaceutical

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52 Ibid.
manufacturers (down from twenty-four in 2015 and thirty-five in 2013), and it has been reported that domestic production of pharmaceuticals and medical products employs up to 6,324 people (although it should be noted that the employment figure is conflated with other chemical sectors and therefore rather inflated). Pharmaceutical production is focused on basic generic products for domestic consumption, but the jurisdiction also produces consumer health products and Chinese medicines. Overall, Hong Kong is a net importer of pharmaceuticals: In 2016, Hong Kong imported HK$5.381 billion and exported HK$628 million of domestic pharmaceuticals and medicinal products (down from HK$860 million in 2015).


55 The figure is reported in the category “chemical products and pharmaceutical.” See “Hong Kong Annual Digest of Statistics,” Hong Kong Census and Statistics Department (2017), p. 150, http://www.statistics.gov.hk/pub/B10100032017AN17B0100.pdf . Branded pharmaceutical companies are represented by HKAPI; as of April 2017, thirty-eight international members of the association are claimed to account for the provision of over 70 percent of prescription medicines in Hong Kong; see Membership of HKAPI, www.hkapi.hk/membership.asp. Local pharmaceutical manufacturers are represented by the Chinese Manufacturers’ Association, see the Chinese Manufacturer’s Association of Hong Kong, www.cma.org.hk. Links accessed 21 December 2017.


57 The notion of “proprietary Chinese medicine” essentially requires that the product is composed solely of the following as active ingredients: (i) any Chinese herbal medicines; or (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or (iii) any medicines and materials referred to in subparagraphs (i) and (ii), respectively. See Chinese Medicine Ordinance (1999, last amended 2010) O.H.K., Cap 549, at 2. Since this research focuses on the regulation of pharmaceutical products, proprietary Chinese medicine is excluded from the scope of the research. It should be noted, however, that a method for preparation of a Chinese medicine composition, such as the method of extraction of a natural substance, can be patentable.

58 Hong Kong Census and Statistics Department, above n. 55, at 299. Hong Kong also re-exported HK$1.544 billion in pharmaceuticals and medicinal products. Ibid.
Faced with increasing competition from imports from China (or, more accurately, multinational companies manufacturing in China), the outlook for Hong Kong’s pharmaceutical industry is bleak and its capacity is “shrinking or at least consolidating.” This is unsurprising, as land, infrastructure, inputs and labor are all significantly cheaper in China and elsewhere in Asia than they are in Hong Kong. Without government intervention, the industry will continue to follow the textiles and electronics industries, which significantly contracted and virtually disappeared as lower cost producers from elsewhere claimed market share.

Somewhat surprisingly, Hong Kong does not host any significant R&D activity in the pharmaceutical sector, and none of the major multinationals in the industry conducts any R&D in the territory. In a comprehensive review of patent databases in Hong Kong and all major markets conducted for this project, Daria Kim found that pharmaceutical patenting activity among Hong Kong residents is “quite modest [and] slightly declining recently,” that nearly half of all Hong Kong filings do not ultimately receive a patent and that the vast majority of patent applications and approved patents were filed by universities. Even with the universities, Hong Kong pharmaceutical patent activity results only in approximately twenty patent filings per year.

Another point of consideration is that the vast majority of university patents are ultimately licensed to other entities to further develop and exploit. This further development and exploitation occurs outside Hong Kong. Thus, while the government presumes that there will be a positive impact of patenting on national innovation policy, this is not the case. In order for industrial policy to benefit, Hong Kong needs to consider how it can further derive benefits from the patent system; that is, how the patent

60 Ibid., at 43–44. However, see Business Monitor International Report Q4 2013, above n. 48, at 69 (recognizing that although Hong Kong currently has little pharmaceutical R&D activity, “given its relatively advanced regulatory regime . . . [it has] considerable potential as a base for biotechnology activity”).
61 Daria Kim, “Patenting Activity in the Pharmaceutical Sector in Hong Kong: National Innovation Perspective” (unpublished, 2015) (on file with author). The sources of data for the study include Patentscope (WIPO); Espacenet, Inpadoc, Patstat (EPO); USPTO, SIPO and HK IPO.
62 See, i.e., “Hong Kong SAR 2013 Policy Address,” above n. 8, at 43. (“We attach great importance to the significant contribution of innovation and technology to the development of the economy and industries. There are a number of drivers for technological innovation in Hong Kong, including our rule of law, internationally acclaimed universities and sound intellectual property rights protection.”)
general landscape

system “interrelates and interacts with other elements of national innovation system.” More specifically, it must “consider how technologies developed by universities can be further absorbed by the domestic industrial sector and benefit the local consumer.” To date, this discussion has simply not occurred and the disconnect between the reality of patenting activity “sharply contrasts the policy aspirations” of the government as “an innovation-led, technology-intensive economy in the 21st century.”

This is in stark contrast to friendly rival Singapore, and even more curious given the level of R&D conducted in other regional markets such as Taiwan, China and Malaysia. Of course, Hong Kong has long championed laissez-faire-style economic liberalism, which means that the pharmaceutical industry does not benefit from large-scale grants/subsidies, tax breaks, preferences or other government largesse. While pharmaceutical companies – like any other technology or research-based company – can benefit by subsidized rent at the Hong Kong Science Park, this is the extent of governmental assistance. Thus, and despite being “a textbook case for an open FDI climate, with international investors treated the same as national counterparts, and with no limits on the extent or type of foreign investment,” Hong Kong has failed to attract significant investment in the pharmaceutical sector. In fact, investment in pharmaceuticals does not rate among the top ten investment sectors – nor was it deemed important enough to merit even in a mention in the direct investment statistics reports published annually over the last five years.

As mentioned above, the government has also recently attempted to establish the territory as a regional hub for clinical trials. These efforts have been hampered by high costs relative to competitors (such as those in China). The government does not offer much in the way of direct subsidies and offers no incentive for companies to conduct trials in Hong Kong. This is unlike several other jurisdictions, which offer a fast-track approval

process where the drugs have been trialed locally. In addition, clinical trial certificates in Hong Kong are valid for only two years (as opposed to five years in several other jurisdictions), and as trials regularly last ten to twelve years this can mean frequent interruptions and delays in the trials and increased costs and administrative burden to the clinicians.

To some extent, it is unsurprising that no branded multinational pharmaceutical company engages in any significant R&D, that local manufacturing is shrinking in the face of increased competition and that the policy push to become a regional hub for clinical trials has largely failed. The jurisdiction is renowned for its open economy, regulatory stability, low tax rates and educated workforce, but fails to offer any specific investment incentives. In itself, this indicates the extent to which other jurisdictions have actively sought to attract and retain the industry through inducements. The contrast is succinctly summarized in the following quotation: “[Hong Kong’s] policy for strategic development of [the pharmaceutical] sector is lacking when compared to Singapore and Malaysia [both of which] have actively promoted biotechnology and pharmaceuticals as new growth areas of their national economy.”

2.2 Policy Planning on Pharmaceutical Innovation

Having described Hong Kong’s general economic and legal climate, the state of the healthcare system and pharmaceutical landscape, it is time to now turn to consider the issue of policy planning in relation to innovation in pharmaceutical products, focusing on current policies and priorities.

Despite the fact that Hong Kong has little manufacturing capacity and no R&D activity, the government has at times discussed the possibility of the jurisdiction becoming a “pharmaceutical centre.” For instance, in October 2012 the Hong Kong Legislative Council discussed a call from industry groups to “develop Hong Kong into a ‘pharmaceutical centre’… [and] attract world-renowned pharmaceutical manufacturers” in order to export to China, as well as to promote Hong Kong as a destination for clinical testing and manufacturing.

70 Chan, above n. 56, at 10.
In the ensuing discussion, Dr. Ko Wing-Man, the Secretary for Food and Health, made two important statements. First, that the Hong Kong Census and Statistics Department “does not have figures on the gross domestic output of the industry of manufacture of western drugs”\(^{72}\) and, second, that the Hospital Authority “does not have detailed statistics on the quantity of different types of generic drugs procured by various clusters [i.e., groups of hospitals] and their respective proportions to the total drugs procured.”\(^{73}\)

That the government would not collect statistics on the production and quantity of medicines is curious, if not somewhat revealing about the state of the local pharmaceutical industry. It is also revealing of the state of the government, which it would appear fails to understand the linkage between patent protection, public health and the pharmaceutical industry. These are startling admissions, which evidence the lack of an integrated approach to pharmaceutical policy.

The second statement of interest is that “specific policies [are] to be put in place in the future to facilitate the development of the pharmaceutical industry, so as to develop Hong Kong into the pharmaceutical centre of the Asia Pacific Region.”\(^{74}\) As well as admitting that as of that date Hong Kong had not put the necessary policies in place, it is worth noting that the government has still failed to take any steps to develop Hong Kong into a “pharmaceutical centre” nor has it outlined a policy focus or priorities for the development of the pharmaceutical sector or even whether such a center would focus on manufacturing or R&D. The likelihood of these discussions maturing into policy is indeed remote.

Innovation promotion is a key component of Hong Kong’s policymaking for future development, but innovation in relation to pharmaceutical products has been left unconsidered in the most recent policy documents. As mentioned above, the 2013 Policy Address signaled the government’s intention to enhance innovation capacity by attaching “great importance to the significant contribution of innovation and technology to the development of the economy and industries” and reinforced its commitment to “focus on the development of the highly competitive sectors of the innovation and technology industries in light of Hong Kong’ strengths.”\(^{75}\)

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\(^{72}\) Ibid., at 588.


\(^{74}\) See above n. 71.

\(^{75}\) The Government of the Hong Kong SAR, “The 2013 Policy Address,” above n. 8 at 43.
However, innovation here is mentioned only in vague terms and without a focus being placed on pharmaceuticals.

More recently, the government has virtually ignored the sector. For instance, the 2015 Policy Address\textsuperscript{76} notes that Hong Kong is one of “the 10 most innovative places”\textsuperscript{77} and emphasizes that the government is setting up “a strategic environment for innovation and technology development” based on five “core strategies,” i.e., (1) providing world-class technology infrastructure for enterprises, research institutions and universities; (2) offering financial support to stakeholders in the industry, academia and research sector to commercialize their R&D deliverables; (3) nurturing talent; (4) strengthening collaboration with the Mainland (China) and other places in science and technology; and (5) fostering a vibrant culture of innovation.\textsuperscript{78} The Policy Address also reiterates that in the near future the government will create an Innovation and Technology Bureau (ITB), that Hong Kong’s R&D expenditure has already increased from $7.1 billion in 2001 to $15.6 billion in 2013, and the government’s ITF has provided about $8.9 billion for more than 4,200 projects.\textsuperscript{79} Virtually nothing, however, was mentioned regarding the pharmaceutical sector.\textsuperscript{80}

More recently, the 2016 Policy Address confirmed the successful establishment of the ITB and clarified its proactive coordination role in supporting “the development of Hong Kong’s innovation and technology industry” as well as the work of the various research actors (such as universities, the Hong Kong Science Park, industrial estates, Cyberport and the Productivity Council) and in “set[ting] up a robust system for scientific research, development and production.”\textsuperscript{81} Nonetheless, while Hong Kong’s policy plans announced research collaboration with sixteen key laboratories,\textsuperscript{82} enhanced protection of the elderly (as a key feature of


\textsuperscript{77} Ibid., at 41.  

\textsuperscript{78} Ibid., at 42.  

\textsuperscript{79} Ibid., at 43–48.  

\textsuperscript{80} In fact, the only reference made to the subject matter consists of mentioning increased efforts to promote Chinese medicines and the development of “authoritative international benchmarks to pave the way for the internationalization of Hong Kong’s Chinese medicine industry.” Ibid., at 194.


\textsuperscript{82} Ibid., at 71.
the health agenda) and increased spending to strengthen the ambulance service and provide some 5,000 public hospital beds and more than 90 operating theaters over a ten-year period,83 pharmaceutical development is again not considered in its plans for innovation.

This lack of political intent can also be seen in terms of institutional support. For example, when the head of the Food and Health Bureau – a government authority in charge of pharmaceutical regulatory matters – was called to report on the pharmaceutical industry performance and development, it became patently clear that Hong Kong does not have a special body in charge of the strategic development of the pharmaceutical industry. More importantly, the discussion revealed that the government had not considered the pharmaceutical industry when it formulated its “key” and “emerging” industries list.84 Even more stunning is that the Hong Kong Census and Statistics Department neither lists the pharmaceutical industry as a separate economic sector nor provides industry-specific statistics – “possibly because it is simply not important enough.”85 This omission is striking and, in combination with the sector being ignored in recent policy address, is at odds with the legislative session on the future development of the pharmaceutical sector in Hong Kong. It thus cannot be said that development of the pharmaceutical sector is a policy priority for the government.

This conclusion may come as a surprise, if only because the vision of transforming Hong Kong into an innovation center for Asia-Pacific has long been a recurring focal point of legislators, if not the government. The first report of the newly established Commission on Innovation and Technology in 1998 envisaged Hong Kong as an “innovation-led, technology-intensive economy in the 21st century, serving the region not only as a business and financial centre, but also a world centre for the development

83 Ibid., at 220–40.
84 See Hong Kong Census and Statistics Department, “Hong Kong Monthly Digest of Statistics” (April 2013) at FC1, www.statistics.gov.hk/pub/B10100022013MM04B0100.pdf, accessed 21 February 2017. The four “key industries” considered by the Hong Kong government to drive Hong Kong’s economic growth provide impetus to the development of other sectors and create employment, including financial services, trading and logistics, tourism and professional and producer services. The government has also identified “emerging industries” as “enjoying advantages for further development,” namely, cultural and creative industries, medical services, education services, innovation and technology, testing and certification services and environmental industries.
of health food and pharmaceuticals” and a marketplace for technology transfer between the mainland and the rest of the world.86

Yet in 2016, the promise is unfulfilled and the reality is that Hong Kong’s innovation focus has shifted to reindustrialization – described as “a potential new area of economic growth for Hong Kong”87 – as well as to supporting technology start-ups so as to promote and commercialize Hong Kong’s digital development.88 The 2016 Policy Address mentions “three cross-disciplinary platforms, namely ‘smart city,’ ‘robotics’ and ‘healthy ageing’” as a focus for the territory.89

Given the shifting nature of Hong Kong’s “innovation,” one may ask why, fifteen years later, this vision of Hong Kong as a pharmaceutical center reappeared on the policy agenda of legislators. One also wonders why the initial vision failed to materialize. While the former is difficult to assess at this point in time, the latter is clear: Hong Kong lacked an integrated and comprehensive pharmaceutical policy framework. Broad statements declaring the zest for technological innovation and a general recognition of the importance of strong intellectual rights protection are not sufficient; rather, forethought, planning and precision as to the particular policy objectives and targeted assistance for pharmaceutical R&D and innovations are necessary in order to turn this vision into reality90 – only then can the role of pharmaceutical patent provisions and policy choices in promoting pharmaceutical innovation be considered and evaluated.

2.3 Constructing a Policy Objective in Hong Kong

Based on the above analysis, it is essential for Hong Kong to define its overall position and strategy in the pharmaceutical sector. The effort thus far has been half-hearted and without sustained progress. Even advocates and supporters of pharmaceutical innovation in Hong Kong have not been

87 Policy Address 2016, above n. 81 at 77. 88 Ibid., at 75, 80–86. 89 Ibid., at 76.
90 See, e.g., Hong Kong SAR Legislative Council, Official Record of Proceedings of 30 January 2013, at 5610, www.legco.gov.hk/yr12–13/english/counmtg/hansard/cm0130-translate-e.pdf, accessed 21 February 2017 (citing Dr. Lo Wai-Kwok’s observation that “in order to achieve the long-term and sustainable development of Hong Kong economy, the SAR Government should formulate a balanced and visionary industrial policy so as to establish a clear policy vision and targets”).
clear in their ambitions and goals – do they want Hong Kong to develop innovative capabilities in certain pharmaceutical sectors or across a wide range of sectors? Are they seeking to develop local innovative capacity in order to supply the domestic and/or export market or to place Hong Kong as an R&D “hub” for multinational pharmaceutical companies specializing in research and clinical trials activities for discovery and product development? Should Hong Kong attempt to attract branded and/or generic manufacturers for employment purposes?

Pharmaceuticals “help patients live longer, healthier and more productive lives,”91 but it is unnecessary for every jurisdiction to engage in pharmaceutical manufacturing innovation. Comparative advantage and economies of scale will naturally mean that certain jurisdictions will be able to produce pharmaceuticals cheaper than others, while government incentives are necessary to attract and maintain large-scale R&D.

Transforming Hong Kong into a pharmaceutical production hub may be too much of a challenge, even with concerted government effort. While Singapore has largely succeeded in becoming a regional pharmaceutical hub over the past two decades, it has done so through meticulous and long-term planning and government support. Hong Kong did not and has not formulated any sector-specific policy and (unsurprisingly) has attracted little to no investment in the sector. Both are comparable “small, high-income, free market economies with an attractive business and investment climate, close in geographic proximity, comparable in terms of population, and sharing a common colonial background”92 – both enjoy similar market sizes, have adequate access to skilled workforce, provide similar levels of regulatory, legal (including IPR) protection and enforcement and political stability.93 The stark difference in performance is owing to the vastly dissimilar policy framework.

As I have written elsewhere with Daria Kim, Singapore has taken great care in prioritizing the pharmaceutical sector (within the more comprehensive framework of the Biomedical Sciences Initiative) and skillfully created a regulatory framework conducive to foreign and domestic investment for high-value R&D and manufacturing. In contrast, Hong Kong continues to lack a clear pharmaceutical policy of any kind.94 As a result, while Hong Kong’s domestic pharmaceutical industry consists of around

92 See Mercurio and Kim, above n. 67. 93 Ibid., at 8–12. 94 Ibid., at 13.
thirty companies producing primarily generic pharmaceuticals predominately for the local market, Singapore’s industry grew from S$6 billion to S$23.3 billion between 2000 and 2010, making pharmaceuticals the leading sector for manufacturing FDI in Singapore and transforming the nation into a pharmaceutical “trading base for the South East Asian region.”

Statements indicating Hong Kong’s desire to become a pharmaceutical hub appear to be little more than puffery without the necessary accompanying policy and regulatory action; such statements also do not appear to be feasible given Hong Kong’s present capabilities and forecasted future. Several jurisdictions in the region, such as Singapore, China, Taiwan and Malaysia, among others, have established and well-developed pharmaceutical R&D and manufacturing sectors, making the possibility of transforming Hong Kong into a regional “hub” unlikely even if the government were to deem it a priority. For these reasons, and for the economic and healthcare factors explored in this chapter, Hong Kong would be better served developing a policy of cost containment that seeks to maintain high quality standards and availability of medicines at the cheapest possible prices.

Of course, designing a policy objective and implementing it through amendments to existing legislation is complicated and nuanced. Broadly, the objective of pharmaceutical policy should be both to provide as much access as possible to innovative drugs in order to meet challenges of complex diseases and to procure the drugs at an affordable rate so as to better serve the broader needs of the population.

At present, Hong Kong has no discernible objective for the patent system in relation to pharmaceuticals. Like many other nations, Hong Kong must use the patent system to balance the incentive to create (globally, as Hong Kong benefits from innovation elsewhere) with broader societal interests. In this regard, Hong Kong must seek to provide the populace with high-quality healthcare, including ample access to affordable and safe medicines, while at the same time restrain rising healthcare costs. Hong Kong is similar to many jurisdictions in that healthcare costs are rising both as a percentage of government spending and at a rate faster than the GDP, necessitating cost-cutting measures such as the reduction of pharmaceutical expenditures through greater use of generic pharmaceuticals.

95 Ibid., at 5.
Without industrial policy concerns, the only choice is to clearly identify access to medicines and cost containment as priorities and construct the pharmaceutical patent system accordingly.

Of course, such a policy cannot be implemented to the detriment of the IP system. Hong Kong has worked for many years solidifying its reputation as a safe and secure jurisdiction that seriously protects IPRs and should not seek to dismantle its standing. This book proposes, however, that Hong Kong devote time, energy and resources into crafting a suitable system for the jurisdiction based on the constructed objective that at the same time is fully compliant with its international commitments.