Pharmaceutical patent law is a controversial and seemingly unsettled area of international IP law. The TRIPS Agreement is just the starting point and complexity is added with every new FTA and addition of sui generis and related rights. The branded pharmaceutical industry has been successful in lobbying governments to legislate for and include in FTAs a maximalist IP agenda that extends the rights and better protects branded drugs from competition on the marketplace. In some respects, provisions that guarantee a certain period of market exclusivity are justified as the process of discovering, inventing and bringing drugs to market is expensive and not without substantial risk. One would hope that even the most ardent NGOs promoting access to medicines would admit that absent an incentive to create, the pipeline of new drugs would cease.\(^1\) At the same time, one must be mindful of the fragile IP balance between inventors and the broader interests of users/society. Moreover, one must also be mindful that one size does not fit all and that these interests can vary between and among jurisdictions. Contextualizing framework agreements and making adequate and appropriate use of the flexibilities provided in the international agreements are crucial for the proper functioning and administration of a pharmaceutical patent system.

This book primarily discusses this balance as it applies to Hong Kong. Hong Kong is not unlike most other nations in many respects – it does not host branded R&D activities or a large and competitive generic industry; it has an aging population; and health costs are rising at a rate faster than the GDP. Of importance to Hong Kong is the place of the rule of law, which the jurisdiction views as its comparative advantage over others in the region. These issues were explored in some detail in Chapter 2, as

\(^1\) WTO, WIPO and WHO Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade 32 (2012) (concluding that the concepts of access to affordable medicine and medical innovation are “intrinsically intertwined”).
was the curious, piecemeal and rather stunted approach Hong Kong has taken to the regulation of pharmaceutical patents and related industrial developmental issues. This chapter provided the background and context necessary in order to formulate a framework of objectives and priorities for Hong Kong. The chapter also develops an argument for an integrated approach that would help ensure that legal and policy measures target specific practical needs and are applied in a balanced and holistic way and that decision-making is based on empirical data and other evidence that reflects the benefits as well as social costs associated with the regulations and legislation. Pharmaceutical patent law and healthcare policy can no longer be viewed and treated as separate entities, and determinations and decisions must be country-specific and made only after clear governmental objectives have been set.

Having reviewed the situation, Chapter 2 concludes with the recommendation that Hong Kong must integrate the law and policy in a more systemic way and set out objectives and priorities for the system that reflect the need to provide the populace with high-quality healthcare and affordable and safe medicines, but without ignoring the burden that rising healthcare costs are placing on the territory's budget. Without large-scale manufacturing and R&D activities in Hong Kong and such activities unlikely to increase in the future, there are no industrial policy concerns to compete for attention. Thus, the only sensible option for Hong Kong is to clearly identify access to medicines and cost containment as priorities and construct the pharmaceutical patent system accordingly. Simply stated, Hong Kong must formulate a policy that maximizes public welfare and minimizes unnecessary spending in order to preserve the long-term welfare of the health system in the territory. Of course, and again, it must do so in a way that is territory-specific and without offending its international obligations or risking its reputation as a center of rule of law and strong IP protection.

The preceding chapters then demonstrated how Hong Kong could benefit from taking a holistic approach to pharmaceutical patent law and policy. Taking an issue-by-issue approach, the book methodically reviews the most important areas of pharmaceutical patent law with a view to making jurisdiction-specific recommendations for Hong Kong. Each chapter reviewed the international framework of WTO and subsequent advances made in FTAs before looking closer at how key jurisdictions have implemented the rules in their domestic laws.

Chapter 3 focused on patentability standards, and more particularly on the obligation under Article 27.1 of the TRIPS Agreement to grant patents.
on inventions, whether products or processes, provided that they are new, involve an inventive step and are capable of industrial application. As demonstrated in the chapter, each of the criteria leaves ample room for tailoring to meet the needs and objectives of a particular jurisdiction with the TRIPS Agreement not providing any guidance as to the meaning and scope of the terms. The chapter also closely examined second use medical patents in this regard given their prominence in modern pharmaceutical development and controversial nature. Patentability standards are of particular importance as the jurisdiction transitions to an examination system. In line with the objectives set out in Chapter 2, the chapter recommended that Hong Kong adopt strict patentability standards that fully respect prevailing international standards (including the granting of second medical use patents) but guard against overprotection and interests that run counter to those of the territory. The specific recommendations made, if adopted, will assist Hong Kong in establishing a fair, predictable and efficient system based on a holistic view of health and other local priorities.

Chapter 4 discussed the emerging standard of patent term extension (PTE). Designed to provide for a minimal period of market exclusivity for a pharmaceutical product and thereby encourage continued R&D and innovation in the field, most developed markets grant PTEs for either unnecessary delays in the granting of a patent or marketing approval of the drug. Hong Kong does not currently grant PTEs, but the international trend is clear and the jurisdiction will very likely consider its adoption in the near future. For Hong Kong, however, it must be clear why it would adopt PTE; the reason for many – that it will lead to greater innovation – is not directly applicable to Hong Kong. With no pharmaceutical R&D, PTE will not directly lead to innovation or sector development in Hong Kong. Of course, as every other economy Hong Kong will indirectly benefit from the advancement of medical science and development of new drugs. More directly, PTE would prolong the period of monopoly sales and therefore increase the costs of drugs, to the detriment of consumers and pharmaceutical spending for the territory. The winner would be the pharmaceutical companies, which would receive a windfall with the extended period of monopoly sales. If and when Hong Kong does decide to implement PTE, it would be well advised to look at the experience of other jurisdictions as a guide. The chapter considered a variety of policy options that would shape the contours of the PTE system so that Hong Kong would pay its share for successful and innovative R&D but at the same time recommended
the adoption of several principles and safeguards to ensure that the public interest was protected against overprotection.

Chapter 5 discussed the important topic of exceptions, with particular focus on the experimental use exception and compulsory licensing. In regard to the former, the chapter finds that Hong Kong could benefit from a broader, more tailored approach that takes account of its position as a pharmaceutical importer with little to no branded operations currently operating in the territory. This is particularly the case with the regulatory review exception, which operates to explicitly allow a generic to “use” a patent to apply for marketing approval without the threat of an infringement claim. In regard to compulsory licensing, the current law in Hong Kong takes an extremely broad approach, and since the jurisdiction is unlikely to issue a compulsory license on pharmaceutical absent a public health emergency or crisis, it may wish to consider narrowing the scope of the law so as to avoid unnecessarily offending pharmaceutical interests or tarnishing its well-earned reputation as a regional leader in the protection of IPRs.

The topic of Chapter 6 was test data exclusivity, a sui generis right akin to an IPR that rewards the creation of standardized and better data as a benefit to society. Like PTE, test data exclusivity is designed to ensure a minimum period of market exclusivity for a successful pharmaceutical product – which would apply even if the originator of the data receives no patent for the product. This encourages the production of useful data where the receipt of a patent is unlikely or nonexistent. The alternative, of providing no protection, would mean either that a third party can “free ride” and immediately use the originator’s data to produce a rival medicine or that the originator does not conduct the tests, much to society’s detriment. While test data protection is the subject of Article 39(3) of the TRIPS Agreement, there is no consensus as to its meaning. Most countries do not read the provision as prohibiting domestic regulatory authorities from registering generic drugs based on the data submitted by the originator. That restraint, however, is included in numerous FTAs, including the HK-EFTA FTA, which demands eight years’ protection. This is unfortunate, as test data protection in Hong Kong and other small jurisdictions seems out of line with the purpose of the right – that is, to encourage and reward the generation of test data – given the market size is too insignificant to influence or determine the decision to conduct trials and other data-generating activities. While the author would have recommended that Hong Kong not adopt test data protection, it is too late. That
said, the chapter recommends Hong Kong take several legislative steps to safeguard the healthcare system and limit the potential negative effects of test data exclusivity.

Chapter 7 discussed the controversial issue of patent linkage. After reviewing the historical development of patent linkage, the chapter questioned the necessity and desirability of patent linkage and highlighted the fact that the context, contours and effects of patent linkage differ between jurisdictions. While patent linkage may have made sense in the US context, its application in other jurisdictions is highly questionable. Patent linkage certainly does not make sense in the Hong Kong context, where generic manufacturers usually wait until the expiration of the patents on a branded drug prior to applying for marketing approval and where market exclusivity for the branded drugs is already greater than that in the United States, Canada and other markets. If Hong Kong were to consider its adoption, careful consideration must be given to ensure the system takes into account policy priorities and objectives and does not unduly burden the health system and access to affordable medicines. Unlike most jurisdictions, which seemingly follow the US approach without much thought, Australia and South Korea offer models that apply patent linkage but at the same time effectively balance the enhanced protection with societal interests and could be used as models should Hong Kong consider the adoption of patent linkage.

The main objective of the book is to reveal Hong Kong’s scattered approach to pharmaceutical patent law and policy law and recommend that a more holistic approach be taken in order to increase coordination between the law and the broader objectives and priorities that should guide health and pharmaceutical policy. In the absence of clear government policies, aims and objectives, this book constructed objectives and priorities for Hong Kong in this regard, and on that basis took an issue-based approach to demonstrate failure of the government to develop appropriate laws for the jurisdiction. In each chapter, shortcomings are revealed and recommendations are made to better coordinate and align with the constructed objectives and priorities. In order to improve efficiency, reduce costs and better provide for the citizens, Hong Kong would be wise to initiate a wholesale review of the system. This book and the underlying research can serve as a starting point for such a review.