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Book Review

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Drugs, Patents and Policy: A Contextual Study of Hong Kong

by Brian Mercurio

Since the creation in 1994 of the World Trade Organization (WTO) – by virtue of the introduction of new trade disciplines on intellectual property, epitomized in the Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement) – the relationship between patent law and access to health has been controversial. It has taken a prominent place in the international discourse characterized by heated discussions and disagreements on how to design policies to provide access to affordable essential medicines and vaccines. As proclaimed by the United Nations 2030 Sustainable Development Goals (SDGs), '[e]nsuring healthy lives and promoting the well-being at all ages is essential to sustainable development' (SDG 3).

With the adoption of the TRIPS Agreement, the world of patents and drug policy has been drastically transformed. Since then, jurisdictions are no longer free to decide which fields of technology are eligible for patents. In a large number of emerging economies before 1994, sensitive social sectors or industries were off patents. For those countries, the adoption of the TRIPS Agreement dramatically altered the required policy framework for pharmaceutical products. This is because the TRIPS Agreement requires that patents be available for all products, on a non-discriminatory basis, 'in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'. As pointed out by professor Brian Mercurio in his enlightening study on Drugs, Patents and Policy – which is the subject of this review – less than 50 countries by 1994 provided pharmaceutical patent protection for processes but not products (p. 2).

Certainly, in the case of pharmaceuticals, the TRIPS Agreement signaled a major departure from the pre-existing international legal regime, as embodied in the 1883 Paris Convention for the Protection of Industrial Property (the Paris Convention). The Paris Convention left 'considerable freedom to Member States to legislate on questions of industrial property according to their interests and preferences'.[1]

The TRIPS literature – in general and specifically the writing on the impact of the TRIPS Agreement on policy making in the field of health – is abundant. Brian Mercurio, however, brings a distinctive contribution to this area by lucidly, scholarly, and pedagogically placing the international framework in the context of a specific jurisdiction, namely Hong Kong. This example is particularly interesting and a good case

1 G.H.C. Bodenhausen, *Guide to Application of the Paris Convention for the Protection of Industrial Property*, World Intellectual Property Organization, 1969, p. 15.

study for a number of emerging economies, as it illustrates the need for a domestic jurisdiction both to be consistent with the existing international framework and to meet the needs of local constituencies to access affordable and safe medicines.

In this case study, an important dimension is the special circumstances that Hong Kong is a jurisdiction with distinct links with China and, at the same time, is a unique model of a free market, liberal economy, and friendly business climate, as well as its traditional reputation for the rule of law and the protection of property rights. What is also important is that Hong Kong's health care system is heavily dependent on public subsidies, and, as is the case in most jurisdictions, public spending on medical and health services is on the rise. Overall, Hong Kong is a net importer of pharmaceutical products and does not host any significant R&D activity in the sector.

The author does not spare criticism of the public health policies pursued by Hong Kong's administration in the implementation of the international framework to respond to the needs of its population. In this context, according to the author, the government has 'not demonstrated awareness of the impact of patents on healthcare costs' and there has been no attempt, in light of its level of development, to tailor the patent regime to match local needs, interests, and priorities. The patent law that remains in force is the 1997 United Kingdom (UK) version.

One key objective of the book is to make recommendations and provide policy options to 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' (p. 11). This is achieved by adopting a comparative legal perspective and by looking at examples in advanced emerging economies.

To undertake this challenging task, the book is organized into several distinct chapters. It begins by providing the contextual framework for laws and policies in the healthcare sector. Subsequent chapters discuss, respectively, standards of patentability, extension of patent terms, exceptions to exclusive rights, test data exclusivity, and linkages between patents and drug regulatory approval. The following sections provide a snapshot of some of these key topics that have been particularly controversial and subject to contrasting views.

Standards of patentability

The chapter on standards of patentability is a resourceful guide on how patentability criteria can, and are, in fact, being used in some jurisdictions to promote various public policy objectives, in particular access to affordable medicines and industrial development. The analysis is guided by the need for cost containment in Hong Kong's public health sector, which requires recourse to rather narrowly defined criteria of patentability. At the same time, the objective to limit patentability is tempered by the desire for Hong Kong to live up to its reputation of being a 'good international citizen' that encourages investment in R&D by providing strong patent protection.

This chapter begins by shedding light on the fact that some leading economies have used the freedom to define domestic patentability criteria to promote their local pharmaceutical industry, i.e. generic producers through narrow, and originators through wide, patent eligibility requirements. The main message for Hong Kong here

is that it lacks such a strategic approach, but instead, and without much reflection, follows 'the path taken by others'.

The examination of one of the requirements for granting a patent, i.e. 'inventive step/non-obviousness' enters into considerable technical detail. It considers, among other things, recent US Supreme Court decisions. India also takes an important place in the review of the approaches taken by several major jurisdictions to the inventive step test. This country is highlighted as applying a 'non-obviousness-plus' standard, as its inventive step definition includes not only non-obviousness, but also the notion of 'technical advance over prior art'. This requires an analysis to what extent the invention has improved pre-existing knowledge. Thanks to a comparison with other jurisdictions, the reader understands that, despite this formal additional step, the difference between the approaches taken by India and by other countries is in reality not substantial.

The chapter also highlights that achieving higher degrees of inventiveness may not necessarily require the exclusion of so-called secondary patents, e.g. new forms or new uses of existing products. Even new forms of known substances may meet a strict inventive step standard or can fall under a restricted definition of patentable subject matter, as illustrated by India's Patent Act, which – in the case of pharmaceutical patents – allows for the patenting of new forms provided they result in the enhancement of the known efficacy of the substance. Considerable attention is given to the extent to which new medical uses of known products should be eligible for patent protection.

According to the author, the introduction of new use patents 'will not directly benefit the industry in Hong Kong, nor will [it] lead to any strengthening of the industry. Instead, the result will be that monopolies will be extended and thus Hong Kong will pay more for pharmaceuticals' (p. 88). But Hong Kong should be prepared to pay higher drug prices for maintaining its foreign investment reputation. The commentators will not seek to second guess the author's evaluation. But whatever the correct conclusion, this is an excellent illustration of the balancing task that awaits policy makers in any country. Other countries may have other priorities and reach different outcomes.

Test data exclusivity

Patents provide their holders with the qualified and demarcated right to prevent others from performing certain acts, such as making or using the patented subject matter. But a patent on a pharmaceutical product will not provide its holder with the right to bring the product to the market. Such marketing approval does not depend on patent-related criteria, but on public health-related requirements associated with the quality of the product, such as safety, efficacy, and overall quality. A national drug regulatory authority examines whether a pharmaceutical product meets these requirements before approving the first marketing of the product. A drug originator company will be required to demonstrate product safety, efficacy, and quality by submitting data generated in time-consuming and expensive pre-clinical and clinical trials. The extent to which originators acquire exclusive rights in this data is controversial.

In a crisp manner, Mercurio explains the different interests at stake and discusses the controversy of how to interpret the TRIPS Agreement in this context. Legal views in favor and against test data exclusivity are set out in significant detail, including the

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option of having generic competitors pay compensation for relying on test data. Mercurio shows sympathy for the view according to which TRIPS cannot be interpreted as sanctioning exclusive rights.

When discussing the scope of data exclusivity obligations, the author draws an important distinction that is seldom discussed in the literature, i.e., the distinction between 'data exclusivity' and 'market exclusivity'. He rightly emphasizes that the former is the stronger form of protection, as it prevents the regulatory authority from even accepting generic applications relying on original test data, while the latter only prevents the actual granting of approval.

Depending on the time required to examine a generic drug, strict test data exclusivity rules may have an impact on the usefulness of the regulatory review exception in case the originator drug is additionally protected by a patent. (The regulatory review exception is discussed separately in the book in the chapter on 'exceptions'). While the generic producer may invoke this exception as a defense against patent infringement, the regulator cannot proceed with the examination until the test data rights expire.

Mercurio clarifies that both modalities, i.e. market and test data exclusivity, are promoted through various free trade agreements (FTA) sponsored by the United States (US), the European Union (EU) and the European Free Trade Association (EFTA). EFTA has developed a third option which instead of exclusive rights provides the data originator with a right to claim compensation from competitors that rely on its original test data.

For the time being, Hong Kong is only bound by a data exclusivity obligation under its 2011 FTA with EFTA. Mercurio emphasizes that this agreement includes an option to create a compensatory liability regime for test data, an option that Hong Kong has so far failed to examine and to implement. This again fits within the overall picture of a government that has widely ignored available public health-related policy options, due to the lack of a clear policy on this matter.

Patent linkage

Patent linkage makes the right to market a generic drug dependent on the patent status of the originator product. This concept, which was introduced in the post-TRIPS era, occupies an important place in the book. Patent linkage is not explicitly regulated in the TRIPS Agreement, but in recent decades has become a common feature of the FTAs concluded by the US. In those jurisdictions that have adopted patent linkage as a consequence of signing an FTA of this kind, the regulator cannot grant marketing approval during the patent term. The latter is reinforced by extensions of the original 20-year term in case of administrative delays in the granting of the patent and in cases of unreasonable delays in the marketing approval. Thus, patent linkage, together with the extension of the original patent term for pharmaceutical products, limits the possibility of generic market entry.

Mercurio analyzes critically how patent linkage could be implemented in a jurisdiction such as Hong Kong that at present does not provide for such a linkage. One of the reasons for this policy is to avoid a scenario where pharmaceutical products are afforded higher protection – through the linkage – than other areas of technology,

where linkage does not exist. Mercurio discusses innovative attempts by the industry to secure a policy change through courts.

In a very systematic manner, Mercurio assesses the merits and options on whether a patent linkage regime should be adopted and, if so, in which form and under which conditions it should be implemented. The author is emphatic in stressing that the delay in the introduction of generic medicines of approximately 3–5 years is not justified in the case of Hong Kong.

Mercurio is of the view that there is no a one-size-fits-all solution. The appropriate solution might be different in big vs. small markets. In smaller jurisdictions, the net result of patent linkage is to delay generic competition, with significant costs to the healthcare system. Thus, a jurisdiction seeking to adopt patent linkage should carefully plan and calibrate the regime. To this effect, the author compares different jurisdictions and how they have attempted to mitigate the restrictive and anticompetitive consequences of adopting a patent linkage regime by introducing public interest safeguards. An example from Australia is to make the granting of an injunction against the marketing of generic drugs dependent on certain requirements, as opposed to the more traditional approach of granting automatic injunctions in cases of alleged patent infringement (p. 202).

The author emphasizes that it is fundamental to adopt a systematic approach to the interface between patent linkage and two important patent exceptions, i.e. the exception to use the patented substance to carry out experiments (experimental use exception) and the exception to allow use of the patented substance to submit a generic drug for marketing approval (regulatory review exception). The domestic patent law should expressly provide that patent linkage does not stand in the way of effectively relying on these exceptions.

Conclusions

Drugs, Patents and Policy by Bryan Mercurio brings fresh air to an area of law where maximalists and minimalists in the design of patent policies have had the upper hand.

Pharmaceutical patent law has experienced significant changes in the 25 years since the establishment of the WTO. While the treatment of medical drugs was for some a marginal component of international IP law, in the post-TRIPS period it has become an area of focus. During this time period, pharmaceutical patent law has at an increasing pace provided new tools to improve the IP protection of innovative firms.

The TRIPS Agreement put an end to the perceived discrimination against pharmaceutical patents. Since then, the patent regime for pharmaceuticals has been enhanced by adding improved layers of protection. Mercurio's book gives special attention to standards of patentability, extension of patent term to compensate for delays in the actual marketing of the product, test data exclusivity, and patent linkage.

One of the great merits of this book, which makes it unique in many respects, is the superb treatment of the international framework and how it could be modulated to meet the special circumstances of a jurisdiction such as Hong Kong. As described by Mercurio, the sensible option for Hong Kong is to identify its priorities and 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' (p. 211).

The recommendations addressed to Hong Kong – recommendations that reflect the singular circumstances of that territory – are also relevant to a number of emerging markets that share with Hong Kong certain challenges, such as scarce R&D activities, a small competitive domestic generic industry, and rising health costs. The book thus constitutes a useful and practical manual that identifies the major issues to be addressed when designing a sound pharmaceutical patent policy that is, on the one hand, consistent with international treaty obligations but, on the other hand, ensures a proper balance between legal protection concerns and the broader objective of providing access to affordable essential medicines and vaccines.

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