Introduction

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Public health, safety and access to reasonably priced medicine and healthcare are recognized policy goals in this sector. At the same time, research and development (R&D) for new chemical entities for medicinal uses is costly. In contrast, chemical entities are prone to imitation, once the exact chemical composition is disclosed. The social benefits of useful medical knowledge exceed the individual benefits of the patient as the consumer of a given drug, since the disclosed knowledge can form the basis of further research. The combination of these factors identifies the production of medical knowledge as a classic case of a public goods problem that describes the risk of underproduction and calls for regulatory intervention to incentivise investment in R&D and disclosure.

Protection of the exclusive patent right is one of the core measures to incentivise investment in R&D and disclosure. However, patent law as an incentive for innovation and, maybe in interaction with competition law, as a means to promote follow-on research have to be coordinated and balanced with the interest in fostering public health, product safety and access to medicine. Facing increased competition from new entrants and generics in the market, and the slow-down of breakthrough research, originator pharmaceutical firms employ various strategies to extend the profitability of their commercially successful products and the market position they have attained based on patent protection. In some cases, it may appear that patent protection is not primarily sought as a means to recoup R&D investment but rather as an instrument to prolong market exclusivity. Against the anticipated expiry of their patents, firms employ various strategies to prolong the life, or, at least, manage the lifecycle of a given patent to delay the decline in profitability of a commercially successful product. Potentially abusive practices, dubbed as ever-greening strategies, include patent filing for new patents in related areas, using patent term extensions, own generic production and pay-for-delay settlements with generic firms. National patent laws and safety regulations may differ widely in this regard.
This book thus takes a comparative approach, by analysing the situation under the laws in the European Union, Japan and the United States and aims to highlight the convergences and divergences to identify the pros and cons of different approaches. The analysis of patent laws and policies in Europe, Japan and the US is promising since these three jurisdictions represent the three most advanced economies with a history of strong patent protection and similar levels of industrial development. In addition, the patent offices of the three jurisdictions are sometimes even referred to as the super-nodes of the network of patent-governing institutions, given the intensity of cooperation and the impact this cooperation has on the international governance system for patent protection.

From a policy perspective, the book explores to what extent patent strategies in general and lifecycle management practices in particular take advantage of patent laws and healthcare regulation and, thereby, disrupt the necessary balance between incentives for innovation and access to affordable medicine and healthcare.

This book consists of three parts. Part I (Dreyfuss, Moufang and Lee) explores the patentability of pharmaceutical innovations, in the US, Europe and Japan. As the path of innovation in the pharmaceutical industry is becoming more incremental, decision-makers need not only to recalibrate the incentives for such innovation arising from patent protection but also to re-assess the impact of patent protection on fundamental research and access for innovative healthcare. Personalised medicine using genetic information and innovative drug delivery systems are two of the many examples where the complexities of policies manifest. In Chapter 1, Rochelle Dreyfuss examines the patentability of genetic diagnostics in the light of recent US case laws. She argues in favour of a carefully crafted research and diagnostic use exception that would balance the need for patent protection and the need for access to underlying information in order to promote fundamental and translation research for personalised medicine. In Chapter 2, Rainer Moufang analyses the explicit statutory exclusion of certain pharmaceutical innovations from patentability in the context of the incompletely harmonized European patent system. In contrast, Nari Lee provides an overview of patentability of medical methods in Japan, where the exclusion of diagnostic, therapeutic and surgical methods for the treatment of humans is maintained without explicit statutory provisions.

Part II includes five contributions (Bagley, Fackelmann, Iseki, Arnold and Imura) from the three jurisdictions surrounding data exclusivity and patent term extensions. Data exclusivity and patent term extension are two measures used to coordinate the need to regulate the safety of
pharmaceutical products in the market with the interest to maintain the incentives of innovation arising from patent law. Related to patent protection, both of these measures sometime are considered to be supplementary to the protection afforded by the patent system. Data exclusivity protection and patent term extension are not internationally harmonized and while there are European regulations on the Supplementary Protection Certificate (SPCs) in Europe, even the interpretation of the core concepts have sometimes led to diverging national practices.\footnote{Council Regulation 469/2009 of 6 May 2009 concerning the creation of a supplementary protection certificate for medicinal products (codified version, replacing Council Regulation 1768/92 of 18 June 1992). OJ of the EU L152.} In this context, Margo Bagley, Christian Fackelmann and Ryoko Iseki discuss the protection of clinical data through data exclusivity schemes and patent term extension in the US, Europe and Japan. Their contributions are followed by the two chapters of Justice Arnold of the High Court of England and Wales, Chancery Division and Patents Court and Judge Imura of IP High Court, Japan, discussing national practices in the light of more recent decisions in the UK and Japan.

Part III (Ullrich, Domeij and Drexl) explores the impact of patent filing strategies and the protection measures of data exclusivity and the term extension on the competition. The European Commission’s Final Report on the pharmaceutical sector inquiry of 2009 is a good example of where such concerns are expressed.\footnote{European Commission, Final Report, 8 July 2009), at paras 1 and seq, p. 14, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html, accessed 1 April 2011.} In this context, the three contributions in Part III look at the debates on patent protection in the context of competition in the market. Hanns Ullrich explores the concept of abusive practices of patent protection emerging in Europe in the context of the pharmaceutical sector inquiry. Bengt Domeij assesses whether the conduct of the innovator firms’ marketing practices during the products switching phase to generic products in the market should be considered anti-competitive. Josef Drexl discusses the question of whether patent applications can, and under which conditions, be considered a violation of competition law in the light of the European General Court’s decision in AstraZeneca, which is a most pertinent question in view of potential future investigations by the European Commission following the Sector Inquiry Report of 2009.