

“Bryan Mercurio’s book breaks new ground in making the link between international legal obligations and domestic policymaking in the field of pharmaceutical patent law. Demonstrating a solid understanding of the fundamentals and nuances of these complex areas, Mercurio’s clearly written book offers expert analysis and recommendations which will garner attention from both scholars and policymakers. With the publication of this book, Professor Mercurio further cements his place as the world’s leading international economic law scholar researching on intellectual property rights.”

– *Lorand Bartels, University of Cambridge*

“Professor Bryan Mercurio once again demonstrates his expertise in both international economic law and intellectual property law . . . The book is a must-read for any scholar interested in this important topic, and in general. The book is innovative in approach, significantly advances the literature and should be engaged with not only by the academic community but also by policy-makers in Hong Kong and elsewhere. Page after page, the book demonstrates how few, if any, scholars possess Professor Mercurio’s ability to expertly understand the details of the patent regime and the pharmaceutical industry, and with it offers clear and practical recommendations as a way forward in this important area of the law and policy . . . I deeply enjoyed [the book] and found it to be a superb piece of scholarship and one that is much needed in the legal literature.”

– *Professor Irene Calboli, Singapore Management University*

“This timely, well-written and carefully analyzed book provides a definitive study of the pharmaceutical patent system in Hong Kong. More broadly, it reveals the far-reaching impacts new international trade and intellectual property standards can have on local health systems. The book strikes a rare but appropriate balance between a global perspective and local contextual analyses. It is a must-read for anybody interested in intellectual property, public health and international trade.”

– *Peter K. Yu, Professor and Director, Center for Law and Intellectual Property, Texas A&M University*

“Professor Mercurio has written the definitive book on this important topic. Innovative, well researched and argued, it will have a significant impact on policy not only in Hong Kong but internationally. It is a must-read for academics, policy-makers and practitioners involved in the area.”

– *Professor Andrew Mitchell, University of Melbourne*

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DRUGS, PATENTS AND POLICY

In pharmaceutical patent law, the problem of lack of policy direction and inappropriate legal framework is widespread – particularly among jurisdictions with little to no pharmaceutical research or manufacturing. This book aims to inform public policy and influence debate through a comprehensive review of Hong Kong’s pharmaceutical patent law. By demonstrating the need for a holistic review of pharmaceutical patent laws and evaluating Hong Kong’s system in light of health policy and economic and social factors, Bryan Mercurio recommends changes to the legal framework and constructs a more efficient and effective system for Hong Kong. He thoroughly evaluates the international framework and best practice models to offer a global perspective to each issue before providing local context in the analysis. While the focus of the book is Hong Kong, the analysis on pharmaceutical patent law and policy extends to other jurisdictions facing issues on reforming their national system.

BRYAN MERCURIO is Professor of Law, Associate Dean (Research) and Vice Chancellor’s Outstanding Fellow of the Faculty of Law at the Chinese University of Hong Kong. He is a leading expert in the intersection between international economic law and intellectual property rights.

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DRUGS, PATENTS AND POLICY

A Contextual Study of Hong Kong

BRYAN MERCURIO

The Chinese University of Hong Kong



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FOREWORD

ANTONY TAUBMAN¹

The law of patents of invention has, for centuries, been shaped by vigorous policy debate and by the development and refinement of the law through contentious proceedings in court. The Anglo patent law tradition, which has partly shaped the law of Hong Kong, is conventionally viewed as being founded on the 1623 Statute of Monopolies; this law was itself passed by the English Parliament amid a roiling political debate about trade and commercial policy and the prerogative of the sovereign to grant monopolies – it therefore sets out the essence of the law of patents of invention in the form of a specific exception to an overarching abolition of monopolies. The more elaborated principles of patent law today can largely be sourced to the jurisprudence developed through historic judicial decisions, by definition in the context of commercial disputes. Contentious policy debate and adversarial judicial proceedings have not only accompanied the evolution of patent law over the centuries, they have in critical ways help to shape the modern law and its practical application.

And this is for good reason. There is much at stake, and the modern patent of invention is a conscious, policy-driven creation of the legislature, not a fundamental artefact of natural law. To be sure, many would share the sense that, in principle, an inventor is entitled to due recognition for the contribution to society of a beneficial new technology – a sense by no means limited to the domain of Western cultures, finding also expression in the Universal Declaration of Human Rights.² Yet the modern system of patent law is a more specific, more complex contrivance, crafted and refined as a utilitarian mechanism for producing public knowledge goods, in the form of usable and transmissible new technologies. At first blush, its

¹ Director, Intellectual Property, Government Procurement and Competition Division, WTO. Any views or analysis presented in this Foreword are the writer's own and do not represent the position of the WTO, its Secretariat or its Members. This Foreword does not endorse or support any of the views, recommendations or criticisms set out in this volume.

² Article 15, International Covenant on Economic, Social and Cultural Rights (1966).

normative logic is counterintuitive – using exclusive private rights to produce inclusive public goods – and reconciling this apparent paradox is the very essence of patent policymaking.³ Ensuring that exclusive rights are such as to promote public welfare was the thrust of the Statute of Monopolies nearly four centuries ago, and remains the central task of the contemporary policy maker in this domain. Technologies, forms of innovation, and means of developing and disseminating new technologies evolve by their very nature, and patent law – while remaining true to certain core principles – has to adapt if it is to continue to serve creators and beneficiaries of new technologies. Informed policy debate, grounded in empirical research, is an invaluable foundation for the necessary elaboration and refinement of patent law.

When it comes to patents on medicines, the policy debate is all the more intense, and the public welfare interests are fundamental. It is self-evident that pharmaceutical innovation and equitable access to the fruits of such innovation are vital for both human well-being and social welfare. And we have strong expectations that policy mechanisms to enable innovation of, and access to, new medicines should deliver in practice – underscored by the articulation of specific targets for 2030 in the 2015 United Nations Sustainable Development Goals (SDG).

The entry into force, more than two decades ago, of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established a new principle at the level of international law that patents should be available for pharmaceutical inventions. This principle was contentious during the negotiations on TRIPS,⁴ and the adoption and implementation of the principle has hardly stilled policy debate in this area. To the contrary – the implementation of TRIPS in more than 130 distinct jurisdictions⁵ has sharpened and focused debate; equally, it has produced a rich trove of empirical data – in the form of distinct legislative

³ Articulated in the TRIPS Agreement itself (Article 7) in notably positive-sum terms: “the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

⁴ Jayashree Watal, “Patents: An Indian Perspective,” in Watal and Taubman (eds.), *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations*, WTO, 1995.

⁵ See TRIPS Article 66 Least-Developed Country Members, providing that “LDC members shall not be required to apply the provisions of this agreement . . . for a period of 10 years from the date of application.” The transitional period was first extended in 2005, IP/L/40 (30 November 2005). In 2015, the Council for TRIPS extended the application of the transitional period until 1 January 2033, IP/L/73, 6 November 2015.

approaches, patent examination guidelines and judicial decisions – from numerous established and emerging patent law jurisdictions seeking to apply the same broad principles in diverse economic, technological and social contexts. This dynamism and diversity opens up new prospects for informed policy debate, despite the formidable challenges of analyzing the data available from numerous national and regional systems. The experience of implementation has also underscored a practical reality that was not well reflected in early debate over TRIPS and public health – that TRIPS articulates general principles to be adhered to, but leaves open considerable latitude at the domestic level on a host of legal and procedural matters that are, in turn, vital for the successful attainment of the ambitious goals set for the patent system in this area.

The 2001 Doha Declaration on the TRIPS Agreement and Public Health responded to the intensification of policy debate over patents and medicines that had been spurred by the implementation of TRIPS in national laws; it has, since then, helped to frame that debate, making clear that the objectives of intellectual property systems (the patent system in particular) and of public health policy are not inherently at odds, but that the TRIPS Agreement must “be part of the wider national and international action to address” the public health problems afflicting developing countries and least developed countries (LDCs), and that it “does not and should not prevent members from taking measures to protect public health.” Further, while the principles of TRIPS are essentially technology neutral, there is a certain recognition that – because of policy and regulatory dimension – pharmaceuticals do require distinct treatment: hence, the TRIPS provisions for protection of clinical trial data, the extended exception in this domain (to at least 2033, reaching beyond the SDG target date) for LDCs (and an earlier extended implementation period for patent protection of pharmaceuticals in developing countries in general), the amendment to the Agreement itself, which created an additional pathway for access to generic medicines for countries particularly reliant on international trade for their pharmaceutical needs, and the broader framing of TRIPS and public health policy articulated in the Doha Declaration.

Professor Mercurio’s past scholarly work has contributed extensively to the literature on intellectual property law in its international legal and policy context, and especially as it is framed by the TRIPS Agreement and subsequent regional and bilateral trade agreements. The present volume helpfully distills and builds upon this work to yield a monograph that is focused, systematic and closely informed on the central choices that confront policy makers today as they seek to adapt the patent

system to the demands of today in the pharmaceutical sector in particular. In doing so, Professor Mercurio has mapped out the current policy choices generally presented to the practical policy maker in a national jurisdiction in a comprehensive and structured manner. He has effectively distilled the developments – often challenging for analysts to follow – in bilateral and regional trade agreements that have significantly altered the legal and regulatory landscape for many national jurisdictions. This work can therefore be abstracted from the individual jurisdiction it discusses and can serve as a practical taxonomy of policy choices faced by many countries – and can serve, also, as a selective guide to the background literature in this inherently complex and necessarily difficult domain of policymaking.

While the present writer would differ – respectfully, collegially and productively – with some of the lines of analysis, policy assumptions and conclusions presented in this volume, he has already benefited from the privilege of reading through the manuscript, an illuminating reading which has precipitated new insights in response, and will continue to refer to the book to assist in understanding the evolving context, and content, of law and policy in relation to patents and public health. Coming as it does from the perspective of an international civil servant, this Foreword is appropriately silent on the specific context of Hong Kong and does not venture to suggest that reform is necessary or called for in any of the areas discussed, or to advocate that the specific recommendations in this book are appropriate or optimal for this or any other jurisdiction. However, in the light especially of continuing practical experience with technical assistance and outreach undertaken in partnership within the multilateral system and with regional and national counterparts, it is clear that attaining improved outcomes for innovation and access to medicines requires situating patent law and related areas (such as test data protection) within their broader policy context: the changing, and diversifying, innovation landscape (including, with relevance for Hong Kong, the recognition of traditions of medical knowledge other than Western pharmacology), the interaction of the patent system with international trade (considering, for instance, the potential role of Hong Kong as an exporter of medicines, including under the system established by the TRIPS public health amendment), and the specifics of national medicines policy (procurement and innovation strategies, the regulatory system, pricing and other market policies, the application of competition policy in this domain, and statistics on actual access to medicines as well as projections of the future disease burden). An optimal, coherent set of policies requires a

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comprehensive grasp of each of these policy domains and their interaction with one another.⁶

The following work therefore provides the policy maker with a critical and informed guide to navigation through a demanding policy landscape; its elaboration and analysis of the legal and policy issues lay out the contours and central features of the landscape, and to engage with its advocacy of certain lines of approach through this journey provides for a rich and informative dialogue about the appropriate path to take.

⁶ Zafar Mirza et al., “Policy Coherence for Improved Medical Innovation and Access” (2013) 91 *Bulletin of the World Health Organization* 315–315A.

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This book is the product of more than fifteen years of studying, examining and questioning the linkages between international trade law and pharmaceutical patents and has benefited from numerous conversations with individuals from all walks of life. The idea to write such a book came long ago, but it would not have been possible if not for the Hong Kong University Grants Committee awarding me a General Research Fund (GRF) (No. CUHK450012) for the project entitled “Intellectual Property Rights and the Pharmaceutical Industry: Evaluating Hong Kong’s Regulatory Framework.” The funding has been much appreciated.

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ABBREVIATIONS

ANDA	Abbreviated New Drug Application
AUSFTA	Australia-United States Free Trade Agreement
CAFTA-DR-US	Dominican Republic-Central America FTA
CETA	Comprehensive Economic and Trade Agreement
CIPR	UK Commission on Intellectual Property Rights
CPC	Community Patent Convention
CPP	Certificate of Pharmaceutical Product
Doha Declaration	Doha Declaration on the TRIPs Agreement and Public Health
DSB	Dispute Settlement Body (WTO)
DSU	Dispute Settlement Understanding (WTO)
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FDA	Food and Drug Administration (US)
FDI	foreign direct investment
FTA	free trade agreement
GDP	gross domestic product
GMP	good manufacturing practice
HA	Hospital Authority (HA)
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
HKAPI	Hong Kong Association of Pharmaceutical Industry
HK-EFTA FTA	Hong Kong-European Free Trade Association Free Trade Agreement
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IP	intellectual property
IPD	Intellectual Property Department (HK)
IPO	Intellectual Property Office (UK)
IPR	intellectual property right
ISDS	investor-state dispute settlement

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ITB	Innovation and Technology Bureau (HK)
ITF	Innovation and Technology Fund
KORUS	Korea-United States Free Trade Agreement
LDC	least developed country
NAFTA	North American Free Trade Agreement
NDA	New Drug Application
NOA	notice of allegation
PCT	Patent Cooperation Treaty
PHOSITA	person having ordinary skill in the art
PPB	Pharmacy and Poisons Board (HK)
PTE	patent term extension
PTO	Patent and Trademark Office (US)
R&D	research and development
SCP	Standing Committee of the Law of Patents
SIPO	State Intellectual Property Office (China)
SPC	supplementary protection certificate
TPA	Trade Promotion Agreement
TPP	Trans-Pacific Partnership
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property
UK	United Kingdom
UPC	Unified Patent Court
US	United States
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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