## TRADE, INVESTMENT, INNOVATION AND THEIR IMPACT ON ACCESS TO MEDICINES

The last two decades have seen great economic change in Asia and this has impacted upon the vexed question of access to affordable healthcare and medicines in many Asian states. In this book Locknie Hsu examines the issue of access to medicines in Asia from a fresh perspective which embraces trade and investment law, innovation, intellectual property law, competition policy and public health issues. Hsu explores the key evolving legal issues in these areas, including ASEAN integration, free trade agreement negotiations (such as those for the TPP), bilateral investment agreements, investor-State disputes and significant court decisions. The book goes on to present proposals for steps to be taken in addressing access to medicines in Asia and will be useful to academic researchers, regulators, lawmakers and global organizations involved in the issues surrounding access to affordable healthcare and medicines.

LOCKNIE HSU is Professor of Law at Singapore Management University, where she has been the recipient of five teaching awards. Previously she has worked with the Singapore Ministry of Trade and Industry as a legal consultant on trade issues including those arising under WTO and free trade agreement issues. She received her legal training from the National University of Singapore and Harvard University and is a member of the Singapore Bar. She is currently Chair of the Trade and Investment Group and a member of the Working Group on Harmonisation of Commercial Laws of the ASEAN Law Association, and co-rapporteur of the Committee on Sustainable Development and the Green Economy in International Trade Law, International Law Association. She is also a member of the editorial board of the Journal of World Investment and Trade.

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An Asian Perspective

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> To Basil and my dear, late parents

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## FOREWORD

The world has witnessed several monumental shifts in international intellectual property (IP) law over the course of the last two decades. Before the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), states had almost unbridled discretion in defining the parameters of their domestic IP rights protection. The level of protection accorded to patents affecting pharmaceutical industries in developing countries was often seen as underwhelming. Indeed, pharmaceutical inventions were non-patentable in more than forty countries. With most major pharmaceutical corporations located in developed countries, it was in the economic interest of developing countries to allow the generic drug market to flourish, thus keeping the cost of pharmaceuticals low and helping to maintain adequate access to affordable medicine. On the other hand, developed countries had the opposite concern of seeking to afford their pharmaceutical corporations market exclusivity for breakthrough inventions. If profits were eroded by the emergence of generic drugs in developing countries, this might also chill the appetite to invest in research and development.

The successful conclusion of TRIPS in 1995 was an important milestone for the protection of IP rights on a global scale, setting minimum standards for the protection of IP rights and striking a balance of sorts between the pharmaceutical industry's interest in recouping the hefty research and development costs associated with drug inventions and the health priorities of developing countries seeking affordable medicine. Given the high stakes involved on all sides, it is perhaps inevitable that TRIPS incorporated various exceptions and ambiguities. As a result post-TRIPS international IP norms may have fallen short of the levels originally envisaged by the developed countries. The evolution of international IP law since TRIPS has been characterized by the efforts of developed countries to achieve the standards of protection they had anticipated or perhaps hoped for from TRIPS but on a piecemeal, bilateral basis rather

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than within a single multilateral forum. In a sense, TRIPS has become just the beginning of the quest to harmonize international IP law and to establish new and higher patent protection benchmarks for pharmaceuticals.

Over the last two decades, there have been important developments with efforts to dilute the exceptions and flexibilities TRIPS had accorded to developing countries by striking fresh bargains conferring trade benefits for enhanced IP protection under bilateral Free Trade Agreements (FTAs). Known as "TRIPS-Plus" provisions, these IP protection commitments go beyond the obligations WTO members had agreed to multilaterally under TRIPS. Much has been written in this regard, but few have significantly shed light on the implications of TRIPS-Plus provisions across Asia, and in this regard, I consider Locknie's book a welcome addition to the existing body of literature on the subject.

Locknie's book is also noteworthy as it comes at a time where we are beginning to see the balance of IP trade slowly shift from the United States to Asia. In the last decade especially, innovation has come increasingly to be recognized as an important plank supporting economic development, and as such the adoption of TRIPS-Plus provisions can sometimes be seen as a means not only to secure trade benefits but also to encourage innovation. Conversely, an aggressive push for strict IP protection by developed countries may need to be moderated as they become increasingly reliant on Asian innovations.

The book first sets the scene with an overview of the diverse issues arising from the intersection between trade and investment law (an area in which Locknie has written extensively), IP law and public health. Locknie then highlights some of the potential pitfalls that TRIPS may pose to Asian countries due to its latent ambiguities, in particular the controversial issue of whether genetic material is patentable, and it offers Asian policy-makers useful recommendations pertaining to this debate by drawing upon lessons emerging from significant recent litigation in the US, EU and Australia. The book also provides a comprehensive and detailed survey of the existing legal frameworks that Asian nations have adopted towards various matters including the patentability of living matter, patentability of new uses of existing medicine, patent extension rules, patent linkage and data exclusivity protection laws and regulations.

Locknie's insightful analysis of the divergent scope and content of the legal frameworks across Asian nations in relation to these issues will certainly be of great use to governments considering the re-evaluation of

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their patent regimes as well as to pharmaceutical companies intending to invest in Asia.

Policy-makers will also find useful a variety of exception clauses Locknie suggests might be included in FTAs. For instance, her detailed analysis of how the failure to include a *Bolar* exception in an FTA (which specifically exempts certain acts from constituting patent infringement) could delay the entry to the market of generic pharmaceuticals in an Asian party is astute and succinct. Finally, her study of the diverse and myriad set of TRIPS-Plus provisions in existing FTAs that Asian nations have entered into with their counterparties is useful in yielding ideas and options for countries aspiring to enter into similar FTAs while seeking to maintain an appropriate balance between national trade interests and the public interest in ensuring access to affordable medicine.

I am certain her scholarly discussion and careful review of the range of options available on the negotiating table will go a long way to level the playing field for all parties involved. I welcome this book and congratulate Locknie on having completed a remarkable and very useful piece of scholarship.

> Sundaresh Menon Chief Justice Supreme Court of the Republic of Singapore

## PREFACE

Additional web-based resources, such as links to further relevant Asian/ ASEAN materials, will be available at www.cambridge.org/9781107072732.

The primary *raison d'etre* of this book is to contribute an Asian voice to the debate on trade, investment, innovation and their impact on access to medicines. After reading many admirable works in the field, it was clear to me that a work that would present salient issues cutting across various areas of law and policy, particularly to the Asian policymaker, lawyer or judge, was not yet in existence. I therefore embarked upon what turned out to be a most educational journey of research on those issues, on Asian approaches (or lack thereof) on intellectual property rights and treaty strategies, and on a number of global, topical developments, that can deeply affect access to medicines. An Asian view was also thought to be timely given that aging (with its concomitant ailments and need for affordable medicines) is a serious issue in many Asian countries, including China, Japan and Singapore. A third reason for presenting an Asian view is that Asian participation in bilateral and regional economic agreements - be they in the form of free trade agreements (FTAs) or investment agreements, has been growing rapidly. Some of these contain legal commitments which could affect how a state may (or may not) regulate the patenting, pricing, distribution of and reimbursement for medicines. Such commitments may also exceed the requirements of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which can pose challenges for developing countries in Asia which aim to keep medicines affordable. Such agreements may also open the door to the possibility of investors taking up investor-state arbitration against signatory states which act or regulate in relation to medicines. This links the access to medicines debate directly to another contentious, global debate on the value and shortcomings of such investment arbitrations. Finally, while intellectual property,

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trade and investment policy issues play a significant role in the present debate, several other types of factors affect access to medicines in Asia, including corruption, the state of national drug procurement processes and the availability of general infrastructure such as roads, transport systems and medical facilities.

The objective of this book is to present within the Asian and global contexts some significant factors which impact on the access question, the existing legal "construct" within which states operate, economic treaty obligations and the exceptions which can be critical, and examples of investment dispute problems which may "travel" into the pharmaceutical domain. Already, certain judicial decisions of Canada on patentability, as they relate to medicines, have been raised as the subject matter of one foreign investor's claim. Patentability of certain subject matter, such as the products of biotechnology involving human genetic material, is not universally accepted. For some countries in Asia, such as Cambodia, Lao PDR and Myanmar, patent law itself is a relatively new area altogether. There remain important areas of uncertainty in Asian laws - such as patentability of such newer types of subject matter - which require clear thought, debate and policy by national governments. Ideally, these areas should be examined thoroughly before governments embark on economic agreements with economically advanced partners. Regional groups such as ASEAN, in particular, have an opportunity to shape a regional perspective on this and other aspects of the access to medicines debate.

Another relatively less debated area in the access discussion – at least in many parts of Asia – is the application of competition law to pharmaceutical patent settlement agreements which may impede competition by generic drug producers. While there have been some significant decisions of late in the United States and the European Union in this context, there have been hardly any in Asia, except for a recent decision of the Korean Supreme Court on a pharmaceutical settlement agreement that was found to be anti-competitive. Again, this is an area in which there is room for national regulators in Asia to study the issues and make clear, strong policies.

This book also aims to provide some innovative suggestions and linkages to further advance access to medicines, particularly in Asia. These suggestions range from treaty negotiation approaches to national policy changes and funding considerations of R&D of medicines. They are not intended to be "magic bullets" but, rather, to be ideas that can be used to contribute to the pool of numerous, excellent initiatives and ideas

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which already exist. To paraphrase a famous Chinese saying (on medicines!), 良药苦口利于病, 忠言逆耳利于行(*liang yao ku kou li yu bing, zong yan ni er li yu xing*): just as a bitter medicine may be good for curing an ailment, earnest words that inconvenience may be good for producing sound actions. It is hoped that this book provides a number of "earnest words" and helpful recommendations.

> Locknie Hsu Singapore

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