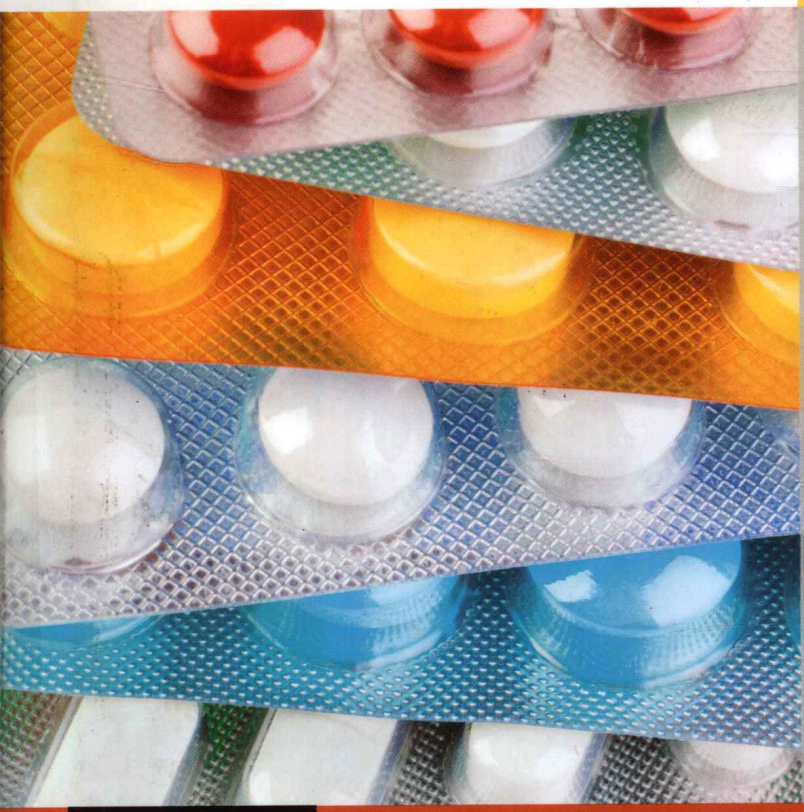
Access to Medicine in the Global Economy

INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS

Cynthia M. Ho



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Preface

WHEN I FIRST began practicing law, I never imagined that I would write this book. My first job was as a patent attorney; in that role, I often represented the interests of large companies, including multinational drug corporations. At the time, I did not seriously question the assumption held by such entities that patents provide a critical incentive to development of new medical treatments. However, since then I have developed a more nuanced view; although I still believe that these companies perform an important role in developing new drugs, patents do not always promote development of the most socially beneficial ones. Moreover, even drugs that are socially beneficial may be of little use to those who cannot afford to purchase them.

The issue of how patents impact medicine has increased in significance within the last decade. Just as I was transitioning from private practice to academia, a landmark international agreement (TRIPS) was concluded that requires most countries to provide patents. Significantly, TRIPS required a fundamental shift in the laws of many countries that previously excluded drugs from patentability. The requirement to patent drugs obviously has implications on the cost of drugs and whether citizens in poor countries have access to them.

The conclusion of TRIPS has increased attention on how patents impact access to medicine, but this new focus has not always led to productive results. Discussions concerning the impact on access to medicine often degenerate into finger-pointing. Patent-owning companies are often vilified as greedy corporations that place profits above people while those who advocate greater access to drugs are accused of stealing private property. These accusations seem to be based on deeply held views about the role of patents (referred to in the book as "competing patent perspectives"). On one hand, patents are seen as a tool to promote innovation, and as such, they can (and should) be modified. On the other hand, patents are viewed as an important property right that should seldom be subject to exceptions, especially considering its limited term. As explained in this book, these competing views have led to confusion and obfuscation of the law. I was inspired to write this book in part to clarify widely prevalent misconceptions, as reflected in both reports from the popular press and in some academic publications.

This book has two principal goals. The first is to provide a clear explanation of the current international infrastructure that requires most nations to provide patent and related rights regarding drugs. A second and complementary goal is to explain how competing patent perspectives play a thus far unacknowledged role in promoting distortion and confusion.

I believe this book can make a unique contribution, even in an area where there is a wealth of existing resources. The primary audience I want to reach includes those who are interested (but not yet experts) on the current issues, especially those who are not familiar with either intellectual property or patent law. In addition, I believe my book may be a resource for those who have some prior knowledge of the issues discussed. I realize it is a challenge for a book to adequately speak to both audiences; however, the book in fact does so. It is designed to explain things using only a minimum of jargon (although necessary terms are defined in the Glossary) visual diagrams and "frequently asked questions" also help to reinforce what might otherwise be complicated material. At the same time, the book provides new legal analysis as well as a new theory of patent perspectives that can provide an important step toward possible solutions through better understanding.

Although this book makes no attempt to provide a grand solution to the long-standing question of how to balance patents and access to medicine, it should promote an eventual solution by clearing away some confusion and facilitating a better understanding of competing views of patents. I strongly believe the best results will emerge once there is both a broad-based understanding of the legal issues and a greater understanding and acceptance of different views. The views of some may be resistant to change, but that does not mean it is not worth trying to do so. It is in that spirit that this book was written.

Cynthia M. Ho
November 12, 2010

Acknowledgments

THIS BOOK WOULD not exist without the assistance and support of a number of individuals and institutions. Ironically, I am grateful to a major publisher of legal books for rejecting an earlier proposal of a textbook on this issue for lack of an "adequate" market. That led me to reconceptualize who might benefit from a book that aimed to explain how international laws impact patents. I then realized that a monograph rather than a textbook could be used in a number of different academic environments, as well as a resource to researchers and policy makers. In addition, reaching a broader audience would be very desirable for this important topic of how laws impact global access to medicine. Needless to say, I am grateful to Oxford (and the anonymous reviewers of my initial proposal) for believing that such a book would be useful. I am similarly grateful to Loyola University of Chicago for providing institutional support to enable me to write it.

In terms of the substance of the book, I have many individuals to thank for providing comments on one or more chapters. I am particularly grateful that some well-known scholars—including some that I have yet to have the pleasure of meeting in person—were so generous with their time. At the risk of omitting someone, I thank the following individuals for their helpful feedback and support: Shamnad Basheer, Vince Chiappetta, Colleen Chien, Carlos Correa, Peter Drahos, Erika George, Daniel Gervais, Joe Grant, Leah Chan Grinvald, Joan Krause, Chunlin Leonhard, Valbona Muzaka, Tu Nguyen, Kevin Outterson, Jerome Reichman, Henning Grosse Ruse-Khan, and Nadia Sawicki. In addition, I owe thanks to a number of people who helped answer specific questions about chapters, including Margo Bagley, Sam Brunson, Thomas Jaeger, Molly Beutz Land, and Ed Lee. I am also thankful to some of these indivduals (and others) for their scholarship, which helped inform my own understanding. Finally, although there are too many students to name in person, I am nonetheless thankful for all the students who read and commented on early draft chapters that I used in class.

I am also grateful for feedback on earlier articles or presentations that evolved into the current chapters. I am especially thankful to Graeme Dinwoodie for his consistent support and encouragement of my work in the area of access to medicine; his support was especially important in the publication of "A New World Order for Addressing Patent

Rights and Public Health," 82 Chicago Kent Law Review 1469 (2007), which formed an important foundation for several subsequent chapters of this book. In particular, I thank Greg Vetter and his colleagues at the University of Houston for inviting me to present an article at its symposium on international aspects of intellectual property this opportunity provided me the opportunity to publish "Unveiling Competing Patent Perspectives," 46 Houston Law Review 1047 (2009), from which I adapted Chapter 6. Similarly, I am grateful to Deakin University and the University of Hyderabad for inviting me to a conference where I was able to present the draft chapter on in-transit patent infringement. I particularly appreciated the supportive comments of Dean Coldicott, Owain Williams, and Vivienne Eggers. In addition, others who provided helpful comments and support on earlier articles that evolved into chapters include Nancy Kim, Susan Kuo, Sean Pager, and Angie Upchurch.

A few individuals deserve special recognition. To begin with, I am very grateful to L. Song Richardson for her helpful feedback and support during the early stages of my writing process. I am also very grateful to Jacqui Lipton, not only for all her substantive feedback, but for bearing with me and responding to the many questions I had about writing my first-ever monograph. I also appreciate the insight and encouragement of veteran authors Cynthia Lee and Alex Tsesis. I am also very thankful for Maggie Chon, not only for her seemingly unfailing support of this project, but for encouraging me to provide draft chapters of my book to her class that resulted in some very helpful feedback. Moreover, I am enormously impressed by and grateful to Peter Yu for reading and providing comments on the entire manuscript. That was not a task I had the audacity to ask of him; however, Peter kindly offered to do so, and I could not turn down his generous offer to essentially do a single-handed peer review.

There is also a small army of individuals who assisted me with the individual elements of the book. I am thankful to Chris Nemes for helping to create the many figures. In addition, I very much thank Patricia Scott, librarian extraordinaire, who always cheerfully responded to my requests to find sometimes obscure references—and at times seemed to work magic to make them appear. I'm also grateful to her for enlisting additional support, especially with foreign language materials from Julliene Grant. I owe a huge debt to a number of student assistants who over a number of years helped provide important research support for this book from its initial conception to current form. At an early stage, I was fortunate to have excellent help from Anna Barriero Megan Simpson and LeighAnne Thompson. More recently, I am grateful to a number of students for not only researching specific issues but also checking the accuracy of the cited sources. I especially thank Kathleen Sullivan Klein, Kate McNamara, Melissa Miltonberger, and Brad Snyder. Brad and Melissa deserve special recognition for helpful comments on the text of the entire book.

Last, but, certainly not least, I am very grateful to my family and friends for putting up with me while I was working on this book. I could not have done it without the consistent and constant support of those who often seemed to have a stronger belief in the book than I did myself.

Introduction

PATENTS ARE FREQUENTLY praised or reviled for their impact on public health. Companies that develop and market patented drugs hail patents as essential to developing drugs that benefit all of society. Conversely, consumer advocates emphasize that patents limit competition and result in inflated prices that frequently impair access to essential and life-saving drugs.

Although some continue to debate whether patents adequately promote innovation in light of short-term access costs, some of the debate is moot because of international laws that *mandate* patents. In particular, all countries that are members of the World Trade Organization (WTO) are *required* to grant patents pursuant to the WTO side agreement known as the Agreement on Trade Related Aspects of Intellectual Property, more commonly known as TRIPS. Admittedly, countries can elect not to participate in the WTO. However, in a global economy, that would be a poor choice for most nations. Indeed, the fact that well over 150 countries across a wide economic spectrum are WTO members suggests that most countries consider participation important.

There is no serious question that TRIPS—and patents—are here to stay.[1] Nonetheless, TRIPS presents a dramatic change to the international landscape. Historically, each nation decided how to best balance promoting long-term innovation versus short-term access. Over the centuries, nations have come to differing conclusions based on differing priorities. A decision to provide patents is not simply an issue of whether a country is rich or poor. Some industrialized countries declined to provide patents on pharmaceutical products until the early 1990s.[2]

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[1] TRIPS has been strongly criticized by some. However, because TRIPS is linked to the WTO, nations are unlikely to abandon the WTO forum even if they dislike related agreements, such as TRIPS. Similarly, although some critics of patents would prefer they not exist, that is not realistic in a world where patents are not only a business reality, but mandatory pursuant to TRIPS.

[2] Spain and Portugal declined to grant patents to pharmaceutical products until 1992.

Today, most developing countries do not have the luxury to decide whether to provide patents on drugs. TRIPS mandates patent protection—including on drugs—for WTO member countries.[3] Such mandatory patent protection is likely to significantly impact access to medicine in countries where resources are already limited. As patent protection is no longer optional, the key question is how much discretion remains for nations to promote maximum access to drugs. A nation's ability to promote access to drugs is especially of importance to low-income countries in which the cost of drugs may be a significant barrier to obtaining access to medicine; drugs constitute a much larger percentage of budgets for individuals in poor countries than in wealthy ones.[4] Ironically, individuals from wealthier countries often pay lower prices for their drugs because their governments both impose price controls on drugs, and often have insurance that further subsidizes their out of pocket expenses. Neither of these things are typically true for individuals in poor countries. Accordingly, their out of pocket expenses for medications often far exceed those in wealthier countries.[5]

This book focuses on international agreements regarding patents and related rights because although many issues impact access to medicine, these are generally poorly understood and deserving of separate treatment.[6] Thus far, those with a vested interest–such as patent-owning drug companies–have largely controlled the development of international patent law, including TRIPS.[7] Moreover, such companies have continued to play an essential role in developing subsequent international agreements that provide more protection to drugs through stronger patent laws as well as regulatory laws that help protect exclusivity of drugs beyond patent rights.

Access to medicine impacts all citizens of the world. Knowledge about how drugs are protected from competition should not be limited to only a few, let alone those with a singular and slanted perspective. Although some people may not have problems in

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[3] Although least-developed countries need not provide patents on drugs yet, all developing countries that are members of TRIPS must currently provide such protection.

[4] Developing countries can spend up to 60% of health care budgets on medicines whereas OECD countries spend about 18%. WHO, *World Medicines Situation* (2004); OECD, *Drug Spending in OECD countries up by nearly a third since 1998*, (Aug. 6, 1998), http://www.oecd.org/document/25/0,2340,en_2649_201185_34967193_1_1_1_1,00.html.

[5] In developing countries, up to 90% of the population pays for drugs out of pocket, making medicines the largest expenditure after food. A. Cameron et al, *Medicine prices, Availability and affordability in 36 Developing and Middle-income Countries: A Secondary Analysis*, 353 LANCET 240 (Jan. 17, 2009), citing WHO, Equitable Access to Essential Medicines: A Framework for Collective Action (2004), 8 WHO POLICY PERSPECTIVES ON MEDICINE 1 (2004).

[6] This book focuses on how patent and related rights increase the cost of drugs and thus limit access to medicine. Other factors that can play a role in the price of drugs (such as domestic tariffs and taxes) will not be addressed here. Similarly, this book does not attempt to address whether improved local medical infrastructure or the use of competition laws can improve access to drugs.

[7] *E.g.*, SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW (2003); PETER DRAHOS WITH JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY (2002).

accessing necessary drugs, global needs impact all. For example, given that many wealthy countries are involved in buying drugs for poorer countries, the cost of drugs also impacts those countries.

This book focuses on the impact of key international agreements on access to patented drugs in the existing commercial reality. It does not focus on either alternative methods beyond the patent system to promote innovation or whether the dominant corporate model for developing new drugs needs to be overhauled. These issues are noted in the book, but cannot be addressed in depth while simultaneously explaining the complex international landscape. In addition, this book assumes that despite proposals for reform, the present reality will most likely continue in the near future such that a better understanding of the laws that impact this reality is useful. In particular, this book assumes pharmaceutical companies will continue to not only make drugs, but seek to maintain and further expand their ability to provide stronger protection of such drugs in the global arena. Accordingly, the book begins with an introduction to how drugs are currently developed and marketed to set the stage for why companies are invested in the existing laws that promote this infrastructure.

In addition to explaining the relevant international laws, this book provides insight on why debates on access to medicine are not only heated, but can result in the promulgation of incorrect information. As explained in more detail in Chapter 6, this book posits that the foundation for this problem may be a spectrum of views on patents benchmarked by two distinct and seemingly irreconcilable perspectives. At one extreme, patents are seen as a mere privilege granted by a nation so that they are inherently subject to limitations to accommodate other societal goals, such as access to medicine. At the other extreme, patents are viewed as an exceptionally strong property right that should seldom (if ever) be subject to exceptions because these rights are presumed critical to promoting innovation. Adherents of each view may believe the other is necessarily incorrect. However, in reality, their strong views may make them incapable of seeing—let alone tolerating—an alternative vision. This phenomenon, as well as the existence of competing patent perspectives, is consistent with social science literature concerning how people process information. In essence, research shows that people will maintain preexisting beliefs despite evidence to the contrary.

Several chapters of the book use these patent perspectives to provide a more nuanced explanation of controversies concerning patents and access to medicine. Although the perspectives are not intended to completely explain controversies, they can provide an enriched understanding. As will be discussed, these perspectives can help explain why not only patent owners, but even those with an interest in promoting access to medicine may be equally susceptible to distorting TRIPS requirements. The influence of perspectives may make those on both sides of the debate vulnerable to overstatements, which undermines credibility, degrades the possibility of productive dialogue, and may engender confusion amongst the broader public. Accordingly, recognition of the existence and impact of these views is just as important as understanding the actual laws because

these views have a strong impact on how international laws are developed and interpreted.

Although the issues involving access to medicine are many and ever-evolving, this book provides a useful introductory resource. In particular, it should be accessible to a broad range of readers with an interest in how laws can impact the availability of lower-cost generic drugs. For example, policy makers, academics, and students from a range of disciplines could benefit from a better understanding of the way international laws impact access to medicine. Although discussion of these laws tends to be limited to those with a background in either patents or international trade, there are clearly implications for public health as well as public policy. Hopefully, this book will help promote not only a better understanding of existing laws, but more balanced future discussions.

The book is divided into three parts. The first provides background information concerning the scientific, legal, and commercial implications of drug development that are relevant to any discussion of patents. The second provides an overview of the current international legal framework, beginning with an introduction to TRIPS. Finally, the third section focuses on the evolving legal framework, including agreements and events subsequent to TRIPS that impact access to medicine. Although each section builds upon other sections, the chapters can be read out of order. For example, the first section provides background information that may not be necessary to those already familiar with how drugs are developed, regulated, or legally protected from competition. To maximize the utility of this book as a resource, individual chapters refer to related chapters. In addition, the Appendix provides a glossary with explanations of terms and common abbreviations. The Appendix also reprints selected provisions of TRIPS that are discussed in the text, as well as a few other important WTO texts.

Part I

Chapter 1 provides an overview of how drugs are brought to market. Although there are many nuances to this process, the goal of this chapter is to focus on themes important to understanding subsequent chapters. This chapter explains how patented versus generic drugs are made, approved for sale, and marketed. It also explains how various laws may protect a drug in the marketplace; the discussion includes, but is not limited to patents. This chapter also focuses on commonalities among the laws of different countries so as to provide a basic understanding of the commercial and legal realities involved with making drugs.

Chapter 2 builds upon the basic patent concepts explained in Chapter 1 to explain an important yet confusing doctrine referred to as "international exhaustion," recognized by some countries. Patent-owning pharmaceutical companies are strongly opposed to this doctrine because it challenges their desired business model of segregating markets to maximize the profit in each. This doctrine impacts whether drugs first sold by the patent

owner in one country may be imported by another into a second country without violating patent laws.[8] A country that recognizes international exhaustion may be able to import cheaper versions of drugs. However, as will be explained in subsequent chapters, countries may be pressured to reject this principle.

Part II

The chapters in Part II explore what is required under TRIPS. In particular, Chapter 3 introduces the overall TRIPS framework that is the foundation of all international laws regarding patents. Subsequent chapters assume knowledge of the basic TRIPS framework and provide more detail on key issues involving controversies about the extent to which TRIPS impacts access to medicine. For example, Chapter 4 explains how domestic patent laws can crafted to promote access to medicine. The remaining chapters focus on different issues involving compulsory licensing.

Chapter 3 provides the foundation of the current international framework: an overview of TRIPS. Although subsequent chapters discus specific issues, this one offers an overview of how TRIPS was concluded and the key provisions relevant to access to drugs. This chapter discusses what must be patented and the extent of patent enforcement rights. Additionally, it addresses the controversial issue of what protection must be provided for clinical data submitted in connection with obtaining approval to market a new drug.

Chapter 4 explains how nations may promote access to medicine consistent with TRIPS, using India's patent laws as an example. As a WTO member, India was required to provide more extensive patent protection under TRIPS than it had in the recent past. However, India's laws were adopted with the goal of continuing to promote access to medicine, as well as to sustain its strong generic drug industry. Accordingly, an examination of India's laws helps to illustrate how nations may attempt to craft patent laws consistent with TRIPS that still promote access to medicine.

Chapter 5 explains the basic requirements for a compulsory license—an exception from patent rights that is permissible under TRIPS, yet highly contested by patent-owning drug companies.[9] This chapter is important not only to lay the foundation for understanding subsequent chapters, but because it dispels common misconceptions frequently propagated by interested parties and the popular press.

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[8] International exhaustion undermines pharmaceutical industry profits because drugs sold at lower prices in developing markets can be imported into wealthier markets where the imports undercut the higher-priced drugs.

[9] Where applicable, a government can impose a compulsory license on a patent, which enables the government (or an entity approved by the government) to make the patented drug, subject only to payment of a government-determined royalty. The patent is not invalidated, but the compulsory license prevents the patent owner from reaping its usual patent premiums for drugs sold under the license.

Chapter 6 builds upon Chapter 5 and also provides a complementary examination of compulsory licenses. Chapter 6 is the first chapter to introduce competing patent perspectives; it provides a case study of Thailand's recent compulsory licenses to explain some of the confusion and controversy concerning them. In particular, the lens of competing perspectives is used to provide an enriched understanding of why there has been so much confusion concerning compulsory licensing. In addition, this introduction to competing patent perspectives constructs a framework for subsequent chapters that revisit how such perspectives have played a role in issues involving access to medicine.

Chapter 7 also builds upon Chapter 5 to explain a complicated and narrow exception to compulsory licenses that is intended to help provide low-cost drugs to developing countries. This chapter also provides an overview of how the exception works and evaluates its utility with a discussion of the single instance where it has been used.

Part III

The last part discusses the evolving global landscape. Chapter 8 begins with an overview of international laws subsequent to TRIPS that further restrict national discretion to tailor patent laws to promote access to medicine. In general, these laws require more protection than does TRIPS, such that they are called "TRIPS-Plus" laws. Subsequent chapters provide more detail on TRIPS-Plus laws. For example, Chapter 9 explains regulatory laws that provide complementary protection to patent laws by limiting competition from generic manufacturers. In particular, Chapter 9 focuses on explaining "data exclusivity" and "patent linkage"—protection provided in the regulatory laws of some countries that may create additional hurdles to the entry of generic drugs. Chapter 10 explains a TRIPS-Plus law in the EU that limits the ability of countries to internationally trade generic drugs. Chapter 10 also provides a case study of the impact of patent perspectives in shaping interpretations of TRIPS; it complements the earlier case study of compulsory licenses in Chapter 6.

The last two chapters revisit the patent perspectives as a lens to better understand how the international framework has evolved since the conclusion of TRIPS. Chapter 11 uses these perspectives to gain insight on international developments since the conclusion of TRIPS. Although some developments are discussed in other chapters, this one uses the perspectives to provide a cohesive method of understanding the overall development of international law and policy. Chapter 12 outlines anticipated issues that will likely increase the existing tensions between providing patent (and related) protection versus promoting current access to medicine. The chapter primarily focuses on proposed solutions. The competing perspectives are also used to explain the genesis for these same proposals as well as the likelihood they will be well received. Although the ultimate outcome of the conflict over access to medicine remains unknown, this chapter attempts to frame current proposals in the context of possible future developments.

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I Background