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INTERNATIONAL PATENT  
LAW AND POLICY



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WEST

# INTERNATIONAL PATENT LAW AND POLICY



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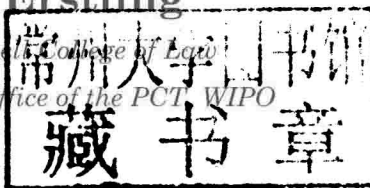
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## DEDICATION

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*In loving memory of my dad: Dr. Emerson A. Cooper, 1924–2012.*

*To God be the glory.*

—M.A.B.

*For my Father in Heaven*

*And in loving memory of my father in Heaven:*

*Professor Aaron T. Gana, 1938–2007.*

—R.L.O.

*To Pixie.*

—J.A.E.

# PREFACE

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The field of patent law has undergone profound changes as the combined pressures of globalization and rapid technological advances have exerted tremendous pressure on the institutions and rules that facilitate the issuance of patents and the traditional justifications for the patent system. Patents remain an important, even if at times controversial, foundation for encouraging innovation and channeling private investments into new scientific endeavors directed at enhancing human welfare. Historically, the industrial development and wealth of nations has been linked with the recognition and enforcement of patent rights, and the ability of patentees to leverage those rights in global markets. Yet, until the conclusion in 1994 of the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement), scholarly commentary on international or comparative aspects of patent law was limited, and teaching materials even more so. As scholars and practitioners in the field, we recognized a need to address this gap systematically, not only for ourselves but for our students who will be practicing patent law in a vastly more complex and institutionally challenging global marketplace. The need for a text that introduces students to the core concepts, doctrines, rationales, and policy implications of global patent regulation, while also exposing them to the practice of international and comparative patent prosecution and enforcement—including multinational litigation—seemed strongly evident. And thus the idea for a casebook exclusively focused on international patent law and policy began to take shape.

This book provides a comparative overview of international patent law and policy, utilizing case law from a variety of countries; excerpts from scholarly materials representing views from vastly different jurisdictions; and international policy documents including treaties, regulations, and laws. Importantly, this book introduces students to the tensions and conflicts that characterize the international patent system, highlighting areas of controversy, presenting comparative views to facilitate analysis of how different national patent laws intersect and interact with various patent treaties, and providing a thorough examination of the practical functioning of the prosecution process in the multilateral context.

As with all book projects, our seemingly simple idea of writing a casebook on international patent law turned out to be incredibly more complex, challenging, and fulfilling than any of us imagined six years ago when our writing first began. Since then, the field of intellectual property, and patent law specifically, has experienced significant changes at national, regional, and multilateral levels. The rise of new and powerful in-

ternational players in the global innovation system such as China and India, the enactment of a major patent reform bill in the United States, the intensification of efforts toward a unified European patent system complete with a regional patent court, and continued pressures from developing and emerging countries regarding the effect of the international patent system on economic development and human development needs and priorities, are all major challenges for the ongoing internationalization of patent law. Against this background of dynamic institutional, doctrinal, and cultural change in the global patent system, trade-offs between the rate of patent filings and the costs of patent administration at the national level continue to force important policy choices to the forefront of international patent governance.

We adopt an explicitly comparative approach to the study of the international patent system. We begin with the premise that the international patent framework, which formally began in 1886 with the conclusion of the Paris Convention for the Protection of Industrial Property, is now properly a “system” of international patent law. This system is not complete in all respects; it certainly is not coherent in every regard in its policy or doctrinal basis, and it remains extremely polarized in various respects, particularly in the application and enforcement of established minimum standards. Importantly, deep divisions remain between the interests of countries that represent the greatest share of the global patent landscape, so-called “emerging markets” of China, India, and Brazil, and those developing and least-developed countries whose interests in accessing patent-protected technology remain focused on ensuring that the system is appropriately balanced to facilitate the explicit public interest goals that are represented in every domestic patent regime. Throughout the book and in every chapter, we endeavor to illustrate, through case law and reference to policy materials and legal commentary, these points of tension, convergence, and compliance with global rules. Although original materials were not available for all doctrines, and not every country or region is specifically mentioned, we have made every effort to ensure that the vast trove of materials on international patent law has been represented whether in the text, in the case selection or in the Notes and Questions.

We lightly edit many of the foreign cases to give greater flexibility to teachers who may wish to emphasize different features of foreign opinions, and to provide an opportunity for students to understand the context of the case and become comfortable with different judicial styles of other legal traditions. For several Chinese and other foreign cases we utilized informal translations because we believe it is important that students preparing to practice in this brave new world must be adequately equipped to understand the way different courts and legal cultures apply the rules that have long been familiar to the traditional actors of North America and Europe.

In *Chapter 1*, we establish the legal framework for international patent law. We begin with a review of the history of the Paris Convention, identify the leading justifications for an international patent system, and then examine the developments that led up to the TRIPS Agreement in 1994, including an overview of post-TRIPS developments. Importantly, we identify and evaluate differences of opinion about the efficacy of the international patent system for economic development, and long-standing concerns of developing countries about the potential welfare costs and burdens imposed by this system.

*Chapter 2* deals with procedural patent agreements, providing a comprehensive overview of the principal provisions of the Paris Convention, the Patent Cooperation Treaty (PCT), and work-sharing initiatives that have been viewed as important tools to manage the burdensome and costly process of patent prosecution faced by applicants filing in the major patent-granting offices.

In *Chapter 3*, we address substantive patent agreements, starting with the 1994 TRIPS Agreement. After providing students with a solid background of the political and negotiating context of TRIPS, we turn to the minimum mandatory provisions of the Agreement regarding patent eligibility and enforcement. Here, students will learn of the WTO's dispute settlement procedure, and study two of the seminal WTO patent cases that interpret the requirements imposed on member states. We also introduce students to the important limits of the requirements in the TRIPS Agreement, in particular those limits introduced to address the supply of patented essential medicines to qualifying countries. In this chapter, students will read an opinion from a federal court in Kenya in which the patent requirements of the TRIPS Agreement are interpreted in the context of human rights—one of the first efforts by a court in Africa to balance the role of patents with public welfare interests.

We turn in Part II of the casebook to the fundamental requirements for patentability and examine each in comparative perspective using case law from different jurisdictions. Despite significant overlap in the patent statutes of all WTO member countries, important differences remain in the requirements of patent eligibility for certain subject matter. *Chapter 4* deals with these subject matter limitations and explores in depth the primary areas of divergence among countries, namely, life forms (biotechnology), business methods and software, and pharmaceuticals and diagnostic methods.

In *Chapter 5* we cover utility, in *Chapter 6* novelty, and in *Chapter 7* inventive step/non-obviousness.

*Chapter 8* covers the disclosure requirements for patents, including enablement and written description and their counterparts in other jurisdictions. We also cover the emerging disclosure of origin requirement, and the difficult question of prior-informed consent and related tensions over the protection of biological diversity, the valuable knowledge about plant



and animal life held by indigenous peoples, and the demands by many developing countries for a patent system that adequately accommodates the protection of these resources. Other protection systems for plants are also discussed in this chapter as are protection regimes for designs and utility models.

In *Chapter 9*, we deal with patent prosecution in some detail, beginning with the basic patent application. We provide an overview of key aspects of internationalizing an application, features of various types of claims, the patent examination process, and patent grant and post-grant proceedings.

Finally in Part III, we cover major issues in patent litigation. First in *Chapter 10*, we address comparative approaches to infringement. Next, we deal with defenses and remedies in *Chapter 11*, and conclude with *Chapter 12* on multinational enforcement of patent rights.

In treatise, case, and article excerpts throughout the book, we have selectively omitted many citations and footnotes without using ellipses or other indicators. Within each chapter footnotes are numbered consecutively. However, within cases and other excerpted material, footnote numbers correspond to those in the original published material. In every chapter we provide notes and questions that highlight developments in international fora, as well as case updates or other relevant information from jurisdictions around the world. In addition, we help students think more deeply about the policy or doctrinal implications of the topics addressed, with questions that facilitate further study, comparison, and analysis. The result, we hope, is a rich and compelling set of materials that will equip students to understand policy arguments for the successful practice of patent law which, as they will learn from this casebook, is ineluctably now a global enterprise.

MARGO BAGLEY  
RUTH OKEDIJI  
JAY ERSTLING

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In the true spirit of a casebook on an important international subject with significant comparative perspectives, various chapters were written as we traversed a number of countries—including Belgium, China, Germany, Kenya, Mexico, Nigeria, Singapore, Switzerland, Tanzania, and Uganda. We are grateful to our hosts in these various countries, and to those individuals—particularly policy officials—who provided us with information that simply could not have been otherwise known or found without their assistance and support.

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