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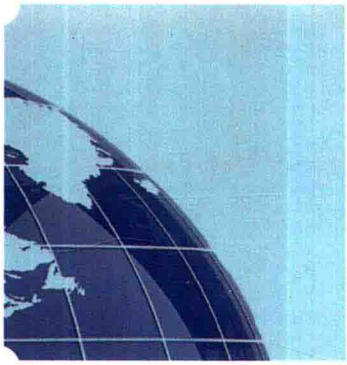
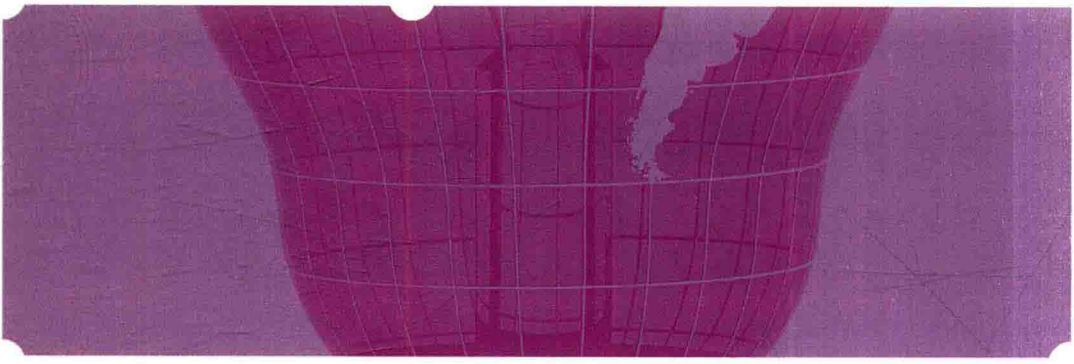


PATENT LAW IN GLOBAL PERSPECTIVE



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Edited by Ruth L. Okediji

Margo A. Bagley

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Oxford University Press is a department of the University of Oxford. It furthers the University's objective of excellence in research, scholarship, and education by publishing worldwide.

Oxford New York
Auckland Cape Town Dar es Salaam Hong Kong Karachi Kuala Lumpur Madrid
Melbourne Mexico City Nairobi New Delhi Shanghai Taipei Toronto

With offices in
Argentina Austria Brazil Chile Czech Republic France Greece Guatemala Hungary
Italy Japan Poland Portugal Singapore South Korea Switzerland Thailand
Turkey Ukraine Vietnam

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Published in the United States of America by
Oxford University Press
198 Madison Avenue, New York, NY 10016

Library of Congress Cataloging-in-Publication Data

Patent law in global perspective / Edited by Ruth L. Okediji, Margo A. Bagley.
pages cm
Includes bibliographical references and index.
ISBN 978-0-19-933427-8 ((hardback) : alk. paper)
1. Patent laws and legislation. 2. Patents (International law) I. Okediji, Ruth L., editor of compilation.
II. Bagley, Margo A., editor of compilation.
K1505.P3747 2014
346.04'8—dc23

2013035975

9 8 7 6 5 4 3 2

Printed in the United States of America on acid-free paper

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PATENT LAW IN GLOBAL PERSPECTIVE

To Tade O. Okediji with love; I thank God
upon every remembrance of you
—R.L.O.

To Samuel S. Bagley and Samuel S. Bagley II;
Two "good and perfect gifts" from God
—M.A.B.

ACKNOWLEDGMENTS

The road to a finished monograph is filled with lessons in patience, humility, and sacrifice. The cost is shared by many along the way whose faithful efforts ensure that the end goal is as intellectually rewarding as it is successful. We are immensely grateful to the wonderful group of scholars who contributed to this volume. Their willingness to join us in addressing various patent law topics from a variety of theoretical perspectives and to offer original contributions has made this book far richer and of greater scholarly consequence than was foreshadowed in our modest proposal.

Like any long journey, despite a sensible timeline, careful preparation, and diligent oversight of the editorial process, there were surprises along the way and opportunities to take shortcuts around the vision we outlined for this intellectual enterprise. We were encouraged to stay the course by a dedicated team of former editors at Oxford, starting with Lori Wood whose gentle prodding first gave us the idea for this work, Kevin Pendergast who remained contagiously indefatigable about the importance of the subject and our approach to it, and finally Matt Gallaway, who ensured our smooth transition to a new editorial team and staff at OUP. Our thanks to Jennifer Gong, Alden Domizio, and others at Oxford for an effective production process and assistance with the finishing touches to the manuscript.

Tucker Chambers and Bethany Mihalik, University of Minnesota Law School Class of 2014, Allyson Schmitt Hicks and Alicia Smith, University of Minnesota Law School Class of 2013, and Joseph Schaffner, University of Virginia School of Law Class of 2013, devoted many hours of excellent research and editing support; Tomas Felcman, Associate Director of the University of Minnesota IP and Development Program, ensured compliance with various substantive and technical requirements, including overall editorial management in finalizing the manuscript; and Bria Goldman supervised and coordinated the many component parts of the submission process.

Finally, our deepest thanks go to our husbands and families who endured with us throughout the entire process including above all, to the Father of all good gifts without whose grace and mercy neither our lives nor this book would have been possible.

Ruth L. Okediji

Margo A. Bagley

PREFACE

Six centuries after making its debut in Venice, Italy, the patent system remains as critically important to national and international economic interests as it is contentious. As patent laws became widespread throughout the eighteenth and nineteenth centuries, so did a greater appreciation and concern for the domestic welfare objectives and broader social effects of patent grants. These concerns were reflected in the earliest national patent laws in Europe, which, to varying degrees, expressed an instrumentalist view of patents as a means to improve the lives and welfare of citizens. The general conditions of patentability characteristic of these pioneer patent regimes—a new invention (novelty), usefulness (utility), time limits on protection (duration), and in many cases, domestic working requirements—are facially consistent with the strong overarching concern that patents should secure technological and economic advantages that inure to the benefit of the patent-granting jurisdiction. The incorporation of several of these standards into modern patent laws, and in to the international patent system, in part reflects the resilience of the public interest as a significant consideration in the design and application of patent laws.

There is little controversy over the general account of patent law's primary goal of promoting public welfare and the importance of patentability criteria and patent policy in reinforcing that objective. There also is little doubt that the grant and exercise of patent rights continues to produce negative externalities both domestically and in the global context. Patent protection has consequences for the innovation system per se, such as in influencing norms that govern scientific research and practice, in raising the costs of access to basic scientific data, and in shaping the pace and extent of private R & D investments. Patent protection also influences the design of regulatory processes for safeguarding public health and safety, access to medicines, healthcare, and other public goods. Further, patent protection increasingly implicates controversial issues in science such as climate change, the food supply, and genetic engineering.

Against this dynamic backdrop and normative complexity of national patent laws, global efforts to harmonize patent protection across borders have become a mainstay of the multilateral economic system, further compounding the nature

and extent of trade-offs associated with global patent cooperation. The conclusion of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1994 ostensibly moved the international community toward greater convergence in patent law standards and, with this, offered hope that the international protection of patents would facilitate access to markets, engender greater cooperation among firms, and produce a stable legal environment with respect to trade in patented goods. Instead, the combined effects of domestic policy trade-offs, competing social welfare considerations, and enduring differences in policy tools to address the negative effects of patent laws *nationally* has produced unexpected, and at times unintended, consequences. These effects are visible both in countries still struggling with basic economic development goals and in those that assumed that enforceable patent standards could replace or effectively delimit the exercise of national policy discretion in response to welfare considerations associated with access to patented products.

As this book demonstrates, very little is settled in patent law and policy, even in those countries with a long history of patent protection. The scholars who have contributed to this volume tackle, among other things, enduring and new questions that revolve around *how* to identify the national public interest with respect to the role of the patent system in innovation and access to new inventions; *what* constitutes a legitimate exercise of sovereign discretion over the public welfare effects of patent protection in light of competing public international law regimes; *which* national agencies and institutions are best suited to assess and interpret the implications of patent enforcement under local conditions; and *when* national or regional implementation of international rules should logically produce divergent practices, particularly with regard to morally sensitive inventions.

The contours of domestic patent laws have always been subject to intensely negotiated trade-offs and compromises among and between industries, institutions, and agencies advancing competing (and, at times, complementary) national interests or priorities. When viewed in a global perspective, and in light of mandatory international patent rules, the wisdom of many of these trade-offs and their benefit—whether to inventors or the public—is far more contestable. As this book also suggests, the consolidation of patent norms in international instruments means that experiments with national patent policy take place and are immediately scrutinized in international public spaces, heightening the political stakes over decisions about what constitutes legitimate incorporation of international rules in domestic law, and what tools can be used to adjust those global rules to fit national circumstances.

This book reveals a global motif of patent law and policy that is as challenging and complex as it is unpredictable. We hope that readers will find, as we did, the arguments and lessons embodied in this collection rich, insightful, thought-provoking, and instructive.

INTRODUCTION

Since the first Patent Act in Venice in 1474, through the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) in 1994, the patent system has been used by countries to accomplish a variety of national objectives, not the least of which has been as a means to secure competitive gains in regional and global trade. The intensified twentieth century efforts to secure export markets by enticing as many countries as possible to participate in a harmonized normative patent law framework have revealed significant limitations in the institutional capacity and political willingness of countries to fully cede the architecture of domestic patent law to a singular trade ethos. At the same time, patent law in many countries faces new and increasingly complex issues that are, in theory, governed by the overarching global patent *acquis*. Some of these new challenges involve moral and ethical considerations, such as patents over life forms and other biotechnology inventions that can only be meaningfully considered in reference to specific sociocultural values. Others implicate policy choices regarding the cost to governments of purchasing patented items to address public and social welfare needs, particularly in developing and least-developed countries. Moreover, enduring questions about the role of patents in innovation and how best to facilitate a robust climate for scientific research and development remain critical to the growth of even the most developed economies. Patent agencies, policymakers, and courts have to confront these questions while carefully maneuvering policy options at the interface of national and international patent protection. In our view, addressing these issues effectively requires analysis of, and some deference to, the domestic environment in which patent law operates.

This book analyzes and explores the scope and effects of various efforts by states and other international actors to reconstruct or, at times resist, the implicit hierarchy of international patent norms within the context of national patent law and policy. For almost every topic and subject addressed, comparative and theoretical approaches reflect the dynamic and complex navigation between the imperatives of the patent regime and the strong public welfare considerations that permeate any understanding of the role of patents in modern society. Authors were not compelled to write on certain themes or topics; nonetheless the

contributions invariably fell in clusters that addressed major issues at the frontiers of patent law and policy.

The book is organized around five broad themes: ***Part I***—*Global Patent Law and the Political Economy of Harmonization*, ***Part II***—*Global Approaches to Subject Matter Standards and Patentability*, ***Part III***—*Patents, Institutions, and Innovation Pathways*, ***Part IV***—*Exceptions and Limitations to Patent Protection*, and ***Part V***—*TRIPS Compliance, Patent Enforcement, and Patent Remedies*. The introductory chapter explores gaps in the international patent system that arguably have fueled global concerns about the welfare effects of patent law harmonization. It draws lessons from the failure of patent harmonization efforts to address public welfare objectives and outlines core elements of a "canon" that could inform a progressive framework for global patent policy while accounting for differences in economic development, national competitive strategies, institutional agility, and rule-of-law tenets.

In Part I, Professors Dreyfuss, Dutfield, Shaffer, and Sell explore various aspects of international patent harmonization, describing problems endemic to the harmonization process while also delineating new methods and opportunities for developing and least-developed countries to contribute effectively in shaping and influencing global patent law norms. Professor Rai adds to this new landscape an assessment of tactical differences in US approaches to global patent law standards, and discusses which of the leading emerging economies is more likely to influence US positions in international patent policy.

In Part II, Professors Bagley, Burk, and Janis examine the chronically complex issue of patent subject matter eligibility and comparative approaches thereto among the major patent-granting jurisdictions, focusing particularly on software, biotechnology patents, plant patent protection, and morally sensitive inventions. Nowhere are the normative divergences of patent law more striking, nor the competing national policy priorities more explicitly stated than in this collection of chapters that address some of the thorniest issues in the national application of patent law standards. Professor Fisher then offers a rich and compelling historical and comparative analysis of the enablement and written description standards, highlighting their policy objectives—communicating an invention to the interested public and providing the quid pro quo for patent exclusivity—and differences in the theory and practice of these disclosure standards in major patent-granting jurisdictions.

Part III of the book explores various innovation pathways that exist both in tension with and complementary to the patent system, offering possibilities for imagining multiple forms of policy levers to encourage a diversity of inventive activity and governance models. Professors Drahos and Thomas address institutional and regulatory approaches to promoting and protecting innovation outside the patent system, such as regulatory exclusivities and approaches to recognize traditional forms

of innovation in communities for whom patent protection is implausibly delinked from social and cultural values. These two chapters uniquely highlight the virtues and problems of non-patent regimes with broader implications for innovation policy and competition over cultural knowledge assets. Professor Parthasarathy and Ms. Walker write on the historical and sociological factors that have shaped institutional and agency responses to controversial innovations in the European context, demonstrating the practical effects of civic engagement with the patent system in the design and implementation of patent law and policy. Their research and interviews with officials and other stakeholders reveal specific social and political factors that helped facilitate incorporation of concerns expressed by the public in the administration and governance of the European Patent Office.

Part IV of the book deals with limits and exceptions to patents, addressing the incoherence of national laws on this topic and negative consequences for nascent transnational innovation models. The chapters discuss the prospects of an improved and more coherent construction of various patent law limitations, and demonstrate how vital such limits are for promoting welfare, protecting markets, and encouraging new forms of innovation. Professors van Zimmeren and van Overwalle provide a comparative analysis of the research exception, emphasizing the importance of greater convergence among leading jurisdictions to foster transborder collaboration and provide greater security for downstream researchers. Dr. Heath offers an in-depth analysis of the intellectual foundations of the exhaustion doctrine, tracing its historical evolution and providing an analysis of comparative legal sources (some not previously translated into English) and judicial decisions dealing with questions involving repair and/or reproduction of patented items, contractual limitations, and the scope of the doctrine. Professor Ho offers a fresh, social science–based approach to the controversial question of compulsory licensing, identifying and distinguishing distinct policy strands that could better inform cases where explicit public interest objectives are at stake. In a similar vein, Dr. Bakhoum focuses on the prospective role of competition law as a policy instrument to balance competing interests in free markets and innovation, particularly in the context of access to medicines in sub-Saharan Africa. He explores the legal opportunities to engage in such a balancing act in the context of the *GlaxoSmithKline* case brought before the South African Competition Commission, and suggests approaches that could serve to strengthen the role of non-patent agencies in facilitating access to public goods.

Finally in Part V, scholars examine domestic compliance with the TRIPS Agreement, patent enforcement, and patent remedies. These chapters reveal the diversity of approaches to TRIPS standards, and a degree of legal innovation by emerging countries such as China and India in the national implementation of TRIPS requirements. Professor Gervais explores how undefined terms in the TRIPS Agreement provide important space for national policy experimentation

in implementing the fundamental patentability requirements of inventive step and industrial applicability. In their chapter, Mr. Khader and Professor Ragavan argue that the non-obviousness standard as implemented by the Indian Patent Office is a heightened standard compared to that of the United States, analyzing grant opinions to illustrate how this standard operates in practice in India. Professor Basheer and Messrs. Sanklecha and Gowda offer an analysis of pharmaceutical patent enforcement in India. Specifically, they examine procedural aspects of patent litigation and argue for the elimination of the temporary injunction phase as an important step in ensuring that the public is not denied access to pharmaceutical products when the integrity of the patent is in question. Their insightful proposals for change underscore the importance of effective enforcement procedures both to the patent holder and the public, and the unusual convergence of interests that should make their development-friendly proposals politically salient in other developing countries. Next, Professor Cotter sets forth a methodological approach to the study of patent remedies, challenging scholars and policymakers to consider the insights offered by comparative law and economics to better understand the nature and implications of divergent national approaches to two major patent remedies: permanent injunctions and damages. And finally, Mr. de Carvalho argues that despite the strong rules established by the TRIPS Agreement, there still remains little correlation between the goals of the Agreement and the rules established therein. Assessing TRIPS compliance by both developed and developing countries, he concludes that the promotion of innovation is far less central to the TRIPS regime than the elimination of trade barriers for pharmaceutical inventions.

The chapters in this book collectively demonstrate that patent law is best understood and, ultimately, defended, in a national context. Nevertheless, patent law is undeniably moored in a global framework that exerts pressure along a continuum of policy choices available to countries as they grapple with numerous issues in the design of their national laws. Overall, the book offers insights from comparative, historical, and institutional analyses that reveal the intricate past, present, and future of patent law in its multifaceted role as an agent of innovation, a facilitator of private investment in scientific research, and, ultimately, an unrivaled instrument of contemporary international economic relations.

TABLE OF ABSTRACTS

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INTRODUCTION	
Chapter 1 **Public Welfare and the International Patent System** *Ruth L. Okediji*	International patent harmonization initiatives have become a mainstay of contemporary international economic relations, as has resistance to those efforts. Since the conclusion of the TRIPS Agreement, resistance to patent harmonization has evolved into normatively complex and coordinated challenges to the patent system at national and international levels. These challenges derive from a number of "gaps" between the goals of the patent system and the social costs of patent protection, particularly in the international context. For example, none of the prevailing arguments for patent harmonization meaningfully address the role of patents in ensuring the supply of public goods, the national welfare implications of international patent protection, or how globalized patent norms fit within a broader international public law framework. Historically, a variety of national policies and less invasive patent harmonization regimes downgraded the effects of these gaps. Combined trade and intellectual property obligations under the TRIPS Agreement and its progeny have, however, significantly constrained policy options, while also unevenly increasing the costs of participation in a liberalized global economy. These harmonization

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	gaps reveal that the current global patent system lacks the institutional and policy capacity to manage the national welfare consequences of contemporary patent harmonization processes, but strips countries of the right to do so without fear of trade reprisals. This chapter explores the implications and consequences of patent harmonization gaps and outlines elements of a core set of remedial principles—a global patent law canon. Future efforts at international patent cooperation must substantially accommodate tenets of this canon or face continual crises of legitimacy that engender new, dynamic forms of resistance to global patent norms.
PART I—GLOBAL PATENT LAW AND THE POLITICAL ECONOMY OF HARMONIZATION	
Chapter 2 **Intellectual Property Lawmaking, Global Governance, and Emerging Economies** *Rochelle C. Dreyfuss*	This chapter discusses the role that emerging economies could play in rendering intellectual property law and lawmaking more responsive to changing conditions. At present, neither the North nor the South is likely to challenge the accommodations made in the WTO TRIPS Agreement. In the North, the politics of change are complex; the South largely lacks expertise. But emerging economies have the political will to improve access to the world's intellectual output on behalf of their poorest citizens. At the same time, they have growing creative sectors and thick legal and political cultures capable of striking new and imaginative balances between proprietary and access interests. Because the goals of these economies are best served by partnering with least-developed countries and members of civil society interested in intellectual property issues, these nations also have an

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Chapter 3 **US Executive Branch Patent Policy, Global and Domestic** *Arti K. Rai*	This chapter assesses the relationship between domestic patent policy positions taken by the US executive branch and its international positions. As the chapter details, in recent years one important area of apparent divergence between domestic and international positions has been biopharmaceutical patent policy. The chapter analyzes dynamics within the executive branch that lead to this divergence and concludes that it probably represents a relatively stable equilibrium. Outside the biopharmaceutical arena, however, China's aggressive, highly government-centered patent and innovation policies may create challenges, both in terms of chilling agency efforts to advocate for proactive approaches to domestic innovation and in ongoing negotiations over the Trans-Pacific Partnership Agreement.
Chapter 4 **Transnational Legal Ordering and Access to Medicines** *Gregory Shaffer and Susan K. Sell*	The politics of pharmaceutical patent protection increasingly involve the interaction of different transnational legal orders (TLOs), and, in particular, a TLO focused on trade and intellectual property protection, and a TLO focused on the human right to health. These transnational legal orders involve recursive interaction between legal norm-making and implementation at the international and national levels. This chapter shows how rival transnational legal orders frame a country's approach to intellectual property protection. Understanding

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Chapter 5 **The Limits of Substantive Patent Law Harmonization** *Graham Dutfield*	Patent law harmonization at the level of principles, rules, and institutional structures is a highly ambitious goal. Its practical intent is to facilitate secure patent coverage on a global scale and for the longest period possible, and to accelerate and cheapen the process of attaining it. Economically the stakes are very high, not just for businesses but also for nations. Generally speaking, harmonization based on high protection standards benefits leading innovator countries and large businesses already enjoying strong market power assisted by their ownership of sizeable intellectual property portfolios. Follower nations and businesses seeking to enhance their innovation levels prefer, understandably, to maintain a greater freedom to copy than such harmonization would allow. This chapter reviews recent harmonization efforts at the international level and explains their lack of success despite the apparent economic and political dominance of advocates and the relative weakness of opponents.
PART II—GLOBAL APPROACHES TO SUBJECT MATTER STANDARDS AND PATENTABILITY	
Chapter 6 **Patent Barbarians at the Gate: The Who, What, When, Where, Why and How of US Patent Subject Matter Disputes** *Margo A. Bagley*	Patent subject matter determinations continue to present a moving target in the United States, primarily for biotechnology, software, business methods, and diagnostic methods, with court decisions, patent office policies, and legislative initiatives sometimes

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	expanding, and sometimes contracting, eligibility boundaries. Moreover, decisions in the United States often have repercussions for patenting abroad. This chapter explores changes in the who (players), what (disputes), when (timing), where (venues), why (theories), and how (mechanisms) of patent eligibility challenges fueling these developments now and for the foreseeable future.
Chapter 7 **Patent Law's Problem Children: Software and Biotechnology in Transatlantic Context** *Dan L. Burk*	The law of patentable subject matter has been in flux now for nearly three decades. On both sides of the Atlantic, courts, administrative agencies, and legislators have struggled with the application of patent law to biotechnology and computer software, the "problem children" of modern patent law. Although this ongoing struggle has not yet produced definitive solutions to the quandaries posed by these technologies, it may have at last defined the problem. Both biological and digital code are increasingly treated under similar standards, suggesting the convergence on a consistent doctrine for information technologies. This chapter traces the major developments in software and biotechnology patenting in Europe and North America, demonstrating the parallel approaches taken by jurisdictions on both sides of the Atlantic, as well as the common issues posed by both technologies.
Chapter 8 **Patenting Plants: A Comparative Synthesis** *Mark D. Janis*	This chapter surveys the state of the law regarding utility patent protection for plants. It considers the practices of the major patenting jurisdictions (the United States, Europe, China, Japan, and South Korea), along with others where agriculture is important to the domestic economy (Canada, Australia, and India, for example).