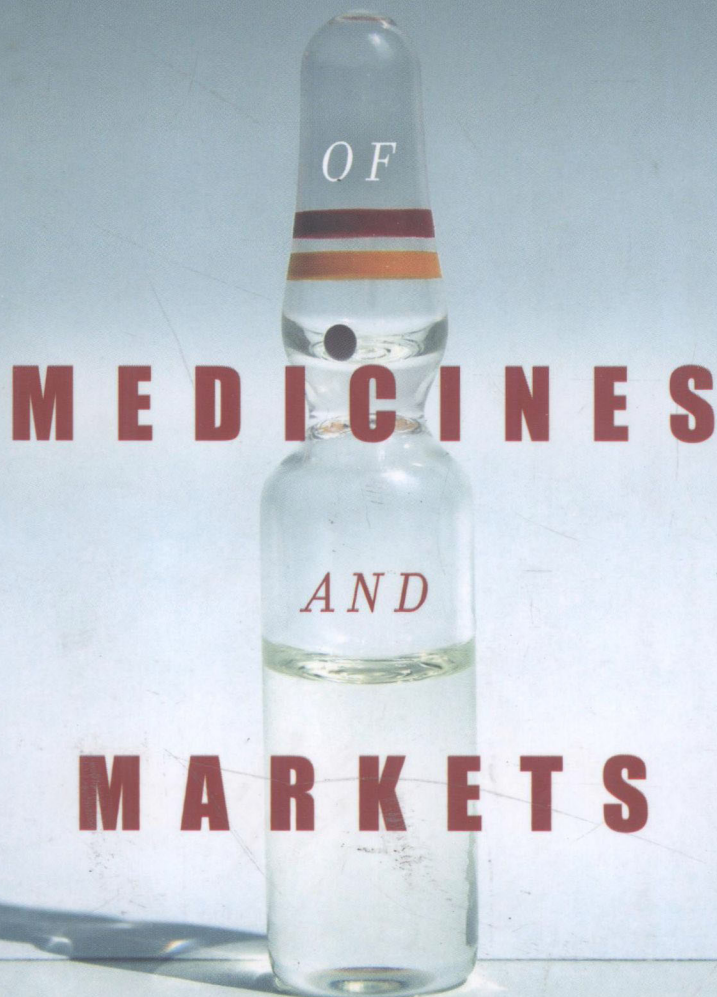


STANFORD STUDIES IN HUMAN RIGHTS

INTELLECTUAL PROPERTY AND
HUMAN RIGHTS IN THE FREE TRADE ERA



ANGELINA SNODGRASS GODOY

Of Medicines and Markets

Intellectual Property and Human

Rights in the Free Trade Era

Angelina Snodgrass Godoy



Stanford University Press
Stanford, California

Stanford University Press
Stanford, California

© 2013 by the Board of Trustees of the Leland Stanford Junior University.
All rights reserved.

No part of this book may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying and recording, or in any information storage or retrieval system without the prior written permission of Stanford University Press.

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

Library of Congress Cataloging-in-Publication Data

Godoy, Angelina Snodgrass, author.

Of medicines and markets : intellectual property and human rights in the free trade era / Angelina Snodgrass Godoy.

pages cm. — (Stanford studies in human rights)

Includes bibliographical references and index.

ISBN 978-0-8047-8560-0 (cloth : alk. paper) — ISBN 978-0-8047-8561-7 (pbk. : alk. paper)

1. Drug accessibility—Central America. 2. Pharmaceutical policy—Central America. 3. Right to health—Central America. 4. Intellectual property—Central America. 5. Drugs—Patents. 6. Free trade—Central America. 7. Human rights—Central America. I. Title. II. Series: Stanford studies in human rights.

RA401.C35G63 2013

338.4'7615109728—dc23

2012043945

Typeset by Thompson Type in 10/14 Minion

Of Medicines and Markets

Stanford Studies in Human Rights

Foreword

AS SHE EXPLAINS, Angelina Snodgrass Godoy first took notice of the coming conflicts around human rights, intellectual property, and the demands of global free trade regimes during a research trip to Guatemala, a country that was slowly emerging from the social ravages of a decades-long civil war and the horrors of a genocide committed against its indigenous populations. As the process of postconflict reconciliation and accounting matured, albeit unevenly and without resolution, the coalitions of local and transnational human rights networks that had coalesced around demands for justice broke apart, the topic of the genocide itself disappeared from national newspapers, and the country retreated into its more mundane struggles with poverty, development, and political transition. But, at the same time, Guatemala, like other countries in Central America, was negotiating the terms of the Central American Free Trade Agreement, the regional version of the earlier NAFTA that had brought Canada, the United States, and Mexico together into a controversial free trade zone. Although Guatemalan human rights activists were not focused initially on CAFTA, they soon realized that the terms of the agreement, especially around intellectual property, threatened the human rights of Guatemalans in more subtle ways. These included the deeply ingrained right to health, because a key provision of CAFTA outlined strong intellectual property protections that would make it more difficult for poor countries like Guatemala to produce cheaper generic drugs that were affordable and locally available.

Some of these drugs represented the difference between life and death for people, including the antiretrovirals that are used to treat patients with HIV. Godoy observed as the serious implications of CAFTA for people in Guatemala soon dawned on patients, government workers, and human

rights activists. What she was witnessing was the emergence of new threats to human rights that did not have the same immediacy and sense of urgency as the kind of massive physical integrity violations that had provoked transnational outrage and had made Guatemala one of the icons of injustice within the international human rights movement. Instead, the looming consequences of CAFTA represented something quite different and, in some ways, farther reaching: a clash between the imperatives of global capital and the imperatives of human rights in countries that had been at the forefront of human rights ratification and promotion, especially after the end of the Cold War.

Godoy decided to study this clash more systematically, and this book is the result. She broadened her empirical focus to include El Salvador and Costa Rica, and the sweep of her analytical frame came to encompass one of the most important questions of our time: whether contemporary human rights and the dominant modes of global freed trade represent fundamentally contradictory approaches to world making and social ordering. *Of Medicines and Markets* uses the struggle to ensure health rights in three Central American countries in the face of pressures to preserve the profit margins of giant, mostly North American, pharmaceutical companies, to reflect more generally on the changing nature of human rights activism, the role of the state, and the ways in which demands for social justice can face implacable structural barriers in smaller countries that lack relative bargaining power in broader political economies. Her book is also a powerful reminder that new struggles for human rights have become difficult to recognize in many cases. As she puts it:

While the iconic figure in decades past was the prisoner of conscience, the courageous dissident imprisoned for daring to speak his mind, today's struggles feature new actors: indigenous people opposing the construction of dams on their ancestral lands; factory workers rallying against the "cut and run" practices of transnational capital; AIDS patients demanding affordable drugs from an industry whose pricing places the pills beyond their grasp.

In the process of revealing for us the landscapes of these new terrains on which human rights activists must now do their work, Godoy gives us a landmark critical history of the right to health in Central America, which

is a key marker of the way in which Latin America more generally has long been a region at the forefront of the postwar development of human rights. Through her empirical study and history of the right to health in Central America, and her analysis of the key role that intellectual property regimes play in complicating this right, she confronts the central problem of human rights promotion in a world shaped by the imperatives of capital. Her reflections on this problem provide a new conceptual model for understanding the practice of human rights and redirect our focus on the form and content of future human rights struggles that are just over the horizon.

Mark Goodale
Series Editor

Acronyms and Abbreviations

ACAM	Alianza Civil por el Acceso a Medicamentos, a coalition of Guatemalan civil society organizations opposed to increased IP protections
ASINFARGUA	Association of Guatemalan Pharmaceutical Industry (<i>Asociación de Industriales Farmacéuticos Guatemaltecos</i>), a trade group representing the interests of leading generic pharmaceutical producers in Guatemala
CAFTA	United States-Central America Free Trade Agreement, also known as DR-CAFTA, United States-Dominican Republic-Central America Free Trade Agreement
Caja	Costa Rican Social Security Institute (<i>Caja Costarricense de Seguridad Social</i>)
FEDEFARMA	Central American Federation of Pharmaceutical Laboratories (<i>Federación Centroamericana de Laboratorios Farmacéuticos</i>), an organization representing the interest of transnational pharmaceutical companies in Central America, including the originator companies associated with PhRMA
GAO	U.S. Government Accounting Office
IDB	Inter-American Development Bank
IGSS	Guatemalan Social Security Institute (<i>Instituto Guatemalteco de Seguridad Social</i>)
IMF	International Monetary Fund

xii Acronyms and Abbreviations

INQUIFAR	Association of Salvadoran Pharmaceutical Industry (<i>Asociación de Industriales Químico Farmacéuticos de El Salvador</i>), a trade group representing the interests of leading generic pharmaceutical producers in El Salvador
IP	intellectual property
IPR	intellectual property rights
ISSS	Salvadoran Social Security Institute (<i>Instituto Salvadoreño de Seguridad Social</i>)
PAHO	Pan-American Health Organization
PDH	Human Rights Ombudsman's Office (<i>Procuraduría de Derechos Humanos</i>), an institution of the legislative branch in Guatemala and El Salvador (the equivalent in Costa Rica is known as the <i>Defensoría de los Habitantes</i>)
PhRMA	Pharmaceutical Research and Manufacturers of America (colloquially referred to as "Big Pharma"), an organization representing the major pharmaceutical companies
TRIPS	WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994
UNICEF	UN Fund for Children
US FDA	U.S. Food and Drug Administration
WHO	World Health Organization
WTO	World Trade Organization

Acknowledgments

I AM DEEPLY INDEBTED to many people who have assisted me in the multi-year process of researching and writing this book. First and foremost, I am very grateful to my informants and collaborators—especially those Central Americans who took time out of their busy schedules to help me understand the dynamics of intellectual property and access to medicines from their vantage point. There are too many such people to name all individually, and some preferred that their participation be anonymous, but all helped me make sense of this complex panorama, and without their generosity and insights this book would simply never have been possible to write.

Over the years I have collaborated with various scholars and scholar-practitioners working on intellectual property issues. In particular, I want to acknowledge my immense gratitude and respect for my close collaborator and friend Alejandro Cerón. I also learned tremendously from my contact with the members of the CEPIAM Network: from Costa Rica, Luis Bernardo Villalobos Solano, Gabriela Arguedas Ramírez, and Victoria Hall; from El Salvador, Eduardo Espinoza Fiallos, Giovanni Guevara Vásquez, and María Angela Elías Marroquín; from Guatemala, Alfredo Moreno and César García; from Honduras, Edna Janeth Maradiaga Martínez and Jorge Sierra; and from Nicaragua, Carlos Berríos and Douglas Quintero. And I have also been greatly enriched by my relationship with a cadre of scholars probing related issues in the Colombian context, including César Rodríguez-Garavito, Diana Rodríguez Franco, and Tatiana Andia.

I am also fortunate to have relied on a range of colleagues and friends in human rights and law and society circles for feedback as this manuscript took shape. Michael McCann, in particular, has been exorbitantly

generous in reading multiple drafts of this work over the years and always providing thoughtful, incisive commentary that has sharpened the final product considerably. My colleagues Jamie Mayerfeld and Glenda Pearson also read chapter drafts and provided feedback, as did David Gartner. I also benefited greatly from the opportunity to share excerpts from this work in other settings, including the LSJ/CLASS Workshare at the University of Washington, the Colloquium on Innovation Policy at NYU, the Universidad de Costa Rica, and the Universidad de los Andes in Colombia. I particularly appreciate the thoughtful feedback provided by Rochelle Dreyfuss, César Rodríguez-Garavito, and Peter Evans in these encounters.

Lastly, my perspectives and thinking have benefited from numerous exchanges with practitioners in this field, including especially Judit Rius Sanjuán and Rohit Malpani. I am greatly indebted to Carmen Pérez of INQUIFAR in El Salvador and to the many pharmaceutical company executives who shared their views with me in all three countries examined in these pages. Karen Vargas served as a particularly helpful friend, advisor, and source of inspiration over the course of my multiple visits to Costa Rica in recent years. In El Salvador, I am also particularly grateful to Rolando González, whose generosity of spirit and practical assistance helped me grapple with the complexities of his small but beautiful country throughout the years I worked on this book.

At Stanford University Press, I've been fortunate to work with Mark Goodale, Kate Wahl, and Frances Malcolm; their contributions to this manuscript have also been considerable and much appreciated. Similarly, Margaret Pinette's precise attention to every detail has greatly improved this work.

This work would also not have been possible without the generous support of numerous organizations. I'm grateful for financial support received from the Puget Sound Partners for Global Health, as well as American Council of Learned Societies and the Ford Foundation. I also benefited from funding provided by the National Science Foundation through Grant No. 0617374 and from the generosity of the Henry M. Jackson Foundation in establishing the Helen H. Jackson Chair in Human Rights, which I currently hold at the University of Washington.

Lastly, to my family, and most especially Estuardo, I owe infinitely more than can be expressed in words; thank you.

Contents

Foreword	vii
Acronyms and Abbreviations	xi
Acknowledgments	xiii
1 Trading Health for Wealth	1
2 A Primer on Pharmaceutical Intellectual Property	21
3 Market Failures and Fallacies	51
4 Local Politics, Strange Bedfellows, and the Challenges of Human Rights Mobilization	79
5 Patient Advocacy and Access to Medicines Litigation	107
6 Writing Globalization's Rule Book	129
Notes	153
References	159
Index	173

Trading Health for Wealth

EDGAR'S SMILE WAS NOT A POLITE nice-to-meet you smirk but one of those grins that first ignited in his coffee-colored eyes and then radiated, broad and beautiful, across his face. He settled into his plastic chair and leaned forward, friendly, engaged, eager to hear the questions we'd come to ask him. Among an organization of strikingly optimistic people, Edgar seemed particularly so. Yet, cast against his unassailably generous spirit, the one question he asked us was devastating: "Why would your Congress make it harder for me to get my medicine?"

My students and I met Edgar in the summer of 2004, in the offices of a Guatemalan HIV+ organization called Gente Positiva. At that time, CAFTA—the U.S.–Central America Free Trade Agreement—was awaiting ratification in all the member countries. The agreement was the first major extension of the NAFTA (North American Free Trade Agreement) model, hailed as a stepping-stone to an eventual Free Trade Area of the Americas; its announcement had touched off battles around labor rights, environmental protection, and threats to peasant agriculture. In addition, critics had begun to raise concerns about the agreement's chapter 15, which governed intellectual property (IP) rights. In Guatemala in particular, a coalition of public health, human rights, and alter-globalization activists had come together to advocate against the IP provisions in CAFTA, which they argued would curtail access to medicines by limiting the availability of low-cost generics. On the day the Guatemalan Congress ratified the

agreement, some took to the streets wearing jerseys emblazoned with the slogan, “My life is not for sale.”

This was a new issue for Central American human rights advocates. Indeed, CAFTA itself was something of a turning point for the movement, marking a new era of engagement with global economic structures.

Guatemala, like some other countries of the region, had only recently emerged from a prolonged armed conflict that had inflicted deep and painful wounds on the social fabric; a UN Truth Commission had declared in 1999 that the atrocities committed in the context of the thirty-six-year war constituted a genocide against the indigenous Maya. When I began research on human rights issues in Guatemala in the mid-1990s, the field was dominated by discussions of postwar justice and reconciliation. Forensic anthropologists spearheaded the scientific exhumations of mass graves littered across the countryside; lawyers undertook the careful work of knitting together testimonies with legal tools, seeking accountability for wartime atrocities; the UN Mission in Guatemala, tasked with verifying compliance with the Peace Accords, issued periodic reports on the status of implementation efforts; human rights organizations documented threats against witnesses in court cases and called for truth telling about past violence. Everywhere, the focus was on issues related to state violence.

But by 2004, when we met Edgar, things had shifted perceptibly. Donor support for the various legal accountability efforts had waned, perhaps in response to disheartening outcomes—even today, the military leaders responsible for crimes against humanity have largely eluded justice—or perhaps in reflection of a broader reframing of global human rights concerns in the wake of 9/11. The UN Mission had left the country. Various forms of international assistance were still present, but they tended increasingly to place priority on alleviating the region’s enduring poverty rather than promoting postwar justice. The genocide had mostly slipped from the headlines. In this context, beginning in 2003, behind closed doors and without any involvement from civil society organizations, the governments of the United States and various Central American countries—Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua—had hammered out a comprehensive agreement that established new rules and procedures for trade relations.

If some in the human rights community had until then considered trade law a technical province of administrative procedures largely unrelated to its core concerns with justice and accountability, such assumptions faded fast when CAFTA's content was unveiled in 2004. Amid the layers of legalese were new rules for doing business across borders; new limits on what national laws could regulate, promote, or prohibit vis-à-vis the conduct of private industry; new institutions for adjudicating disputes between corporations and governments; and new ways of envisioning the social contract.

Given the history of Central America, it was not difficult to imagine that these ways of reconfiguring corporate relationships with states in an interdependent global arena could have human rights implications. This was nowhere clearer than in Guatemala, once the proverbial “banana republic” where an attempt to nationalize lands held by a U.S. corporation—United Fruit, now known as Chiquita—had triggered the ouster of democratically elected President Jacobo Arbenz in a 1954 coup backed by the CIA (Central Intelligence Agency). The violence that followed the coup rapidly devolved into civil war, as a series of U.S.-backed dictators took turns battling Marxist guerrillas and eventually waging genocide against the country's indigenous majority. So, some seven years after the signing of the country's Peace Accords, when the text of CAFTA was made public, those paying attention immediately recognized what was at stake and scrambled to organize in response.

But it was an uphill battle: Prolonged civil wars had turned societies inward, had polarized them along ideological lines, and had decimated civic engagement. The issues in the agreement were complex and cloaked in language that was difficult to understand. And poverty, the lack of education, and underemployment already had the majority of the region's population locked in a daily struggle for subsistence, in which informing themselves on the finer points of trade law, let alone manning the barricades, seemed a tall order. While progressive unions, peasant groups, and—to a lesser extent—environmental organizations rallied their bases to oppose relevant chapters in the agreement, there *was* no preexisting Central American advocacy group dealing with intellectual property. The issue was brand new.