Journal of Legal Medicine

ISSN: 0194-7648 (Print) 1521-057X (Online) Journal homepage: https://www.tandfonline.com/loi/ulgm20

Patently Innovative: How Pharmaceutical Firms Use Emerging Patent Law to Extend Monopolies on Blockbuster Drugs and Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries

by Ron A. Bouchard (Biohealthcare Publishing (Oxford Limited) Oxford, United Kingdom, 2012), 275 pages, $205.00.; by Kenneth C. Shalden, Samira Guennif, Alenka Guzman, & N. Lalitha, Eds. (Edward Elgare Publishing Limited, North Hampton, Massachusetts, 2011), 339 Pages, $145.00.

Stacey B. Lee J.D.

To cite this article: Stacey B. Lee J.D. (2013) Patently Innovative: How Pharmaceutical Firms Use Emerging Patent Law to Extend Monopolies on Blockbuster Drugs and Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries, Journal of Legal Medicine, 34:1, 149-155, DOI: 10.1080/01947648.2013.768509

To link to this article: https://doi.org/10.1080/01947648.2013.768509

The Journal of Legal Medicine, 34:149–155

0194-7648 print / 1521-057X online
DOI: 10.1080/01947648.2013.768509

PHARMACEUTICAL AND INTELLECTUAL PROPERTY

PATENTLY INNOVATIVE: HOW PHARMACEUTICAL FIRMS USE EMERGING PATENT LAW TO EXTEND MONOPOLIES ON BLOCKBUSTER DRUGS, by Ron A. Bouchard (Biohealthcare Publishing (Oxford Limited) Oxford, United Kingdom, 2012), 275 pages, $205.00.

INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH: ACCESS TO DRUGS IN DEVELOPING COUNTRIES, by Kenneth C. Shalden, Samira Guennif, Alenka Guzman, & N. Lalitha, Eds. (Edward Elgare Publishing Limited, North Hampton, Massachusetts, 2011), 339 Pages, $145.00.

Reviewed by Stacey B. Lee, J.D., Baltimore, Maryland[*]

INTRODUCTION

In taking two very different, but novel approaches, Ron A. Bouchard's *Patently Innovative: How Pharmaceutical Firms Use Emerging Patent Law to Extend Monopolies on Blockbuster Drugs* and Kenneth C. Shalden, Samira Guennif, Alenka Guzman and N. Lalitha's *Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries*, address the growing complexity of how issues of intellectual property affect access to medications. These books initially appealed to me because of my interest in examining the extent to which Trade-Related Aspects of Intellectual Property (TRIPS) and TRIPS-Plus requirements impede developing countries' access to affordable medicines. Although I have a legal, rather than economic background, recently my research has shifted in a more empirical direction. In selecting these books, I sought analysis that offered empirical support to many of the legal and policy issues at the center of the access to medicine debate. What I found was that both books delivered. One of the strongest contributions of these authors is their ability to strike the right chord in their subject matter approach to appeal to scholars in the fields of health law, international policy, intellectual property, and economics.

TRIPS has governed the global community, and more directly, developing countries' access to medicines for nearly two decades. Bouchard's book,

[*] Assistant Professor, Johns Hopkins University Carey Business School, Baltimore, Maryland. Address correspondence to Professor Lee at 100 International Drive, Baltimore, Maryland 21202, or via e-mail at staceyb.lee@jhu.edu. [Editor's Note: The numbers in brackets in the text refer to pages in the reviewed work.]

Patently Innovative, examines "linkage regulations" that are the latest incarnation of intellectual property protections for pharmaceutical products used in TRIPS-Plus agreements.[1] Using an empirically based approach, the book explores the negative implications these regulations have on health policy and medical innovation.

Shadlen's book, *Intellectual Property, Pharmaceuticals, and Public Health*, also addresses implications of TRIPS and TRIPS-Plus intellectual mechanisms, but from a different vantage point.[2] The editors present their findings through country-themed chapters. An issue garnering increased attention is how the World Trade Organization's 2016 deadline, which requires all countries to comply with the universal pharmaceutical patent regime of TRIPS, will further compromise developing countries' access to medicine. This book advances the discussion by using national experiences. Shadlen draws on detailed case studies from the Americas, Africa, and Asia to illuminate the stark contrasts among countries and within regions in terms of their abilities to develop the knowledge, technological innovation, and manufacturing capabilities necessary to provide access to healthcare services in the midst of the rapidly approaching TRIPS deadline.

PATENTLY INNOVATIVE

This book examines the intersection of traditional patent law and emerging linkage regulations for pharmaceutical products on the global stage. For those not well versed in the evolution of intellectual property's influence on the availability of medicines, the Introduction and Background provide a succinct overview that aids in placing the author's findings in context. Notwithstanding the complexity of the empirical analysis used throughout the book, the beginning sections contain a straightforward explanation of basic terms and processes that form core concepts in later chapters.[3] For example, the Introduction explains that patents are property rights, which include the ability to exclude others from making, using, or selling an invention. [24] In the pharmaceutical industry, the property rights associated with patents include the exclusive right to market, sell, and dispense medications. In the United

[1] SISULE F. MUSUNGU & GRAHAM DUTFIELD, MULTILATERAL AGREEMENTS AND A TRIPS-PLUS WORLD: THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) (2003), *available at* http://www.geneva.quno.info/pdf/WIPO%28A4%29final0304.pdf. TRIPS-plus agreements are activities aimed at increasing the level of protection for rights holders beyond that which is given in the TRIPS Agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions. Such intellectual property rules and practices have the effect of reducing the ability of developing countries to protect the public interest and may be adopted at the multilateral, plurilateral, regional, and/or national level.

[2] The term "editors" and the first author Shadlen are used interchangeably throughout this review.

[3] Such terms include patents, linkages, and life cycle regulation. Explained processes include those used for new drug approval, patent linkage drug approval, and patent listings.

States and Canada, this period of exclusivity is 20 years after the filing date. In other words, a generic drug is only available for sale after the expiration of the brand name drug's patent. [25]

Next, Bouchard introduces readers to the central thesis of the book. The remaining five chapters address how the use of "linkage agreements" can extend the exclusivity normally afforded only through patents. These agreements bind patent protection for marketed pharmaceuticals to the drug approval process. Linkage regulations also permit brand name manufacturers to list as many patents as are considered "relevant" to a marketed product on a patent register. [25] Similar to the introductory sections, Bouchard provides a concise, easy to follow background on the intent of the Canadian and United States' linkage regimes. Linkages are thought to support two key assumptions that underpin public health policy and the economic and industrial policies in industrialized nations. [131] First, linkage agreements are assumed necessary to motivate and increase the amount of innovation that occurs within the economy. Second, it is presumed that "public health goals are best met by encouraging innovation in private industry, essentially by merging public health goals with industrial development goals buttressed by an intellectual property rights regime." [131]

A key finding of Bouchard's empirical data, however, is that the blending of industrial and health policy goals is counterproductive to improving public health outcomes. [225] Bouchard surmises that sophisticated manufacturers find it more cost effective to extend a monopoly on an existing profitable product than to invest the time and research and development on innovation. For example, low evidentiary requirements and follow-on drug development enable pharmaceutical manufacturers to identify attractive new and follow-on candidates for continued market exclusivity after the initial patent expires. A net effect of this strategy is that rather than increasing the flow of new technologies and innovation, the data suggests that linkage agreements and other intellectual property rights actually inhibit innovation. [224–26]

Another conclusion borne out by Bouchard's empirical data is that this extension of market exclusivity on brand-name drugs occurs despite the fact that between 50% to 75% of the patents challenged on the merits may be invalid or are not infringed by generic competition. [254] This has the troubling consequence of keeping less expensive generics out of the hands of the public for longer than necessary. The book lays out similar findings and their implications through chapters devoted to the empirical analysis of: Drug Approval (Chapter 3); Pharmaceutical Innovations and Drug Approval Patenting Linkage (Chapter 4); Drug Patenting in Multiple High-Value Cohorts (Chapter 5); the Implications of the Empirical Data (Chapter 6); and Future Directions (Chapter 7). Although the chapters occasionally stray off into minute detail, the chapter conclusions do an admirable job of refocusing the reader on the chapters' central points and main findings.

The two strongest chapters in the book are Chapters 6 and 7. Here Bouchard draws important implications about the use of linkage agreements for the international community. Since 2010, there has been a rapid increase in the usage of linkage agreements on a global level. Bouchard attributes this to the growing number of Free Trade Agreements (FTAs) involving the United States. These agreements include TRIPS and other multilateral and bilateral agreements with Canada, Mexico, Australia, Korea, and others [2] and require participating nations to incorporate linkage and other intellectual property provisions in their patent systems in exchange for preferential trade terms. Interestingly, the majority of countries negotiate these agreements outside the purview of the World Trade Organization (WTO). Bouchard notes that because these provisions require stronger intellectual property protection than required by TRIPS, they are commonly referred to as TRIPS-Plus agreements. [253] The European Commission has reported numerous instances where member nations have attempted to implement institutional pharmaceutical linkage regimes despite the fact that European Union law prohibits them. [253]

Supported by empirical findings contained in Chapters 3 through 5, Bouchard probes deeper into an evolving landscape that raises the question of whether the pharmaceutical industry is using linkage as an emerging stepping-stone in its efforts to control the movement of drugs across international borders. As support for this theory, he notes a growing number of legal disputes where countries without linkage regulations have attempted to import or export drugs and had these shipments seized by nations alleging that the shipments are in violation of domestic patent laws linked to international trade agreements such as TRIPS or FTAs. [254] In addition, based on his empirical findings, Bouchard shows that linkage agreements arguably present a broader scope of intellectual property protections than previously recognized. After examining the confluence of events over time, Bouchard points out that linkage agreements have quietly emerged as a key driver of both public health costs and medical product regulation on a global scale for both developed and developing nations. [255]

INTELLECTUAL PROPERTY, PHARMACEUTICALS, AND PUBLIC HEALTH

Shalden's book opens by painting the reader a portrait of the current global landscape, in which increased globalization of trade and production and the harmonization of national regulations regarding intellectual property rights have fundamentally altered the global political economy. These changes have been mirrored in the pharmaceutical industry and have dramatically

influenced developing countries' access to essential medicines and protection of public health.

Because this book is a collection of country specific assessments, the editors devote the introduction to describing seminal events in the evolution of intellectual property's role in the countries' access to medicine. This section provides a common understanding of the issues and allows the reader to delve into any of the 11 country-specific chapters with sufficient historical knowledge to follow the various authors' points.

For example, the editors describe how changes ushered in through TRIPS and the Doha Declaration have dramatically altered countries' access to essential medicines. TRIPS gave pharmaceutical patent holders the exclusive right to prevent unauthorized third parties from making, using, offering for sale, selling, or importing their drugs. [4] One of the TRIPS requirements is that WTO member countries must provide a minimum of 20 years of patent protection to all pharmaceutical products and processes. The Agreement also includes a number of transitional provisions. Developing countries like India had until January 2005 to implement the pharmaceutical provisions while least developed countries, like Bangladesh, are not required to extend patent protections to pharmaceutical products until 2016. [4]

As the editors note, the looming TRIPS deadline will undoubtedly further complicate an already contentious debate on how to make essential medicines affordable to developing countries. In illuminating some of those inherent challenges, the editors discuss several of the more controversial aspects of TRIP, including compulsory licenses and parallel importation. [16–19] While many of the country specific chapters, including the chapters on Brazil, India, Mexico, South Africa, and Thailand address these topics, the book's Introduction and Background sections on the concepts serve as helpful previews.

The book also contains several useful charts and graphs. In particular, after reading the chapter about South Africa's public health care challenges, I found myself referring to the charts depicting the health expenditure ratios of countries grouped by gross domestic product (GDP) [10]. These materials are useful in gaining perspective on the scope of each countries' unique challenges. In particular, I found the chapters on Bangladesh and South Africa notable for how they illuminated this complex terrain.

Bangladesh

Padmashree Gehl Sampath, an international expert on innovation and technology, writes the chapter on Bangladesh. She bases her findings regarding Bangladesh's pharmaceutical sector on her sector-wide survey conducted in 2007 and updated in 2010. The implications Sampath draws from the data answer critical questions in the global access debate. Specifically, her research addresses the strength of Bangladesh's generic market and whether it can

evolve to become the primary low cost provider of generic versions of patented drugs to least developed and developing countries.

Bangladesh is a least developed country that constructed an innovative response to the intellectual property requirements imposed by TRIPS. When India became TRIPS compliant in 2005, a vacuum was created in terms of the availability of generic alternatives to patented drugs. [310] As Sampath's data illustrates, Bangladesh possesses the pharmaceutical industry to fill that void. Currently, the country exports a wide range of pharmaceutical products to 67 different countries and is in partnership with numerous Chinese, Indian, and other international firms to expand their technological knowledge. [310] Saladin's analysis provides strong evidence that if Bangladesh's local firms focus on producing generic versions of important medicines at globally competitive prices, they could fill the vacuum created by India's absence as one of the major generic manufacturers to the developing world. [321]

Interestingly, Sampath's research shows that the major obstacle to enhancing the competitiveness of Bangladesh's local firms in the global arena is a national inward focus. Sampath's survey reveals that local pharmaceutical manufacturers primarily concentrate on retaining profits that accrue from their dominant positions within the domestic market. Sampath's research also shows that this typically is achieved at the expense of making generic drugs available to the poor in other countries. [322] Sampath further shows that exports comprise less than five percent of the total production of even the largest Bangladesh pharmaceutical company. [322] This limited approach provides insufficient incentive for pharmaceutical manufacturers to invest strategically in acquiring the skills to reverse engineer active pharmaceutical ingredients.

What is interesting about the issues facing Bangladesh is that they differ from those of other least developed countries. Sampath's article suggests that reorienting the country's policy framework to balance local innovation with greater incentives to export will enable Bangladesh to take full advantage of TRIPS flexibilities in the near future.

South Africa

Heinz Klug, a law professor, former chairperson of the ANC Constitutional Committee and temporary advisor to the WTO on legal issues regarding access to medicines, writes the chapter on South Africa. Klug relies on his first-hand knowledge and experience as a legal and political advisor in South Africa to assess the country's demand for medicines.

According to Klug, one of two approaches dominates South Africa's demand for essential medicines. First, there is the traditional economic concept of demand, which focuses on the marketplace and the economic value of the different sectors. [44] Second, there is the human rights approach, which

focuses on the demand from multiple viewpoints, including the imposition of legal duties or constitutional recognition. [44] Klug points out that while the human rights demand for affordable medicines has driven the public debate, he is doubtful that those strategies will produce a long-lasting resolution to the problem of affordable medicines. Klug also is skeptical that international approaches, such as the Doha Declaration, will provide an effective long-term remedy. According to Klug, dissatisfaction with these approaches has led to a new phase of legal activity within South Africa. [45]

Klug devotes a sizable portion of his article to discussing several legal cases that demonstrate this new approach. In doing so, Klug presents case analysis in a manner that is easily grasped by lawyers and non-lawyers alike. One such example is his description of a complaint the Treatment Action Committee (TAC) brought before South Africa's Competitive Commission. The TAC alleged that a number of pharmaceutical companies colluded in maintaining artificially high prices for particular medicines. The commission agreed and found the companies guilty of price fixing and collusion. [46] The companies ultimately reached an out-of-court settlement with the government, which included granting at least three generic manufacturers voluntary licenses on three major HIV/AIDS-related antiretrovirals. Because of this legal action, there was a major shift in the power dynamics in the South African access-to-medicine debate. [46] Unlike approaches taken by other countries, South Africa has used the legal system to make notable advances in its quest for broader access to medicines.

CONCLUSION

In many ways, how intellectual property rights, TRIPS, and TRIPS-Plus agreements will affect developing countries access to medicines will turn on how countries exploit the policy options in the new global environment. These two books address those challenges in different ways. For readers interested in a substantive, empirically-supported discussion on the latest intellectual property mechanisms shaping the access to medicine debate, Bouchard's book is a well-written choice. For readers looking to delve into issues that are at the heart of several different countries' struggle to conform their health systems, economy, and pharmaceutical sectors to the TRIPS regime, Shadlen's book is a must read.