

Our Health in the Balance: Cheap drugs now or better drugs later?

Review Of: Intellectual Property and Health Technologies: Balancing Innovation and the Public's Health

By: Joanna T. Brougher
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To provide the greatest possible benefit to the public's health, patent law must strike the right balance between promoting innovation and increasing access to affordable medicines.¹

Joanne Brougher has structured her book, *Intellectual Property and Health Technologies: Balancing Innovation and the Public's Health*, as a rapid introduction to patent law and related issues impacting medical technology and the delivery of medicine. The book is pitched to a professional and academic audience that, while outside intellectual property law practice itself, is engaged in the related fields of biomedical research, the commercialization of medicines and medical devices, and the practice and business of medicine itself. Brougher seeks to outline the basics of current intellectual property law in the context of health technologies, and then goes on to develop a discussion of recent and contemporary issues and controversies arising from the intersection of patents and medicines. In the former she succeeds, in the latter she falls somewhat short.

¹ JOANNA T. BROUGHER, INTELLECTUAL PROPERTY AND HEALTH TECHNOLOGIES: BALANCING INNOVATION AND THE PUBLIC'S HEALTH, at vi (2013).

Joanna Brougher is a patent attorney and adjunct lecturer at the Harvard School of Public Health. While this book was being written, she served as in-house counsel for a small clinical-phase biotech with a platform based predominantly on monoclonal antibodies.

Brougher's book is divided into nine chapters, and while there is a general progression from basic background information to contemporary issues, it still reads as a series of nine essays on related topics. The book lacks a developed thesis because it is intended as an introduction to the topics covered. Nevertheless, the author repeatedly returns to the theme highlighted in the subtitle - the purported balance between the promotion of innovation and the improvement of public health. It opens with two concise chapters, the first offering a thumbnail sketch placing the U.S. patent system in the context of intellectual property as a whole, and then moving on to outline the requirements for obtaining a patent, together with an introduction to infringement, enforcement, and the defenses to infringement. Perhaps because the book is directed at "health technologies", Brougher then dives directly into some recent developments in U.S. jurisprudence concerning patentable subject matter that are of particular interest to the biomedical community. Chapter 3 outlines some of the background and case law concerning the patenting of genes, culminating in the U.S. Supreme Court's ruling in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,² holding that natural gene sequences are not patent eligible subject matter, but a trivial manipulation copying all the parts of the gene that actually code for protein produces a sequence that is eligible.³

Chapter 4 addresses patents for medical procedures, including a brief analysis of *Bilski v. Kappos*⁴ and the important 2012 *Mayo Collaborative Services vs. Prometheus Laboratories*,

² *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013).

³ *Id.* at 2119.

⁴ *Bilski v. Kappos*, 130 S.Ct. 3218 (2010).

*Inc.*⁵ ruling. *Myriad* concerned patent claims for genes as well as procedures for testing for defects in them, and is thus revisited from the diagnostic perspective in Chapter 4, which is where some of the flaws in this book become apparent. While the Chapter 3 discussion of *Myriad* follows the issue to its second and concluding appearance on the docket of the Supreme Court, the Chapter 4 discussion, perhaps drafted earlier, leaves *Myriad* after the Federal Circuit had ruled for the second time⁶ (on remand from the Supreme Court) but confusingly leaves the narrative hanging at that point.

At this point the book again changes tack and reverts to a more general discussion of the role of federally funded researchers in the innovation and translation of knowledge, with the fifth chapter reviewing how the Bayh-Dole Act⁷ seeks to incentivize universities and their academic researchers to patent and commercialize inventions arising from government supported research. This essay would provide a useful primer for junior faculty wrestling with the intellectual property implications of their research, or indeed for those, especially in start-ups, who might license and commercialize intellectual property from universities.

Chapter 6 is an excellent chapter that introduces the reader to issues concerning patents protecting products that are licensed by the Food and Drug Administration (FDA). As the pre-market development period for most drugs consumes a good proportion of any patent exclusivity term, Congress has enacted special rules for drugs. These rules provide for patent term extension under certain conditions and, in addition, for non-patent exclusivity achieved by FDA commitments to withhold marketing authorization from competitor products over periods that

⁵ *Mayo Collaborative Services vs. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012).

⁶ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303 (2012).

⁷ *University and Small Business Patent Procedures Act of 1980 (The Bayh-Dole Act)*, 35 U.S.C. §§ 200-212 (2006). See also *Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 2188 (2011) (noting both the official and common names of the Act).

can exceed the patent term. The exercise of these mechanisms is of tremendous economic significance to those producing, buying, and regulating the sale of drugs. Brougher provides a concise introduction to the main issues before segueing into a further chapter that addresses the important Hatch-Waxman⁸ provisions that govern the orderly transition from drug monopoly to competition. These provisions incentivize the first competitor to achieve licensure for a competing drug, and create a safe haven for generic drug manufacturers to exploit patented materials for the purposes of pre-market regulatory activities required to ensure that generic drugs are ready to enter the market when the last of the various exclusivities expires for the innovator drug.

Unfortunately, many of the most important and innovative drugs today- including nearly everything produced as a result of the biotechnology revolution- are licensed as biologics⁹ and thus, unlike small molecule drugs, were never covered by the Hatch-Waxman Act. Brougher's penultimate chapter describes how the 2010 Biologics Price Competition and Innovation Act (BPCIA)¹⁰ creates a pathway to license so called 'biosimilar' drugs, providing statutory exclusivity for innovator biologics as well as a Hatch-Waxman-like mechanism for managing the transition from monopoly to competition. As with the material covering gene patents and diagnostic methods, the biosimilar chapter addresses relatively recent events and controversies that, while remain unresolved today, have seen significant developments since the book was written.

⁸ The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁹ See 21 C.F.R. 600.3(h) (2014) (describing biologics as drugs that are grown in live organisms rather than made by synthetic chemistry).

¹⁰ Biologics Price Competition and Innovation Act of 2009 § 7002, 42 U.S.C. § 262 (Supp. V 2012).

Chapter 9 is largely unrelated to rest of the U.S.-centric book in that Brougher quickly reviews some international aspects of drug patenting with a nice introduction to the roles of the United Nations' World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), and the related Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). A single chapter is obviously inadequate to do justice to the sociopolitical complexities of managing the balance between innovation and access to medicines in a world with such marked disparities in technological development, national income, and standards of healthcare. As a massively populous country hosting an advanced pharmaceutical industry supplying drugs to much of the world while its own population often lacks access to essential medicines, India is a fascinating intersection of these issues. Brougher provides some detail of the how the Indian patent system has sought its own balance in the interests of the Indian people - the world's largest democratic electorate.

Brougher is too sophisticated to reiterate the most simplistic liberal critique of the economics of healthcare technologies, i.e., that bad corporations, their attorneys, and government cronies sacrifice the health care interests of the people at the altar of "big pharma" profits, while totally ignoring the generation-on-generation benefits that biomedical innovation has delivered globally. Nevertheless, in analyzing the public health implications of statutes, economic actors, and key judgments, the author often returns to the theme that patients may have less than complete or optimal access to such technologies. Apart from her misgivings, no solution is really sought or proposed. This is perhaps because, as indicated in her subtitle, Brougher really feels that a balance between public health today and public health in the future requires some compromises. We hear a lot about legislators, regulators, judges, and corporations in this book,

but while Brougher points to the lack of substantive representation of the interests of today's patients, the issue is left unexplored.

Overall, this volume is bit of a mixed bag. As noted above, many of the chapters provide useful essays introducing drug patents and intellectual property aspects of development and commercialization in the United States. On the other hand, while the international issues of drug patenting are inescapable because it is impossible to prevent the flow of knowledge across national borders, drug patenting outside the U.S. is only addressed as an afterthought. In addition, the attempts to address "current" controversies are already somewhat outdated, and even the non-specialist reader would do better to read the many excellent blogs on these topics¹¹ - including some of the informative pieces that the author has posted herself.¹² While more a criticism of the publisher and editor than the author, the text is distractingly peppered with typographical and grammatical errors. The work is inconsistently referenced, mixing footnotes and endnotes, and varying between redundant serial citations to the same case and a total failure to cite a source for some of the more fascinating nuggets of information that had this reviewer reaching for Westlaw and Wikipedia to learn more. The price point is going to put this book beyond the range of the casual reader, student, or academic, but it will be a useful addition to academic or professional libraries, particularly for those in science and industry involved in drug development, or non-specialist counsel coming to these issues for the first time.

¹¹ See, e.g., Kurt R. Karst, *Stirring the Pot of AIA Alphabet Soup: Now that Hatch-Waxman IPR Challenges Are Passé, Are PTAB CBM Patent Challenges the Next Big Thing?*, FDA LAW BLOG (June 24, 2014), archived at <http://perma.cc/4U2P-CPE9> (exemplifying up-to-the-moment discussion of current developments in drug patent litigation in a format that is accessible to those working in law, science or industry).

¹² See, e.g., David Fazzolare & Joanna Brougher, *FDA Accepts First Biosimilar Application from Sandoz for Filgrastim Biosimilar*, BIOMEDINNOVATIONS BLOG (Aug. 12, 2014, 9:50 AM), archived at <http://perma.cc/C8W7-BU2P> (illustrating that topics covered in Brougher's book continue to move forward rapidly today).