

BOOK REVIEW

Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: Past, Present and Future*, 2nd ed. (World Scientific, 2009)

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Our so-called post-industrial society is one whose axial feature is the interaction between computer-driven digital and life science-driven bio-technologies. The primary legal mechanism that undergirds the allocation of rights in this new information-centred epoch is intellectual property. Perhaps only a few industrial sectors have benefitted more from the dynamics of that interaction than the pharmaceutical industry. Perhaps also, only a few industrial sectors have fully appreciated and optimally exploited the power of intellectual property than that sector. How did that happen? How has it continued to unfold, and what does the future hold for the continued co-evolution of life sciences, business and intellectual property regimes, especially patents? Find out, if you are inclined to, for whatever reason, by picking up a copy of this fascinating book.

This book was first published in 2003 under the title of *Intellectual Property Rights and Life Sciences Industries: A Twentieth Century History* by a different publisher. According to the author, the point of departure between the two editions lies with the change in subtitle. The focus of the present edition is, in part, on the exploration of “what it means to ‘invent’ in the life sciences, and how patent law in this area is shaped not only by economic interests, but also by highly contestable assumptions concerning life, science and the boundaries to be drawn between the natural and the human-made.”¹ Another point of departure between the two editions is the present edition’s more elaborate volume and its attempt, albeit without complete success, to exclude the agricultural sector from its analysis. While the basis for focusing the analysis in this book on the private industrial sector, and not the public sector, is appreciated, it does not seem that the author was able to sustain that difficult boundary.

The book is precisely structured to conform to its title. Divided into four parts, the first part (chapters 1-3) introduces the book. This section is quite unique to the extent that it seduces the reader upfront with a mouth-watering narrative akin to a case study, in its account of “seven tales of a patent” in chapter two. In a very

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¹ Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: Past, Present and Future*, 2d ed. (World Scientific, 2009) at 3.

creative historical, albeit in sometimes a seemingly anecdotal fashion, the author zeroes in on the narrative of the colour mauve (quinine/coal tar), aspirin, warfarin, streptomycin, tagamet, zantac and losec, polymerase chain reaction, and oncomice to underscore how diverse:

the ways that knowledge of some natural phenomenon or other having, or being made to have, a health-related or industrial application is first acquired then evolves into, or suddenly becomes one of the discoveries that can be patented irrespective of how incomplete or even erroneous the knowledge may be or whether the initial discovery was pure fluke or an accident waiting to happen once the right person comes along.²

Aside from underscoring the role of serendipity, rationality and even blissful ignorance in life sciences innovation, the “seven tales of a patent” also provides the foundation for understanding the roots of the modern pharmaceutical industry on dyestuff and chemical industries, a development in which the Germans had a pioneering head start over the rest of Europe and the United States. In chapter three, the author lays the maps for the interaction between pharmaceutical interest groups and the patent regulatory process. He taps into the theories of institutionalism and explores the schemes, including propaganda, framing, branding, corporate consolidations, forum selection, ever-greening etc. through which the pharmaceutical industrial interests and other pro-intellectual property organizations were able to influence the patent systems to achieve a friendly regulatory and interpretive capture of that system.

Part II (chapters 4-6) provides, in a more dedicated historical outlook, an account of the role of institutionalism in influencing the regulatory and interpretive capture of the patent system from the past. Using specific case studies, from aniline to indigo, and the interplay of corporate strategies and individual entrepreneurships, the author outlines the co-evolution of knowledge in both organic chemistry and life sciences.³ He notes that traditionally, many of the companies involved in these enterprises in Europe have been the heaviest users of the patent system, a system that has co-evolved with developments in innovations in those key industrial sectors. Germany’s head start in organic chemistry positioned it to lead the primary chemical and new industry of synthetic dyestuff, which was to branch off into different sectors including photochemical, perfumes and, most importantly, pharmaceuticals. A combination of several factors, not the least of which was the existence of a vibrant patent system, as in Germany, or lack thereof as in Switzerland, operated to give those two countries a competitive edge in the pre-war WW II era in Europe and, indeed, globally. This was an era in which, for the most part, America depended on Germany for its pharmaceutical supplies.

A combination of two factors was to launch America into the pharmaceutical industry. The first was WWII wherein reliance on Germany for pharmaceuticals was no longer feasible; hence a desperate America (as part of the allied forces)

² *Ibid.*, at 4-5.

³ He identifies life sciences industries as a reference to such industries involved in the “scientific abilities to isolate, purify, synthesise, modify, manipulate, and commercially exploit the molecular properties of microorganisms, plants, animals, including humans and other organic raw materials,” *ibid.*, at 59.

embarked ruthlessly on a strategy of pharmaceutical self-sufficiency, beginning with urgently needed antibiotics for the war injured. This would involve expropriation of German-owned US chemical patents. Before now, the US and most of Europe have accused the Germans of having an unfair monopoly of the chemical and pharmaceutical industrial sectors. The second factor was the emergence of biotechnology and the shifting of therapeutic interests from synthetics to chemicals found in humans and animals such as hormones. America's subsequent domination of antibiotics innovations and their ensuing markets as evident in such leading products such as penicillin, cephalosporin, etc. as well as that country's domination of natural product-based industries, especially those involved in the making of hormones and hormone-based products including insulin, adrenalin, cortisone, contraceptives, steroids, etc. launched American firms, and by extension the country, into an aggressive patent management strategy.

Coupled with its head start in biotechnology, and significant public sector research funding, America's domination of the pharmaceutical industry in the post WWII period was only to be expected. As part of that transformation, a pharmaceutical industrial interest group also evolved in America with a dedicated commitment to secure regulatory and interpretive capture in America's patent policy. Despite some counter initiatives that subjected the pharmaceutical industry to closer scrutiny, sometimes depicted as anti-patent movements by politicians and other stakeholders outside the industrial sector and on both sides of the Atlantic, the industry was able to navigate the big transition by securing patents on "life" through the life-as-chemistry analogy. The latter was the basis for patents in chemical and synthetic dyestuff industries. Nonetheless, by now, it was clear that other stakeholders, including generic drug makers, diverse NGOs and citizen groups have begun to pay attention to the cozy relationship between pharmaceutical industries and the patent systems in America and elsewhere.

In part III (chapters 7-11), the book focuses on the contemporary landscape of America's domination of pharmaceutical industry and the dynamic relationship between the big pharmaceutical companies, small start-up biotech firms, corporate and university or publicly funded research, and the patent system. Part III provides a narrative of contemporary developments in life sciences innovation from the landmark discovery of DNA, to the human genome project initiative, to specific developments in virtually all branches of biotechnology, including genetics, genomics, proteomics, etc. It highlights epochal scientific breakthroughs in biopharmaceuticals as well as other contentious developments in cloning technology, stem cell and generative medicine. The author draws a compelling link between these developments and the corresponding evolution in the American patent system as significantly espoused by the Supreme Court's decision in *Diamond v. Chakrabarty* that endorsed the extension of patents "to anything under the sun made by man." According to Dutfield:

The decision in *Diamond v. Chakrabarty* was the first success in the campaign by industry to clarify (and later to change) patents rules in the biotechnology field in ways that suited their interests. General Electric did not pursue this affair because the invention in question has commercial promise

but because the company was seeking to ensure that the barrier to patenting of microorganisms would henceforth be lifted.⁴

In a regional and sometimes country-by-country analysis, the author focuses on the European Union and four leading global pharmaceutical countries: US, UK, Germany and Switzerland, exploring how some restraints, in the last three countries, in regard to “patents on life,” or gene patents, could not sustain the pressures arising from America’s pro-patent and pro-industry disposition. Like in America, the pharmaceutical industry stakeholders in these countries were able to convince their national governments of the commonality and convergence of their corporate and national interest in regard to stronger patent protection. Even in the US, the initial reluctance of the USPTO towards biotechnology or related patents left that institution isolated, requiring a calculated retreat. Despite the overall precautionary approach in specific countries, the European Commission issued a Directive on Legal Protection of Biotechnological Inventions in 1989.

Notwithstanding the victory of pharmaceutical interest groups across the Atlantic in ensuring the evolution of patent law in their often selfish interest, their mismanagement of biotechnology patents, as reflected in US-based Myriad Genetics patents on breast cancer genes: BRAC1 and BRAC2, was perhaps what was required to fire up opposition to the “patent on life” in Europe and US. The company embarked on aggressive protection of its patents to ensure a brazen monopoly on breast cancer diagnostics; it “used its patent rights to have all of its rival testing programs closed down” in the US and attempted to have same done in Europe and Canada.⁵ The author notes that “it could be argued that the biggest danger to gene patenting in Europe was not Greenpeace, but ironically, Myriad Genetics.”⁶

The rest of this section maps out how the same domestic strategy, which the pharmaceutical industry interests used to secure regulatory and interpretative capture of US and European intellectual property, made its way to Geneva to influence the international intellectual property process toward a more global intellectual property standard under the WTO TRIPS Agreement. In a little departure from the extant European and US narrative, this section explores extensively the nature of the forum politics and counter regime dynamics and strategies in which the developing world engaged the US-led developed countries’ imposition of a stringent intellectual property order. The section provides a quick tour of strategic regimes including WTO, WIPO, CBD, and FAO, highlighting contentious points of tension (e.g. access and benefit sharing over genetic resources, disclosure of origin of such resources used in life science innovation) and resistance by developing countries on the development ramifications for a universal intellectual property framework for life sciences.

It is the author’s overall impression that, because patents are embedded in the world of science rather than that of commerce, in the pharmaceutical sector, the patent system has not translated to optimum impact for those most in need. He argues that “the key issue facing policy makers today is not whether or not to have a patent system, but how to build a patent system that meets certain objectives,

⁴ *Ibid.*, at 197.

⁵ *Ibid.*, at 225-226.

⁶ *Ibid.*, at 228.

among which are how to build the health of the population while establishing or maintaining an innovative and wealth-generating pharmaceutical industry.”⁷

In the final chapter of this part, the author poses and reflects on the question: “Would we have got where we are today without patents?” He recognizes that the analytical tool to address this question is not available. He contends that the best we can do is to speculate. But he counsels that we must be fully aware of the limits of an economic analysis of the patents system that does not seem to account for the possibilities of a world without patents. As that world is not possible at the moment, “[t]he best we can do is reduce the built-in inequities and imbalances”⁸ in the patent system.

Part IV concludes with the author’s reflection on the future of patents and the life sciences industry, a reflection, he argues, that ought to be informed by the past and present trend in the co-evolution of intellectual property rights in the life sciences already explored. The author anchors his reflection on the 2007 European Patent Office perspective on how the future patent regime would evolve, which it identifies as a competition between “market rules — a [future] where business is the dominant driver, whose game? — a [future] where geopolitics is the dominant driver, trees of knowledge — a [future] where society is the dominant driver, and blue skies — a [future] where technology is the dominant driver.”⁹

Dutfield contends that the main issue is not which of these scenarios is most plausible, and notes that they are hardly exhaustive or mutually exclusive. He is inclined to evaluate the relative similarity between each scenario in the context of patent regulation. He sees no future for patent harmonization, and notes there will be a shift in dominant players as well as in the innovation environment and, consequently, in business strategies. Public interest in intellectual property, he predicts, will increase both in the developed world and elsewhere. He concedes that progress in life sciences makes for tough prediction-making. Yet, he is confident that

[i]t will surely transform lives for the better. But we cannot be sure exactly how and what downsides there would be. Tremendous wealth will be generated by science but it is far from certain that human society would be culturally, spiritually, or politically better off or freer, or that the material fruits of science will reach all mankind and not be monopolized by a lucky few.¹⁰

Two important features of this book are its accessibility and its balanced analysis. Rarely are subjects as esoteric and often as passionate as patent, especially in the context of the equally esoteric and often passionate narrative of convergences in life science disciplines and pharmaceutical research and development rendered readily accessible to the uninitiated in a balanced way.¹¹ The book contains an incredible amount of scientific and historical information compressed in very smooth

⁷ *Ibid.*, at 320.

⁸ *Ibid.*, at 336.

⁹ *Ibid.*, at 353-354.

¹⁰ *Ibid.*, at 359.

¹¹ The author notes that “a reviewer of the first edition [of this book], an employee of a well-known Swiss life science corporation, criticized it for being ‘a patently negative view of industry’”, *ibid.*, at 3. This reviewer does not share this view, certainly not in regard to the present edition.

flowing prose. The author is arguably one of the most prolific intellectual property scholars on a global scale, and has written on diverse aspects of intellectual property law and policy. His masterful handling of the subject matter(s) of this book, and his ease in navigating all the disciplinary intersections in the history of science and life sciences, law, and pharmacology demonstrates the depth of his expertise in the field. In this reviewer's opinion, this book is compelling reference material in diverse disciplines within its ambit, and could be relied upon by a cross section of professionals, researchers, entrepreneurs, policy makers and diverse stakeholders interested in the complex and yet evolving relationship between patents and the life sciences industries.