# The IP Law Book Review

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## JUSTIFYING INTELLECTUAL PROPERTY, by Robert P. Merges

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PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED WORLD: LIBER AMICORUM JOSEPH STRAUS, edited by Wolrad Prinz zu Waldeck und Pyrmont, Martin J. Adelman, Robert Brauneis, Josef Drexl and Ralph Nack

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PROPERTY OUTLAWS: HOW SQUATTERS, PIRATES, AND PROTESTERS IMPROVE THE LAW OF OWNERSHIP, by Eduardo Moisés Peñalver and Sonia K. Katyal Reviewed by Ann Bartow Pace Law School

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JUSTIFYING INTELLECTUAL PROPERTY, by Robert P. Merges. Harvard University Press, 2011. 422 pp. Hardback \$59.95.

Reviewed by Amy L. Landers, Pacific McGeorge School of Law. alanders@pacific.edu

Robert Merges' scholarship has a continuing and significant influence on intellectual property law. As the saying goes, the author's reputation precedes him. THE COMPLEX ECONOMICS OF PATENT SCOPE, coauthored by Merges, is responsible for insight into patent law and the encouragement of invention. His ongoing work in the field of intellectual property law has been widely influential.

In JUSTIFYING INTELLECTUAL PROPERTY, Merges considers concepts that are extraordinarily complex and controversial. As Merges' earlier writing recognizes, the current intellectual property system relies primarily on utilitarian justifications.<sup>2</sup> As another leading work authoritatively states, "[t]oday it is acknowledged that analysis and evaluation of intellectual property law are appropriately conducted within an economic framework that seeks to align that law with the dictates of economic efficiency."<sup>3</sup> In its broadest form, the intellectual property system has been supported by the incentive story—that is, legal protection provides incentives to invest in the creation of new works that ultimately inure to the benefit of the public.

In a departure from this framework, JUSTIFYING INTELLECTUAL PROPERTY omits nearly all discussion of utilitarianism.<sup>4</sup> Rather, Merges introduces the book with an unequivocal rejection of this basis as a sufficient foundational justification for IP law, explaining that "[t]he empty promises and ethical holes in the utilitarian theory of IP are just too glaring" (p.83). In its stead, Merges draws on legal philosophers John Locke, Immanuel Kant, and John Rawls to support the book's central proposition that "IP law deserves a place in a just and rational modern

state" (p.196). According to Merges, the principle justification for IP law is the individual creator (p.72).

JUSTIFYING INTELLECTUAL PROPERTY is a rich and thoughtful work that raises important questions. Merges considers the selected legal theorists with depth and clarity. Difficult concepts are handled with thoroughness and subtlety. A number of the propositions are undoubtedly provocative. By placing the primary emphasis on the creator, the book seeks to move the focus of the IP system to one that, at an operational level, inures to the benefit of a professional creative class. This work emphasizes that intellectual property is a property right that allows creators to control who may use the work, and—if used—to specify the terms (p.242).

In doing so, Merges neatly solves certain problems associated with the current IP system. Nevertheless, it is a rare case that one can attempt to move a system's foundations without creating disruption. By advocating strong property rights in IP, JUSTIFYING INTELLECTUAL PROPERTY asserts a number of challenging propositions about a system that some currently regard as too powerful.

In JUSTIFYING INTELLECTUAL PROPERTY, Merges expands on his prior work in Lockean theory<sup>5</sup> by advancing that the expenditure of labor justifies appropriation through the mechanism of intellectual property rights. Merges explains that Locke's TWO TREATISES OF GOVERNMENT demonstrates that the effort expended through the work of one's body allows one to legitimately claim ownership to creations assembled from the public domain (p.35). To place this claim in context, Merges explains that IP fits within Locke's overarching goal toward human flourishing (p.41). That is, Merges uses Locke's labor theory to support the book's central thesis that IP is justified as a property right. As Merges explains, "[c]rowning this labor with property serves two ends: it honors the effort involved and calls forth more of it" (p.38).

One controversial aspect of the book considers that Locke's property theory translates to intangibles. As Merges explains, "Locke's ideas work perfectly well in the context of creative work, so long as we picture removal not as something literal and physical, but as something arising from a necessary convention or shared understanding" (p.39). Among other support, Merges cites Locke's AN ESSAY CONCERNING HUMAN UNDERSTANDING ("ESSAY") that describes Locke's own work as that of "an Under-Labourer in clearing Ground a little, and removing some of the Rubbish, that lies in the way of Knowledge."

Certainly Locke's justification for property, and ultimately government, is stated in terms of tangibles and the labor of the body. As Justin Hughes has recognized, "it is not always clear that the creation of an idea involves labor" as Locke used that term. One plausible reading of Locke's description of himself as an Under-Labourer is that this image operates as a metaphor rather than a belief. That is, Locke's reference may have been a modest attempt to contrast his writing as the effort of an "Under-Labourer" with the work of "master-builders, whose mighty designs, in advancing the sciences, will leave lasting monuments to the admiration of posterity," citing the work of physicist Isaac Newton and mathematician Christiaan Huygens. 8

One can identify from Locke's ESSAY that he perceived a clear distinction between mental and physical acts. As one example, Locke describes "invention" as the mental creation of a complex idea that is the "voluntary putting together of several simple ideas in our own minds; so he that first invented printing, or etching, had an idea of it in his mind, before it ever existed." This quote suggests, and it is implicit throughout Locke's ESSAY, that man creates the intangible in the mind and appropriates or manipulates tangible objects with the body. According to Locke's ESSAY, one's mind is one's soul and responsible for the exercise of liberty. Given Locke's reverence for the mind, one might query whether Locke would have considered ideas as property without fuller discussion.

Regarding Kant, Merges explains that the legal concept of property is necessary for creators to have access and control over objects in order to exercise the full extent of their autonomy (p.72). According to the book, "[f]reedom to appropriate is so basic, so tied to matters of individual will and personal choice, that Kant finds it unthinkable to rule out large categories of things from the domain of the potential ownable" (p.72). Acknowledging that the application of this author-centric view will be "jarring" to some readers, Merges argues that a property label for IP is consistent with Kant's idea of a free rational will if one views creativity as a choice to carry out a work (pp.75, 79). Pushing against the trend in recent scholarship that recognizes the significant influence of social and cultural forces on creativity. Merges relies on Kant to shift the emphasis back onto the creator. In this vein, he explains that a creator's work inspires others: "Like a many-sided flint, sparks fly off a work of genius, igniting other minds, other individual creators, who are inspired to stretch themselves and thereby reach their potential" (p.92).

Next, Merges considers Rawls' A THEORY OF JUSTICE to conclude that those in the original position<sup>12</sup> would have categorized IP as a basic right despite the fact that its benefits fall disproportionally on creative professionals (p.110-11). JUSTIFYING INTELLECTUAL PROPERTY finds that those wishing to live in a society that fosters an autonomous and creative citizenry would have chosen IP as a basic right (p.112). Just as Rawls rejected a utilitarian conception, Merges similarly finds that those considering IP in the Rawlsian state are "not required to maximize social welfare with respect to their 'productive decisions'" (p.111). In essence, Merges considers creativity as an act of liberty due to its relation to the individual and one's autonomy (p.117).

Even if one does not accept that IP would be considered a basic right, JUSTIFYING INTELLECTUAL PROPERTY concludes that IP would not violate Locke's second principle of justice. 13 To demonstrate this point, Merges describes that the majority—a core—of every work derives from an individual's talent, vision, and will. This viewpoint holds that society's interest derives solely from inputs beyond the creator and sits at the periphery of the right. According to Merges, societal claims—such as those that seek costless redistribution—derive from this periphery (p.122-23). According to this account, this value is redistributed fairly in return for society's contribution in the form of, as some examples, access to the work after the right expires, benefits that derive from the existence of the work, and through taxation of IP-protected works. In contrast, the creative core of a work—the individual's contribution—supports what Merges describes as an "ineluctable property" claim, an "inviolate property right," and an "immovable substrate" (pp.122-23). Merges explains that this core derives from the Rawlsian concept of desert, which represents a legitimate claim to an entitlement. 14

For Merges, reliance on Locke, Kant, and Rawls demonstrates that intellectual property derives from an act of human creativity that arises from an individual's "attention, effort, and personal vision" (p.114). Each philosopher brings individual support for Merges' claim that IP has a central role in a society (p.305). Through this lens, classic utilitarian concerns, such as the burdens that such rights place on society, can be expected to recede in importance.

Given that Merges accepts that agreement with IP's foundational principles is unlikely to coalesce, he writes that policy discourse should remain on the midlevel principles of the law (pp.144-45). These midlevel principles include nonremoval, proportionality, efficiency, and dignity, with the fullest treatment in the book given to proportionality and dignity.

Because midlevel principles derive from the study of the detailed rules applied in practice, Merges finds that such principles do not depend on any particular foundational theories for their validity (p.140). As Merges explains, at the midlevel "[t]he conversation is more productive—and a lot more civil!—than it would be if participants tried to conduct it at the ultimate normative level" (p.144). Merges likens these points of discussion to the "Midelevel Bar and Grille,"—a place where there may be ample disagreement but a common vocabulary (p.141).

Perhaps, as Merges suggests, the Midelevel Bar and Grille is an excellent starting point for policy discussion. Nonetheless, foundations have a way of impacting policy and, ultimately, the real world. As one example, Merges' foundational focus on creators reverberates through his later discussions preferencing the contributions of creative professionals at the midlevel. This suggests that the lines between these layers are quite permeable and that therefore discourse cannot be so easily confined. Engaged consideration of foundational principles might be civil, could be useful, and is likely to be inevitable.

Intellectual property is rife with pressure points. Are there limitations that can relieve them? JUSTIFYING INTELLECTUAL PROPERTY notes several—antitrust, misuse, the First Amendment, and other limitations built into current law. Perhaps one of most fascinating parts of the book is an eloquent application of the principles of proportionality to contextualize the U.S. Supreme Court's decision in eBay v. MercExchange. 15 Applying the principle that the right should be proportional to the value or significance of the work, JUSTIFYING INTELLECTUAL PROPERTY explains that eBay stands for the rule that injunctions should not confer excessive leverage to intellectual property rights holders (p.166-67). In Merges' view, proportionality permits the limited government modification of a holder's property right and operates as a useful analytic tool for examining important questions that arise in IP. As he observes, "[i]t is hard to defend a legal system that permits grossly distorted transactions" (p.190).

How far can such exceptions go? According to Merges, not as far as others might have it. As he explains, "[t]his freedom to either waive one's rights entirely, or else hold onto them for purposes of economic exploitation or simple aesthetic preference, is what property is all about" (p. 228). As one example, JUSTIFYING INTELLECTUAL PROPERTY rejects the position that copyright in the digital realm should be subject to liability rules and a system of compulsory licensing. Rather, Merges reiterates that digital copyright should be treated as a property right

subject to the waiver and consent of rights holders (pp.249-55). Further, Merges argues that re-mixers should not obtain significant leeway under fair use because doing so might prevent a market for the use of portions of musical works from ever developing (pp.251-54). Given the technological shift that has occurred for digital works, Merges predicts that, "IP rights may have to be strengthened for those rights to continue their traditional function of adequately rewarding hard-working creators" (p.250).

This review's description of the limits of IP explored in the book is not complete. Further, as Merges suggests, the problems that are presented to the IP system are difficult, complex and in a state of flux. The strength of IP rights, *eBay*, waiver, and limitations at the boundaries are critical issues. Moreover, how these doctrines interact appears to be as important as each one individually.

Certainly, the line between IP rights and allowable use cannot be drawn with precision. It is also an extremely significant point of contention. The need for access to informational inputs for new works is an issue that touches far more than remix culture. An alternative viewpoint might hold that the ecosystem that contributes to outcomes includes more than creators, and some of those inputs can be central to a work's existence. In other words, even if one accepts that creators are entirely necessary to a work, individuals are rarely sufficient. Moreover, even talented creative professionals can be stymied by other's strong property rights.<sup>18</sup> Although JUSTIFYING INTELLECTUAL PROPERTY makes a fascinating case, the principle that IP must be treated as a property right to accomplish a creator's goals is a challenging proposition.<sup>19</sup> As JUSTIFYING INTELLECTUAL **PROPERTY** recognizes. the contributions of earlier creators are inspirational to those who create later—that is, "genius awakens another genius" (p.92). That vibrant image can conform to IP law only if relatively firm lines can be identified and maintained as the creative process engages. It seems instructive that a number of high technology industries arose in the absence of IP enforcement, or in areas in which IP law created safe harbors.<sup>20</sup> This suggests that compartmentalization between inspiration and use of another's work is difficult to maintain, and not uniformly productive.

As for individual creators, the central message of JUSTIFYING INTELLECTUAL PROPERTY goes far toward dissolving the misconception that creative work is generated through the intervention of inspiration, genius, or otherwise inexplicable phenomena. Instead, Merges' archetypical creator is J.K. Rowling, who created the Harry Potter series based on "individual will and commitment" (p.134). Under

this view, one who undertakes the hard work to develop a piece earns the right to control it.

JUSTIFYING INTELLECTUAL PROPERTY does not claim that IP law must advance all creativity. Rather, the book favors particular sources of expression—that is, those that derive from a creative professional class. According to Merges, professional creators bring the world value in the form of "cultural icons and shared touchstones" (p.233). To Merges, the principle of autonomy and the pursuit of profit create no inconsistency. JUSTIFYING INTELLECTUAL **PROPERTY** examines organizations, small entities, and individuals as potential sources of creative output. Of these, the work emphasizes individual professionals and small scale organizations as the primary sources of groundbreaking work. Against this background, the work claims that strong IP protection should operate to enable professionals to earn a living. As it states, "the care and feeding of this class is an essential—maybe the essential function of the IP system" (p.247). In part, this argument pushes against the arguments made for less intrusive IP rights to facilitate the democratization of culture geared to enable amateurs to create secondorder works (p.245). The reasons are two-fold: first, because "[p]rofessionals and the high-quality work they do are still crucial to the industries that rely on IP rights;" and second, "solid respect for IP rights is also the most flexible and accommodating policy, one capable of supporting a thriving bottom-up cultural movement as well" (p.196).

Certainly shared culture existed long before IP law and continues to exist outside of it. Further, as a universally present characteristic in everyone, creativity exists in many forms. <sup>21</sup> JUSTIFYING INTELLECTUAL PROPERTY'S prioritization of economically significant works leaves the student, amateur, and the average citizen out of the core creativity calculus.

Merges acknowledges that an approach favoring the creative professional "may be uncomfortable for some" (p.247). As the book finds that foundational principles derive from autonomy and effort, exceptional treatment of commercially significant works does give one pause. Perhaps privileging economically relevant works represents an effort toward carving out areas in which IP can be implemented more moderately. If so, preferences for the determination of ownership, validity, and enforcement would most strongly inure to those that Merges argues represent the central purposes of IP. Presumably, this would allow a vibrant community of information sharing among non-professionals. On the other hand, counter-cultural and amateur works may share many of the humanly

expressive elements of the type described by Locke, Kant, and Rawls. In some cases, perhaps more so.

In AN ESSAY CONCERNING HUMAN UNDERSTANDING, Locke asserts that "[i]deas thus made up of several simple ones put together, I call Complex; such as are Beauty, Gratitude, a Man, an Army, the Universe." Intellectual property theory, although made of smaller components, is similarly rife with complex (and frequently moving) parts. Certainly, this brief overview cannot hope to capture all of the complexity of Merges' JUSTIFYING INTELLECTUAL PROPERTY. Merges adds to his influential body of scholarship by adopting foundational principles that focus on the author, the creator, and the designer to support the legal institution of intellectual property. Virtually every page includes rich and cross-referenced dialogue. The work examines layers of theory, which are then applied to specific problems.

The work can be expected to trigger debate and discussion. As it describes (and a review of the scholarly literature confirms), there are propositions in the book that are not part of any universal consensus. Perhaps, as Rawls suggests, judgments are best made after consideration of all possibilities and examination of their support from relevant philosophical argument.<sup>23</sup> For its part, JUSTIFYING INTELLECTUAL PROPERTY makes a clear, thorough and interesting case for its theories.

#### **ENDNOTES**

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<sup>&</sup>lt;sup>1</sup> Robert P. Merges and Richard R. Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839 (1990).

<sup>&</sup>lt;sup>2</sup> See Robert P. Merges, Rent Control in the Patent District: Observations on The Grady-Alexander Thesis, 78 Va. L. Rev. 359 (1992) ("Intellectual property–especially patents–is a largely utilitarian discipline.").

<sup>&</sup>lt;sup>3</sup> William M. Landes and Richard A. Posner, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW, 4 (The Belknap Press of Harvard University Press, 2003).

<sup>&</sup>lt;sup>4</sup> There are roughly two pages that stand as the exceptions. Robert P. Merges, JUSTIFYING INTELLECTUAL PROPERTY, 46-47 (2011).

a. they are to be of the greatest benefit to the least-advantaged members of society (the difference principle).

<sup>&</sup>lt;sup>5</sup> Robert P. Merges, Locke Remixed ;-), 40 U.C. Davis L. Rev. 1259 (2007).

<sup>&</sup>lt;sup>6</sup> John Locke, AN ESSAY CONCERNING HUMAN UNDERSTANDING, Epistle to the Reader, 11 (Penguin Classics, 2004).

<sup>&</sup>lt;sup>7</sup> Justin Hughes, The Philosophy of Intellectual Property, 77 Geo. L.J. 287, 311 (1988).

<sup>&</sup>lt;sup>8</sup> Locke, supra note 6, at 11.

<sup>&</sup>lt;sup>9</sup> Id., at 265

<sup>&</sup>lt;sup>10</sup> Id. at 266 (distinguishing modes of the mind from those of the body, and describing "mixed modes" that include both).

<sup>11</sup> Id. at 223 ("the idea of liberty, is the idea of a power in any agent. . . according to the determination or thought of the mind"); id. at 231-32 ("To the question, what is it determines the will? The true and proper answer is, the mind."); id at 278 ("our idea of our soul, as an immaterial spirit, is of a substance that thinks"). Locke acknowledges that the exercise of liberty involves physical capability. Id. at 230 ("a man falling down a precipice, though in motion, is not at liberty because he cannot stop that motion, if he would.").

<sup>&</sup>lt;sup>12</sup> The original position is a hypothetical construct created by Rawls, which represents an initial status quo. In this position, decision makers must articulate principles for society as a whole. These principles include the manner in which fundamental rights will be determined, as well as the economic opportunities and social conditions for that society. Members in the original position operate as equal, but under a "veil of ignorance"—that is, these decision makers do not have any advance knowledge of their future place in society. John Rawls, A THEORY OF JUSTICE 11-19 (Revised Edition, The Belknap Press of Harvard University, 2003).

<sup>&</sup>lt;sup>13</sup> Rawls' second principle of justice holds that "Social and economic inequalities are to be arranged so that:

b. offices and positions must be open to everyone under conditions of fair equality of opportunity.

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<sup>&</sup>lt;sup>14</sup> Id. at 88 (explaining that those who "have done what the system announces it will reward are entitled to have their expectations met").

<sup>&</sup>lt;sup>15</sup> eBay v. MercExchange, 547 U.S. 388 (2006).

<sup>&</sup>lt;sup>16</sup> For a description of patent holdup, see Mark A. Lemley and Carl Shapiro, Patent Holdup and Royalty Stacking, 85 Tex. L. Rev. 1991 (2007).

<sup>&</sup>lt;sup>17</sup> Merges refers in general terms to the work of Lawrence Lessig, William Fisher and others as representative of this view (p. 228).

<sup>&</sup>lt;sup>18</sup> See Marjorie Heins and Tricia Beckles, Will Fair Use Survive? Free Expression in the Age of Copyright Control (Brennan Center for Justice, 2005).

<sup>&</sup>lt;sup>19</sup> See James Bessen and Michael J. Meuer, PATENT FAILURE: HOW JUDGES, BUREAUCRATS AND LAWYERS PUT INNOVATION AT RISK, 93 (Princeton University Press, 2008) ("'Property' is not a ritual incantation that blesses the anointed with the fruits of innovation....").

<sup>&</sup>lt;sup>20</sup> See Mark A. Lemley, Patenting Nanotechnology, 58 Stan. L. Rev. 601, 606-14 (2005) (observing that computer hardware, software, the Internet, biotechnology and other industries developed in the absence of significant patent enforcement); Thomas Rogers, et al., FAIR USE IN THE U.S. ECONOMY: ECONOMIC CONTRIBUTION OF INDUSTRIES RELYING ON FAIR USE (Computer and Communications Industry Association, 2007) (detailing the economic contribution of industries that rely on fair use and safe harbors).

<sup>&</sup>lt;sup>21</sup> James C. Kaufman & Ronald A. Beghetto, Beyond Big and Little: The Four C Model of Creativity, 13 Rev. of Gen. Psych. 1-12 (2009).

<sup>&</sup>lt;sup>22</sup> Locke, supra note 6 at 159.

<sup>&</sup>lt;sup>23</sup> Rawls, supra note 12 at 42-43.

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INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT: THE ROLE OF NGOS AND SOCIAL MOVEMENTS, by Duncan Matthews. Edward Elgar, 2011. 286 pp. Hardback \$125.00.

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Non-governmental organizations (NGOs) fall within the diffuse family of the "non-", including non-state actors more broadly. As observed astutely, "[a]ny attempt to define NGOs in positive rather than negative terms is problematic, beyond the observation that they tend to be private citizens' groups established to further certain common objectives of their members. The objectives pursued by NGOs differ considerably." Neither market nor state, the third space inhabited by these types of organizations defies attempts at positive articulation, at least within the state-centric rubrics of international law or international relations.

This famously amorphous negative domain thus requires further specification, if only to make better sense of its many moving parts. In his book, INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT: THE ROLE OF NGOS AND SOCIAL MOVEMENTS, Duncan Matthews, a Professor of Intellectual Property Law at Queen Mary, University of London, achieves this necessary particularity by exploring the impact of NGOs within global intellectual property (IP) regimes. Further narrowing the inquiry, he focuses on "public action NGOs" engaging in "non-governmental public action by, and on behalf, of disadvantaged people and [their] impact . . . in reducing poverty and exclusion" (p.11). In examining this subset of NGO activity, he employs three additional analytical frames: (1) the specific IP domain of public health, contrasted with agriculture, genetic resources, and traditional knowledge (AGRTK); (2) the relationship of these two distinct IP regimes

to the typically separate legal domains of human rights and/or development; and (3) the impact of the relevant NGOs within developing as well as industrialized states. This last dimension means that this book is the culmination of an ambitious comparative methodological inquiry—covering different perspectives not just between NGOs located in the global North and South, but also among emerging economies that have been major norm generators through their international as well as domestic IP initiatives.

About a decade ago, the UK Commission on Intellectual Property Rights (CIPR) issued a ground-breaking report on the interplay between IP, human rights and development.<sup>3</sup> Chaired by the late John H. Barton, an American IP scholar, the CIPR analyzed the existing global intellectual property legal regimes from the perspective of their impact on lesser advantaged states and populations. It attempted to bridge the gap between the current instrumental and utilitarian emphasis within IP discourse and the universal, natural rights-inflected language of human rights<sup>4</sup> and, in this regard, noted the contributions of NGOs. In this study, Matthews goes far beyond a mere nod to these efforts. Front and center of this book are NGOs operating not only within Geneva-based international IP norm-setting as it relates to human rights and development, but also within various national contexts within selected developing countries.

Matthews makes several distinct contributions to the existing literature on the role of NGOs in global governance. His sustained focus on public interest NGOs adds much-needed depth to the growing literature on NGOs generally. He explores the reasons underlying differences among NGO strategies within three developing countries: South Africa, Brazil and India. These case studies also provide a common platform for further elaboration of and support for two widely acknowledged network organization approaches to this area: coalition-building and framing theories (pp.5-9). And in the course of providing all of the above, Matthews also accomplishes one important (although possibly thankless) task: he provides a clear and concise descriptive summary of relevant treaty frameworks and other legal provisions for both IP and human rights.

Each of the book's strengths is significant. It is truly an achievement to have simultaneously navigated so many analytical vectors and technical intricacies demanded by IP. Yet although descriptively and analytically successful, the book is perhaps insufficiently critical of its normative implications. This suggests that a network organization approach to NGOs may be in need of complementary theories or further development on its own. Reviewing this book provides signposts for additional possible lines

of theoretical elaboration useful for the study of all transnational non-state actors, including the public action NGOs scrutinized here.

Liberally sprinkled throughout this book are sidebars containing excerpts of significant primary source material. Chapters on public health (Chapter 2), AGRTK (Chapter 3) and human rights (Chapter 7) can stand alone as reference tools for these legally and technically challenging areas. The area of AGRTK can be especially arcane and baroque, consisting of overlapping multiple IP global regimes such as breeder's rights and protection of plant genetic resources by patent or *sui generis* laws. In addition to these IP regimes, AGRTK is governed by environmental and biosafety regimes, not to mention the food security, poverty reduction and sustainability aspects that are critical to any development focus (pp.52-91).<sup>6</sup> The book easily clarifies and summarizes these different domains, and moreover provides a short historical overview of each.

Matthews includes an abundance of material on developing country NGOs in addition to the more accessible international NGOs based in various sectors of the global North. With the assistance of Viviana Muñoz Tellez, who is currently a Geneva-based policymaker, he participated in "over 60 interviews with representatives of NGOs, broader social movements, indigenous communities, and local communities in developing countries," as well as their counterparts in industrialized countries (pp.7-8). The resulting narratives resist essentializing the "South" or "developing countries" as one monolithic bloc with indistinguishable histories and motives.

In the public health arena, for example, Matthews describes how South Africa's government was pressured by NGOs with roots in the previous anti-apartheid and gay rights movements, which then turned their efforts towards a campaign for access to affordable medicines by "[s]eeking recourse to the human rights principles enshrined in the South African Constitution" (p.103). By contrast, Brazil's emergence from dictatorship in the mid-80s as a result of social movements for democracy led to its establishment of a universal health care system, including a commitment to access to affordable medicines. One consequence is that by the mid-90s, Brazil was one of a handful of countries with a policy of universal access to anti-retroviral treatment for HIV/AIDS (pp.125-30). However, this policy eventually collided with the patent protection mandated by TRIPs Article 27, which sets forth that "patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology." To implement its obligations under TRIPS, Brazil introduced protection for pharmaceuticals, an area that was previously unprotected (p.129), 10 along with compulsory licensing provisions to balance the stronger patent protection (p.130). The role of Brazilian NGOs co-evolved with the government's strong commitment to public health. While local NGOs had a less prominent role than their South African counterparts in addressing the initial policy conflicts between patents and public health, they (like the South Africans) began to mobilize in response to U.S. challenges to these compulsory licensing provisions and, in doing so, relied on the language of human rights contained within the Brazilian constitution (pp.133-34).

India's colonial legacy led to a commitment by its government in 1970 to exclude from patent protection essential goods such as pharmaceuticals (p.164). Like Brazil, the Indian government was obligated to modify this approach in the mid-90s in response to TRIPS. It then collaborated with an expert panel—not exactly a NGO, but still a non-state actor in the form of the aptly named National Working Group on Patent Laws (p.166), which in turn became an institutional locus for public debate on the conflict between patents and public health. This non-state institution influenced Indian Supreme Court rulings by pointing out, *inter alia*, that the new obligations with respect to patent law could conflict with the Indian constitutional provision on the right to life (p.167).

Through these and other case studies, Matthews points to both similar and different catalysts for social movements cohering into NGO activity. In all three countries, for example, NGOs were mobilized by the TRIPS Agreement's insistence on patent protection for pharmaceuticals as well as the right to health recognized by their respective constitutions. They also all fulfilled a need for advocacy and assistance in technical subject matter that may not be easily understood by civil society. But these NGOs also had differing roles vis-à-vis their governments, based on specific cultural, political and historical contexts. In weaving together these comparative approaches to public health and IP, Matthews also gives brief but critical background to important IP and development disputes, at both international and national levels. Most of the legal literature focuses on the former, especially the work of NGOs around the Development Agenda in the World Intellectual Property Organization (WIPO). Of course, Matthews discusses the Development Agenda (pp.248-50), but does not limit himself to this obvious international initiative by developing countries.

The primary theoretical framework of this book is fairly straightforward: Matthews claims that coalitions between NGOs and developing countries "may provide a counterweight to the traditionally close relationship between industry groups and developed countries...." (p.6). He also relies on what he calls the "corollary" to coalition-building theory: "framing"

(pp.7-8). Using the language of human rights, for instance, NGOs were able to re-frame the property-oriented, technical and economically instrumental language of IP favored by industrialized blocs into a more public interest-oriented and less parochial discourse—one that substantively impacted IP law and policy-making by and within developing countries. The result is that IP is now connected more explicitly not just to human rights regimes but also to the production of other public goods such as global public health and environmental sustainability.

The book provides much evidence to support the use of both coalitionbuilding and framing as two critical tools used to turn IP towards a larger horizon of public interest goals. In the area of farmers' rights, for example, Matthews traces the important influences of international NGOs on UN-led initiatives in the area of food security through the language of "farmers' rights," which includes, among other things, the "right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture" and "the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture" (pp.60, 74-84). On a domestic level in India, the sustained activity of NGOs resulted in a decision by the Indian government to implement a *sui generis* system rather than a patent system for protection of plant genetic resources—no small victory (p.195). The normative core of Matthews' comparative approach is an implicit commitment towards greater involvement by civil society within the often faceless machinations of global law and policy-making. NGOs may not have the ability to make treaties but, in partnership with states, they can affect public norm-setting, interpretation and implementation. The book is replete with concrete instances of this process. Thus the book's successes are considerable. It adds a tremendous amount to our sense of how NGOs operate on the ground. It is exceedingly well-documented and detailed, and demonstrates the power of coalitions and framing.

However, the subject matter may have outgrown the existing theoretical approaches. Social science literature on NGOs dates to the mid-1990s, around the same time that many of these global IP issues became highly politicized areas of law. NGO scholarship is dominated so far by coalition-building, network organization or nodal governance theories (hereinafter network theories), including framing theories. Early work by Margaret Keck and Kathryn Sikkink from an international relations perspective focused on "networks . . . motivated primarily by *shared principled ideas or values* (transnational advocacy networks)." As they put it, "[w]hat distinguishes principled activists of the kind we discuss in this volume is the

intensely self-conscious and self-reflective nature of their normative awareness. No mere automatic "enactors," these are people who seek to amplify the generative power of norms, broaden the scope of practices those norms engender, and sometimes even renegotiate or transform the norms themselves." In this account, the outcome of the policy efforts of NGOs is assumed without analysis to be laudable. Similar thematic concerns and assumptions underlie Matthews' project of exploring public action NGOs.

While successful in predicting whether and how these networks operate (p.201), 13 network theories of NGOs and other non-state actors typically omit discussion of accountability, legitimacy and representation. These qualities are arguably essential to any public policy-making sphere, whether of states or non-state actors such as NGOs intervening on behalf of the public in the name of the public interest.<sup>14</sup> The burgeoning number and influence of NGOs both domestically and internationally, 15 particularly their influence in the domain of development, 16 make assessment along these governance dimensions crucial. While one might agree with the substantive positions taken by many of the so-called public action NGOs highlighted in Matthews' book, he neither critically evaluates the scientific bona fides of their advocacy positions, nor suggests any criteria of legitimacy for evaluating their impact. In the area of AGRTK, for example, NGO advocates have been deeply concerned with transgenic technology coupled with food industry concentration in the global North. 17 However, some recent academic critiques claim that Northern (particularly European) exported industrialized countries' attitudes towards NGOs have environmental risk assessment to developing countries, without fully considering possible benefits to the rural poor of transgenic technology within these countries. 18 While state actors are fallible, so too are non-state actors such as NGOs. 19 Thus NGOs may have too little accountability for the human rights claims they make on behalf of others, and moreover may not be fully representative of those others for whom they claim to speak.<sup>20</sup> And although their expertise may be of great assistance, particularly in technically complex areas, their legitimacy ought to be measured by the same evidence-based policy-making standard that is expected of state actors.<sup>21</sup> This is especially the case where NGOs serve in a co-regulatory capacity with states, rather than simply an advocacy role as seems to be the case with most of the NGOs studied in Matthews' book. Indeed, Matthews does not differentiate explicitly between the different possible roles that NGOs play within global IP regimes, ranging from consultative activities and technical assistance (emphasized here) to engaging in more overt regulatory strategies (perhaps under-emphasized).

Even if governance attributes such as accountability or legitimacy are satisfied, can the value added to the law-making process by NGOs be justified within a state-centered framework of international law? A global administrative law framework derived in part from international relations theory and political philosophy could provide some normative scaffolding for the assertion of human rights on behalf of third parties by NGOs.<sup>22</sup> It would also supplement a network theory approach in important ways. One significant question is whether public action NGO activity is qualitatively different from the actions of other non-state actors such as intergovernmental organizations or for-profit firms or any combination of these and state actors.<sup>23</sup> For example, does the work of these public action NGOs fill a need not otherwise occupied by other subjects of transnational law?

A possible, partial answer suggested by global governance theory is that NGOs inhabit a space opened by simultaneous market and government failure.<sup>24</sup> Along similar lines, a liberal economic analysis of non-profit organizations might predict that "N[G]Os produce certain public goods desired by one or some segments of the society, but not by a majority. According to this theory, the more diverse a society is, the more extensive the N[G]O sector is likely to be."<sup>25</sup> Evidence uncovered by Matthews seems to provide some support for these views. All extant theories of NGOs—whether influenced by network, global governance, marketgovernment failure or other approaches—could benefit from detailed case studies such as those explored by Matthews. What legal scholars can bring to the table in this interdisciplinary scholarly endeavor is precisely what Matthews provides: a deep understanding of the law (rather than "norms" more generally) and a nuanced understanding of how NGOs can affect different aspects of formal legal regimes. Legal scholars can also illustrate how raw state power may be tempered by legal institutions and legal rules around which social movement goals may coalesce through the efforts of non-state actors such as NGOs.

NGOs pierce the monopoly of states on legitimate political representation. Despite their location in the terminological realm of the "non-," these institutions have contributed constructively and materially to global regulation of knowledge goods via their linkage of IP, human rights and development. Professor Matthews has deftly and meticulously contributed to our growing grasp of civil society actors and their expanding influence within global legal regimes. This is no minor feat, either for him or the subjects of this book.

#### **ENDNOTES**

<sup>&</sup>lt;sup>1</sup> Philip Alston, The 'Not-a-Cat' Syndrome: Can the International Human Rights Regime Accommodate Non-State Actors? in Philip Alston ed., NON-STATE ACTORS AND HUMAN RIGHTS 3 (Oxford University Press, 2005).

<sup>&</sup>lt;sup>2</sup> Menno T. Kamminga, The Evolving Status of NGOs Under International Law: A Threat to the Inter-State System?, in Philip Alston ed., NON-STATE ACTORS AND HUMAN RIGHTS, 93-111 (Oxford University Press, 2005); see also Jens Steffik and Claudia Kissling, Why Co-operate? Civil Society Participation at the WTO, in Christian Joerges and Ernst-Ulrich Petersmann eds., CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND INTERNATIONAL ECONOMIC LAW, 135, 142-43 (Hart Publishing, 2011); Rephael Harel Ben-Ari, The 100-Year Story of Ameliorating a Formal Normative Status for International Non-Governmental Organizations (1912-2012): Contextual Historical Analysis of Past and Present Attempts (unpublished work-in-progress on file with author).

<sup>&</sup>lt;sup>3</sup> Report of the Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy (2002), available at: www.iprcommission.org.

<sup>&</sup>lt;sup>4</sup> Typical of this attempt is the following excerpt from the CIPR executive summary: "The conferring of IP rights is an instrument of public policy, which should be designed so that the benefit to society (for instance through the invention of a new drug or technology) outweighs the cost to society (for instance, the higher cost of a drug and the costs of administering the IP system). But the IP right is a private one, so the financial benefits and costs fall on different groups within society. The IP right is best viewed as one of the means by which nations and societies can help to promote the fulfilment of human economic and social rights. In particular, there are no circumstances in which the most fundamental human rights should be subordinated to the requirements of IP protection. IP rights are granted by states for limited times (at least in the case of patents and copyrights) whereas human rights are inalienable and universal." Id.

<sup>&</sup>lt;sup>5</sup> See Margaret E. Keck and Kathryn Sikkink, ACTIVISTS BEYOND BORDERS: ADVOCACY NETWORKS IN INTERNATIONAL POLITICS 35 (Cornell University Press, 1998); see also John Braithwaite

and Peter Drahos, GLOBAL BUSINESS REGULATION 31 (Cambridge University Press, 2000).

<sup>&</sup>lt;sup>6</sup> See, e.g., the International Union for the Protection of New Varieties of Plants ("UPOV") (1961, 1978, 1991); the International Treaty on Plant Genetic Resources ("ITPGR") (2001); the Convention on Biological Diversity ("CBD") (1992); the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") (1994)). See also Keith Aoki, SEED WARS: CASES AND MATERIALS ON PLANT GENETIC RESOURCES AND INTELLECTUAL PROPERTY 69-90 (Carolina Academic Press, 1983) (also discussing the International Undertaking on Plant Genetic Resources for Food and Agriculture).

<sup>&</sup>lt;sup>7</sup> Muñoz Tellez is currently a Programme Officer at the South Centre, an intergovernmental organization of developing countries based in Geneva, Switzerland. See also Duncan Matthews and Viviana Muñoz-Tellez, Bilateral Technical Assistance and TRIPS: The United States, Japan and European Communities in Comparative Perspective, 9 J. World Intell. Prop. 629, 649-50 (2006).

<sup>&</sup>lt;sup>8</sup> See Angela P. Harris, Race and Essentialism in Feminist Legal Theory, 42 Stan. L. Rev. 581 (1990).

<sup>&</sup>lt;sup>9</sup> See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, Legal Instruments–Results of the Uruguay Round, art. 27, 33 I.L.M. 1125 (1994) at: http://ow.ly/8W4B1 [hereinafter TRIPS] Article 27.

<sup>&</sup>lt;sup>10</sup> Ironically, Brazil complied with TRIPS with provisions that arguably went beyond its minimum obligations, with respect to date of implementation (it did not take advantage of the 10 year transitional period for developing countries) and overly-strong pipeline protection for patent applications. Matthews at pp.129-30.

Margaret E. Keck and Kathryn Sikkink, supra note 5, at 35 ("these relations can be characterized as forms of transnational networks, but we distinguish three different categories based on their motivations: (1) those with essentially instrumental goals, especially transnational corporations and banks; (2) those motivated primarily by shared causal ideas, such as scientific groups or epistemic communities; and (3) those motivated

primarily by shared principled ideas or values (transnational advocacy networks)."

<sup>&</sup>lt;sup>12</sup> Id.

Matthews at p.201 ("Evaluating Network Success or failure . . . Networks influence politics at different levels because the actors in these networks are simultaneously helping to define an issue area, convince policymakers and publics that the problems thus defined are soluble, prescribe solutions, and monitor their implementation. We can think of networks being effective in various stages: (1) by framing debates and getting issues on the agenda; (2) by encouraging discursive commitments from states and other policy actors; (3) by causing procedural change at the international and domestic level; (4) by affecting policy; and (5) by influencing behavior changes in target actors").

<sup>&</sup>lt;sup>14</sup> See, e.g., Steve Charnovitz, Accountability of NGOs in Global Governance 38, Geo. Wash. U. Legal Studies Res. Paper No. 145 at 5-6 (May 4, 2005), available at http://ssrn.com/abstract=716381; Ruth W. Grant & Robert O. Keohane, Accountability and Abuses of Power in World Politics, 99 American Political Science Review 29 (2005).

<sup>&</sup>lt;sup>15</sup> See Kamminga, supra note 2 at 97 (noting "more than 2,500 NGOs currently have consultative status with ECOSOC" and estimating "number of domestic NGOs . . . into the millions."); see also Tony Hill, Three Generations of UN-Civil Society Relations, Global Policy Forum (April 2004), available at: www.globalpolicy.org/component/content/article/177-un/31824-three-generations-of-un-civil-society-relations.html (By 2003, a total of 2,350 separate NGOs had gained consultative status within the UN system).

<sup>&</sup>lt;sup>16</sup> See François Bourguignon, Development at a Turning Point, in Jean-Paul Fitoussi and Joseph E. Stiglitz eds., THE G20 AND RECOVERY AND BEYOND: AN AGENDA FOR GLOBAL GOVERNANCE FOR THE TWENTY-FIRST CENTURY 121-126 (Paris Group, 2011) ("The total amount of funds channeled towards developing countries by these 'private' actors was recently estimated to be around \$ 50 billion a year, 40 per cent of total DAC aid").

<sup>&</sup>lt;sup>17</sup> See, e.g., Mary K. Hendrickson and William D. Heffernan, Opening Spaces Through Relocalization: Locating Potential Resistance in the Weaknesses of the Global Food System, 42 Sociologia Ruralis 347 (2002).

<sup>&</sup>lt;sup>18</sup> See, e.g., Sakiko Fukuda-Parr, The Role of Government Policy: For Growth, Sustainability and Equity, in Sakiko Fukuda-Parr ed., THE GENE REVOLUTION: GM CROPS AND UNEQUAL DEVELOPMENT 227-28 (Routledge, 2008) ("[W]hat are the interests of the stakeholders in the developing countries, of local seed companies, research institutions . . . and last, but not least, the farmers themselves? . . . Alternatively, where are the interest groups for a pro-poor agenda?"); see also Robert Paarlberg, STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA (Harvard University Press, 2008); Ronald J. Herring, Stealth Seeds: Bioproperty, Biosafety, Biopolitics, in Ronald J. Herring ed., BIOTECHNOLOGY AND THE POOR: BIOTECHNOLOGY IN DEVELOPMENT STUDIES (Routledge, 2007).

<sup>&</sup>lt;sup>19</sup> For an analogous analysis of policy discourse in the public health arena, see Cynthia M. Ho, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENT AND RELATED RIGHTS (Oxford University Press, 2011).

<sup>&</sup>lt;sup>20</sup> See, e.g., Paarlburg, supra note 18 at 99, 126-46 (UN organizations such as FAO and UNEP influenced by NGOs advocating against transgenics); see id. at 100-06 (faulting NGO advocates of "food production for domestic and local markets based on peasant and family farmer diversified and agroecologically based production systems" for emphasizing sustainability at the expense of poverty-reduction).

<sup>&</sup>lt;sup>21</sup>See Kamminga, supra note 2 at 110 (noting that "not all NGOs are praiseworthy" but also claiming that "[b]y contributing the views of civil society, they confer badly needed legitimacy on the international system. . . By contributing expertise, NGOs also help to improve the quality of international decisions. Many subjects of international conferences have become so technical that numerous States, not only the smaller ones, find it hard to muster the necessary specialist knowledge. Furthermore, by providing their information and expertise for free, NGOs offer significant savings to the inter-State system. Many underfunded IGO programmes would not be able to carry out meaningful activities without the substantive input received from NGOs").

<sup>&</sup>lt;sup>22</sup> See Benedict Kingsbury, Nico Krisch, and Richard B. Stewart, The Emergence of Global Administrative Law, 68 Law & Contemp. Prob. 15, 43 (2005) ("These different models of international ordering can be juxtaposed to three different normative conceptions of the role of global"

administrative law: internal administrative accountability, protection of private rights or the rights of states, and promotion of democracy.").

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<sup>&</sup>lt;sup>23</sup> Id. at 20 ("Five main types of globalized administrative regulation are distinguishable: (1) administration by formal international organizations; (2) administration based on collective action by transnational networks of cooperative arrangements between national regulatory officials; (3) distributed administration conducted by national regulators under treaty, network, or other cooperative regimes; (4) administration by hybrid intergovernmental–private arrangements; and (5) administration by private institutions with regulatory functions.").

<sup>&</sup>lt;sup>24</sup> See Gráinne de Búrca, New Governance and Experimentalism: An Introduction, 2010 Wisc. L. Rev. 227, 232 ("The rise or creation of new governance systems can be seen as a response to two broadly different kinds of impetus or background conditions. The first of these—sometimes referred to in the literature as strategic uncertainty—is the need to address complex policy problems which have not shown themselves to be readily amenable to resolution whether through hierarchy, market, or otherwise...); see also Jyh-An Lee, The Greenpeace of Cultural Environmentalism, 16 Widener Law Review 1, 38 (2010) (positing that non-profit organizations arise when there is contract failure, market failure and government failure).

<sup>&</sup>lt;sup>25</sup> Lee, supra note 24 at 39 (citing Burton A. Weisbrod, THE VOLUNTARY NONPROFIT SECTOR: AN ECONOMIC ANALYSIS 67-68 (Lexington Books, 1977).

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TRADEMARK AND COPYRIGHT LITIGATION: FORMS AND ANALYSIS-VOLUME I: CEASE-AND-DESIST DEMANDS THROUGH ELECTRONIC DISCOVERY, by Mark V.B. Partridge and Phillip Barengolts. Oxford University Press, 2011. 544 pp. Paperback \$250.

Reviewed by Timothy Cahn, Kilpatrick Townsend LLP. tcahn@kilpatricktownsend.com

Demonstrating that some "who do" also can teach, author-practitioners Mark V.B. Partridge and Phillip Barengolts have created an informative resource consisting of "actual and recommended sample documents for federal court trademark and copyright litigation" along with commentary on related issues of law, procedure, and tactics. TRADEMARK AND COPYRIGHT LITIGATION: FORMS AND ANALYSIS is a recent addition to Oxford University Press' practitioner law publishing program, a series that has featured attorney-written works on patent prosecution, internet crimes, software licensing, and other timely and interesting areas of legal practice. As advertised, the focus in TRADEMARK AND COPYRIGHT LITIGATION is on presenting a wide variety of sample pleadings, motions, and discovery materials used in trademark or copyright Indeed, fully more than 400 pages of the text (and an litigation. accompanying disc) consist of these examples, while fewer than 100 pages contain the authors' commentary or analysis. For better or worse, there is far more by way of "forms" than "analysis" here.

The authors are Chicago-area attorneys who bring a wealth of expertise honed over several decades litigating trademark and copyright disputes. They also teach an LL.M. course at the John Marshall Law School in Chicago, and an educator's focus on pedagogy is evident throughout the organization and presentation of the materials in TRADEMARK AND COPYRIGHT LITIGATION. The authors hope that their work, by providing actual samples of materials filed in trademark and copyright cases, will fill a void in the field of "how-to" books on litigation. They do

not intend the forms to be "perfect examples of how things are done" but only real ones (p.xiii). Ultimately, the authors hope that the samples and commentary will be "useful to both novice and experienced litigators in preparing and litigating cases in this field" (p.xiii).

The organization of TRADEMARK AND COPYRIGHT LITIGATION is logically sound and easy to follow. It proceeds chronologically from prefiling case assessment, cease-and-desist demands, and jurisdiction and venue considerations, through Complaints, Answers and Counterclaims, preliminary injunctions, motions to dismiss, and concluding with written discovery, depositions, discovery disputes, and electronic discovery. Most chapters begin with a brief, one or two-page introduction in which the authors highlight issues relevant to the phase of litigation under consideration. On the whole, the authors succeed in covering a significant portion of the types of pleadings and motions most commonly recurring in trademark or copyright litigation.

Much of this resource's value to practitioners and professors alike stems from the authors' well-informed selection of the exemplars included. The pleadings, motions, and other documents included in TRADEMARK AND COPYRIGHT LITIGATION are high quality, well-researched, and carefully drafted litigation materials. They apparently were prepared (not always by the authors themselves) by attorneys knowledgeable of the finer points of trademark or copyright law who are able to express themselves effectively as litigators. Reading the sample Motions to Dismiss or Motions for Temporary Restraining Order, for example, affords one the opportunity to be instructed (or, in the case of an experienced practitioner, to be reminded) about important areas of law, practice, and strategy common to trademark or copyright litigation. Indeed, much of the substance of copyright or trademark law contained within TRADEMARK AND COPYRIGHT LITIGATION will be gleaned from close reading of the fine examples chosen by the authors. The reader must take into account, of course, that most of the exemplars are works of advocacy, and their representation of the law cannot be accepted fully without taking into account the original purpose of these documents: to persuade a judge to the advocate's point of view. The forms, it must be said, are starting points, not ending points, for reviewing the law represented there.

In addition to the points of law discussed within the forms themselves, the authors provide their own commentary and analysis, not only on the substance of copyright or trademark law, but often with respect to litigation procedure and strategy as well. These analyses, however, are distributed unevenly over the course of the work. The early chapters on case and

forum assessment and the latter ones on discovery procedures, for example, include considerably more analysis than the middle chapters on pleadings and motions, some of which include in total only a few paragraphs of commentary. In this reviewer's opinion, TRADEMARK AND COPYRIGHT LITIGATION succeeds best when the authors supplement the form examples with their own substantive commentary on them.

The first chapter on "Case Assessment" crisply introduces the topic and showcases the authors' evident expertise. The authors begin appropriately where a seasoned litigator advising a commercial client should start: identifying the client's objectives in potentially initiating trademark or copyright litigation. In a brief but substantive section, the authors cogently discuss a wide array of strategic considerations while underscoring the importance of the client's adoption of a proactive strategy to enforcement of its rights, rather than merely responding ad hoc to infringement concerns as they arise. The authors balance the risks of filing litigation against the risks to the client of not taking action in the face of encroaching infringement. They pose crucial strategic questions about what type of cases the brand owning client should consider initiating. They observe that "[o]ne approach is to take on the easy cases first, building a record of successful enforcement through publicly available consent judgments and settlements. Another approach is to pursue a prominent test case where a solid victory will create precedent to deter other infringers" (p.2). The authors' incisive chapter on case assessment alone justifies the book's \$250 purchase price.

One might have hoped that the authors would have included a similar discussion of strategic *defensive* considerations for clients who are presented with the claim that they infringe another's rights and who need to decide quickly whether, and how hard, to fight. But the authors' excellent and detailed review of the early investigation a client should undertake when contemplating litigation—e.g., types of witnesses to interview, documents to review, sources of useful public records—applies equally to the defendant in receipt of an infringement notice as to the plaintiff contemplating bringing a lawsuit.

Case assessment naturally requires an understanding of the fundamentals of law, and the authors deliver in Chapter 1 a helpful summary of key governing trademark and copyright principles. What sets this summary of trademark law apart from the myriad others is that its focus is through the lens of litigation. Thus, we encounter not only discussion, for example, of the levels of trademark distinctiveness, the importance of secondary meaning, and the kinds of consumer confusion that invite infringement, but the authors also continually focus their subject matter back to the

practicalities of litigation, e.g., the relevance of surveys, the possible impact of a defendant's insurance coverage, the availability or not of a jury, and much more. With any summary work of this nature, there will be important topics not addressed. For this reviewer, the most glaring omission in the summary of trademark law and types of actionable confusion is any mention of the increasingly-important theory of *reverse* trademark confusion. Indeed, two of the forms included by the authors, Form 5.5 and 5.7, rely prominently on the reverse confusion theory of infringement, making its omission from the discussion all the more perplexing.

The section on copyright law is briefer, and one senses that the authors have more expertise to share when it comes to trademark cases. This section highlights several copyright law issues—e.g., the importance of using the correct test for "substantial similarity," scope of protection, and fair use—that experience shows time and again are featured in copyright litigation.

The second and third chapters address other important pre-filing issues: (1) cease-and-desist (or "demand") letters and (2) forum considerations. Even the newcomer to trademark and copyright litigation quickly must learn to understand the function, risks, and strategies related to cease-and-desist correspondence. Because most trademark and copyright disputes resolve at the cease-and-desist stage before litigation is ever filed, a large portion of the practitioner's career likely will be devoted to evaluating, preparing, sending, and negotiating demand letters. The authors' chapter on demand letters introduces two relevant issues, and includes three fine examples of such letters, but leaves the reader wanting more.

The chapter opens by raising the concern that demand letters might provoke counterclaims (e.g., trade libel), followed by a cogent presentation of the broad protections for litigation-related demand letters found in the case law developed under *Noer-Pennington*. The authors correctly leave the impression that clients who send demand letters in good faith likely will be safe from tort liability.

The authors also highlight the risk of declaratory actions, but, in this reviewer's opinion, the subject deserves more than a single paragraph of commentary. As a result of the Supreme Court's having expanded declaratory judgment jurisdiction in *MedImmune*<sup>2</sup>, putative infringers who receive demand letters now have an easier time successfully filing a declaratory judgment ("DJ") action in their home venues and making it stick under first-to-file rules. Thus, the brand-owning client must carefully review not only *whether* to send a demand letter, but also *how* to word the

demand to potentially avoid being "DJ-ed" in an unfavorable forum. The authors present three examples of demand letters, but give no indication whether or not the particular wording used is more, or less, likely to present substantial risk of provoking a DJ action for non-infringement.

The third chapter on choosing a forum for copyright and trademark disputes helpfully recognizes that federal civil courts are not the only alternative for a client with a trademark or copyright infringement problem. The International Trade Commission ("ITC"), the Trademark Trial and Appeal Board ("TTAB"), arbitrations, the U.S. Customs and Border Protection ("CBP"), and even foreign tribunals all may have advantages that an informed client should consider. The authors are at their best succinctly discussing the various procedures and available remedies that may make one type of forum more or less advantageous than another. Their experience as litigators shines through in this chapter. Further, they ably summarize the law relating to personal jurisdiction, highlighting jurisdiction as it relates to internet activities and the *Calder*<sup>3</sup> effects test. This reviewer appreciates too the inclusion of less familiar types of jurisdiction, such as *in rem* jurisdiction and *in personam* jurisdiction obtained pursuant to the whole-contacts doctrine of FRCP 4(k)(2).

Chapters 4 through 6 feature a significant variety of sample pleadings, injunction motions, and motions to dismiss. There is little separate commentary or analysis here, but nonetheless the exemplars themselves will be highly educational for those willing to work with them. Indeed, much of TRADEMARK AND COPYRIGHT LITIGATION proceeds based on a show, not tell, method and leaves much for the reader to investigate for him or herself. For example, the final 38 pages of Chapter 4 consist of a Complaint and Answer & Counterclaim in a trademark infringement matter. introduced simply by the comment that this involved a "complicated dispute" where both parties "take a detailed narrative approach to pleading, attempting to tell a persuasive story about the dispute" (p.119). With only this general point about narration, the reader is left to determine what potential lessons of strategy, procedure, and drafting are illustrated by these 38 pages of pleadings. The authors might have used the form pleadings in Chapter 4, for example, to explain the appropriate uses of "information and belief' pleading in trademark cases, the strategies for pleading use of a mark that is often found in conjunction with a geographical designation, the tactic of pleading general and specific forms of relief, the risks and benefits of narrative-type pleading, and much more. But, then TRADEMARK AND COPYRIGHT LITIGATION would either have had to focus more narrowly or would have been a more voluminous work. I cannot fault the authors' choice to be comprehensive in scope but compact in execution by leaving

much of the analytic detail to be investigated by the reader. For those with the patience and fortitude to examine the forms and tease out their finer points with reference to other works, there are many helpful illustrations compiled here.

The authors' selection of examples is especially valuable because they have included both basic complaints and motions that cover all the requirements standard to trademark and copyright pleadings and motions, as well as more complex pleadings and motions that introduce a substantial variety of legal issues. The basic pleadings can be adapted by practitioners for use in many straightforward trademark infringement matters. (One wonders why the authors did not include a basic copyright infringement complaint, however. Indeed, on the whole, copyright law is not as well represented in this resource as trademark law.) As for the more "exotic" pleadings and motions, they introduce a great variety of legal issues that go beyond mere infringement matters, including "John Doe" seizure orders in anticounterfeiting matters, alleging proper ownership of trademarks and copyrights, the unavailability of "niche market" fame in trademark dilution matters, fraud on the PTO, cybersquatting, relevance of Rule 9(b) heightened pleading standards, copyright infringement based on unauthorized "deep linking" between web sites, and much more. These sample motions make for interesting and informative reading on some of the most current substantive areas of copyright and trademark litigation.

The final four chapters all deal with discovery: written discovery. depositions, discovery disputes, and electronic discovery. In Chapter 7 on written discovery, the authors provide well-formulated examples of the types of interrogatories, production requests, and requests for admission that cover the basic factual discovery needed for some types of copyright and trademark litigation, as well as sample responses and objections. authors begin by urging the reader to be familiar with the uses for and rules governing each type of written discovery, and by offering a few general introductory observations. The authors' commentary, though, is likely too cursory and general to be very helpful. More helpful would have been more directed commentary concerning strategy for the particular discovery issues common to trademark and copyright litigation related to, for example, ownership, use, protectability, compliance with registration requirements, and damages. There also is no mention of contention interrogatories to flesh out and narrow an opponent's theory of the case or defense.

The authors redeem themselves with their insightful discussion included in the remaining chapters on discovery and deposition practice. They cogently explain preparing a deposition outline and offer insights, such as the authors' five "Deposition Gets": "Get the facts," "Get the names," "Get the admissions," "Get ready for trial," and "Get to know the witness" (p.414). They include pithy advice on preparing one's own witnesses for deposition and a germane overview of the rules governing depositions generally, including objections at depositions. This chapter would have been even more useful had the authors included a sample 30(b)(6) deposition notice used in trademark or copyright litigation.

Chapter 9 on discovery disputes also contains helpful insights and forms appropriate to all types of litigation, including copyright and trademark litigation. The authors contrast the temptation to be needlessly contentious in discovery and thus driving up litigation costs with the benefits gained from seeking rapport with opposing counsel. The authors helpfully remind the reader that "[e]very communication with opposing counsel should be written with the understanding that it may come before the court" (p.426). The sample discovery objections, deficiency letters (also called "meet and confer" letters), and motion documents illustrate good litigation form. The forms avoid the all-too-common practice of issuing boilerplate objections and demonstrate discovery objections that are appropriately explained and They model the practice of seeking principled compromise through exchange of correspondence directed at supposed deficiencies in discovery responses. Further, the authors helpfully highlight how to deal with discovery issues that recur in many types of commercial litigation, including, for example, the tactic of seeking to force the deposition of senior company executives to effect settlement leverage and the use of protective orders. In the final chapter devoted to electronic discovery, the authors provide extensive practical advice for dealing with electronically stored documents in light of clients' obligations to identify and preserve their reasonably accessible electronic documents.

TRADEMARK AND COPYRIGHT LITIGATION succeeds as a work of reference that compiles a diverse and relevant sampling of litigation documents commonly used in trademark and copyright cases. Some of the forms will be instructive simply for the trenchant synopses of law contained therein. Some—especially the more basic trademark pleadings and discovery materials—could be adapted and used by practitioners where appropriate. But in this reviewer's opinion, TRADEMARK AND COPYRIGHT LITIGATION likely will find its highest and best use as a supplemental pedagogical resource for law professors and experienced practitioners seeking to educate students in the class or associates in the conference room about the practice of trademark and copyright litigation. Though it will not replace texts or casebooks covering the substance of trademark or copyright law or litigation procedures, this treasure trove of

litigation examples can serve to guide, stimulate, and educate those who would seek to become copyright and trademark litigators themselves.

### **ENDNOTES**

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<sup>&</sup>lt;sup>1</sup> This text is from the book's back cover.

<sup>&</sup>lt;sup>2</sup> MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 131-32, note 11 (2007) (rejecting "reasonable apprehension of imminent suit" as prerequisite to declaratory judgment action).

<sup>&</sup>lt;sup>3</sup> Calder v. Jones, 465 U.S. 783, 788-89 (1984).

### The IP Law Book Review

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PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED WORLD: LIBER AMICORUM JOSEPH STRAUS, edited by Wolrad Prinz zu Waldeck und Pyrmont, Martin J. Adelman, Robert Brauneis, Josef Drexl and Ralph Nack. Springer, 2009. 910 pp. Hardback \$239. 1

Reviewed by Timo Minssen, Centre for Information and Innovation Law, University of Copenhagen. Timo.Minssen@jur.ku.dk.

On December 14<sup>th</sup> 2008, one of the world's most renowned patent scholars, Prof. Dr. Dres. h.c. Joseph Straus, celebrated his 70<sup>th</sup> birthday. Shortly thereafter, a great number of colleagues and friends gathered in his "academic home," the Max Planck Institute at Munich's Marstallplatz,<sup>2</sup> to congratulate and pay tribute to this "distinguished grandmaster of intellectual property law."<sup>3</sup>

One of his birthday presents was a colossal book honoring his lifelong dedication to intellectual property law and his widely recognized achievements, not only in his primarily patent law-related research and teaching, but also in creating the Munich Intellectual Property Law Centre and in leading, developing, and administering academic endeavors at the famous Max Planck Institute for Intellectual Property, Competition and Tax Law<sup>4</sup> with its tremendous library and research network. In over 900 pages this so-called *liber amicorum*<sup>5</sup> comprises 60 (!) articles written by friends, colleagues and pupils from more than 15 different countries in Asia, America, and Europe. The articles address a wide range of legal, economic and policy perspectives on various challenges related to the title of the book: PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED ECONOMY.

Starting with Rainer Moufang's portrayal of the fascinating life and career of Professor Straus and the leitmotivs of his work (pp.VII–XVII), which is followed by the table of contents and a brief description of the contributors (pp.XIX–XXX), the book sets out to address a remarkable variety of crucial

issues in the complex debates shaping today's technology-related intellectual property law. Besides dealing with topics that directly concern Professor Straus' primary research interest, i.e. international and comparative patent law with a special focus on the policy aspects raised by biotechnology and the interface of IPR with competition law, the book also features contributions discussing various procedural, multi-jurisdictional, and public policy aspects from a more general perspective.

The essays are thematically organized in 10 chapters, covering elemental questions of substantive patent and utility model law (Chapter 1); the delicate task of balancing exclusive patent rights with free market competition, addressing both system-immanent limitations on intellectual property protection (Chapter 2) and additional restrictions imposed by competition and antitrust laws (Chapter 3); technology specific problems concerning the adjustment of patent law to rapid developments in biotechnology and the pharmaceutical sector (Chapter 4); the legal protection of employee's inventions (Chapter 5); fundamental issues related to IPR procedure, enforcement, and liability (Chapter 6); the protection of technology against unfair competition (Chapter 7); multijurisdictional aspects of IP (Chapter 8); recent developments in national IP and competition legislation (Chapter 9); and public policies influencing the development of intellectual property law (Chapter 10). Finally, the book concludes with an additional chapter listing Prof. Straus' numerous and multifaceted publications (Chapter 11).

While many of the articles are kept reasonably short, the sheer scope and size of this book obviously presents a challenge to any reviewer bound to comply with page limitations. In order to do the book "some justice" one approach could be to briefly summarize and comment on each chapter and article. Alternatively, the review could focus on a selection of articles covering specific issues that are of particular concern in current debates and that reflect the research focus of the celebrant. Considering the significant recent case-law developments and debates relating to the patentability of biotechnological and pharmaceutical inventions in both Europe and the U.S., as well as Professor Straus' main area of specialization, this review will follow the second approach and concentrate on the articles presented in Chapter 4 (Biotechnology, Pharmaceuticals and Patent Law).

Chapter 4 comprises seven articles on more than 100 pages (pp.197–304). It begins with an insightful analysis by the prominent IP Professor Martin J. Adelman from George Washington University Law School, who also happens to be a "good friend of many years" to Professor Straus and one of the book's co-editors.<sup>7</sup> In his paper titled, "The Inadequacies of the Section

271(e)(1) Jurisprudence of the United States Supreme Court" (pp.197–208), Adelman delivers a creative critique of recent U.S. case law developments concerning the applicability of the U.S. experimental use exemption with a particular focus on research tools. He follows the unusual approach of constructing hypothetical cases based on the facts of *Roche v Bolar* in order to demonstrate the effects of the decisions in *Eli Lilly v Medtronic* and *Merck v Integra*. Based on his convincing analysis Adelman arrives at the conclusion that the U.S. Supreme Court in *Merck v Integra* unfortunately "failed to do a clear, thoughtful and thorough job in this important case" (p.208). More specifically he criticizes the fact that the U.S, Supreme Court not only left unanswered the position of research tools with respect to Section 271(e)(1), but also refused to discuss the fairness of depriving the patent holder of all its benefits with respect to the genus claim (p.208).

Most stakeholders and academics would probably agree with Adelman that the Supreme Court decision was far too ambiguous and that further clarification is necessary to create reasonable legal certainty. The proper scope and application of experimental use and regulatory approval exceptions will therefore certainly continue to be vividly debated in the years to come. The controversy will be particularly fierce with regard to research tool patents. Ideally these exceptions should guarantee that patent laws aimed at providing incentives for technological innovation do not unduly restrict scientific research, innovative medical product development, and generic product competition. 12 In that respect, some judges and commentators will persist in highlighting the social harms that can result from a narrow interpretation of the exceptions, as demonstrated by the Merck decision, the (initial) invalidation of restrictively licensed stem-cell patents, and empirical studies suggesting that valid patents may—if the U.S. experimental use exception is narrowly construed—increasingly delay or restrict scientific research.<sup>13</sup> Others have argued that the ambiguous Supreme Court judgment may have gone far beyond what is necessary when limiting patent rights through research exemptions, thereby threatening the economic incentives provided by patents for the further development of innovative research technologies. <sup>14</sup> In that context it might also be worth adding that while experimental use and regulatory approval exceptions in the U.S. and the E.U. differ significantly in their history, scope, and application, these exceptions will presumably become even more essential to patent law and related regulatory policy in both Europe and the U.S. 15 It is therefore indispensable that any debates on the appropriate scope of research exemptions in both Europe and the U.S. also consider the impact of the generally more restrictive recent case law on patentable subject matter, inventive step/non-obviousness, sufficient disclosure, and industrial application/utility. These cases have made it generally more difficult to receive patents on *immature* research results and undeveloped tools that are merely the objects (not subjects) of further research. This indicates that research exemptions should not be regarded as being the sole solution mechanism for tackling more or less significant problems. <sup>16</sup>

Related to this issue is also another possibility that—due to focus and page limitations—could not be sufficiently addressed in Adelman's paper: the introduction of a liability rule regime to facilitate access to research tools. That this seemingly wonderful idea might face specific difficulties in the biotechnological and pharmaceutical sector has been thoroughly discussed in Professor Straus' research. In addition to the potential difficulties associated with the determination of appropriate royalties in absence of a free market mechanism and potential conflicts with Articles 27, 30 and 31 of the TRIPS agreement, he reminds us that a liability rule regime would preclude exclusive licensing agreements. Unfortunately, however, such agreements still seem to be absolutely essential for some types of biotechnological research tools. <sup>17</sup> This is because an exclusive license guarantees exclusivity of research with the licensed invention, permitting the licensee a better prospect of recouping invested capital in the license itself. 18 Therefore, exclusive licensing may be particularly important for pharmaceutical research programs seeking to develop commercial applications for genetic inventions such as drug targets, rather than for research tool uses, considering the risks and costs associated with such development. 19 Although a potential liability regime definitely represents an interesting idea that deserves further consideration, sufficient capital investments and market returns may still depend upon the possibility of preventing such unlicensed research uses. 20 This clearly indicates that particularly with regard to biotechnological research tool inventions, the scope of research exceptions remains a tricky issue. The significance of further debate has also been emphasized by Professor Straus, who noted in 2004 that although the empirical studies available at that time had not demonstrated significant problems with development, licensing, and use of research tools, this may be more a function of ignorance of (or disdain for) the legal rules than of any recognition of what they are or should be.<sup>21</sup> All this adds particular weight to Adelman's disappointment with the jurisprudence of the U.S. Supreme Court. The next time the Supreme Court is confronted with similar questions it should indeed spend more time on these crucial issues. Although it seems to be impossible to deliver clear-cut answers, and the Supreme Court is generally prevented from giving judgment where there is no "live case or controversy" under the Constitutional bar in Art. III, §2, cl. 1, the establishment of more coherent principles creating greater legal certainty would be most welcome. As recently as on August 31<sup>st</sup>, 2011 this was confirmed by the Federal Circuit decision in *Classen Immunotherapies*, *Inc. v. Biogen IDEC*,<sup>22</sup> where a split panel re-invigorated the debate as to the scope of the experimental use exception from infringement and the scope of the Hatch-Waxman "safe harbor" for drug-related testing under 35 USC §271(e)(1). The majority opinion and a strong dissent affirm the need to revisit this topic.

Professor Adelman's article is followed by Shoshana Berman's thoughtful consideration of the hazards of biotechnology for law and society in her paper "Legal and Moral Reflections on Modern Biotechnology in Use & Misuse" (pp.209-227). She begins with a description of international legislation addressing potential threats posed by dangerous or offensive uses of biotechnological inventions and highlights potential conflicts with the freedom of scientific research, and fundamental rights (pp.209-210). In that respect she delivers a thorough explanation of biotechnology's dual-use dilemma, i.e. in particular the blurred borders between peaceful and offensive uses of biotechnology, which lies at the heart of these conflicts. Moreover, Berman discusses unwanted risks stemming from the inherent unpredictability of biotechnology (pp.211-214). That point follows a random look at bio-safety and bio-security legislation, as well as case law from the U.S., the U.K. and the E.U. (pp.214-221). Her overview of recent judgments and legislation nicely demonstrates that in recent years serious efforts have been made by legislators and courts to control the use of and prevent the misuse of biological agents, although in a climate of uncertainties many conflicts and controversies still remain (pp.221-226). In her conclusion Berman regards the determination of an adequate balance in conflicts between human rights and national or international security to be one of the most difficult issues (p.226). While she considers the application of the "precautionary principle" to be necessary, she admonishes at the same time that "any normative framework for preventing, decreasing or minimizing any hostile use or misuses" must also respect the basic value of an "undisturbed continuation of scientific research" and the opportunity to publish scientific research results that do not unduly impede efforts to protect national security, as well as public health and safety. Berman then identifies the following questions as central (p.227):

1. How can scientific information on controversial issues be framed and communicated by the media, to be best absorbed and seriously received by policy makers, scientists and the general public?

- 2. What mechanisms can be applied for mediating between expert advice and warnings on risks and dangers and the common tendency of the individual to distance himself from threats and warnings?
- 3. What criteria shall be applied for resolving conflict of interest and controversies between the utilitarian-economic approach to scientific research, especially now in the field of new biotechnology and other approaches such as political, ethical, moral; social or religious?

Having dealt with these issues both as a judge and lecturer, Berman finally notes that there is a "growing gap between scientific expertise and judicial knowledge." Since "no man is an island"<sup>23</sup> she concludes that there is a clear demand for cross-ventilation between all the relevant disciplines. which "Professor Straus is practicing in his daily chores" (p.227). While Berman concentrates on issues relating to misuses of biotechnology in warfare and the potentially extreme dangers posed by insufficiently controlled peaceful uses of viruses and bacteria, many of her findings will certainly also have to be discussed in (perhaps only seemingly) less dramatic settings. One could, for example, think about similar problems related to novel scientific insights in epigenetics and nanotechnology. Recent research demonstrates that these rapidly developing disciplines are blurring the frontiers of science and present particular legal, social, ethical, and scientific challenges.<sup>24</sup> Once again, law is having difficulty in keeping up with these rapid technological developments and finding answers to the questions identified by Berman will be essential even in these areas.

The third paper in Chapter 4 with the title "Biotechnological Patenting and Innovation" (pp.229-241) is authored by Michael Blakeney. It discusses a variety of issues that are of particular concern when discussing patents on biotechnological inventions. In combining his patent law analysis with scientific facts and economic insights, such as Machlup's views on the interplay of patenting and innovation, he addresses some crucial topics, including overly broad claims and actual or potential problems that these might create for biotechnological research (pp.230-233), patents on research tools (p.232), licensing issues (p.233), patent thickets (pp.233-236) and patent pools (pp.236-238). Finally, Blakeney makes some remarkable comments on the interplay of patents with competition law (which could as well have made his paper part of Chapter 3). He examines in particular the impact of competition law upon biotechnological licensing (p.238), as well as on patent pools and cross licensing (pp.238-240). In his conclusion he refers to Professor Straus' earlier realization that patents not only play a significant role as competitive tools in various biotechnology contexts, but also for preserving the value in biodiversity and in distributing benefits to source communities (p.241). Blakeney finally notes that "in both of these areas further research is necessary to examine the extent to which competition policy can preserve the benefits which every patenting should secure," a finding which corresponds well with the increased scrutiny of patent law by competition/antitrust authorities and courts in both Europe and the U.S.

Somewhat related to these conclusions is the subsequent article by Tanuja Garde entitled "Circumventing the Debate over State Policy and Property Rights: Section 3(d) of the Indian Patents Act Law" (pp.243-254). Garde analyzes the historical and constitutional background to §3(d) of the Indian Patents Act. This is an extraordinarily interesting provision, since it was introduced to prevent so-called "evergreening" strategies typically employed by the pharmaceutical industry. More specifically §3(d) provides that the following does not constitute an invention under Indian patent law:

"[t]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."<sup>25</sup>

Besides explaining the Indian debates on the redistribution of real property and the very critical post-independence evaluation of the patent system, which led to fierce opposition during India's accession to the WTO/TRIPS and to the introduction of this (in)famous provision (pp.243-250), Garde also examines its actual impact on selected decisions relating to patents and patent applications by the pharmaceutical giant Novartis (pp.250-253). She concludes that §3(d) effectively limits "the ability to obtain property rights in incremental pharmaceutical innovation, where currently the bulk of pharmaceutical research and developments occurs, including medicines that may be more effective in tropical climates, such as heat stable forms, but not necessarily more efficacious" (p.254). She also observes that by denying any patents on such inventions, §3(d) "circumvents a battle over determination of just compensation or equitable remuneration, as required when issuing a compulsory license." Finally, she remarks that this calls for an examination of whether §3(d) might actually violate TRIPS, and in particular the anti-discrimination clause in Article 27 TRIPS (p.254). Considering Novartis' continuing challenges to Section 3(d) at the Indian Supreme Court and recognizing that so-called "evergreening" strategies are also fiercely debated under U.S. and European patent, competition, and

pharmaceutical regulatory law, Garde's analysis provides valuable input. Since India is currently undertaking great efforts to strengthen its domestic generic industry, a similar examination of the Indian regime on data and market exclusivities would probably lead to equally interesting results.

Next, the paper "Medical Use Claims: EPC 2000 and its Impact on Prosecution and Enforcement" (pp.255-274) by Hans-Rainer Jaenichen, Jürgen Meier, and Niels Hölder analyzes the significance of the 2000 revision of the European Patent Convention ("EPC 2000") and its "new" Articles 54(4) and (5) EPC<sup>26</sup> for the prosecution and enforcement of medical use claims. The authors start by highlighting the general relevance of patents as incentives in the pharmaceutical sector, describing the increasing costs of (bio-) pharmaceutical R&D, the high proportion of pharmacologically interesting compounds that fail before reaching the clinical trial phase, and the comparatively low success rate of those compounds that actually make it to the clinical trial stage. The authors then explain the particular concept and significance of compound patents, first medical use patents and patents for second (and subsequent) medical uses. After mentioning several examples of conventional small molecule pharmaceuticals and large-molecule biologics that were successfully protected by compound protection, the authors point out that, in some cases, the identification of first, second and further medical uses may actually provide the first prospects for profit (pp.255-256). Besides providing examples of such inventions, which enjoy simplified purpose-limited claim protection under the EPC 2000, the authors also refer to the necessity for additional forms of protection that may complement patent protection, such Certificates. Supplementary Protection data protection/market exclusivity, and orphan drug and pediatric regulations (p.256). Next, they deliver a brief description of the European Patent System, followed by a more detailed analysis of how the European Patent Office ("EPO") and national systems, such as the U.K. and Germany, deal with patents covering various medical use-claims of known compounds. In that respect the authors refer to many different patent scenarios involving a variety of medical-use categories, such as novel target populations, routes of administration, claimed additional technical effects or treatment regimes. They describe how these categories are addressed by European courts in both patent prosecution and enforcement litigation, including various direct and indirect infringement situations (pp.257-274). The authors also note the often stricter approach of national courts in considering validity and infringement, for example, in cases where the claim is essentially directed to an unpatentable method of medical treatment. They finally conclude that while the EPC 2000 has basically left the legal situation for prosecuting and enforcing purpose-limited claims covering the first medical use unchanged,<sup>27</sup> the new Article 54(5) EPC relating to second medical uses has now incorporated into the EPC what has been developed in many years by the EPO's jurisprudence.

Although it is generally believed that the purpose-limited compound claims that are now available for second medical uses under Article 54(5) EPC 2000 have substantially the same effect as the previously used Swiss-type claims, the authors identify two main advantages (p.274). First, the new regime provides, in combination with Article 138 EPC 2000, legal certainty since national courts will now have to respect the patentability of second medical use inventions (which might also encompass cleverly phrased claims on treatment regimes and in particular claims that make the treatment regime a feature of the composition itself). Second, since a purpose-limited second medical use claim under Article 54(5) EPC 2000 covers—in contrast to the previously available Swiss-type claims—off-label uses, the new format is likely to increase the protection of such specific uses and, under the principles of indirect infringement, "offers and deliveries of non-customized products suitable and intended/used therefore" (p.274). Besides clarifying advantages that the EPC 2000 entails for patentees during patent prosecution and litigation, another of the authors' achievements lies within their interesting explanation of the various categories of second medical use claims that patent offices are typically Readers who are not so well-acquainted with confronted with. pharmaceutical patenting, the EPC and the case law of the EPO, will be astonished by the great number and variety of purpose-limited patents for second medical uses of known pharmaceutical compounds already granted On the other hand, those more familiar with (bio-) pharmaceutical R&D will find confirmation. The increasing relevance of medical use claims clearly reflects the current paradigm shift in Encouraged by rapid scientific advances in pharmaceutical R&D. molecular biology and an enhanced understanding of cellular pathway mechanisms, epigenetics and the interplay of genes and proteins, the industry is increasingly focusing on the development of personalized medicines, novel applications of known small molecule drugs, as well as cutting edge large-molecule biologics or biosimilars. This will create a variety of challenges in several legal areas, including patent related law and the legal framework for regulatory exclusivity periods. With respect to patent law, the scope of the aforementioned exclusions from patentability of medical methods, which is expressly permitted under Art. 27 TRIPS, is one of the most discussed issues. The debate is particularly intense in the case of diagnostic methods.

That specific topic is addressed in the following paper on the "Purpose and Limits of the Exclusion from Patentability of Medical Methods, Especially Diagnostic Methods" by Rudolf Kraßer (pp.275-288). In providing an initial overview on the genesis and substance of the excluding provisions in the EPC (including references to German case law and legislation on diagnostic methods and second medical uses), the author describes the systematically correct "delinking" of considerations related to the "industrial applicability" requirement from the patent ban on medical procedures under the EPC 2000 (pp.275-278). Next, the author considers the various rationales for excluding medical procedures from patentability (pp.279-281) and describes case-law developments primarily from Germany and the EPO's Technical Boards of Appeal (TBA) and Enlarged Board of Appeal (EBA), demonstrating that the general European bar to the patentability of medical methods is still very restrictively interpreted as applied to diagnostic methods (pp.281-288). In his concluding remarks Kraßer generally welcomes the more recent case law from the EPO as abolishing false interpretations to be found in earlier case law and establishing proper principles for a variety of problems, such as the question of when a diagnostic method is to be considered as "practiced on a human or animal body" and who should be considered as carrying out such methods. However, he also notes flaws in the EBA's definition of the term "diagnostic method." Quite correctly he points out that by focusing on the deductive activities of medical practitioners, the EBA failed "to consider the possibility that a restraint can take place during the data collection phase that a doctor needs as the basis for his conclusion." According to Kraßer, this drains the established principles "of any practical relevance." In that respect the authors also admonishes that the application of Article 84 EPC (on the claim clarity) does not constitute an appropriate legal means "to resuscitate the exclusion to the extent called for by the spirit of the law."

Professor Kraβer's analysis clearly demonstrates that Europe is currently going through its own national, international, and supranational debates on patentable subject matter. Due to the particular European legal framework the debate is characterized by specific dynamics raising some questions that are rather unique to the European setting. This was confirmed in a series of seminal decisions by the EPO and the Court of Justice of the European Union (CJEU) both pre-<sup>28</sup> and post-dating<sup>29</sup> the author's analysis. However, as illustrated by Kraβer's data collection example, recent European developments also address several issues that are very similar to those currently discussed in the U.S. in the aftermath of the U.S. Supreme Court decision in *Bilski v. Kappos*.<sup>30</sup> Thus, comparative studies of these developments are now more interesting than ever. Besides the impact of the

new case-law on patentability exclusions relating to abstract ideas and computer programs (which was the main focus of *Bilski*), the patentability of medical uses, dosage regimes, procedures and diagnostic methods seems in light of the above described paradigm shift in (bio)-pharmaceutical R & D to be the most relevant field for comparative studies. interesting for this technology is a series of Federal Circuit decisions that were influenced by *Bilski*. One of these cases, i.e. *Prometheus v. Mayo*, <sup>31</sup> will soon be considered by the U.S. Supreme Court, which will provide further clarification for biotechnological and pharmaceutical sciences. Other cases might follow. In that respect, Kraßer's discussion provides valuable comparative input. Furthermore, it will be interesting to explore how the U.S. courts decide upon the closely related question concerning the appropriate scope of protection to be conferred to such inventions. As for the U.S., the post Bilski CAFC decisions in Prometheus v. Mayo and AMP v. USPTO<sup>32</sup> indicate that this question is particularly controversial in the case of pharmaceuticals and DNA- or protein-related inventions. appropriate scope of protection for such inventions is also heavily debated in Europe and has led to completely divergent national interpretations of Directive 98/44/EC (E.U. Biotech Directive). In some national European patent systems, such as Sweden, Denmark, and the U.K., as well as at the EPO and the USPTO, full product protection seems—at least in principle and despite recent challenges—still to be available for qualified DNA- and protein-related inventions. In contrast, however, a number of European states, such as Italy, France, and Germany, have enacted legislation that effectively limits the scope of protection conferred on such inventions. Some national rules even oblige the patent applicant to include the claimed function of complete or partial human DNA (or even protein) sequences with a structure that is concordant to naturally occurring sequences directly into the patent claims, thereby automatically limiting the scope of protection of the patent to that particular function. Obviously, this special treatment of (human) DNA-related technology raises fundamental questions as to the proper interpretation of i.a. Article 27(1) TRIPS. Moreover, this legislative diversity stands in stark contrast to the harmonization goal of E.U. This has stimulated a widespread debate on the proper interpretation of the E.U. Biotech Directive and it was clear that guidance from the CJEU was required.<sup>33</sup> In July 2010 some of these question were answered by the CJEU in C-428/08, Monsanto Technology LLC, v. Cefetra BV, where the CJEU held the scope of product claims on DNA sequences in sova beans to be limited to their function as claimed and not applicable to any other product, such as soya meal used for nutrition, in which the sequences did not fulfill their specific function.<sup>34</sup>

*Monsanto* was decided after the publication of the book and arguably leaves some issues unresolved due to the specific factual circumstances underlying the case and the specific focus of the decision.<sup>35</sup> Interestingly, some of the questions addressed in this case are discussed by the last article in Chapter 4 titled "Special Legislation for Genetic Inventions—A Violation of Article 27(1) TRIPS?" (pp. 289-304). It was written by another of the editors, Wolrad Prinz zu Waldeck und Pyrmont, who examines how far legal rules that exclude patent protection or limit its effects in biotechnology comply with the anti-discrimination clause of Article 27(1) TRIPS. He begins by explaining developments in the biotechnological sector (p.290) and the hotly contested debates over broad patents on multifunctional biotechnological products that resulted in the aforementioned national legal responses (p.291). This is followed by a description of various national legislation that introduced restrictive infringement rights and claim limitation for certain DNA- or protein-related inventions into French, German, Italian, and Swiss patent laws in order to mitigate the envisaged negative effects of overly broad biotechnology patents (pp.291-293). Next, the author scrutinizes the definition of "discrimination" (pp.293-295) and the extent of permissible "differential" treatment under TRIPS (pp.295-He also discusses various policy aspects and rationales against permitting sectoral derogation from general provisions. Prinz zu Waldeck und Pyrmont concludes that "restricting the scope of gene patents to the disclosed purpose while maintaining the principle of absolute product protection for all other technical fields," such as in German, French, Italian, and Swiss patent law, "undoubtedly violates Article 27(1)" TRIPs and adds that even a broad interpretation of TRIPS cannot justify such legislation (p.304). From a practical point of view, the author further warns that "using the fact that the object of the invention is a "gene" as the basis for a legal categorization does not appear very helpful" due to the increasingly disputed and "fuzzy" definition of a gene. 36 Finally, he observes that such technology-specific (patent) legislation "is backwards oriented and bears the danger of becoming obsolete or ill-fitting with the progress of technology" (p.304).

While other commentators,<sup>37</sup> as well as the AG and the CJEU in *Monsanto*, have taken a different view, it should perhaps be noted that an interesting "middle position" was expressed by Professor Straus in 2003. He differentiated between gene sequences whose isolation required an inventive activity and those situations where the examination of the relevant state of technology reveals that the inventive merit "merely" lies in the clarification of the function of a newly discovered gene that had been isolated by application of routine techniques.<sup>38</sup> In the first situation, which

due to scientific developments has become very rare, full product protection might perhaps be justified, whereas the latter situation would arguably only justify purpose limited product protection. This is certainly an appealing idea. However, today it seems as if these discussions have indeed lost some of their practical relevance. There are basically four related main reasons for this notion: 1) most of the sometimes overly broad patents that were granted in the early days of the biotechnological revolution have now expired or are about to expire; 2) recent advances in synthetic biology have made it possible to construct genes or proteins that do not necessarily correspond to natural sequences and to influence their specific functions; 3) due to legislative and procedural changes it has generally become easier to attack overly broad product claims during patent litigation; and 4) as for patent prosecution, rapid scientific developments and the strict application of basic patentability requirements, such as inventive step and sufficient disclosure, have made it more difficult to receive full product patents on naturally occurring DNA and protein sequences. These are often already disclosed or have been isolated by routine methods. Moreover, an increasing number of naturally occurring functions have been identified or can be predicted by the application of modern technology (although it may be argued that these functions and their interplay have proven to be much more complex than previously contemplated). As a consequence, modern science is focusing on truly inventive applications of gene and protein technology which are often more limited in scope and therefore do not raise the same problems with regard to full product protection. Accordingly, both the author's interesting contribution and the conflicting CJEU judgment in *Monsanto* illustrate very nicely that legal reactions once more appear to have difficulties in keeping up with scientific developments. Be that as it may, emerging technologies will certainly pose similar questions in the future and the general significance of this discussion for the development of legal doctrines and principles remains undisputed. Prinz zu Waldeck und Pyrmont is therefore generally correct in pointing out that legislators and policy makers should be extremely cautious before introducing technology-specific patent legislation. In that regard it should particularly be recognized that, while problems with overly broad product patents appeared to be most severe ten years ago, the strict application of patentability requirements and further solution mechanisms seem now to have taken effect. Hopefully, this will alleviate some of the initial concerns about impeding effects on biomedical research, which – as also pointed out by the author (p.300)—have often not been validated.<sup>39</sup> Last but not least, it is important to realize that the early grant of (from a hindsight perspective) perhaps overly broad patents has been an important factor in stimulating the biotechnological revolution.<sup>40</sup>

Since this review only addresses a selection from among the contributions, it should be added that most of the remaining authors have written equally interesting essays on equally exciting topics. It can further be concluded that the editors, most of whom also contributed papers, have generally succeeded in the difficult task of structuring, systemizing, and arranging the different parts. This has resulted in a very readable book. But are there any flaws?

Considering the numerous useful case law citations, as well as the size and scope of the book, a minor imperfection may perhaps be found in the general absence of any cross-references, indexes or tables of cases. Those deeply engaged in legal research might realize this ellipsis as it renders serious study of this book a little more inconvenient. Yet, it should also be born in mind that this might have delayed the completion of the book and timing is obviously a crucial factor for such a special birthday present. These minor slips are therefore excusable, although they should perhaps be remedied by a supplement satisfying even the most pedantic, nit-picking critics.

Leaving aside these subtleties, it can be assumed that Professor Straus has studied his birthday present with great pleasure and interest. While he might not fully agree with some of the findings and proposals presented in it, the overall theme of the book indeed "reflects Joseph Straus' pronounced interest in the patent system and the challenges that it faces both on a national and international level." There is no doubt that the editors and authors have compiled a magnificent book and a worthy tribute to honor the career of a truly exceptional patent scholar. For years to come, this immense collection of essays will provide stimulation and inspiration to many academics and their students. Consequently, this book is also of great interest to stakeholders, policy makers, judges, and practitioners.

This is an extraordinarily interesting book well suited to honor the outstanding career of an extraordinary scholar in an extraordinarily exciting era for intellectual property and competition law. It ought to be found in any library that has reserved space for IP-related literature.

### **ENDNOTES**

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<sup>&</sup>lt;sup>1</sup> This review does not consider legal changes that have occurred after August, 2011.

<sup>&</sup>lt;sup>2</sup> The seat of the Max Planck Institute for Intellectual Property & Competition Law.

<sup>&</sup>lt;sup>3</sup> Rainer Moufang, in Wolrad Prinz zu Waldeck et al. (eds.), PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED WORLD: LIBER AMICORUM JOSEPH STRAUS (Springer, 2009), at VII.

<sup>&</sup>lt;sup>4</sup> Since 1 January 2011 the MPI for Intellectual Property, Competition and Tax Law has been split to form the MPI for Intellectual Property and Competition Law, and the MPI for Tax Law and Public Finance. At the same time these Institutes, along with the MPI for Foreign and International Social Law, have joined together to form the Munich Max Planck Campus for Legal and Economic Research.

<sup>&</sup>lt;sup>5</sup> The concept of a so-called *liber amicorum* (lat: book of friends) stems from a respected tradition of civil law countries to pay tribute to respected legal scholars. A typical *liber amicorum* is comprised of a collection of essays that have been written by close friends, colleagues and pupils (such as doctoral students). It is also often referred to as mélange (Fr.), Festschrift (Ger.), or festskrift (Sw./Dan./Norw).

<sup>&</sup>lt;sup>6</sup> This approach has been applied by Alison Firth, Book Review–Patents and Technological Progress in a Globalized World: Liber Amicorum Joseph Straus, 32 E.I.P.R. 4, 184-189 (2010) (providing a comprehensive review covering virtually each of the book's 60 articles).

<sup>&</sup>lt;sup>7</sup> In the introduction to his paper, Adelman mentions that as a Marshall Coyne Visiting Professor of International Law at George Washington University Law School, he and Professor Straus have co-taught several chemistry and biotechnology related patent law courses. Professor Straus and Adelman have also collaborated in establishing Professor Straus' "baby," the Munich Intellectual Property Law Centre.

<sup>&</sup>lt;sup>8</sup> This paper would thus also have fit into Chapter 2.

<sup>&</sup>lt;sup>9</sup> Roche Products v Bolar Pharmaceuticals, 733 F. 2d 858 (Fed. Cir. 1984).

<sup>&</sup>lt;sup>10</sup> Eli Lily v Medtronic. 5 U.S.P.Q. 2d 1760 (E.D. Pa. 1987).

<sup>&</sup>lt;sup>11</sup> Merck v Integra Life Sciences, 545 U.S. 193 (2005).

<sup>&</sup>lt;sup>12</sup> Cf. the abstract of Joshua D. Sarnoff and Henrik Holzapfel, A Cross-Atlantic Dialog on Experimental Use and Research Tools, ExpressO (2007),

available at http://works.bepress.com/joshua\_sarnoff/1/ (last visit 10 May, 2011).

<sup>&</sup>lt;sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> See Wolrad Prinz zu Waldeck und Pyrmont, Research Tool Patents after Integra v. Merck–Have They Reached a Safe Harbor?, 14 Mich. Telecomm. & Tech. L. Rev. 2, pp. 367-446 (2008), available at SSRN: http://ssrn.com/abstract=1132025 (concluding after an examination of U.S. and European statutory law and practice, obligations imposed by international treaties, and the rationale of the patent system, that "to preserve the necessary incentives for the creation of research tools—the next judicial decision should clarify that neither of the two exemptions from infringement extends to the use of research tools in experiments. Allowing access to research tools under any of the exemptions—though arguably having a positive short term effect—would endanger the development of sufficient (and needed) innovative research technologies which may have a greater negative impact on the pace of biotechnological research than occasional lack of access to a needed resource.").

<sup>&</sup>lt;sup>15</sup> Cf. Henrik Holzapfel and Joshua D. Sarnoff, A Cross-Atlantic Dialog on Experimental Use and Research Tools, 48 IDEA 2, 224 (2008) available at http://law.unh.edu/assets/pdf/idea-vol48-no2-holzapfel-sarnoff.pdf (last visit 10 May, 2011).

<sup>&</sup>lt;sup>16</sup> Concerning the U.S. utility requirement, the CAFC has made this explicit in In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005). Similar case-law can be found in Europe. For a comparative overview, see Timo Minssen, När anses en bioteknologisk uppfinning vara komplett och praktisk användbar–Part I–USA, NIR 201-60 (2008), & Part II–Europe, NIR, 339-387 (2008) (in Swedish).

<sup>&</sup>lt;sup>17</sup> Joseph Straus et al., Genetic Inventions and Patent Law: An Empirical Survey of Selected German R&D Fustitutina, 22 (Verlag, 2004).

<sup>&</sup>lt;sup>18</sup> Cf. Henrik Holzapfel and Joshua D. Sarnoff, supra note 15 at 222-223.

<sup>&</sup>lt;sup>19</sup> Id.

<sup>&</sup>lt;sup>20</sup> Id.

<sup>&</sup>lt;sup>21</sup> Id. at 224 (referring to Straus et al., supra note 17, at 25; John P. Walsh et al., Working Through the Patent Problem, 299 SCIENCE 1021 (2003)).

<sup>&</sup>lt;sup>22</sup> Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011).

<sup>&</sup>lt;sup>23</sup> Citing John Donne, Mediations XVII.

<sup>&</sup>lt;sup>24</sup> A good overview about current research and unsolved questions concerning the "epigenetic or histone code" is provided by Bryan M. Turner, Defining an epigenetic code, 9 Nature Cell Biology 2-6 (2007), and id. Simplifying a complex code, 15 Nature Structural & Molecular Biology 542-544 (2008); Cf. M. Rothstein et al., The Ghost in Our Genes: Legal and Ethical Implications of Epigenetics, 19 Health Matrix 1 (2009); M. Rothstein et al., Ethical Implications of Epigenetics Research, 10 Nature Reviews Genetics, 224 (2009); Antonei B. Csoka & Moshe Szyf, Epigenetic side-effects of common pharmaceuticals: A potential new field in medicine and pharmacology, 73 Medical Hypotheses 5 (2009), at 770-780.

<sup>&</sup>lt;sup>25</sup> Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

<sup>&</sup>lt;sup>26</sup> Under the EPC 1973 first medical use claims were protectable under Article 54(5) EPC 1973. Second medical use claims have previously been accepted by the EPO as so-called "Swiss-type" claims. The EPC 2000 editorially amended Article 54(5) EPC 1973 to become Article 54(4). Moreover, the EPC 2000 introduced the new Article 54(5) EPC 2000, which provides for the purpose-limited protection of second and further medical use claims. As a consequence, the so-called "Swiss-type" claims became obsolete.

<sup>&</sup>lt;sup>27</sup> Adding that "the only, though substantial, legal difference to a purpose-limited compound claim for a second medical use as now admissible is that the first medical use claim is not limited to a specific indication by definition, which is why an infringement action requires less detailed evidence. In all other respects the enforcement is similar."

<sup>&</sup>lt;sup>28</sup> See G 1/04, OJ 5/2006, 334 (diagnostic methods). Note that due to the different legal framework, the European discussion raises sometimes comparable but also slightly different issues than in the U.S.; cf. Eddy D. Ventose, Making Sense of the Enlarged Board of Appeal in

Cygnus/Diagnostic Method, EIPR 145-50 (2008); Sven J.R. Bostyn, No Contact with the Human Body Please! Patentability of Diagnostic Method Inventions after G01/04, EIPR 238-44 (2007).

<sup>&</sup>lt;sup>29</sup> Cf. Recent EPO Enlarged Board of Appeal decisions on Art. 52, 53 & 54 EPC in G 0003/08 (May 2, 2010-computer implemented inventions); G 2/08 (February 19, 2010–dosage regime); G 1/07 (February 15, 2010-method for treatment by surgery); G 2/06 (November 25, 2008-embryonic stem cells).

<sup>&</sup>lt;sup>30</sup> Bilski v. Kappos 130 S. Ct. 3218. Cf. Timo Minssen and Robert M. Schwarz, US Patent Eligibility in the Wake of Bilski v. Kappos: "Business as Usual" in an Age of New Technologies?, 30 Biotech. L. Rep. 1, 3-56 (2011).

The patent challenger sought review of the recent CAFC decision in Prometheus Laboratories, Inc. v. Mayo Collaborative Services, 628 F.3d 1347 (Fed. Cir. 2010)(Lourie, J.). In 2011, the Supreme Court granted certiorari, see: In Mayo Collaborative Services v. Prometheus Laboratories, Inc., Supreme Court No. 10-1150. Cf. the prior decisions in Mayo Collaborative Services v. Prometheus Laboratories, Inc., \_\_ U.S. \_\_ (2010)(per curiam), grant of certiorari, vacation and remand from the Supreme Court in light of Bilski v. Kappos, 130 S.Ct. 3218 (2010), prior opinion, 581 F.3d 1336 (Fed. Cir. 2009) (Lourie, J.), where the Federal Court once again reversed the District Court to rule Prometheus' methods to be patent-eligible subject matter under 35 USC §101.

On July, 29<sup>th</sup> 2011 the CAFC rendered a split decision in the "Myriad-case," which might pave the way to a Supreme Court showdown, see: Association for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011)(Lourie, J.). The majority held that claims on "isolated DNA" and "cell-based drug screening methods" are patent-eligible under 35 USC §101, but that the "comparing" or "analyzing" method claims are not. Cf. the previous District Court ruling in Assoc. for Molecular Pathology et al. v. U.S. Patent and Trademark Office, 94 U.S.P.Q. 2d 1683 (S.D.N.Y. 2010). See also Alan J. Morrison's penetrating critique of Judge Sweet's ruling in: Rethinking the Gene Patent, 29 Biotech. L. Rep. 6, at 609-614 (2010).

<sup>&</sup>lt;sup>33</sup> For a more detailed discussion cf. Timo Minssen, Es bleibet dabei: Eine schwedische Stellungnahme zur europäischen Debatte über den absoluten Erzeugnisschutz bei der DNA Patentierung, KLIFOR 3 at 93-97 & KLIFOR

4 at 105-120 (2008, in German), available at: www.lu.se/o.o.i.s?id=12588&postid=1145006 and (last visit 11 May 2011).

<sup>&</sup>lt;sup>34</sup> Cf. Robert Fitt & Edward Nodder, An Uncertain Future for Gene Patents: The View from Europe, 29 Biotech. L. Rev. (6), at 615, 619-621 (December 2010) (Analyzing Case C-428/08, Monsanto Technology LLC, v. Cefetra BV of 6 July 2010.) Note further that on 9 December 2010 the EPO Enlarged Board of Appeal decided on the exclusion from patentability of "essentially biological processes" in the consolidated cases G 2/07-Broccoli/PLANT BIOSCIENCE and G 1/08-Tomatoes/STATE OF ISRAEL (concluding inter alia that "A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC").

<sup>&</sup>lt;sup>35</sup> The facts of the case did not concern human DNA and the decision focused mainly on article 9 of the Biotech Directive. Yet, the decision also contains general statements on TRIPS and further stipulations of the Directive, such as Article 5. For further analysis and criticism of the judgment, cf. Michael A. Kock, Court of Justice of the European Union Limits Patents on DNA Sequences: Much Ado About Nothing or The Beginning of Erosion for Biotech Patents?, 11 BSLR 1, 3-12; Michael A. Kock. Purpose-Bound Protection for DNA Sequences: In Through The Back Door?; 5 JIPLP, 495-513 (2010).

<sup>&</sup>lt;sup>36</sup> Referring to Christopher M. Holman, The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Legislation, 76 UMKC Law Rev. 295, 307 (2007). Cf. Kilger, Feldges, Jaenichen, The Erosion of Compound Protection in Germany: Implementation of the EU Directive on the Legal Protection of Biotechnology Inventions—The German Way JPTOS 7, 569 (2005).

<sup>&</sup>lt;sup>37</sup> See e.g. Tine Sommer, The Scope of Gene Patent Protection and the TRIPS Agreement–An Exclusively Nondiscriminatory Approach?, 38 IIC 30 (2007).

<sup>&</sup>lt;sup>38</sup> Cf. e.g. Joseph Straus, An Updating Concerning the Protection of Biotechnological Inventions Including the Scope of Patents for Genes–An Academic Point of View, [2003] OJ EPO Special Issue 166; Cf. Product patents on human DNA sequences: where do we stand in Europe?, 326 Comptes Rendus Biologies 10, 1111-1114.

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<sup>&</sup>lt;sup>39</sup> The author refers to several empirical studies demonstrating that the existence of patents on genes so far had only an insignificant negative impact on biomedical research "as researchers in the biomedical have found working solutions."

<sup>&</sup>lt;sup>40</sup> This has also been repeatedly emphasized by Joseph Straus, see e.g. Straus, in: Kieff (ed.), PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, Vol. 50 of Advances in Genetics (Elsevier Academic Press, 2003), 75. Cf. Minssen, supra n. 33.

<sup>&</sup>lt;sup>41</sup> As noted by the editors in the preface.

# The IP Law Book Review

IP Law Center, Golden Gate University School of Law

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PROPERTY OUTLAWS: HOW SQUATTERS, PIRATES, AND PROTESTERS IMPROVE THE LAW OF OWNERSHIP, by Eduardo Moisés Peñalver and Sonia K. Katyal. Yale University Press, 2010. 304pp. Paperback \$45.00.

Reviewed by Ann Bartow, Pace Law School. abartow@law.pace.edu

Law professors Sonia Katyal (Fordham) and Eduardo Peñalver (Cornell) have produced a vivid and engaging chronicle of "the complex phenomenon of property disobedience." Property disobedience is civil disobedience that has some relationship to property, be it real property, intellectual property, natural resources or even chattels. People who engage in illegal property disobedience are denominated property outlaws. Those who act decisively in spheres in which the law is less certain, such as by boldly asserting the right to make fair use of a copyrighted work, are denominated property "altlaws" by Peñalver and Katyal. They describe the objective of this project as an effort to identify some of the ways in which property disobedience has sometimes spurred innovation and actually strengthened the rule of law. They also implicitly suggest that almost any act of civil disobedience can be categorized and analyzed as property disobedience, using the tools and lenses they employ throughout the tome.

This book challenges the notion that rigidly fostering stability in the private ownership of property is the only appropriate goal of the legal system. The authors assert that dynamic sociopolitical responses to civil disobedience by lawbreakers sometimes propel beneficial legal reforms in a wide array of contexts. Property outlaws with clean hands and good hearts, they argue, can productively draw attention to the need to reform ossified property laws. In the words sometimes attributed to the historical rock star of successful civil disobedience Mohandas Ghandi: "First they ignore you, then they ridicule you, then they fight you, and then you win."

The book discusses the mechanics of social change in a number of contexts that often don't seem linearly linked to "property" in any traditional sense, until the authors connect the dots. It opens with a description of a lunch counter sit-in to protest racial discrimination in North Carolina in 1960, and moves smoothly to a discussion of the copyright law-based impediments to legal distribution of the 1987 documentary about the civil rights movement, "Eyes on the Prize," and the protests by anti-copyright activists that this triggered. The intersection of real property laws and racism is juxtaposed with the conflicts between intellectual property rights and an audiovisual documentary account of that intersection. Illegal acts led to changes in the law in the first instance, and to some increase in public access to an important source of historical information in the second.

Peñalver and Katyal's accounts of these and myriad other acts of civil disobedience that have effected changes in property laws are presented in an erudite and detailed but still accessible manner that makes this tome very appealing. I began reading it with a little bit of trepidation, because so many books touted as putting forth an "intriguingly counterintuitive proposition" (those words appear in a blurb on the back cover) are often riddled with caricatures of the status quo, crafted to artificially inflate the seeming intelligence and importance of the authors' observations. Like most areas of the law, property ownership is complicated, often inconsistent and sometimes completely incoherent. Anytime a work purports to be the Grand, Unified Theory of anything, my inner cynic is activated and on high alert.

But I never got the sense that these authors were choosing anecdotes to illustrate some purported monolithic "common wisdom" and build a case against its conveniently constructed flaws. Nor are they heavy handed with the conclusions they draw from their examples, nor the reactions and responses they recommend. They do not oversell their thesis, and give the reader room to independently process the stories they tell, which is a real strength of the tome. In fact, they claim not to have "a general theory of shifts in legal regimes, or even in property law" (p.15) at all. I found this really refreshing.

The authors sketch out a flexible taxonomy of outlawism that separates acquisitive from expressive disobedience, and intentional law breaking from actions taken in a shifting framework of legal uncertainty. They explain that context is important but rarely determinative and provide a rich and varied menu of potential responses to a range of ownership law transgressions. The open-minded reader will be persuaded that sometimes law breakers should be accommodated, rather than punished.

Peñalver and Katyal appropriately tell stories from many different regions of the world. Chapter 6, entitled "Acquisitive Altlaws: The Treatment Action Campaign, Patents, and Public Health" is particularly gripping in its account of struggles in South Africa and Brazil for access to drugs that treat HIV/AIDS. The authors make a succinct but convincing case that western patent law regimes literally privilege property over human life. Aggressive assertions of intellectual property rights across borders in general can look awfully colonial. It is hard not to pull for the outlaws in this scenario.

At the same time, the authors acknowledge that too little law enforcement can also be problematic, which resonated powerfully with me. Moreover, the intersection of this book and my real space life somewhat complicated my reaction to it. I am spending the year in China on a Fulbright grant. One of the defining characteristics of Shanghai, where I currently reside, is the chaos one often finds in public spaces, despite China's reputation for being a highly authoritarian nation. Simply crossing city streets in every Chinese city I have visited is an extremely dangerous endeavor. As another Fulbrighter put it, in China you have to repress everything you think you know about traffic rules, traffic patterns, and traffic safety, or death awaits Bus drivers plough through crowds and red lights with seeming Motorists rarely wear seat belts, and tend to impinge on impunity. Bicyclists do not wear helmets, and expect designated bike lanes. pedestrians to cede right of way to them on sidewalks.<sup>2</sup> I pay a lot more attention to my surroundings as a pedestrian in Shanghai than I ever have before, but that hasn't kept me entirely safe, and every day I walk in fear of getting hit by a bicycle yet again, or sideswiped by a peddler's cart, or pulverized by a bus that routinely runs a red light, or flattened by a taxi taking a shortcut over the sidewalk. It did not surprise me at all to read in the New York Times that "traffic accidents are the leading cause of death for people in China under the age of 45."<sup>3</sup>

I'm further informed, and believe, that there are laws that would regulate transportation-related conduct if they were enforced; but for reasons economic and political, they are not. As a general matter traffic probably flows far faster in a city of 23 million people when it is largely unpoliced. However, individuals who are adversely affected by the self-serving behaviors of others pay a heavy price for this anarchic efficiency.

Social scientists could provide more nuanced explanations for the dangerous state of China's roads, and economists more erudite buzz words, but the bottom line is that everyone tries to get where they are going as quickly and conveniently as possible. They don't follow any discernible set of proscribed rules, nor expect any one else to. And it is profoundly clear

that obeying rules as a lone actor will not make you or anyone else any safer. People have to believe in the justicial and pragmatic validity of traffic laws for them to have any effect, especially if the government is not going to enforce them energetically. The same is true of property and intellectual property laws, as Katyal and Peñalver explain far more elegantly.

The authors refer to Robert Cover's famous essay<sup>4</sup> "Nomos and Narrative"<sup>5</sup> periodically in their text (per index, pp.25, 32, 77, 141; 234-35), and it seems clear they were, like so many legal scholars, greatly influenced by Cover's trenchant observations about laws and social norms. They build from Cover's assumption that when people align their behaviors with their personal perceptions of right and wrong and that puts them in conflict with the legal system, productive challenges to the exigent laws sometimes ensue, while other times justice may simply be achieved in an alternative sphere, outside the world of courts or police officers. And of course there is at least one more possibility, which is that there can be negative consequences when people ignore the law in favor of their own preferences, see e.g. the dangerous roads of China. As Greg Lastowka has noted in his own review of this book, lawbreaking isn't always heroic and sometimes outlaws are just bad news.

The book closes with a description of San Francisco Mayor Gavin Newson's decision in 2004 to provoke a legal fight about the boundaries of California citizenship rights by issuing marriage certificates to same-sex couples in contravention of existing law. This dramatically ratcheted up the legal and civic debates about discrimination against lesbians and gays. Whether this rather profound act of civil disobedience will result in positive and permanent legal changes remains unclear, but the authors, and this author, too, are optimistic.

If the volume had been written to my personal specifications rather than reflecting the authors' own interests and desires, it might have included a few more examples of acts of well intentioned civil disobedience that backfired, further entrenching socially undesirable property laws. Sometimes that can happen, as outlaws who meaningfully threaten the positive and peaceful aspects of property stability tend to inspire cautionary tales when they come to regrettable ends, because history is usually written and controlled by the machinery of the status quo. But it is still a terrific book as-is, and I emphatically recommend it to readers.

### **ENDNOTES**

http://travel.state.gov/travel/cis\_pa\_tw/cis/cis\_1089.html#traffic\_safety.

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<sup>&</sup>lt;sup>1</sup> www.quotedb.com/quotes/2776.

<sup>&</sup>lt;sup>2</sup> The U.S. State Department explained the situation as follows: "Traffic is chaotic and largely unregulated, and right-of-way and other courtesies are usually ignored. The average Chinese driver has fewer than five years' experience behind the wheel and the rate of traffic accidents in China, including fatal accidents, is among the highest in the world. Cars, bicycles, motorbikes, trucks, and buses often treat road signs and signals as advisory rather than mandatory. Pedestrians never have the right of way, and you should always be careful while traveling in, or even walking near, traffic. Child safety seats are not widely available in China, and most taxis and other cars do not have seat belts in the back seats. Motorcycle and bicycle accidents are frequent and often serious. If you decide to ride a bike or motorcycle, wear a helmet."

<sup>&</sup>lt;sup>3</sup> www.nytimes.com/2011/07/27/world/asia/27rail.html.

<sup>&</sup>lt;sup>4</sup> Actually it was a law review issue foreword, which makes all the attention it has garnered in the years since its publication even more remarkable.

<sup>&</sup>lt;sup>5</sup> Cover, Robert M., "The Supreme Court, 1982 Term–Foreword: Nomos and Narrative" (1983). Faculty Scholarship Series. Paper 2705. http://digitalcommons.law.yale.edu/fss\_papers/2705.

<sup>&</sup>lt;sup>6</sup> http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1939899.