INNOVATION FOR THE 21ST CENTURY: A RESPONSE TO SEVEN CRITICS

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In March 2009, the blog Truth on the Market hosted a symposium on my book, *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law*.[1] The *Alabama Law Review* has been gracious enough to publish revised versions of insightful commentary by Dan Crane, Dennis Crouch, Brett Frischmann, Scott Kieff, Geoff Manne, Phil Weiser, and Josh Wright. In this response, I will address the comments by substantive area, starting with antitrust law, continuing with copyright law, and concluding with more general critiques.

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1. MICHAEL A. CARRIER, INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW (2009).

I. ANTITRUST HISTORY

We begin with Geoff Manne's comments. At the end of my Article, I will respond to his general critiques. In this Part, I address his antitrust comments, and in the next I turn to innovation markets.

Professor Manne first criticizes my use of the "pendulum" metaphor for antitrust's history. As he puts it: I employ the oft-utilized metaphor that "swing[s] . . . from under- to over-enforcement (and back again)" before arriving at an optimal level of antitrust enforcement.[2] Let me offer two responses.

First, my general antitrust history, which is limited to four pages,[3] does refer to a "pendulum," but in the context of judicial analysis. In contrast, Commissioner Bill Kovacic's critique of the concept specifically lamented commentators' exaggeration of the role played by high-level agency appointments, as well as the "too hot" enforcement of the 1960s and 1970s, "too cold" enforcement of the 1980s, and "just right" enforcement of the 1990s.[4]

My primary focus, instead (and in contrast to most of the commentators using the pendulum metaphor) is the IP-antitrust intersection, which makes up two chapters of the book.[5] Commissioner Kovacic does not address the intersection in his article. And, more relevant, whether we call the history of IP-antitrust analysis a "pendulum" or an "evolution" should not matter much. For as a descriptive matter, there indisputably has been a shift from courts that refused to impose antitrust liability for patent-based activity (1890–1912) to courts that aggressively applied patent misuse and antitrust (1912–1960s) to courts that have applied a more deferential approach (1977–present).

More important than the descriptive name we append to the history, however, is what we do with it. Professor Manne concludes that the book "is no exception" to the trend that "everyone who adopts the pendulum narrative does so to make the point that today's antitrust enforcement is too lax and should be beefed up."[6] With respect, that is not the case.

Nowhere do I conclude that antitrust needs to be "beefed up" across the board of its innovation-related scrutiny. To show just how far we've come, and how limited is the canvas on which my antitrust proposals appear, let me set the stage:

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2. Geoffrey Manne, *Review of Michael Carrier's* Innovation for the 21st Century, 61 ALA. L. REV. 553, 554 (2010).

3. CARRIER, *supra* note 1, at 61–64.

4. William E. Kovacic, *The Modern Evolution of U.S. Competition Policy Enforcement Norms*, 71 ANTITRUST L.J. 377, 383–91 (2003).

5. CARRIER, *supra* note 1, at 71–99.

6. Manne, *supra* note 2, at 555.

> Promoting innovation has not traditionally been one of antitrust's top priorities. In the mid-20th century, courts adopted a rigid stance toward IP, automatically condemning tying and licensing arrangements. In the 1970s, the Justice Department followed a "Nine No-No's" policy that assumed that an array of harmless licensing activities violated the antitrust laws.
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> By the 1980s, the tide had turned. Courts applied the more lenient Rule of Reason to licensing arrangements and upheld blanket licenses containing price fixing. Congress passed laws creating a federal court to hear patent appeals, requiring Rule-of-Reason analysis for joint ventures engaging in research and development, and limiting the range of activities that demonstrated patent misuse.
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> By the 1990s, innovation was even more explicitly recognized. The antitrust agencies jointly issued Guidelines for the Licensing of Intellectual Property that appreciated the procompetitive benefits of licensing and recognized that IP does not necessarily indicate market power. More enlightened analysis of business activity, including patent pools, standard setting organizations, and new product introductions, conformed to this approach.
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> Because of this advance, the breadth of my antitrust proposals is far less than it would have been a generation ago. There is no urgent need, for example, to address licensing or patent pools. I conclude that antitrust only needs three recommendations to improve its treatment of innovation. And one of those proposals encourages the agencies and courts to continue on their path of not punishing the activities of standard-setting organizations.[7]

Looking out across the universe of antitrust's treatment of IP and innovation issues, I concluded that drug patent settlements between brand and generic firms presented the setting in which more aggressive antitrust enforcement was most necessary. And while I offer a framework for innovation markets, which could be viewed as increasing enforcement over a "no innovation markets" baseline, the analysis does not necessarily lead to more aggressive treatment, as revealed by my dissents from the multiple Federal Trade Commission (FTC) innovation market challenges in which the merging firms had products in preclinical studies.

A final point stems from Professor Manne's statement that "this book is largely about unilateral conduct (and to a lesser extent mergers) [as op-

7. CARRIER, *supra* note 1, at 292 (footnotes omitted).

posed to] cartels."[8] As a result, "it's not at all clear . . . that [Jonathan] Baker's work [defending antitrust] refutes the relevant portions of Crandall & Winston [calling into question the need for antitrust]."[9] Leaving aside the independent critiques of Crandall & Winston that I synthesize in the book,[10] cartels do in fact present the relevant framework for my treatment of settlements and (at least the coordinated elements of) standard-setting.

One relevant case study is provided by payments from brand-name drug firms to generics to settle patent litigation and delay entering the market (a subject I discuss in detail below). These payments disappeared when first challenged, only to reappear when the antitrust coast was clear. Between 1992 and 1999, eight of the fourteen final settlements between brands and generic first-filers involved reverse payments.[11] In 2000, the FTC announced that it would challenge such settlements.[12] In the succeeding four years, between 2000 and 2004, *not one* of twenty reported agreements involved a brand firm paying a generic filer to delay entering the market.[13] During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry.

In 2005, after the *Schering* and *Tamoxifen* courts took a lenient view of these agreements, the reverse payment floodgates opened. In 2005, three of eleven final settlements (27%) between brand-name and generic firms included such payments. In 2006, fourteen of twenty-eight settlements (50%) contained these provisions.[14] And in 2007, fourteen of thirty-three settlements (42%) included such compensation.[15] Equally concerning, in 2006 and 2007, roughly 70 to 80 percent of settlements between brand firms and first generic filers involved reverse payments.[16] In short,

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8. Manne, *supra* note 2, at 554.
9. *Id.*
10. CARRIER, *supra* note 1, at 66.
11. FEDERAL TRADE COMMISSION BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2005 4 (2006), *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf [hereinafter *FY 2005 Agreements*].
12. Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary, Abbott Laboratories and Geneva Pharmaceuticals, Inc., File No. 981-0395 (F.T.C. Mar. 16, 2000), *available at* http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm.
13. *FY 2005 Agreements*, *supra* note 11, at 4.
14. FEDERAL TRADE COMMISSION BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006 4 (2007), *available at* http://www.ftc.gov/reports/mmact/MMAreport2006.pdf [hereinafter *FY 2006 Agreements*].
15. FEDERAL TRADE COMMISSION BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2007 3 (2008), *available at* http://www.ftc.gov/os/2008/05/mmaact.pdf [hereinafter *FY 2007 Agreements*].
16. *Id.* at 5 (11 of 16 agreements, or 69%); *FY 2006 Agreements*, *supra* note 14, at 6 (9 of 11 agreements, or 82%).

cartels present a more appropriate framework for reverse payment agreements than unilateral conduct.

II. INNOVATION MARKETS

For more specific antitrust analysis, Professor Manne turns to innovation markets, offering three critiques.

First, he is unclear about the scope of my proposal. In case there is any ambiguity in the book, let me be completely clear: my innovation markets framework applies only to the pharmaceutical industry. This setting provides a unique opportunity to address concerns that have been leveled against the concept. While it is conceivable that an innovation markets framework could apply outside the pharmaceutical industry, my framework is not so designed.

Second, to the extent I offer "little more than a stylized merger analysis" under the Horizontal Merger Guidelines, that actually is an improvement over the current state of affairs.[17] In its consent decrees, the FTC, which is responsible for antitrust enforcement in the pharmaceutical industry, has not explicitly considered many of the relevant factors that I suggest.

Each of the five steps in my framework promises to improve innovation markets analysis. The first step, evaluating market concentration, incorporates the realities of innovation in the pharmaceutical industry. A firm in preclinical studies, with roughly a 1 in 4,000 chance of reaching the market, offers far fewer concerns than a firm in Stage III of clinical studies with on average a 57% likelihood of reaching the market.

This is revealed through my second step, which assesses competitive harm. The theory behind innovation markets—"that a merger between the only two, or two of a few, firms in [research and development] might increase the incentive to suppress at least one of the research paths"[18]—applies more directly to firms that are closer to the market, as these firms have a heightened incentive and ability to suppress R&D paths.

Third, the merging firms can rebut the agencies' claim of concentration by showing that at least one other firm is likely to reach the market. Fourth, the merging firms can proffer an efficiencies defense. Fifth, a "Schumpeterian" defense can be offered by small firms that would not otherwise be able to navigate the regulatory process.

Incorporating these stages in the five-part framework carves out space in the analysis for factors that are crucial but have not been explicitly considered in the analysis. I flesh out these points in the book with case studies. For example, I conclude that the FTC should not have challenged the

17. Manne, *supra* note 2, at 553.
18. CARRIER, *supra* note 1, at 297.

innovation market for "CD4-based therapeutics for the treatment of AIDS and HIV infection" in the Roche-Genentech merger since Roche was in preclinical studies and Genentech was in Phase I.[19] In contrast, the FTC correctly challenged the merger between Baxter and Immuno, in part because—in the market for fibrin sealants (which are used to stop bleeding)—each firm was at least in Phase II.

Pivoting to defenses that the merging parties could offer, I show that likely entry by two nonmerging parties in Phase III supports my conclusion that the FTC should not have challenged the merger between Pfizer and Warner-Lambert in the market for an inhibitor for solid cancerous tumors. And I explain why an increased likelihood that a new product will reach the market should count as an efficiency in the setting of fatal, difficult-to-treat diseases such as Pompe Disease. Given that the FTC in 2004 split 3–1–1 on the issue whether to challenge the merger of Genzyme and Novazyme, which were developing treatments for this disease, such a framework could prove helpful.

Third, Professor Manne points to a "fundamental flaw[]" in innovation markets: "[t]hat we don't know about the relationship between market structure and effect . . . ."[20] I agree that there is no simple answer to the question of which market structure is most conducive to innovation. But in recent years, scholars—such as Rich Gilbert, Jonathan Baker, and I—have explored this issue in more fine-grained settings.[21]

It is along these lines that several of the factors tilting ideal market structures in the direction of monopoly or competition show the importance of the latter in pharmaceutical innovation. Without repeating all my arguments from the book, elements of the industry that reflect competition's significance include the prevalence of products (rather than processes), high rate of technological opportunity, and appropriability.[22]

By conducting the analysis at the level of the industry, I aim to avoid the paralyzing uncertainty posed by a single, unknowable relationship between market structure and innovation. At the same time, a review of the FTC's innovation market challenges uncovers common characteristics that provide significant assistance in analyzing these issues.

One example upon which Professor Manne focuses involves drastic innovation, which (stated most simply) displaces demand for the existing product. There is a vast literature on the issue, though the Denicolo and

19. *Id.* at 313.

20. Manne, *supra* note 2, at 555.

21. *See, e.g.*, Jonathan B. Baker, *Beyond* Schumpeter vs. Arrow: *How Antitrust Fosters Innovation*, 74 ANTITRUST. L.J. 575 (2007); Michael A. Carrier, *Two Puzzles Resolved: Of the Schumpeter–Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L. REV. 393 (2008); Richard Gilbert, *Looking for Mr. Schumpeter: Where Are We in the Competition–Innovation Debate?*, *in* 6 INNOVATION POLICY AND THE ECONOMY 159, 165–75 (Adam B. Jaffe et al. eds., 2006).

22. CARRIER, *supra* note 1, at 300–03.

Franzoni paper Manne cites does not address drastic innovation, but rather the importance of the innovation, as measured by the "level of the investments . . . it is able to attract."[23] Also as an aside, patent rights do not "carry over into market structure"—in fact, patent protection often *reduces* the need for other mechanisms, such as size, to appropriate investments.[24]

My use of the concept of drastic innovation underscores the benefits of competition where one of the merging firms developing the next product generation has a monopoly in the existing product market. A quick look at the two innovation market challenges in which this concept could be applied is instructive.

In the first, the FTC challenged Glaxo and Wellcome's merger, which encompassed the R&D market for noninjectable treatment for migraine headaches. Because Glaxo already possessed a monopoly on injectable migraine treatment, it would have a natural incentive to suppress the new product. In the second, Glaxo Wellcome would be tempted to suppress its prophylactic herpes vaccine (which it and merging partner SmithKlineBeecham were researching) so as not to cannibalize sales from its current monopoly in a herpes-suppression drug.[25]

III. STANDARD-SETTING

Turning to the next antitrust chapter, Professor Josh Wright and Aubrey Stuempfle (hereinafter Wright) focus on the complex standard-setting issues I do not address in the book.

A. Breach and Deception

First, Professor Wright asks which of two activities—deception or breach—could form the basis of a Section 2 monopolization violation.

It should be clear that Section 2 can apply to cases of deception. Where a defendant deceives a standard setting organization (SSO) and attains monopoly power as a result, Section 2 liability could be appropriate.

The category of "breach," in contrast, is more complicated, as it can be parsed to distinguish two scenarios. In the first, similar to the *N-Data* case I discuss below, the patentee increases price after the standard has been locked in and it has gained monopoly power. As Wright points out,

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23. Vincenzo Denicolò & Luigi A. Franzoni, *Rewarding Innovation Efficiently: The Case for Exclusive Rights*, George Mason University and Microsoft Conference on The Law and Economics of Innovation, at 4 (May 2008), http://innovationforum.gmu.edu/2008/papers/reward.pdf.

24. Albert N. Link & John Lunn, *Concentration and the Returns to R&D*, 1 REV. INDUS. ORG. 232, 233 (1984).

25. CARRIER, *supra* note 1, at 308 n.56.

this likely would not result in liability because of *NYNEX v. Discon*, which protected the "exercise of market power . . . *lawfully* in the hands of a monopolist."[26]

The second scenario, however, seems to fall somewhere between breach and deception. How should we categorize a patentee's promise to accept reasonable and nondiscriminatory (RAND) licensing in the process of standard selection, followed by its subsequent imposition of royalty terms arguably not consistent with the RAND commitment? This conduct may or may not be deception, depending on the facts of the case. But it could play a role in attaining monopoly power since the patentee's commitment to accept RAND terms could have been central to its selection in the standard.

Of course, the difficulties of determining RAND and challenges facing courts taking on this task warrant great caution. Nonetheless, Section 2 liability could apply since the patentee's RAND commitment could have played a role in having its patent incorporated into the standard (and gaining monopoly power). In short, certain conduct may not fall neatly into categories of breach and deception.

B. The (Section) 5-Ton Elephant in the Room

One of Professor Wright's overriding critiques (mirrored by Professor Phil Weiser) is that I should have more directly addressed the use of Section 5 of the FTC Act in the standard-setting context. Wright and Weiser are correct that this is one of the most debated issues in antitrust today.

My goal in the chapter was to emphasize as strongly as possible my main point that SSOs and their IP rules deserve deference. By explaining the procompetitive effects of SSOs, as well as the essential role played by IP rules, such as licensing and disclosure rules, I sought to make the strongest, cleanest case for antitrust to continue its deference and to gain support from as many readers as possible.

The downside of seeking consensus, of course, is sweeping some issues under the rug. Professors Wright and Weiser look under the rug, and reasonably ask my views on Section 5.

This issue was most recently raised in the FTC's 2008 complaint against N-Data, which licensed patents used in equipment employing Ethernet, a popular networking standard. N-Data's predecessor had committed to license its technology for a one-time royalty of $1,000 per licensee. But N-Data later demanded royalties "far in excess of that commitment."[27] The FTC challenged N-Data's action, claiming an unfair method

26. NYNEX Corp. v. Discon, Inc., 525 U.S. 128, 136 (1998).

27. Press Release, Federal Trade Commission, FTC Challenges Patent Holder's Refusal to Meet Commitment to License Patents Covering 'Ethernet' Standard Used in Virtually All Personal Comput-

of competition and unfair act or practice under Section 5 of the Federal Trade Commission Act. The majority asserted that N-Data's behavior harmed consumers and businesses and explained that its exercise of its "unique" authority was needed to "preserv[e] a free and dynamic marketplace."[28]

I could have (as I do below) criticized the N-Data complaint in the book. Would that have been worth the price of losing some consensus? Perhaps. But the difficulty of staking out a position on N-Data is that it would have divided readers into those who would have been N-Raged and those who would have thought my discussion N-Lightened. Instead, I decided it was worth encouraging everyone to adopt my conclusion that "[g]iven SSOs' significant procompetitive justifications, courts and the antitrust agencies should consider their activity under the Rule of Reason."[29] And that is yet another reason I am grateful for the *Alabama Law Review's* publication of this symposium, which allows me to weigh in on important developments that did not make it into the book.

I believe there is a role for Section 5 of the FTC Act, and think it is beneficial that the FTC is considering how to justifiably apply this provision.[30] One concern with Section 5, however, is that it should not automatically assume the role of a backstop for antitrust claims that come close, but do not quite satisfy, the Sherman Act. The challenge of applying Section 5 to breach cases (for which this presents a straightforward case devoid of the RAND promise I mentioned above) is ensuring that there is a standard that justifies such enforcement.

That is my primary concern with the *N-Data* complaint. I am not convinced that the majority in *N-Data* adequately set forth a framework that justified the application of Section 5. Also contributing to concern are facts revealed in Chairman Majoras's dissent from the complaint, including (1) an initial level of royalties that was nominal (2) set by a predecessor eight years ago (3) for a product for which no licenses were sought in the eight-year period and (4) for a royalty increase to which the SSO's Patent Administrator did not object.[31]

I do not have a fully formed framework for Section 5 that I will, in this limited space, now unveil. But it is worth examining whether such a framework is possible. Consider the case in which a patent holder enters

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ers in U.S. (Jan. 23, 2008), *available at* http://www.ftc.gov/opa/2008/01/ethernet.shtm; *see also* Statement of the Federal Trade Commission, *In re* Negotiated Data Solutions LLC, File No. 0510094, *available at* http://www.ftc.gov/os/caselist/0510094/080122statement.pdf.

28. Press Release, Federal Trade Commission, *supra* note 27.

29. CARRIER, *supra* note 1, at 342.

30. *See* 2008 FTC Workshop: Section 5, http://www.ftc.gov/bc/workshops/section5/index.shtml (last visited Mar. 10, 2010).

31. *See* Dissenting Statement of Chairman Majoras, *In re* Negotiated Data Solutions LLC, No. 0510094, at 5 (F.T.C. Jan. 23, 2008), *available at* http://www.ftc.gov/os/caselist/0510094/080122majoras.pdf.

into a RAND commitment in good faith, without any fraud or deception. One year later, however, to take advantage of its monopoly power, it negotiates a significant royalty increase that raises the price paid by consumers.

Because this activity occurs after the patent holder has gained monopoly power, *NYNEX* could preclude Section 2 liability. But the next question is whether this conduct should be subject to challenge. One option, as Professor Wright suggests, would involve patent or contract law.[32] Another potential option is Section 5.

What could a Section 5 framework look like? Perhaps some combination of monopoly power, a price increase that does not appear justified, causation, and higher consumer prices. These elements flesh out the statutory standard, which limits the range of unfair practices targeted by the FTC to those that "cause[] or [are] likely to cause substantial injury to consumers" and are "not reasonably avoidable by consumers."[33]

Of course, there are obvious costs to expanding Section 5 to price increases. And maybe those costs preclude the application of Section 5 at all. But I would allow the FTC to attempt to construct a limited framework. With such a framework in hand, we could decide that the costs of such an approach are too high. Or that the patent or contract approach is the right answer. But before we bury Section 5, we should at least see if a justifiable framework is possible.

C. Causation

The third issue that Professor Wright raises is causation. The most important recent decision in this area is the D.C. Circuit's 2008 opinion in the *Rambus* case.[34]

Rambus developed computer memory technologies known as DRAM (dynamic random access memory), which processes information and is used in computers, printers, and cameras. Rambus participated in the Joint Electron Device Engineering Council (JEDEC), a semiconductor engineering SSO made up of DRAM manufacturers and purchasers as well as producers of complementary products. The SSO's disclosure policy was not clear, leading the Federal Circuit to find that it suffered from "a staggering lack of defining details."[35]

The FTC nonetheless found that Rambus "engaged in representations, omissions, and practices likely to mislead JEDEC members," which "sig-

32. *See* Bruce H. Kobayashi & Joshua D. Wright, *Federalism, Substantive Preemption, and Limits on Antitrust: An Application to Patent Holdup*, 5 J. COMPETITION L. & ECON. 469 (2009).

33. 15 U.S.C. § 45(n) (2006).

34. Rambus Inc. v. F.T.C., 522 F.3d 456 (D.C. Cir. 2008).

35. CARRIER, *supra* note 1, at 332 (quoting Rambus Inc. v. Infineon Technologies AG, 318 F.3d 1081, 1102 (Fed. Cir. 2003)).

nificantly contributed to its acquisition of monopoly power."[36] The Commission concluded that "'but for Rambus's deceptive course of conduct, JEDEC either would have excluded Rambus's patented technologies from the JEDEC DRAM standards, or would have demanded RAND assurances . . . with an opportunity for *ex ante* licensing negotiations.'"[37]

In 2008, the D.C. Circuit, focusing on causation, reversed the Commission's conclusion.[38] It explained that "if Rambus's more complete disclosure would have caused JEDEC to adopt a different (open, nonproprietary) standard, then its failure to disclose harmed competition and would support a monopolization claim."[39] But how did the D.C. Circuit flesh out its causation standard? In other words, how did the court interpret "would have caused" in the sentence above?

It did not find this standard satisfied by its assumption that "Rambus's nondisclosure made the adoption of its technologies somewhat more likely than broad disclosure would have."[40] So "somewhat more likely" is not enough.

What, then, was the FTC's alleged deficiency? That it "expressly left open the likelihood that JEDEC would have standardized Rambus's technologies *even if Rambus had disclosed* its intellectual property."[41] In other words, the lack of disclosure could not definitively be pinpointed as the catalyst for monopoly power. The D.C. Circuit in essence applied a "but for" standard by which the plaintiff would need to show that the monopolist's deceptive conduct was the *sole* reason it acquired monopoly power.

Turning to the facts, did Rambus have monopoly power before the selection of the standard? The Commission's 2006 opinion[42] included exhaustive evidence on this crucial point. A quick review of the evidence casts serious doubt on the proposition.

First, there was significant evidence of alternative technologies. The Commission cited 12 examples of viable, if not preferable, alternatives to the Rambus technologies offered by Samsung, Cray, Mitsubishi, Texas Instruments, IBM, Micron, and Silicon Graphics.[43] The Commission found that "JEDEC members . . . gave these alternatives serious, searching consideration" and that "the technologies as to which Rambus subsequently revealed patent claims sometimes were chosen only after pro-

36. *In re* Rambus, Inc., No. 9302, 2006 WL 2330117, at 68 (F.T.C. Aug. 2, 2006).
37. Rambus Inc. v. F.T.C., 522 F.3d at 461 (quoting *In re* Rambus, Inc., No. 9302, 2006 WL 2330117, at 74 (F.T.C. Aug. 2, 2006)).
38. *Id.* at 463.
39. *Id.* at 463.
40. *Id.* at 463–64.
41. *Id.* at 466.
42. Opinion of the Commission, *In re* Rambus, No. 9302, at 74–77 (F.T.C. Aug. 2, 2006), *available at* http://www.ftc.gov/os/adjpro/d9302/060802commissionopinion.pdf.
43. *Id.* at 76 n.412.

longed debate."[44] As the Cisco representative explained: "[I]n typical design activity one can make any number of choices, including choosing an interface that was not encumbered by a patent or royalty."[45]

Second, JEDEC members were "highly sensitive" to costs. Just to offer a few examples, Rambus's primary JEDEC representative stated that "customers are willing to leave performance on the table in exchange for having lower cost systems."[46] Compaq "'stressed that price was the major concern for all of their systems'" and Sun "'echoed the concerns about low cost [and] really hammered on that point.'"[47] As an internal Rambus e-mail summarized: "Our industry is very cost sensitive."[48]

The reason for the sensitivity was readily apparent. The Commission concluded that "[t]he total cost of payments for Rambus's undisclosed patents could amount to several billion dollars, with some individual DRAM manufacturers each paying hundreds of millions of dollars."[49] To pick one example, the Commission noted that "Rambus's requested royalty would cost Micron hundreds of millions of dollars . . . the equivalent of 25-50% of Micron's R&D expenditures."[50]

Third, the inclusion of patents in the standard would, for obvious reasons, tend to increase cost. It thus is not a surprise that numerous witnesses testified that knowledge of patents "was an important factor in their decisions."[51] Sun "would have strongly opposed the use of royalty-bearing elements in an interface . . . specification."[52] Sanyo's representative explained: "If I understood that there was IP on the [technology], I would have . . . changed my direction and voted to take the [alternative]."[53] IBM's representative noted that "[p]atent issues are a concern on every JEDEC proposal" and that when a technology was considered for the first time, "it was especially valuable to have the consideration of patents so that we could possibly avoid them."[54] Micron's knowledge of Rambus's patent applications "would have caused [them] to oppose [Rambus technologies]."[55] JEDEC minutes stated: "The important thing is disclosure. If it is known that a company has a patent on a proposal then the Committee

44. *Id.* at 76.
45. *Id.* at 76 n.411.
46. *Id.* at 75 n.406.
47. *Id.* at 75.
48. *Id.* at 75 n.404.
49. *Id.* at 75–76.
50. *Id.* at 76 n.410.
51. *Id.* at 75.
52. *Id.*
53. *Id.* at 75 n.407.
54. *Id.*
55. *Id.*

will be reluctant to approve it as a standard."[56] Numerous other examples appear in the record.

In short, there is significant evidence that absent deception, Rambus would not have obtained monopoly power. There were numerous viable alternatives, and JEDEC members were sensitive to cost and tried to avoid patented technologies whenever possible. Based on this evidence, the reasonable conclusion would appear to be that the FTC showed that Rambus's disclosure "would have caused" JEDEC to adopt a different standard.

IV. THE *MICROSOFT* CASE

Keeping with the theme of antitrust issues that could have been more fully developed in the book, Professor Weiser correctly observes that I discuss, but do not offer proposals for, the *Microsoft* case.

Of all the facets of the *Microsoft* case, the European Union's case most directly implicates the IP-antitrust intersection. The facts, which are complicated, are explored more fully in the book.[57] For now, suffice it to say that Microsoft denied rivals information needed to connect non-Microsoft work group servers (which provide services used by office workers such as file and print sharing) with Windows computers and servers.[58]

Microsoft claimed that its protocols and specifications (which provide the rules of interconnection and other documentation) were protected by patents, copyrights, and trade secrets. The crucial question, of course, is whether Microsoft should be compelled to share its IP-protected interfaces. The natural framework in which courts address these issues is the essential facilities doctrine, which provides that a monopolist cannot deny to its competitors facilities that are necessary to compete in a particular market. Assuming (in the U.S.) that this doctrine survives *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*,[59] the question is whether the denial of a firm's IP violates it.

In nearly all cases, the answer should be no. The right to exclude is the core of the IP right, and thus should ordinarily be viewed as sacrosanct. Of additional concern is that IP essential facility claims tempt courts to force the sharing of helpful (albeit not essential) facilities. For example, in *Intergraph Corp. v. Intel Corp.*, the district court—before being re-

56. *Id.*
57. CARRIER, *supra* note 1, at 89–92.
58. *Id.* at 90 (citing Case T-201/04, Microsoft v. Comm'n, 2007 E.C.R. II-3601 ¶¶ 160, 162 [hereinafter CFI Decision]; Press Release, European Commission, Antitrust: Commission Welcomes CFI Ruling Upholding Commission's Decision on Microsoft's Abuse of Dominant Market Position (Sept. 17, 2007), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/07/359).
59. 540 U.S. 398 (2004).

versed by the Federal Circuit—found that access to business information could constitute an essential facility.[60]

But the fact that IP-protected products should *almost never* be treated as an essential facility does not mean that they should *never* be so treated. For the Microsoft case raises a setting in which such claims should carefully be considered. The European Union has followed such an approach, finding that, under Article 82, a refusal to deal could constitute an abuse of dominance in "exceptional circumstances," such as where a refusal (1) relates to a product indispensable to behavior on a neighboring market, (2) excludes competition on that market, and (3) prevents the appearance of a new product for which there is potential consumer demand.[61]

It is difficult to see U.S. courts applying such a framework. But should they? That question can be answered only by considering the benefits of (strictly) imposing liability for monopolists' conduct that prevents interoperability as well as the administrative and error costs that would accompany such a framework. The costs of such a framework would be high. For there is no guarantee that the analysis would be applied with the level of strict scrutiny that is required. Loose interpretations of indispensability, in particular, would be dangerous.

But, again, interoperability has significant benefits.[62] The literature has recently offered two important accounts of the concept. In one, Weiser explores the relationship between platforms and applications.[63] In the second, Pamela Samuelson recounts the existence of multiple impediments to interoperability.[64]

I cannot resolve all the issues presented by interoperability and administrative or error costs in this space. But in the end, Professor Weiser is right that this presents an important issue for ongoing debate, and the two articles offer a reasonable starting point for exploring at least the issues related to interoperability.

V. DRUG PATENT SETTLEMENTS

Turning to the last antitrust chapter, Dan Crane explores settlement agreements by which brand-name pharmaceutical companies pay generic firms to drop patent challenges and delay entering the market. Professor Crane is right that the direction of the payment, by itself, is not what is suspicious about brand drug firms' payments to generics for delay.

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60. 3 F. Supp. 2d 1255, 1278 (N.D. Ala. 1998), *vacated*, 195 F.3d 1346 (Fed. Cir. 1999).
61. CFI Decision, *supra* note 58, ¶ 332.
62. CARRIER, *supra* note 1, at 167–70.
63. Phil Weiser, *Regulating Interoperability: Lessons from* AT&T, Microsoft, *and Beyond*, 76 ANTITRUST L. J. 271 (2009).
64. Pamela Samuelson, *Are Patents on Interfaces Impeding Interoperability?*, 93 MINN. L. REV. 1943 (2009).

Rather, in the context of settlements under the Hatch-Waxman Act, three characteristics raise concern. First, in contrast to other patent settlements—by which an alleged infringer pays the patentee and enters the market—the generic agrees not to enter the market, which more directly threatens competition.

Second is the unique setting provided by the Hatch-Waxman Act. As I discuss in detail in the book,[65] the Act's drafters crafted a nuanced regime that addressed many of the concerns that existed at the time of enactment in 1984.

They fostered innovation by providing brand-name drug companies with patent term extensions, nonpatent market exclusivity (for new chemical entities and new clinical investigations), and an automatic 30-month stay for brand firms that sued generics that had challenged the patent's invalidity or claimed noninfringement.

At the same time, they fostered competition by (1) allowing generics to rely on brand firms' studies, thereby accelerating entry; (2) resuscitating the experimental use defense by overturning *Roche v. Bolar* and exempting from infringement the manufacture, use, or sale of a patented invention for uses "reasonably related to the development and submission of information"[66] under the FDA Act; and (3) encouraging generics to challenge invalid or noninfringed patents by creating a 180-day period of marketing exclusivity for the first generic firm to do so.

This last element is crucial. One of the central goals motivating the drafters was to ensure the provision of "low-cost, generic drugs for millions of Americans."[67] Generic competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed."[68] Generic challenges to brand patents thus are a central aspect of the Act. Settlements by which generics agree not to challenge patents threaten the drafters' intentions.

Third, in the Hatch-Waxman setting, reverse payments are often the only indicator of a patent's invalidity or lack of infringement. At the risk of oversimplifying, settlements within the scope of a valid patent are legitimate. Settlements dividing markets under cover of an invalid patent are not.

But the most direct way to determine these issues, patent litigation, cannot be utilized. For the significant analysis and testimony on complex issues—such as patent claim interpretation and infringement analysis—cannot be inserted as mini-trials in antitrust litigation. Nor would an analysis of the merits of the patent infringement case even be reliable: after a

65. CARRIER, *supra* note 1, at 347–57.
66. 35 U.S.C. § 271(e)(1) (2006).
67. 130 CONG. REC. 24,427 (1984) (statement of Rep. Waxman).
68. *Id.*

case settles, the parties' interests become aligned, with a generic firm lacking the incentive to vigorously attack a patent's validity or challenge a claim of infringement.

In many cases, therefore, reverse payments offer crucial indirect evidence of a patent's invalidity. Brands that pay generics more than they ever could have gained from entering the market raise red flags of potential invalidity. Further hoisting such flags are the parties' aligned incentives. Because the brand makes more by keeping the generic out of the market than the two parties would receive by competing in the market, the parties have an incentive to split the monopoly profits, making each better off than if the generic had entered.

What is particularly concerning about reverse payments is not the direction of the payment. Instead, it is that the payments often make possible agreements that do not reflect the parties' reasonable assessment of success in patent litigation.

Let me offer an example. An agreement concerning the generic's entry date, without any cash payment, often reflects the odds of the parties' success in patent litigation. By way of example, if there were ten years remaining in the patent term and the parties agreed there was a 60% chance that a court would uphold the patent's validity, the mean probable date of entry under litigation would occur in six years.

A brand is likely to gain additional exclusivity by supplementing the parties' entry date agreement with a payment to the generic. Continuing the example above, the brand could pay the generic to gain an additional three years (for a total of nine years) of exclusivity. The monopoly profits the brand earned in these three years would vastly exceed the reduced profits it would earn from sharing the market with the generic. Even with a payment to the generic, the brand would still come out ahead. And the generic would also benefit since the payment would exceed the profits it could have gained by entering the market.

In buying more exclusivity than the patent alone could provide, reverse payments tend not to reflect an objective assessment of validity. In most cases, the patentee would not pay more than its litigation costs unless it believed it was buying later generic entry than litigation would provide. Notice that I said "most" and not "all." In the book, my presumption of illegality for reverse payments is rebuttable, and I allow the parties to rebut it in several settings in which they could demonstrate the payment's reasonableness.[69]

Professor Crane's attention to the recent wave of settlements lends further support to placing the burden on the settling parties to demonstrate that the payment reflects a reasonable assessment of success in the patent

69. CARRIER, *supra* note 1, at 378–82.

infringement case. No longer are brand firms making simple cash payments for generics not to enter the market. Instead, they are paying generics for IP licenses, for the supply of raw materials or finished products, and for helping to promote products. They are paying milestones, up-front payments, and development fees for unrelated products.[70] And, in the latest trend, they are agreeing not to launch authorized, brand-sponsored generics.[71]

Many of these provisions—such as a supply agreement by which a brand pays a generic *even if it does not supply the product*—exceed the fair market value for the item. Of particular concern, side payments appeared in nearly all the settlements that restrained generic entry but few of the settlements that did not. Nor is the product provided by the generic typically even one that the brand had sought before settlement.[72]

Congressman Rush's proposed legislation would prohibit agreements by which a generic firm receives "anything of value" in exchange for not researching, developing, manufacturing, marketing, or selling the generic product.[73] Such a formulation would cover not only the initial wave of direct payments from brand to generic but also the recent wave of "side deals."

Professor Crane is correct that lawyers can be creative with these arrangements. But in many cases, it will be far more likely that the generic is being paid to delay entering the market than to provide needed services. For example, do generics typically have the promotion experience that would make them the natural choice for such work? The same often goes for patent licenses for unrelated products, backup manufacturing services, and other types of arrangements. If brands typically do not enlist generics for these projects outside the settlement context, that should raise eyebrows.

Crane also points to the *Schering-Plough* case.[74] Though the FTC's condemnation was reversed by the Eleventh Circuit, the Commission had developed strong evidence that Schering had paid the generics to delay entering the market. Even though there were significant safety and market concerns with one product, for example, Schering (1) did not include its knowledgeable employees in the negotiations,[75] (2) failed to request sales

70. *FY 2006 Agreements*, *supra* note 14, at 4–5.

71. FED. TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT 3 (2009).

72. *Paying Off Generics to Prevent Competition with Brand Name Drugs: Hearing Before the Senate Comm. on the Judiciary*, 110th Cong. 17 (2007) (statement of Jon Leibowitz, Comm'r of the Federal Trade Comm'n), *available at* http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

73. Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. § 2(a) (2009), *available at* http://www.govtrack.us/congress/bill.xpd?bill=h111-1706&tab=related.

74. *In re* Schering-Plough Corp., 136 F.T.C. 956, 1060–61 (2003).

75. *Id.* at 1019.

projections or research relating to the drug,[76] (3) never followed up on unfulfilled requests for information,[77] and (4) did not object when the generic suspended its work.[78] If Schering were in fact interested in the generic's product, this course of conduct—especially when contrasted with other products they were considering—would not make sense.

So even if some creative arrangements could slip through the cracks, congressional legislation would still be valuable in blocking at least a subset of these concerning agreements.

In short, I agree with Professor Crane that the direction of the payments does not, by itself, warrant close scrutiny. I also agree that—due to the Hatch-Waxman framework—it has been typical for the direction to flow from brand-patentee to generic-infringer.

I part ways from Crane, however, in considering in my analysis (1) the importance of competition and generic patent challenges at the heart of the Hatch-Waxman Act, (2) the unique position of reverse payments in determining patent validity in this context, and (3) the latest wave of settlements, which create ever more numerous versions of "three-drug Monte."

VI. THE SUPREME COURT AND *TRINKO*

Professor Weiser raises the important point that the Supreme Court might not be inclined to apply *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*[79] to expand antitrust liability in the context of reverse payment settlements.

For starters, as Weiser and I have both previously discussed,[80] *Trinko* was decided on a motion to dismiss. In the case, incumbent local exchange carrier (ILEC) Verizon refused to share its network with rivals. In assuming the efficacy of the Telecommunications Act of 1996, the Court pointed to penalties and reporting requirements imposed on Verizon. But as applied to billion-dollar industries, the agency's fines—as former FCC Chairman Michael Powell has explained—"are trivial [and] are the cost of doing business to many of the[] companies."[81] Given that the Court addressed these issues at the motion-to-dismiss stage, it seemed only to assume the effectiveness of the regulatory regime's remedies.

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76. *Id.* at 1037.
77. *Id.* at 1043.
78. *Id.* at 1051.
79. 540 U.S. 398 (2004).
80. Michael A. Carrier, *Of* Trinko*, Tea Leaves, and Intellectual Property*, 31 J. CORP. L. 357 (2006); Philip J. Weiser, *Federal Common Law, Cooperative Federalism, and the Enforcement of the Telecom Act*, 76 N.Y.U. L. REV. 1692 (2001).
81. *Agenda and Plans for Reform of the FCC: Hearing Before the Subcomm. on Telecomms. and the Internet of the H. Comm. on Energy and Commerce*, 107th Cong. 17 (2001) (statement of Michael K. Powell, Chairman, FCC).

Applying this framework to Hatch-Waxman, it is possible that the Court could assume that the regime is effective. While possible, that approach would neglect the ubiquitous presence of settlements, which dispense with the promotion of competition and patent challenges at the heart of the Act. It would be harder, in other words, to sweep effectiveness under the rug when the very class of agreements takes such direct aim at the Act's purposes.

If I can expand the point, I recognize that my proposal is ambitious. While *Trinko* has engendered significant commentary, none of that commentary has yet advocated a new tool for plaintiffs! I need to be clear, then, that I am far from certain that the Supreme Court—if it were interested in applying *Trinko* to pharmaceutical settlements—would necessarily come out my way. In fact, given the trend in the Court, which has proven beneficial to antitrust defendants in recent years, the odds may well be against me.

But my proposal is not based on what I predict the Court is likely to do. Instead, it teases out the importance of a factor that, until now, has received insufficient attention: the effectiveness of a regulatory regime. The Court has focused on the *existence* of such a regime in downplaying the need for antitrust. But before it forces antitrust to step down, the Court should direct some inquiry to the *effectiveness* of the regulatory regime. For if it does not, then it is dispensing with antitrust in a setting in which regulation may not be effective.

To be sure, difficult issues could arise where Congress deliberately creates an ineffective regime. But Hatch-Waxman does not confront such issues. The drafters themselves lamented reverse payments, with Senator Hatch finding such agreements "appalling"[82] and Representative Waxman explaining that such agreements were an "unfortunate, unintended consequence" of the Act that "turned [the law on its] head."[83] In short, this is not a setting in which there are close calls about whether the drafters intended to create a regulatory regime that fostered competition and patent challenges.

VII. PEER-TO-PEER ASYMMETRIES

Turning to copyright law, one of my proposals addresses dual-use technologies, such as peer-to-peer (P2P) file-sharing software. These technologies can be utilized (1) to create revolutionary new forms of interaction and entertainment or (2) to facilitate widespread copyright infringement.

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82. 148 CONG. REC. 15,354 (2002) (statement of Sen. Hatch).

83. Brief for Representative Henry A. Waxman as Amicus Curiae in Support of Petitioner, FTC v. Schering-Plough Corp., 548 U.S. 919 (2005) (No. 05-273) (Sept. 30, 2005), 2005 WL 2462026.

How, then, should copyright law treat these technologies? Should it consider the technology's primary use? Determine whether it has a substantial noninfringing use? Examine its creator's intent? Courts have considered these tests, among others, in applying copyright law to dual-use technologies.

In my proposal, I show how most of these tests threaten to stifle innovation. In his post, Brett Frischmann recounts the reasons why, in particular, discussing the three asymmetries I develop.

First, I introduce an "innovation asymmetry," which highlights why courts tend to overemphasize a technology's infringing uses and underappreciate its noninfringing uses.[84] I contend that

> [t]he costs of infringing uses can be quantified . . . [and] are accentuated by the abundant evidence: because infringement has already occurred, plaintiffs need not speculate about future potential infringement. Surveys of downloaded works present tangible evidence of (often massive) copyright infringement to the court on a silver platter.
>
> Moreover, the costs are vivid in threatening the copyright industries' business models. Finally, all of the tasks needed to demonstrate harms from copyright infringement can easily be undertaken by the recording and motion picture industries. . . .[85]

On the other hand, noninfringing uses are less tangible. It is difficult to put a dollar figure on the benefits of enhanced communication and interaction.[86] The uses also are more fully developed over time. When a new technology is introduced, "no one, including the inventor, knows all of the beneficial uses to which it will eventually be put."[87] I offer numerous examples of inventions for which nobody foresaw the eventual popular and revolutionary use (including, just to pick two, the telephone, which Alexander Graham Bell thought would be used primarily to broadcast the daily news, and the phonograph, which Thomas Edison thought would be used "to record the wishes of old men on their death beds").[88] Finally, I contend that "[t]he disappearance of [noninfringing] uses (along with the new technology) will not be lamented as it would be less likely to disrupt settled expectations."[89]

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84. CARRIER, *supra* note 1, at 128–30.
85. *Id.* at 128–29.
86. *Id.* at 129.
87. *Id.* (internal citations omitted).
88. *Id.*
89. *Id.* at 130.

Second, I introduce an error-costs asymmetry.[90] One type of error (a *false positive* or Type I error) occurs in the P2P setting when a court erroneously shuts down a technology. The other type (*a false negative* or Type II error) occurs when a court mistakenly upholds the technology even though it should have imposed liability.[91] I contend that in the Type-II-error case, "society can witness the effects of the technology."[92] I argue that "Congress can always step in to compensate copyright holders."[93] Professor Frischmann is correct that as a practical matter, such relief may not be immediately forthcoming. But copyright holders have had some success at getting Congress's attention, so it at least is within the realm of possibility.

In contrast, in the Type-I-error case, "consumers will never know what they are missing."[94] Will, Frischmann asks, this hold true for every technology? Perhaps not. But if we know anything about innovation, it is that we don't know a lot about the uses to which fledgling products will eventually be put. If the inventors themselves often cannot discern the ultimate use, we cannot be confident that courts can.

Finally, I unearth a litigation asymmetry that arises from the effect of the test on technology manufacturers. I contend that

> [p]rotracted litigation is expensive and favors those with deep pockets. . . . In contrast, upstart dual-use manufacturers often lack the financial resources to wage lengthy legal battles. . . . [G]iven that some of the most revolutionary innovation comes from small inventors—such as the "upstarts who developed the first MP3 players" in the 1990s, which paved the way for the iPod—such consequences are severe. A legal standard that does not resolve the issue of secondary liability at an early stage of the proceedings will lead to debilitating uncertainty and exert a chilling effect on innovation.[95]

I recount several cases in which technology companies were forced into bankruptcy as a result of litigation.[96]

As a concluding note, Frischmann suggests that I should have more fully engaged arguments about the benefits of requiring technology manufacturers to implement cheap, easy technological fixes. Given the impor-

90. CARRIER, *supra* note 1, at 131.
91. *Id.*
92. *Id.*
93. *Id.*
94. *Id.*
95. *Id.* at 131–32 (quotation omitted).
96. *Id.* at 132.

tance of the issue, and my continuing engagement with these ideas, I will take Frischmann up on his invitation in future work.

For our purposes here, let me just explain my concern that such determinations introduce complexity and eliminate early disposition of a case.[97] For example, litigation over which fingerprinting system to adopt presents a nuanced factual question and forces judges to grapple with intractable issues about the sufficiency of various solutions. In *Napster*, even though the company examined dozens of audio fingerprinting systems and installed one that "was able to prevent sharing of much of plaintiffs' noticed copyrighted works," the court demanded "zero tolerance" and shut down the service.[98]

More broadly, I explain that feasibility questions could "enmesh courts in disputes comparable to those that have bedeviled design defect litigation in products liability."[99] For in cases involving manufacturing flaws, courts can compare a product to the manufacturer's standards. In contrast, there is no objective standard of comparison for design defects since the product is used in its intended condition. Courts lacking a benchmark could be tempted to find that defendants failed to do enough.

VIII. THE PATENT PROPOSALS

Turning to patent law, Dennis Crouch raises several points about my patent recommendations. Let me address the four major ones.

The first is the most far-reaching. Professor Crouch concludes that I "rather consistently choose[] sides in favor of reducing patent rights."[100] I am not certain that is the case. As I discuss below in response to Scott Kieff's post, I did not include many potential proposals—covering patentable subject matter, nonobviousness, and a robust experimental use defense, to name just a few—that an array of patent scholars has offered in recent years and that would have more significantly weakened patents.

In addition, the three patent proposals I offer do not consistently reduce patent rights. The first, to be sure, could be placed in such a category (although my proposal is far from the only one to recommend a post-grant opposition system). The second clarifies existing case law, fleshing out the framework for relief that the Supreme Court articulated in *eBay Inc. v. MercExchange, L.L.C.*[101] And the third explains why more aggressive

97. *Id.* at 137–39.

98. A&M Records, Inc. v. Napster, Inc., 284 F.3d 1091, 1096–97 (9th Cir. 2002); *Symposium,* Sony v. Universal*: The* Betamax *Decision Twenty Years Hence*, *Panel 2, Play: The Revolution Arrives*, 34 SW. U. L. REV. 179, 193 (2004).

99. Diane Leenheer Zimmerman, *Daddy, Are We There Yet? Lost in* Grokster-*Land*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 75, 92 (2005–2006).

100. Dennis Crouch, *Reviewing Part III of* Innovation for the 21st Century: Patent, 61 ALA. L. REV. 587, 587 (2010).

101. 547 U.S. 388 (2006).

proposals for experimental use in the setting of biotechnology research tools are not appropriate at this time. This last setting stands in contrast to my more ambitious proposal for material transfer agreements (MTAs), which implicate patents far less directly.

Second, Professor Crouch raises a significant practical comment: Is the game of preventing holdup worth the candle of increased litigation costs and potential reduced innovation incentives? Rather than debate this on a theoretical plane, let me offer some examples that arise from an application of *eBay* and *MedImmune, Inc. v. Genentech, Inc.*[102]

In emphasizing the default position of injunctive relief but recognizing the propriety of damages in certain settings, I offer a proposal consistent with that articulated by the Supreme Court in *eBay*. In making clear what factors the courts should consider in applying the four-part framework for determining appropriate relief, my proposal could provide guidance to lower courts.

And as the post-*eBay* cases reveal, there have been several cases in which (1) the patentee does not directly compete with the alleged infringer, (2) the infringed claims make up a small part of the defendant's product, and (3) a defendant would suffer greater hardship from the grant of an injunction than a plaintiff would suffer from its denial. For example, in *Paice LLC v. Toyota Motor Corp.*, defendant Toyota's hybrid vehicles infringed plaintiff Paice's patents, which implicated only a part of the hybrid transmission among the tens of thousands of parts making up a typical car, and injunctive relief threatened adverse effects on third-party dealers and suppliers.[103] And in *z4 Technologies, Inc. v. Microsoft Corp.*, Microsoft infringed z4's product activation software that was a "very small component" and not related to the "core functionality" of Windows in a setting in which injunctive relief would have required Microsoft to release new versions of its Windows software in 600 variations in more than 40 languages.[104]

MedImmune paved the way for cases like *Teva v. Novartis*,[105] which could have significant effects in the Hatch-Waxman setting. Here, oversimplifying slightly, the first generic to challenge a brand patent's validity or claim noninfringement is entitled to a 180-day period of marketing exclusivity. The temptation is for the brand and first-filing generic to settle patent litigation with the generic agreeing not to enter the market. The bottleneck arises because if the brand decides not to sue other generics and the first-filing generic does not enter the market, then subsequent generics

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102. 549 U.S. 118 (2007).

103. No. 2:04-CV-211-DF, 2006 WL 2385139, at *2 (E.D. Tex. Aug. 16, 2006), *vacated in part on other grounds*, Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1315 (Fed. Cir. 2007).

104. 434 F. Supp. 2d 437, 441–42 (E.D. Tex. 2006).

105. Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330 (Fed. Cir. 2007).

cannot enter. By increasing the scope of declaratory judgment actions, these generics might be able to sue the brand and ultimately enter the market.

Third, to be clear, I intended to limit my argument about the benefits of challenging invalid patents to invalid patents. While others have called into question the entire patent system, that is not and never has been my goal.[106] In contrast, I recognize the importance of patents, especially in the pharmaceutical and biotechnology industries.[107]

Fourth, my post-grant opposition system—which Professor Crouch notes is similar to that contained in the Patent Reform Act of 2009 (though not identical, as my broader windows for challenge attest)—does not consider the PTO's "current mantra favoring rejection."[108] Innovation incentives could be affected by a more robust mechanism for challenging patents in this environment.

But there can be no question that numerous invalid patents have been issued. While the subset of litigated patents does not precisely reflect the universe of all patents, the findings of John Allison and Mark Lemley, Kimberly Moore, and the University of Houston's PATSTATS that roughly thirty to fifty percent of litigated patents are invalid would lend strong support to a mechanism to reduce the incidence of such patents.[109]

In addition, I build into my opposition system various measures—such as one-way fee shifting mechanisms and a system based on maintenance fees—that could allow the regime to be calibrated to reduce adverse effects on innovation incentives. But given the prevalence of invalid patents, together with less-than-ideal current alternatives (initial patent application review, validity litigation, and reexamination), post-grant opposition makes sense.

IX. MATERIAL TRANSFER AGREEMENTS

Many scientists need tangible materials for their research. Unlike the situation of patented research tools, scientists often cannot circumvent a refusal to license materials. In providing materials, the owners frequently require recipients to enter into material transfer agreements (MTAs).

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106. Michael A. Carrier, *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation*, 56 VAND. L. REV. 1047 (2003).

107. CARRIER, *supra* note 1, at 47.

108. Crouch, *supra* note 100, at 590.

109. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998); Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 385 (2000); INST. FOR INTELLECTUAL PROP. & INFO. LAW, UNIV. OF HOUSTON LAW CTR., PATSTATS: U.S. PATENT LITIGATION STATISTICS, DECISIONS FOR 2000–2004, ¶¶ 1–16, 23–24, http://www.patstats.org/Composite%20Table%20(2000-2004).html (last visited Mar. 10, 2010).

There are two responses to Professor Crouch's question as to why I cover MTAs in the book. First, patent issues sometimes are implicated, as reach-through provisions attest. Second, MTAs offer a useful comparison to patented research tools by revealing empirical evidence demonstrating withheld materials, abandoned research lines, delays in receiving materials, and publication restrictions.[110]

My proposal requiring recipients of federal funding to agree to the provisions of the uniform biological MTA would lower transaction costs by increasing adherence to the model agreement. In addition, I would, as I discuss below, suggest model publication terms for transfers between university and industry.

X. THE UNADDRESSED COMMENTARY

Scott Kieff correctly points out that in the book, I do not specifically address the work of many important patent scholars such as Richard Epstein, Polk Wagner, John Duffy, and himself.

Just because a scholar does not appear in the book, however, does not mean that his or her work has not influenced me. My patent proposals, as discussed above, are modest in nature. Many patent scholars have advocated more aggressive sets of proposals. But several decisions I made in cabining my universe of patent proposals relied in part on the insights of the property scholars Professor Kieff references. Let me offer a few examples, referencing these scholars' writings (and leaving aside for the moment the effects of recent changes in the law).

First, I did not offer a proposal on nonobviousness, as a reduced need for reform is apparent from the empirical studies by Polk Wagner and Chris Cotropia, together with Greg Mandel's important work on hindsight bias.[111]

Second, I did not address patentable subject matter, based in part on arguments such as those offered in the Wagner/Risch/Lemley amicus brief[112] and Duffy brief[113] in the Federal Circuit in *In re Bilski*.

A third example comes from Professor Kieff's own work. At the 2008 George Mason University and Microsoft conference on the Law and Economics of Innovation, I had the pleasure of responding to his work on the

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110. CARRIER, *supra* note 1, at 281–83.

111. Christopher A. Cotropia, *Nonobviousness and the Federal Circuit: An Empirical Analysis of Recent Case Law*, 82 NOTRE DAME L. REV. 911 (2007); Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391 (2006); Lee Petherbridge & R. Polk Wagner, *The Federal Circuit and Patentability: An Empirical Assessment of the Law of Obviousness*, 85 TEX. L. REV. 2051 (2007).

112. Brief of Amicus Curiae of 22 Law and Business Professors in Support of Appellants, *In re* Bilski, 545 F.3d 943 (Fed. Cir. Apr. 7, 2008) (No. 2007-1130), 2008 WL 1842281.

113. Brief of Amicus Curiae Regulatory Datacorp, Inc. in Support of Neither Party, *In re* Bilski, 545 F.3d 943 (Fed. Cir. Apr. 7, 2008) (No. 2007-1130), 2008 WL 1842273.

cumulative effect of recent changes in patent law.[114] My consideration of this work played a role in the drafting of my chapter on *eBay* and patent remedies, in which I sought to ensure that the concept of patent trolls did not play a role in the construction of a relevant framework.

Finally, in my discussion of research tools in the biotechnology industry,[115] I specifically rely on the empirical work of Joseph Straus,[116] not to mention studies in Australia and Japan,[117] along with several surveys by John Walsh and his coauthors,[118] and nuanced explorations of the biotechnology industry, such as those by David Adelman.[119]

I could have explained these decisions in the book. Along similar lines, in the introduction to my patent section, I discussed why (as Professor Crouch points out) Supreme Court and Federal Circuit opinions such as *KSR*, *Medimmune*, and *Seagate* reduced the need for certain proposals and why *eBay* reduced the ambition of my recommendation on patent remedies.[120] In the end, however, with a book already weighing in at 400+ pages, it seemed reasonable not to address each of these points.

And that is one reason why I am grateful for this symposium, as well as Professor Kieff's attention to the issue. For while the modesty of my patent proposals could allow one creatively to read between the lines to discern an indirect reliance on the property scholars, such discernment is far less direct than our discussion here.

XI. UNCERTAINTY IN PATENT LAW

Professor Kieff also points to the changes that patent law has experienced in recent years to ask whether too much uncertainty has been introduced into the system.

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114. F. Scott Kieff, *Removing Property from Intellectual Property and (Intended?) Pernicious Impacts on Innovation and Competition* (2007), http://innovationforum.gmu.edu/2008/papers/removing_property.pdf.

115. CARRIER, *supra* note 1, at 261–64.

116. *Id.* at 263 (citing Joseph Straus, *Genetic Inventions and Patents—A German Empirical Survey*, at 5–6, Jan. 24, 2002, http://www.oecd.org/dataoecd/36/22/1817995.pdf).

117. *Id.* (citing Dianne Nicol & Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry, Centre for Law and Genetics Occasional Paper No. 6*, at 92, 175, 256–57 (2003), *available at* http://www.ipria.org/publications/reports/BiotechReportFinal.pdf; Sadao Nagaoka, An Empirical Analysis of Patenting and Licensing Practices of Research Tools from Three Perspectives, Presentation to OECD Conference on Research Use of Patented Inventions, at 18–20 (May 18–19, 2006), http://www.oecd.org/dataoecd/20/54/36816178.pdf).

118. *Id.* at 261 (citing John P. Walsh et al., *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RES. POL'Y 1184, 1188 (2007)).

119. *Id.* at 264 (citing David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 987 (2005)).

120. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007); MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007); *In re* Seagate Tech., LLC, 497 F.3d 1360 (Fed. Cir. 2007); eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

Kieff and I debated this last year at the conference mentioned above. He is correct that the global effect of changes to various aspects of patent law—made in rapid succession and sometimes ambitiously—is difficult to ascertain. But particular changes, even though they may be more flexible than the previous law, appear to solve certain problems. Examples include:

(1) *In re Seagate*[121] (prior to which willful infringement was alleged in, according to one study, 92 percent of patent cases[122]),

(2) *Merck v. Integra*[123] (in which the Supreme Court made clear that the statutory experimental use doctrine applied not just to drug products in clinical trials, but also to those in preclinical studies), and

(3) *MedImmune v. Genentech*[124] (which paved the way for cases like *Teva v. Novartis*,[125] increasing the likelihood of declaratory judgment actions and opening the Hatch-Waxman bottleneck discussed above).

Do the patent proposals I offer increase uncertainty? Given that I aim to clarify the *eBay* framework and that I do not currently call for an expansion of the experimental use doctrine to cover research tools in the biotechnology industry, the issue would seem to devolve to my proposal for a post-grant opposition. For reasons I discuss, though, and assuming that challenges to invalid patents should play a role in any patent system, my proposed opposition would, as discussed above, appear superior to the alternatives.

There is still the counterargument, of course, that any challenge to patents could reduce innovation incentives. That is a difficult question to answer comprehensively, though, as I mention above, I incorporate mechanisms into my post-grant opposition proceeding that allow the regime to be calibrated to reduce the magnitude of any such effect.

Addressing a related issue, Kieff asks "[w]hat is so precarious" about the state of affairs for biotechnology research tools "and why would a few lawsuits disrupt it?"[126] The answer stems from the Federal Circuit's re-

121. *Seagate*, 497 F.3d at 1371.
122. Kimberly A. Moore, *Empirical Statistics on Willful Patent Infringement*, 14 FED. CIR. B.J. 227, 232 (2004).
123. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 195 (2005).
124. *MedImmune*, 549 U.S. 118.
125. Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330 (Fed. Cir. 2007).
126. F. Scott Kieff, *An Inconvenient School of Thought*, 61 ALA. L. REV. 591, 594 (2010).

striction of the experimental use defense, which has led to an array of everyday conduct by lab researchers technically constituting infringement.

This state of affairs rests precariously on industry's continuing to refrain from suing universities. In the book, I describe the symbiotic relationship between these two actors. My point, though, is that a few lawsuits could disrupt this fragile equilibrium. As I conclude: "[I]f companies begin to sue universities, the dangers of stifled innovation would rise, and the informal norms would be stripped away, laying bare the constricted state of the case law."[127]

XII. THE "TWO BOOKS" CRITIQUE

We begin our final Parts where we began this Article—with several critiques from Professor Manne. The first is that this is really two books rolled into one. Manne is right that Section I provides information of a more basic nature. My first five chapters offer a background on the IP and antitrust regimes, with an emphasis on the intersection of the two regimes, as well as innovation.

As should be apparent by now, Sections II (copyright), III (patent), and IV (antitrust) are more sophisticated, plunging into ongoing, cutting-edge debates and offering ten proposals designed to foster innovation. The two sections are related, however. Section I is designed to provide the reader with the tools needed to understand the proposals.

XIII. THE "INSUFFICIENT SUPPORT" CRITIQUE

Professor Manne levels perhaps his most fundamental critique that I "canvass[] both sides of some pretty heated debates," state that these "are matters about which we are profoundly uncertain," and "with what seems . . . to be little support . . . then choose[] sides."[128] I respectfully disagree. Rather than debating on a lofty plane, let's take a look at the book's objective, followed by the proposals.

The book's goal, in a nutshell, is to foster a greater appreciation for innovation among the patent, copyright, and antitrust regimes. To be sure, the regimes come to the innovation beachhead in different guises. The patent system comes under scrutiny and with numerous fix-it books and proposals in tow. The antitrust system sails with the wind at its back, having cleaned up much of its innovation act in the past generation. And the copyright regime swims upstream, with recent developments pushing it further from the innovation shore.

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127. CARRIER, *supra* note 1, at 267.
128. Manne, *supra* note 2, at 553.

One of the central difficulties, which will not be news to any readers, is that innovation's importance is matched by its difficulty of measurement. Partly as a result, antitrust courts have historically focused on the more measurable indicator of price. And copyright courts have emphasized the more observable effect of infringement.

The project of this book is to put innovation front and center. As I conclude early on: "The difficulty of measuring innovation does not mean it should be ignored. It only means, given its importance, that we need to redouble our efforts to account for it."[129]

Conceiving the project in these terms explains why I crafted chapters the way I did. In the copyright arena, for example, the law of secondary liability has amassed new tests, bells, and whistles in the past decade. My book is not intended to trod the well-worn path of showing how this latest judicial treatment, as revealed in cases such as *Napster*, *Aimster*, and *Grokster*, smartly updates the older "VCR" test for a modern P2P era. There is plenty of that commentary already.

Instead, what I seek to do is offer the strongest possible manifesto for innovation in this setting. Without repeating the forty pages of my chapter on P2P and other dual-use technologies, I argue for a return to the *Sony* standard, which defers to technologies as long as they are "capable of substantial noninfringing uses."[130] My chapter develops numerous arguments that reveal the consequences of insufficiently appreciating innovation. Others, including Fred von Lohmann and Tony Reese, have voiced some of these arguments before.[131] But I seek to expand these arguments in a chapter that

- (1) explores the creativity–innovation tradeoff,
- (2) introduces the innovation asymmetry,
- (3) develops the error-costs asymmetry,
- (4) unearths the litigation asymmetry,
- (5) analyzes P2P's benefits in distribution, promotion, and fostering the "long tail," and

129. CARRIER, *supra* note 1, at 2.

130. Sony Corp. of America v. Universal City Studios, Inc., 464 U.S. 417, 442 (1984).

131. R. Anthony Reese, *The Problems of Judging Young Technologies: A Comment on* Sony*, Tort Doctrines, and the Puzzle of Peer-to-Peer*, 55 CASE W. RES. L. REV. 877, 890–91 (2005); Fred von Lohmann, *How Hollywood Has Been Trying To Disrupt Disruptive Innovation*, EE TIMES ONLINE, http://www.eetimes.com/disruption/essays/vonlohmann.jhtml (last visited Mar. 10, 2010).

- (6) explores the tip of the innovation iceberg, which considers P2P's future roles in offering a potential antidote to cloud computing and Google's search engine.

Addressing Manne's critique head on, does this consider two sides of the issue before superficially selecting one? I don't think so. Again, I am offering the strongest argument for the incorporation of innovation into copyright's secondary liability analysis, where it is currently absent. As I explore above, my three asymmetries present new arguments supporting innovation in this setting.

But what about my attempt to address the creativity–innovation tradeoff? The tradeoff arises since copyright infringement could harm creativity while attempts to punish intermediaries could stifle innovation. In my book, I address this tradeoff in the setting of P2P and CD sales. I conclude that innovation is far more directly affected by the test selected than creativity. As I explain in the book,[132] this point is supported by the findings that (1) there are numerous reasons why CD sales have declined in recent years, (2) copyright holders have many potential remedies other than targeting P2P networks, (3) individual artists play a crucial role in creativity, and (4) innovation can create new markets and models for copyrighted works.

Perhaps there is an economic model that could more definitively resolve the creativity–innovation tradeoff. But if there is, I haven't seen it. And I would be surprised if such a universal framework of apples and oranges were available.

Space prevents me from exploring each of my proposals in this level of detail. But before moving on, let me make one other point.

One of the tools I use in several chapters involves an exploration of the legislative history. In the settings in which I enlist them, we find the histories covered in dust, not employed as useful guides to an appropriate analysis. My analysis of the histories reminds us how the drafters of the DMCA targeted pirates, not household devices; how statutory damages were designed to assure adequate compensation, not stifle investment and innovation; and how the Hatch-Waxman Act encouraged generic competition, not settlements prohibiting patent challenges. Where courts have gone astray, these unexploited tools offer significant benefits.

XIV. Error Costs and Other Pragmatic Considerations

Professor Manne's final general point is that "there is almost no discussion of error costs in the book—no discussion of bureaucratic agency

132. Carrier, *supra* note 1, at 120–28.

issues, judicial process problems, public choice problems, and the like."[133] Considered a bit more broadly, however, error costs and pragmatic considerations appear in most of the book's proposals.

For starters, I show how error costs support presumptive illegality for drug settlements.[134] And, as discussed above, I reveal how error costs play an essential role in my P2P chapter.[135]

Pragmatic concerns underlie my other proposals as well. Stated briefly, my recommendations for statutory damages and the *eBay* framework for patent relief are designed to be simple enough to be easily applied by courts. Congress can enact a post-grant opposition system similar to the one I propose, and, in fact, is considering one as I write.[136]

Finally, universities can adopt material transfer agreements (MTAs), which have often accompanied the transfer of materials to researchers. Business realities were front and center in my crafting of this proposal. I concluded that academia and industry were more likely to agree on model publication terms, which prohibit delay in publishing research findings, than on reach-through licenses that reserve rights to materials owners (and cannot realistically be restricted when firms believe their "crown jewels" are at stake). As I conclude: "[I]f firms assert that reach-through provisions are needed because of a specific material's importance, it would be counterproductive to second-guess the decision and demonstrate the superiority of adherence to the UBMTA."[137]

CONCLUSION

One of the most crucial issues affecting our economy today is the effect of law on innovation. This book explores, in particular, the effects of the copyright, patent, and antitrust laws. And it offers proposals to remove the roadblocks that these laws have imposed. As we seek to foster innovation in the 21st century, the critiques and elaborations offered in this symposium highlight some of the most pressing issues that confront us.

133. Manne, *supra* note 2, at 556.
134. CARRIER, *supra* note 1, at 370–71.
135. *Id.* at 131.
136. *See* Patent Reform Act of 2009, S. 515, 111th Cong. § 5 (2009); H.R. 1260, 111th Cong. (2009).
137. CARRIER, *supra* note 1, at 289.