THE RIGHT BALANCE OF COMPETITION POLICY AND INTELLECTUAL PROPERTY LAW: A PERSPECTIVE ON SETTLEMENTS OF PHARMACEUTICAL PATENT LITIGATION

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ABSTRACT

The issue of the proper role of antitrust law in evaluating patent litigation settlement agreements has come to the forefront of IP and competition policy with the recent challenges, brought by the Federal Trade Commission, the attorneys general of the individual states, and private litigants, to agreements in the pharmaceutical arena. The agreements share the common feature of an "exclusion payment" from a brand-name drug manufacturer (the patentee) to a generic drug manufacturer (the accused infringer) in exchange for a promise by the generic company to refrain from marketing its product for some time. The courts that have examined these agreements have varied in their approach and conclusions. One court of appeals found a *per se* antitrust violation, while another found a similar agreement to be legal after concluding that the exclusion payment fell within the patent right. This article argues that informed antitrust analysis of these agreements must take due note of the characteristics of patent property rights, namely that they are more "probabilistic" in nature than other property rights. After considering the nature of the patent grant, the article concludes that exclusion payments do not fall within the scope of a patentee's exclusionary right. They are not, therefore, immune from antitrust scrutiny. As we show, barring anticompetitive exclusion payments in settlement negotiations

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balances IP and competition policy by preventing collusive bargains that harm consumer welfare without discouraging efficient settlements.

I. INTRODUCTION

This article explores the appropriate balance between antitrust and IP law in the context of a recent and contentious IP-antitrust topic, the analysis of exclusion payments made in the settlement of patent litigation. Historically, the policies underlying antitrust law and intellectual property ("IP") law[1] were often seen as being in conflict, with IP law being viewed as designed to "promote" monopolies and antitrust being designed to "combat" them.[2] More recently, it has been recognized that these two legal regimes, properly understood, seek to promote innovation and the general welfare, albeit through two somewhat different mechanisms – IP law by protecting the property rights and interests of (and thus financial returns to) inventors, antitrust law by combating restrictions on the competitive process that may harm consumers and slow innovation.[3] As a 2003 Federal Trade Commission ("FTC") report on the interrelationship of competition and patent law explained[4], enlightened public policy aimed at pro-

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1 We use the terms "antitrust law" and "competition law" interchangeably in this article, although "competition laws" may be deemed broader than antitrust laws to encompass all other legal rules that promote market processes. Thus, "competition policy" refers to the full panoply of legal institutions that promote reliance on markets, rather than government, to guide the use of society's resources. Although "intellectual property law" encompasses a variety of legal schemes (including, for example, patent, trademark, copyright, and trade secret law), this article focuses on patent law—that branch of intellectual property law that creates general federal statutory incentives for innovation. Patent law historically has been viewed as being in great tension with competition law.

2 This stereotypical generalization was never entirely accurate. Patents typically do not confer monopoly power in an economic sense, and in the past (prior to the injection of economic analysis into competition policy), antitrust law often did more to create artificial impediments to efficient business transactions than to correct "monopolistic" interferences with efficient market transactions.

3 The work of Professor Michael Porter demonstrates the importance of competition and antitrust policy in promoting innovation. He explains that competition has a direct role in stimulating innovation because firms seek and achieve competitive advantage through innovation. He and his colleagues have concluded that strong antitrust enforcement was positively associated with successful, internationally competitive and innovative industries. Michael E. Porter, *The Competitive Advantage of Nations* 662-64 (The Free Press 1990).

4 *See* Fed. Trade Commn., *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, http://www.ftc.gov/os/2003/10/innovationrpt.pdf (accessed Sept. 11, 2005).

moting innovation and welfare[5] requires that an appropriate balance be struck between these two legal regimes. Patent litigation settlements, with their potential to create either procompetitive efficiencies or horizontal collusion, bring the need for that balance into focus.

The great majority of patent disputes settle before trial[6] and the great majority of those settlements are procompetitive.[7] "A settlement can save public and private resources that would otherwise be consumed by litigation, and it can provide certainty that will encourage business investment."[8] Many settlements contribute to marketplace competition because they result in a license or cross-license that allows the accused infringer to market or continue marketing its product.[9] Moreover, a cross-license may provide a procompetitive benefit by

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5 The term "innovation" refers in this article to economic growth (encompassing both increases in the quantity and improvements in the quality of output) that is brought forth by technological change. The term "welfare" is used herein to refer to "total surplus," that is, the difference between the value (measured in a unit of account, such as a currency) of goods or services produced in a market and the costs of producing those goods or services. Total surplus is divided between "consumers' surplus" (the aggregate difference between consumers' willingness to pay for the output of the market and what they are charged) and "producers' surplus" (profits plus "Ricardian rents," the return to a scarce productive asset apart from profits). *See* Thomas W. Ross & Ralph A. Winter, *The Efficiency Defense in Merger Law: Economic Foundations and Recent Canadian Developments*, 72 Antitrust L.J. 471, 473-74 (2005) (summarizing the concepts of "total surplus" and "consumer surplus"). We will not delve into the policy debate as to whether antitrust law should promote "total surplus maximization" or "consumer welfare maximization"; as a practical matter, under most circumstances, policies that advance total surplus maximization generally are consistent with the maximization of consumers' surplus.

6 Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1501 (2001).

7 We refer to an agreement among competitors that furthers efficiency and enhances consumer welfare as procompetitive. We refer to an agreement that does not plausibly further efficiency and harms consumers as anticompetitive. *See e.g. FTC v. Ind. Fedn. of Dentists*, 476 U.S. 447, 459 (1986).

8 *In re Schering-Plough Corp*., No. 9297, slip op. at 37 (Fed. Trade Commn. Dec. 18, 2003), http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf, *vacated*, 402 F.3d 1056 (11th Cir. 2005) (accessed Sept. 12, 2005).

9 *Antitrust Guidelines for the Licensing of Intellectual Property* 5-6 (FTC & US Dept. of Just. 1995) (discussing the procompetitive benefits of licensing) [hereinafter *IP Licensing Guidelines*]; Willard K. Tom & Joshua A. Newberg, *Antitrust and Intellectual Property: From Separate Spheres to Unified Field*, 66 Antitrust L.J. 167, 174 (1997); *see also* Robert J. Hoerner, *Antitrust Pitfalls in Patent Litigation Settlement Agreements*, 8 Fed. Cir. B.J. 113, 115 (1998) (stating that patent settlement agreements will be analyzed similarly to patent licensing agreements).

eliminating the problem of "blocking patents" that potentially could prevent both parties from bringing their products to market.[10]

Courts generally favor settlements as an efficient means to avoid litigation,[11] but these public policy considerations do not mean that all settlements are presumptively efficient regardless of the cost. Because the patentee and accused infringer may be horizontal competitors when they enter the settlement agreement, they may attract antitrust scrutiny if, for instance, they agree to allocate markets or fix prices as part of the settlement.[12]

The issue of the proper role of antitrust in evaluating patent litigation settlement agreements has come to the forefront of IP and competition policy with the recent challenges, brought by the FTC,[13] the attorneys general of the individual states, and private litigants, to agreements in the pharmaceutical arena. The exact terms of the settlement agreements at issue in these cases vary, but they share the common feature of requiring a payment from a brand-name drug manufacturer (the patentee) to a generic drug manufacturer (the accused infringer) in exchange for a promise by the generic company to refrain from marketing its product for some time. We will term the payment from the brand-name company to the generic an "exclusion payment."

The courts that have undertaken an antitrust analysis of these agreements have varied in their approach and conclusions. One court of appeals found an interim settlement agreement that included an exclusion payment to constitute a *per se* antitrust violation.[14] Other courts have found a similar

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10 *IP Licensing Guidelines*, *supra* n. 9, at 28 ("Settlements involving the cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements.").

11 *E.g. Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) ("Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming.").

12 *U.S. v. Masonite Corp.*, 316 U.S. 265, 274, 276 (1942).

13 The Commission resolved three matters by entering consent orders with each of the parties (*Abbott/Geneva, Hoechst/Andrx* and Bristol-Myers Squibb). *See In re Abbott Laboratories*, No. C-3945, slip op. at ¶ 2, http://www.ftc.gov/os/2000/05/c3945.do.htm (Fed. Trade Commn. May 26, 2000) (accessed Sept. 8, 2005); *In re Hoechst Marion Roussel, Inc*., No. 9293, slip op. at ¶ 2, http://www.ftc.gov/os/2001/05/hoechstdo.htm (Fed. Trade Commn. May 11, 2001) (accessed Sept. 8, 2005); *In re Bristol-Myers Squibb Co.*, No. C-4076, slip op. at 1, http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf (Fed. Trade Commn. Apr. 18, 2003) (accessed Sept. 8, 2005). The Commission issued a decision in a fourth matter following a trial before an administrative law judge. *In re Schering-Plough Corp*., slip op. at 1.

14 *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-08 (6th Cir. 2003), *cert. denied*, 125 S. Ct. 2297 (2005).

agreement to be legal, in part because they concluded that the exclusion payment fell within the patentees' exclusionary right.[15] Commentators also have varied in their analysis.[16]

In this article, we set forth our thoughts on how to approach the antitrust analysis of these agreements in a manner that balances concerns about the significance of the patent property right with those focused on the competition eliminated by the agreement. After providing a background discussion of patent law characteristics that are crucial to informed antitrust analysis, part II of this article examines the nature of a patentee's "right to exclude," and concludes that exclusion payments do not fall within the scope of the patent grant. Nor does the patent right pre-empt antitrust analysis of the agreements. Part III discusses antitrust law's traditional approach to agreements between potential competitors to eliminate uncertain competition, and argues that the same analysis should apply to exclusion payments made in the settlement of pharmaceutical patent litigation. Part IV addresses some of the policy concerns that arise in the antitrust analysis of these agreements. We conclude with general comments about the implications of the patent-antitrust interface and their application here.

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15 *Schering-Plough Corp*, 402 F.3d at 1075-76; *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 541 (E.D.N.Y. 2005). In our view, jurisprudence in this area is far from settled. Accordingly, we will not delve into the details of particular cases brought by the FTC and other plaintiffs in this area, but, rather, will focus on more general principles that inform the evaluation of settlement agreements including exclusion payments.

16 *See* Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 750 (2002) (arguing that exclusion payments should be permitted when the likelihood of success of the patentee's infringement suit is high); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *The Interface Between Intellectual Property Law and Antitrust Law*, 87 Minn. L. Rev. 1719, 1759 (2003) (arguing that a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful); M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 Geo. Mason L. Rev. 359, 361, 367 (2002) (arguing for a rule of reason approach because courts lack experience with exclusion payments).

II. EXCLUSION PAYMENTS DO NOT FALL WITHIN THE SCOPE OF THE PATENT GRANT

A. *The Analysis of Exclusion Payments in Recent Cases*

Two courts have recently considered the antitrust analysis of exclusion payments by beginning with the question of whether the patentee's exclusionary right allowed it to pay a potential competitor to stay-off the market. Concluding that the patent grant included this right, those courts halted any analysis of the settlements' affect on competition.

In *Schering-Plough Corp. v. FTC*,[17] the Court of Appeals for the 11th Circuit reversed an FTC decision that settlement agreements between a brand-name pharmaceutical manufacturer, Schering-Plough Corporation, and two generic drug companies, Upsher-Smith Laboratories, Inc. ("Upsher") and American Home Products Corporation ("AHP"), violated the antitrust laws. In litigation and before the Food and Drug Administration ("FDA"), Uphser and AHP had maintained that their products did not infringe the patent and that it was invalid.[18] In both agreements, the parties settled patent litigation, and the two generic manufacturers agreed to refrain from marketing their generic products until a specified date years following the settlement, but prior to patent expiration. In exchange, Schering made a $60 million cash payment to Upsher, which the parties maintain was solely for a license conveyed by Upsher to Schering,[19] and a $15 million cash payment to AHP.

The 11th Circuit defined the proper analysis of antitrust liability as requiring "an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[20] In its analysis of the first factor, the court

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17 402 F.3d at 1076.

18 Schering's patent covered a formulation of its product and related only to the type and viscosity of the material that coats the potassium chloride crystals, providing the tablet with its extended-release mechanism. Upsher and AHP maintained that they had designed generic products having the same extended-release profile as Schering's product, but that used a non-infringing coating material. *In re Schering-Plough Corp*., slip op. at 34.

19 The Commission found that Schering's $60 million payment to Upsher was not solely for the license, but also represented compensation for the delayed generic entry date required by the agreement. *Id.* at 79. The 11th Circuit reversed as unsupported by substantial evidence. *Schering-Plough Corp.*, 402 F.3d at 1071. While that holding raises a number of interesting administrative law issues, they are not the subject of this article.

20 *Schering-Plough Corp.*, 402 F.3d at 1066.

explained, "[b]y virtue of its *'743 patent*, Schering obtained the legal right to exclude Upsher and [AHP] from the market until they proved either that the *'743 patent* was invalid or that their products, Klor-Con and Micro-K 20, respectively, did not infringe Schering's patent."[21] In its analysis of the second factor, the court held that payments from the patentee to the accused infringer, solely in exchange for the accused infringer's promise to refrain from marketing a competing product until a later date, as was undisputedly the case in the Schering/AHP settlement, "to be within the patent's exclusionary power, and 'reflect a reasonable implementation' of the protections afforded by patent law."[22] With regard to its third factor, the court concluded the agreements were not illegal because they "fell well within the protections of the '743 patent."[23] Thus, the 11th Circuit held, without any examination of the patent claims, that because Schering had alleged, although not proven, patent infringement, its patent gave it the right to pay generic manufacturers to refrain from marketing a competing product.

In the case, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, the district court for the Eastern District of New York considered whether a patent litigation settlement agreement between Bayer Corporation, the manufacturer of the antibiotic Cipro, and a generic challenger, Barr Laboratories, Inc., violated the antitrust laws. Bayer is the owner of a patent that claims the active ingredient of Cipro, ciprofloxacin hydrochloride. In its application to market a generic version of Cipro, Barr conceded infringement, but alleged that the patent was invalid. Bayer eventually settled all patent litigation under terms which prevented Barr from entering the market until the patent expired and, over the life of the agreement, Bayer made payments to Barr totaling approximately $398 million dollars. Subsequent generic manufacturers lost their challenges to the patent's validity.[24]

The district court ruled on summary judgment that the agreement did not violate the antitrust laws because it "[had] not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the *'444 Patent*."[25] According to the court "there is no injury to the market cog-

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21 *Id*. at 1066-67.

22 *Id.* at 1072 (quoting *Valley Drug Co.*, 344 F.3d at 1312); *see also id.* at 1073 (quoting *Valley Drug*, 344 F.3d at 1309) ("It is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit . . . .").

23 *Id*. at 1076.

24 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. at 519-20.

25 *Id.* at 540.

nizable under existing antitrust law, as long as competition is restrained only within the scope of the patent."[26] In finding that the exclusion payments fell within the scope of the patent, the court "concluded that patent law imposes no such restriction against cash payments by a patent holder," and relied upon a patent's statutory presumption of validity.[27]

We believe that a view of a patentee's right to exclude as encompassing the right to pay a potential competitor to stay off the market misinterprets the nature of that right on several fronts and disrupts the appropriate balance of patent and competition policy. First, that analysis ignores patent law characteristics that are crucial to informed antitrust analysis. It wrongly presumes that a patentee who has not yet proven its allegations in court could exclude all competitors for the term of the patent. Second, because it ignores crucial patent law characteristics, the analysis misunderstands that the source of the exclusion in such an agreement is the payment--not the patent--and, therefore, patent rights cannot justify the exclusion. Exclusion achieved through payment rather than through the strength of the asserted patent is not within the scope of the patent. We develop each point below.

B. *Characteristics of Patent Law*

Patent law is a utilitarian set of property rules that derives legitimacy to the extent it promotes innovation and welfare.[28] Thus, the patent law system is not sacrosanct; aspects of patent law that undermine these goals are properly subject to reform. Indeed, commentators have argued that the heavier role of government in shaping the contours of patent rules as compared to other proper-

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26 *Id*. at 535.

27 *Id*. at 536, 536 n. 21. See also, In re Tamoxifen Citrate Antitrust Litigation, No. 03-7641, 2005 WL 2864654, at *17 (2nd Cir. Nov. 2, 2005) ("[S]o long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the namufacture and distribution of the patented product.").

28 This conclusion follows from the words of the patent and copyright clause of the US Constitution, which seeks "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Thus, property interests flowing from patent grants (arguably unlike certain other property rights) would not seem to be accorded the dignity of natural rights that merit protection regardless of their utility in advancing science and technology.

ty rules strongly suggests that patent law may be, relatively speaking, a rather socially inefficient form of property protection.[29]

Hearings on competition policy and the patent system organized by the FTC and the Justice Department, held in 2001 and 2002, found some evidence of this inefficiency. Evaluating the implications of those Hearings, the FTC Competition-Patent Report[30] found that although, for the most part, the patent system works well in fostering innovation, "questionable patents" (patents that are likely invalid or that contain claims that are likely overly broad) are a significant concern and can harm innovation. More precisely, the Report concluded that questionable patents (1) may directly deter third parties from undertaking innovative research due to litigation risks and costs; and (2) may create licensing difficulties that substantially raise transactions costs and deter agreements that disseminate the fruits of innovation.[31] To deal with these problems, the Report urged specific patent law reforms designed to improve patent quality and minimize the anticompetitive costs of the patent system.[32]

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[29] Significantly, Landes and Posner, two leading market-oriented proponents of strong property rights, have argued that

> [e]quating intellectual property rights to physical property rights overlooks the much greater governmental involvement in the former domain than in the latter . . . . Government is continuously involved in the creation of intellectual property rights through the issuance of patents, copyrights and trademarks. Skeptics of government should hesitate to extend a presumption of efficiency to a process by which government grants rights to exclude competition with the holders of the rights.

William M. Landes & Richard A. Posner, *The Political Economy of Intellectual Property Law* 23-24 (The AEI Press 2004), http://www.aei-brookings.org/admin/authorpdfs/page.php?id=985 (accessed Sept. 8, 2005).

[30] Fed. Trade Commn., *supra* n. 4.

[31] *Id*. at 5-7. Licensing difficulties include "defensive patenting" by third parties in response to questionable patents. *Id*. at 6. As patents proliferate, the costly "stacking" of royalty claims on multiple patents looms increasingly serious. *Id*. at 7. The "patent thicket[s]" that result from such activities raise the costs of agreements among technology developers and thereby retard contractual arrangements aimed at increasing the flow of innovation. *Id*. at 6-7.

[32] *See id*. at 6-7. That the proliferation of patents (documented in the Report) raises concerns should not be read to suggest that "mass patenting" by corporations has no possible efficiency explanations. One scholar, Paul J. Heald of the University of Georgia Law School, has argued that patenting may: (1) reduce information costs to firms, by allowing them to assemble a portfolio of rights that signals information about themselves more cheaply than by other means; (2) prevent other firms from obtaining technological inputs necessary to the first firm's production; (3) reduce the cost of monitoring team production (patent output may be a useful, albeit imperfect, measure of the contribution of individual team members); and (4) effectively partition information assets (patent assets can readily be transferred under a liability regime that does not require the transferee to enter into costly protective agreements and that

Antitrust law is not designed to "step in the breach" created by questionable patents or faulty patent rules. The fact that certain "bad patents" exist does not mean that antitrust may be used as a sword to attack the statutorily guaranteed right to exclude that flows from legitimate patents. But the problematic nature of certain patents does suggest that antitrust analysis should not shy away from closely scrutinizing transactions involving patent questions, if those transactions hold out the possibility of extending market power beyond the legitimate scope of the property right a patent generates. As we develop below, the "legitimate scope" question properly should be informed by the fact that patents may be deemed "probabilistic" property rights;[33] the complexity of patent claims often creates ambiguity as to whether particular third party activity may properly be blocked by the patent.[34] As we explain, antitrust enforcers may properly take into account these peculiar attributes of the patent system in weighing the wisdom of proposed interventions; an antitrust challenge does not undermine a patent-created property right, if the patentee's claims as to the nature and breadth of the right are inaccurate.[35] In fact, according less legal respect to illegitimate invocations of patent rights may implicitly enhance the val-

creates statutory "gap filler" rules). Paul J. Heald, *A Transaction Costs Theory of Patent Law* 12, 21, 31, 33-34, http://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID385841_code030407500.pdf?abstractid=385841&mirid=1 (accessed Sept. 8, 2005). Heald's theory suggests that patent law may be seen as a cost-reducing title recordation system that promotes the efficient transfer of information assets. Although this theory may be interesting, it lacks much empirical support at this time; in contrast, the FTC Competition-Patent Report refers to substantial testimony documenting the costs of patent proliferation. Future empirical work may shed light on the extent to which industry-specific patent proliferation is more beneficial than harmful.

33 Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 395 (2003) [hereinafter *Patent Settlements*]. It is further developed in Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Persps. 75 (2005).

34 Obviously, the scope of property rights other than patents may be less than certain, but, in general, there is far less uncertainty about the coverage of such rights—particularly rights to tangible property. For example, the right to possess an automobile is merely a question of who holds title, and the extent of the rights covering a plot of land turns on relatively straightforward questions, such as the existence and location of an easement or a boundary line. The boundaries of a complex, patent-protected industrial process or processes may be far less clear.

35 Whether the patent was issued erroneously because it did not meet the statutory standards for patentability is a separate issue, best resolved through patent reforms that improve patent accuracy by, for example, facilitating simple post-grant appeals. As already discussed, antitrust authorities are not well-positioned to cure the problem of "bad patents." Of course, if a court or an administrative body strikes down a patent, property rights-based objections to antitrust enforcement are eliminated.

ue of well-founded patent invocations, thereby actually strengthening patents' ability to drive innovation.

C. *The Outcome of Patent Litigation is Uncertain*

One manner in which the ambiguity associated with patent allegations manifests itself is through the uncertain outcomes of patent litigation. It is incorrect to begin the examination of whether an exclusion payment falls within the scope of the patent right from the premise that the patentee could exclude all competitors for the term of the patent. There is no certainty that a court will find that an accused product actually infringes – a matter on which the patentee has the burden of proof.[36] In fact, accused infringers frequently win litigation by demonstrating that they do not infringe the asserted patent. A survey of judicial decisions addressing infringement during 2003 showed that courts found the patent not infringed 75% of the time.[37] A more optimistic study still shows patentees losing litigation 42% of the time.[38]

Even when infringement is conceded, the fact that a patent has been issued by the Patent & Trademark Office ("PTO") is no guarantee that the patentee will prevail and the court will uphold a patent's validity, despite the statutory presumption of validity.[39] "The validity of a patent is always subject to plenary challenge on its merits. A court may invalidate a patent on any substantive ground, whether or not that ground was considered by the patent examiner."[40] Empirical studies have demonstrated that courts invalidate about half of all issued patents litigated to judgment on validity issues. A study examining nearly all written, final validity decisions by the district courts and the U.S. Court of Appeal for the Federal Circuit from 1989 through 1996 found that 46% of patents challenged in litigation were invalidated.[41] A more recent survey of judi-

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36 In patent litigations, the patentee bears the burden of proving that the accused product infringes its patent by a preponderance of evidence. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984).

37 U. Houston L. Ctr., *PATSTATS: U.S. Patent Litigation Statistics* ¶ 23, http://www.patsats.org/2003.html (accessed Sept. 9, 2005).

38 Kimberly A. Moore, *Judges, Juries, and Patent Cases: An Empirical Peek Inside the Black Box*, 99 Mich. L. Rev. 365, 385 (2000).

39 35 U.S.C. § 282 (2000) ("A patent shall be presumed valid.").

40 *Magnivision, Inc., v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997); *see id.* (providing that "[a] patent shall be presumed valid" but "[i]nvalidity of the patent" shall be a defense "in any action involving the validity or infringement of a patent . . . .").

41 John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 187, 205 (1998).

cial decisions addressing validity during 2003 found 58% of the patents invalid.[42]

The FTC's survey of patent litigation in the pharmaceutical industry between brand-name drug manufacturers as patentees, and generic drug manufacturers as accused infringers, parallels these trends. Of the 30 cases resolving patent litigation over a ten year period, the generic applicant prevailed by proving either invalidity or noninfringement 73% of the time.[43]

As a matter of probabilities then, it is clearly inappropriate to simply assume that a patentee could exclude a competitor from the market simply because he asserts that to be the case. Informed antitrust analysis will acknowledge this fact and recognize that exclusion payments cannot be justified on the basis of the patentee's unproven assertion of its right to exclude.

D. *The Payment and not the Patent Provides Exclusion Resulting From the Agreement*

But could an exclusion payment made in the settlement of patent litigation be justified as falling within a patent's scope for other reasons—either because the patent grant includes the right to make exclusion payments without any demonstration of infringement and validity, or because the patentee later demonstrated infringement and the infirmity of the validity challenge? Any such attempt is flawed because it misunderstands the nature of the patent right and the purpose and effect of the payment. We turn first to the payment.

The purpose of the payment is also informed by an understanding of particular attributes of the patent system. It is most easily understood by examining the context in which patent licensing and settlement negotiations are conducted, under a cloud of threatened or continued litigation. A patentee's power to exclude accused infringers or to dictate the terms under which they may enter the market is never absolute and never described by the patentee's unilateral views of its patent coverage until it obtains a final, successful court judgment on validity and infringement. Until that time, the patent's power to exclude competitors is tempered by the statistically high probability that either the patentee

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42 *PATSTATS: U.S. Patent Litigation Statistics*, *supra* n. 37, at ¶¶ 1-16.

43 Fed. Trade Commn., *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 16, http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (accessed Sept. 9, 2005) [hereinafter *FTC Generic Drug Study*].

will fail to prove infringement or the accused infringer will demonstrate invalidity.[44]

If the parties settle or avoid litigation by agreeing to a patent license, the stronger the patentee's validity and infringement arguments, and the higher the probability that it will win the threatened litigation, the more advantageous the terms it can negotiate.[45] The licensee/accused infringer accepts a degree of limitation on its ability to compete freely in the market in proportion to its view of the patent merits and the probabilistic outcome of litigation. One economist has described patent rights as "probabilistic" for this reason.[46] That degree of limitation, which might be manifested by the size of a royalty payment or the extent of a use restriction, reflects the "exclusionary power" of the patent at the time of the agreement.

An accused infringer/licensee might agree to refrain from marketing its product for an agreed length of time in acknowledgement of a patent's exclusionary power. One would expect that, absent other consideration, the agreed-to entry date reflects the exclusionary power of the patent at the time of the agreement. The Commission's consideration of the Schering/Upsher agreement illustrates this point. The Commission began its consideration of the exclusionary power of Schering's patent with the simple but fundamental principle that, short of a final court judgment on the issue, the parties' collective expectation of the outcome of their litigation—as reflected in a genuine, arms-length settlement—represents the most accurate assessment of the subject patent's exclusionary

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44 Errors in granting patent rights may be expected. As previously noted, Professor Landes and Judge Posner have cautioned against an expansive view of intellectual property rights inefficiencies involved in the process of their creation. *See* Landes & Posner, *supra* n. 29, at 23-24; *see also* Natl. Research Council Comm. Intell. Prop. Rights, *A Patent System for the 21st Century* 46-62, http://www.nap.edu/html/patentsystem/0309089107.pdf (accessed Sept. 18, 2005) (discussing the patent invalidity rate and the factors affecting the issuance of invalid patents).

45 *See e.g.* Michael J. Meurer, *The Settlement of Patent Litigation*, 20 RAND J. Econ. 77, 77-79 (1989) (discussing that a patentee will often settle a dispute by licensing the patent exchange for royalty payments to avoid the threat of having its patent invalidated; the terms of the license depend, in part, on the probability of the patentee prevailing in litigation.); Jean O. Lanjouw & Josh Lerner, *The Enforcement of Intellectual Property Rights: A Survey of the Empirical Literature*, NBER Working Paper Series, Working Paper 6296, 1-4, 19 (1997), http://www.nber.org/papers/w6296, (the likelihood that the patentee will win the patent litigation increases the value of the patent).

46 Shapiro, *Patent Settlements*, *supra* n. 33, at 395.

power.[47] The parties' negotiations in that case would have fixed only the time of entry of the alleged infringers, because no money damages were at issue.[48] Therefore, a hypothetical no-payment compromise on the entry date would most accurately reflect their collective expected outcome of litigation, i.e., the exclusionary power of Schering's patent, and would not be illegal.[49]

Any payment provision in the settlement agreement—beyond the expected savings in litigation costs[50]—would affect the compromise entry date in one direction or another: a payment from the alleged infringer to the patent holder, i.e., a royalty, would be made to gain an earlier entry than a compromise on the date alone. A payment of this kind is unremarkable and indisputably within the limits of a patent's exclusionary power. A payment in the opposite direction, however—an exclusion payment—purchases a *later* time of entry than a compromise on the date alone.[51] A patentee would not make a substantial payment if it believed it could exclude the competition for that period solely on the basis of its patent.[52] Thus, the payments from the patentee to the accused infringer in the recent pharmaceutical patent litigation settlements purchased a

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47 *In re Schering-Plough*, No. 9297, slip op. at 25-26; *id*. at 34 ("An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable.").

48 This is common in the context of patent litigation under the Hatch-Waxman Act because the alleged infringer there (i.e., the ANDA applicant) need not enter the market in order to challenge the referenced patent. *See Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000) (filing of ANDA with Paragraph IV Certification "automatically creates a cause of action for patent infringement").

49 *In re Schering-Plough*, No. 9297, slip op. at 25-26; *see also* Hovenkamp *et al.*, *supra* n. 16, at 1762.

50 The expected savings in the cost of litigation represent merely the transaction costs of litigation versus settlement and, therefore, do not affect the substantive merits of the dispute (i.e., the expected outcome of litigation). *See In re Schering-Plough*, No. 9297, slip op. at 37 n. 69; Hovenkamp *et al.*, *supra* n. 16, at 1750-51.

51 Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L. Rev. 1767, 1786 (2003) (explaining that a payment from the brand to the generic distorts the generic's incentives to negotiate for the earliest entry date possible).

52 Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 28 (2004) (noting that the willingness of the brand company patentee to make the very large payments at issue in most of these cases indicates significant doubts about the validity of the patent or the strength of the infringement claim: "A firm willing to pay roughly $75 million per year to keep an alleged infringer out of the market when a successful preliminary injunction would have done the same thing for the cost of obtaining the injunction indicates that the prospects for a preliminary injunction were very poor.").

degree of exclusion that could not be obtained solely through the exclusionary power of the patent.[53] Close consideration of the economic relationship between branded and generic pharmaceuticals, discussed in Section III below, confirms that the purpose and effect of the payments is to purchase the generic's guaranteed exclusion from the market and reveals the parties' incentives for structuring the agreement in this manner.

E. *The Nature of a Patentee's Right to Exclude*

We turn now to the question of whether the nature of a patentee's right to exclude, i.e., the scope of its patent right, includes the right to purchase exclusion that could not have been obtained through the strength of the patent at the time of the settlement agreement, and conclude that it does not. Patent policy limits the scope of the patentee's exclusionary right by defining the extent of that right according to the scope of the patent claims.[54] The term "patent scope" is commonly used to refer to the subject matter encompassed by the patent claims. The scope of the patentee's exclusionary right is defined by aspects of patent policy in addition to the patent claims, however. In particular, patent policy requires that the source of any exclusion be the patent and not other means.

A patent grants a statutory right to "exclude others from using, offering for sale or selling [the invention] throughout the United States . . . ."[55] The patent system "embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and non-obvious advances in technology and design in return for the exclusive right to practice the invention for a period of years."[56] The Patent Act and controlling case law has established two methods by which a patentee may exercise its right to exclude. It may seek and obtain an injunction from a court or it may persuade the accused infringer unilaterally to

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53 As we explain in Section III, *infra*, the exclusion payment can also be accurately viewed as purchasing "insurance" against the chance that the accused infringer will win the patent litigation and enter the market earlier than the agree-to date. Whether we characterize the payment as purchasing a later entry date than they would have otherwise agreed to or as purchasing insurance against the chance of earlier entry is irrelevant to the indisputable fact that the payment purchases exclusion that could not otherwise be obtained solely through the patent. Both characterizations of the payment are two sides of one coin.

54 See e.g. *Mallinckrodt, Inc. v. Medipart, Inc*., 976 F.2d 700, 706 (Fed. Cir. 1992).

55 35 U.S.C. § 154(a)(1) (2005). The basis for that statutory right is found in Article I, Section 8, Clause 8 of the U.S. Constitution, which gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8.

56 *Bonito Boats, Inc., v. Thunder Craft Boats, Inc*., 489 U.S. 141, 150-51 (1989).

decide to accede to the patent.[57] Pursuant to the Patent Act, a patentee may seek, and a court may grant, "injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."[58] The justification for the use of permanent injunctions in patent cases arises from the constitutional and statutory bases for the right to exclude, as well as a patent's status as personal property.[59] It is important to note that before obtaining a court-awarded permanent injunction, the patentee must win its patent case by proving infringement and warding off any challenges to the validity of its patent. When a patentee exercises its right to exclude by obtaining a permanent injunction, it obtains that exclusion through the merits of its patent case and the strength of its patent – in other words, the patent's "exclusionary power" at the conclusion of the case.

If a patentee has not yet won its patent litigation, but wishes to exclude an accused infringer for the course of the litigation, the Patent Act supplies but one means for accomplishing that goal. The patentee must seek a preliminary injunction from the court, pursuant to 35 U.S.C. § 283. In considering whether to award a preliminary injunction, a court considers the dispositive factor of a patentee's likelihood of success on the merits.[60] If a patentee succeeds in obtaining a preliminary injunction, it does so through the strength of its patent case, by demonstrating the exclusionary power of the patent.

The Patent Act acknowledges only one other method by which a patentee may exercise its right to exclude—by unilaterally and unconditionally refusing to license its patent.[61] If a competitor chooses to exit or refrain from entering the market in the face of that refusal, it is unilaterally acceding to the strength of the patent merits and the exclusionary power of the patent.

Thus, a patentee has the right to try to exclude allegedly infringing products by instituting a lawsuit—or even by merely threatening a lawsuit. "The heart of [a patentee's] legal monopoly is the right *to invoke the State's*

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57 In addition, the patentee may license the patent and obtain compensation for the use of its property, rather than exclude all infringers. *Fromson v. Western Litho Plate and Supply Co*., 853 F.2d 1568, 1576 (Fed. Cir. 1988) ("In a normal [patent licensing] negotiation, the potential licensee has three basic choices: forego all use of the invention; pay an agreed royalty; infringe the patent and risk litigation.").

58 35 U.S.C. § 283 (2005).

59 *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1246-47 (Fed. Cir. 1989) ("[i]nfringement having been established, it is contrary to the laws of property, of which the patent law partakes, to deny the patentee's right to exclude others from use of his property.").

60 *See e.g. Hybritech Inc. v. Abbott Laboratories*, 849 F.2d 1446, 1451-58 (Fed. Cir. 1988).

61 35 U.S.C. § 271(d) (2005).

power to prevent others from utilizing his discovery without his consent."[62] When it asserts its patent and threatens a lawsuit, the patentee can hope that the strength of its patent allegation convinces the accused infringer to accede and unilaterally decide to exit the market. Alternatively, if the accused infringer views the patent allegation as sufficiently weak to warrant continuing with the accused activity, the patentee's recourse for exercising its right to exclude is to institute litigation and invoke the State's power through a judicially granted injunction. Neither path guarantees success for the patentee. As both economists and legal scholars have remarked, "a patent is not a right to exclude, but rather a right to *try* to exclude."[63] Importantly, exclusion achieved by either path will be based on the exclusionary power of the patent. Patent policy establishes that the scope of the patent grant encompasses exclusion obtained through the power of the patent; but nothing in patent policy suggests that the scope of the patent includes the right to obtain exclusion through means not based on the patent, including through a payment.

Patent law's right to exclude is not unfettered or free to be exercised by means outside this paradigm, in any manner the patentee sees fit. A patent confers a property right. "The right to exclude recognized in a patent is but the essence of the concept of property."[64] Indeed, the Patent Act grants patents "the attributes of personal property."[65] The antitrust agencies also view patents as they do other property.[66] Just as the use of tangible property is constrained by other legal regimes, so too is a patentee's use of its intellectual property. A patentee must exercise its property right—it's right to exclude—in a manner that is consistent with other laws. "[P]atents are property, and entitled to the same rights and sanctions as other property."[67] No where does the Patent Act suggest otherwise. On the contrary, as the Supreme Court has explained, "[s]ince patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed so as not to derogate from the general law beyond the necessary requirements of the patent statute."[68]

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62 *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (emphasis added).

63 Hovencamp *et al*., *supra* n. 16, at 1761 (emphasis added) (paraphrasing assertion of Shapiro, *supra* n. 33, at 395).

64 *Richardson*, 868 F.2d at 1247.

65 35 U.S.C. § 261 (2005).

66 IP Licensing Guidelines, *supra* n. 9, at §§ 2.0-2.1.

67 *Contl. Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 425 (1908).

68 *U.S. v. Masonite Corp.*, 316 U.S. 265, 280 (1942).

For that reason, the "self-help" of exclusion by means not dependent on the strength of the patent and that violate other laws cannot be justified by a reference to the patent right. No one would argue that by making an unproven accusation of patent infringement, a patentee becomes entitled to the "self-help" remedy of confiscating the accused product in order to exclude it from the market. Confiscation is simply not a component of the patentee's exclusionary right (*i.e.*, not within the scope of the patent grant), and it violates other laws, even if the patentee were to eventually prove infringement and defend a validity challenge in court. The patentee obtained exclusion through the confiscation, not the exclusionary power of the patent, and his actions must be judged on that basis.

In the same vein, the scope of the patent grant does not include the right to pay potential competitors to stay off the market because the source of the exclusion is the payment, not the exclusionary power of the patent. Because the payment falls outside the scope of the patent grant, antitrust law may judge its legality.[69] The principle that a patentee may exercise the scope of its patent rights in excluding competitors from the market without violating the antitrust laws[70] is simply irrelevant to the antitrust analysis of an agreement that achieves exclusion through a payment. Courts have long held that a patentee "cannot extend his statutory [patent] grant by contract or agreement."[71] The settlements at issue are subject to antitrust review because they obtain "protection from competition which the patent law, unaided by restrictive agreements, does not afford."[72]

The analysis does not change when only validity is at issue in the patent litigation. Some have suggested that any exclusion obtained through a payment must be viewed as within the scope of the patent when infringement is conceded and only validity is at issue in the underlying patent litigation.[73] The patent is

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69 We explain in Section III, *infra*, why purchasing a horizontal competitor's exclusion from the market in the context of a patent litigation settlement can be anticompetitive and violate the antitrust laws.

70 *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) (patent laws "are *in pari materia* with the antitrust laws and modify them *pro tanto*." (as far as they go)).

71 *Masonite Corp.*, 316 U.S. at 277; *see also Singer*, 374 U.S. at 196-97; *U.S. v. Line Material Co.*, 333 U.S. 287, 308 (1948); *Ethyl Gasoline Corp. v. U.S.*, 309 U.S. 436, 456 (1940).

72 *Masonite Corp.*, 316 U.S. at 279.

73 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d at 531-41 (rejecting argument that possibility of patent's invalidity took payment outside the scope of the patentee's exclusionary right, where infringement had been conceded).

presumed valid, so the exclusion is conclusively presumed to fall within the patent scope.[74] This argument contains two flaws.

First, it misunderstands the nature of the presumption of validity, which is simply a procedural device for allocating the burden of proof to an accused infringer who seeks to demonstrate a patent's invalidity in patent litigation.[75] "The presumption has no separate evidentiary value"[76] in patent litigation and it should not be accorded that value in antitrust litigation.

Second, the argument misunderstands the analysis under which an exclusion payment falls outside the patent scope. Importantly here, the presumption of validity does not alter the fundamental nature of an exclusion payment as the purchase of exclusion that could not have been obtained through the power of the patent. Nor does it alter the patent policy that awards exclusion based only on the power of the patent. It is these key points, rather than any distinction between the burdens of proof for infringement and invalidity allegations made in patent litigation that removes an exclusion payment from the patentee's right to exclude.

F. *Other Restrictive Agreements May Fall Within the Scope of the Patent*

An argument that exclusion payments fall within the scope of the patent based on an analogy with other agreements that would be illegal under the antitrust laws absent the assertion of the patent[77] misses the point that in those cases the source of the exclusion remains the exclusionary power of the patent rather than a payment. For example, a horizontal geographic market allocation would normally be a *per se* antitrust violation.[78] However, the Patent Act explicitly provides that a patentee may grant a license to a limited territory, allowing it to

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74 *Id.* at 533 (argument for antitrust liability based on potential invalidity of the patent "results in undermining the presumption of validity that Congress has afforded patents"); *id.* at 535 ("Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.").

75 *Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1534 (Fed. Cir. 1983).

76 *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983).

77 *Valley Drug Co.*, 344 F.3d at 1304-05.

78 Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, vol. XII, ¶ 2030, 210 (Aspen 2000) (noting that naked market division agreements are unlawful *per se*).

establish a geographic market allocation.[79] In the face of the patentee's assertion of its patent rights, through litigation or otherwise, the licensee/accused infringer secedes territory to the patentee based on its assessment of the probability that the patent might exclude it completely, i.e., the patent's exclusionary power at the time of the agreement. Were the licensee to secede that territory not because of the merits of the patentee's infringement allegations, but because the patentee offered it a payment to do so, the antitrust analysis of the agreement would change dramatically. The patent would no longer shield the agreement from antitrust scrutiny because the payment would not be within the scope of the patent.

The same principles apply to other "market-allocations" allowed in patent licenses, such as field-of-use restrictions and production limits.[80] The ability to impose such limitations is within the "exclusionary right" of the patent owner because the patentee licenses only some portion of its bundle of property rights included within the patent grant. The licensee accepts limited competition due to the patent's strength. The antitrust analysis will differ depending on whether the licensee agreed to the market-allocation in recognition of the exclusionary power of the patent or, as revealed by the agreement and the market structure in which it arises, the licensee was paid by the patentee to do so.[81]

G. *Prohibiting Exclusion Payments is Consistent with Patent Policy*

Some have worried that prohibiting exclusion payments would lessen the value of the patent and undermine the patent system's incentive to innovate.[82] This concern misunderstands that exclusion payments actually distort the

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79 35 U.S.C. § 261.

80 *B. Braun Med., Inc. v. Abbott Labs*., 124 F.3d 1419, 1426 (Fed. Cir. 1997) (discussing field-of-use restrictions); *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1578 (Fed. Cir. 1990) (upholding quantity limitations in a patent license).

81 We are not advocating an analysis based on an examination of the parties' subjective thought process. Rather, as described in Section III, *infra*, an examination of the agreement in the context of the market structure of the relevant industry should reveal the source of the exclusion, as it does in the pharmaceutical patent settlement matters. As a practical matter, there may be circumstances in which it is difficult to discern whether the source of the exclusion is the patent or a payment, but the exclusion payments made in the context of brand/generic pharmaceutical patent litigation do not appear to present that difficulty, for the reasons described *infra*.

82 *Valley Drug Co*., 344 F.3d at 1311.

patent system's incentive structure by allowing the patentee rights not granted by Congress.

Patent policy provides that the exclusionary power of the patent is proportionate to the inventor's contribution to his field.[83] If a patented invention is truly revolutionary compared to the prior art, the patent claims are much more likely to be found novel and non-obvious over the prior art than are claims reciting only a minor distinction.[84] Moreover, the claims protecting a pioneering invention can be broadly drafted to cover a wide range of possibly infringing products as compared to claims protecting a minor improvement.[85] Thus, patent policy intends that claim scope and strength will be governed by the extent of the inventive contribution. That policy encourages greater leaps of technological innovation.[86] It would be contrary to that fundamental policy of patent law to allow a patentee to supplement the exclusionary power of its patent with exclusion payments. Such payments give the patentee a degree of market control that its inventive contribution could not provide and distort the patent system's incentive structure as established by Congress.

By enacting the patent laws, Congress has implicitly balanced the trade-off between the static efficiency of competition and the low prices against the dynamic efficiency of increased incentives to seek patentable innovations. A proper economic welfare analysis of patent rights must take as given the patent rules specified by Congress with the presumption that those rules properly and correctly balance static and dynamic efficiency.[87] Exclusion payments reach

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83 *Infra*, text accompanying notes 85-86.

84 The nonobviousness requirement of 35 U.S.C. § 103 establishes a patentability step - a level of development beyond the prior art that must be accomplished before a patent can issue. In its leading case interpreting the statute, *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court noted that an invention "which is new in the sense that the same thing has not been made before, may still not be patentable if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent." *Id*. at 14 (quoting S. Rep. No. 1979, 82d Cong., 2d Session, 6 (1952), *reprinted in* U.S.C.C.A.N. 1952, p. 2394.) Thus, the greater the difference between "the new thing and what was known before," the more likely the patent is to be nonobvious and valid.

85 *Augustine Med., Inc. v. Gaymar Indus., Inc*., 181 F.3d 1291, 1301 (Fed. Cir. 1999) ("Without extensive prior art to confine and cabin their claims, pioneers acquire broader claims than non-pioneers who must craft narrow claims to evade the strictures of a crowded art field. Thus, claim scope itself generally supplies broader exclusive entitlements to the pioneer.").

86 *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & Econ. 265, 267-271 (1977) (discussing the economic incentive for "patent mining" provided by broad patents).

87 Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. Rev. 33, 36-37 (2004) (discussing the "ever-present in-

beyond the "right to exclude" granted by Congress in the Patent Act and disrupt that balance.

In sum, any analysis of whether a patentee's exclusionary right includes the right to make exclusion payments and preempts antitrust scrutiny of those payments must take into account all characteristics and features of patent policy, including the probabilistic nature of the patent right at the time of settlement. Ignoring the true nature of patent rights and imbuing them with an absolutism they lack in real-life negotiations disrupts the balance of IP and competition policy by treating IP rights as sacrosanct to the detriment of competition concerns. As a leading article discussing patent settlements explains,

> The legitimate exclusion value of a pharmaceutical patent is the power it actually conveys over competition, which is in turn a function of the scope of the patent and its chance of being held valid. What the pharmaceutical patentees who agree to exclusion payments seek is something more—a guaranteed insulation from competition, without the risk that the patent is held invalid. IP policy does not offer such a guarantee . . . .[88]

III. EXCLUSION PAYMENTS MADE IN THE SETTLEMENT OF PATENT LITIGATION

Having established that patent law does not shield patent litigation settlement agreements including exclusion payments from antitrust scrutiny, we now apply that scrutiny. Such settlements between brand and generic pharmaceutical companies are horizontal restraints that violate the antitrust laws if they "unreasonably" limit competition.[89] To assess the reasonableness of a horizontal restraint, courts begin by asking whether the conduct appears to be a practice that would "always or almost always tend to restrict competition and decrease output, . . . or instead [is] 'designed to increase economic efficiency and render markets more, rather than less, competitive.'"[90] Horizontal restraints are evaluated along an analytical continuum in which a challenged practice is examined in the detail necessary to understand its competitive effect.[91] Although it is true

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centive to perpetuate the monopoly profit at consumers' expense" created by the pharmaceutical market structure).

88 Hovenkamp *et al.*, *supra* n. 16, at 1761-62.

89 *State Oil Co. v. Barkat U. Khan and Khan and Assocs.*, 522 U.S. 3, 10 (1997) ("Although the Sherman Act, by its terms, prohibits every agreement in 'restraint of trade,' this Court has long recognized that Congress intended to outlaw only unreasonable restraints.").

90 *Broad. Music, Inc. v. Columbia Broad. Sys.*, 441 U.S. 1, 19-20 (1979) (quoting *U.S. v. U.S. Gypsum Co.*, 438 U.S. 422, 441 n. 16 (1978) (internal quotations omitted)).

91 *See Cal. Dental Assn. v. Fed. Trade Commn.*, 526 U.S. 756, 781 (1999) ("What is required . . . is an enquiry meet for the case, looking to the circumstances, details, and logic of

that "when there is an agreement not to compete in terms of price or output, 'no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement,'"[92] it remains necessary to consider whether the parties offer plausible and cognizable efficiency justifications for the agreement in determining the extent of the inquiry required.[93] A horizontal restraint may have legitimate procompetitive efficiencies when it creates a new product or improves the operation of the market, for example.[94]

A. *Economic Relationship of Branded and Generic Pharmaceuticals*

The economic incentives created by the market structure in which generic entry occurs shed light on the purpose and likely effects of settlement agreements including exclusion payments. That market structure makes generic entry "a uniquely significant market event"[95] in the lifecycle of a branded drug product. A generic drug enters the market at a price well below its branded counterpart, with the first generic entrant coming in at a price, on average, 25% lower than the brand's price.[96] Each subsequent generic entrant causes prices to fall more.[97] Sales of a branded drug erode rapidly once a generic version is introduced.[98] Many health plans encourage or even mandate the use of generic versions of branded drugs whenever possible. Almost all states in the United

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a restraint."); *see also In re Polygram Holding, Inc.*, No. 9298 (Fed. Trade Commn.), slip op. at 22 (July 24, 2003), http://www.ftc.gov/os/2003/07/polygramopinion.pdf (accessed Sept. 15, 2005) (discussing development of a continuum of analysis in the jurisprudence of horizontal restraints), *aff'd*, 416 F.3d 29 (D.C. Cir. 2005).

92 *Natl. Collegiate Athletic Assn. v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 109 (1984) (quoting *Natl. Socy. of Prof. Engs. v. U.S.*, 435 U.S. 679, 692 (1978)).

93 *Cal. Dental Assn.*, 526 U.S. at 774-78; *see also PolyGram*, No. 9298, slip op. at 22-29 (discussing an analytical framework that considers the whether an agreement is inherently suspect and proffered efficiency justifications before determining whether the full balancing test of the rule of reason is required).

94 *Natl. Collegiate Athletic Assn.*, 468 U.S. at 101-03.

95 *In re Schering-Plough Corp.*, No. 9297, slip op. at 19.

96 How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharm. Indus., Cong. Budget Off. xiii (July 1998) [hereinafter CBO].

97 Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. Econ. & Mgmt. Strategy 75, 88 (Spring 1997).

98 Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition in the US*, 10 Supp. 2 PharmacoEconomics 110, 121 (1996) (brand lost 50% of prescriptions within a year of AB-rated generic entry); *see also* CBO, *supra* n. 96, at xiii (AB-rated generics captured roughly 44% prescriptions dispensed by pharmacies for the brand).

States encourage generic competition through laws that allow pharmacists to dispense a generic drug when presented with a prescription for its branded counterpart, unless the physician directs otherwise.[99] These policies work together to ensure that the impact of generic substitutes on the sale of brand-name drugs is both rapid and dramatic. Within the first full year after launch of a generic product, the corresponding branded drugs lose an average of 44% of their sales to the lower-priced generic.[100] A recent study indicates that generic penetration now typically exceeds 75% after just two months.[101]

The market structure in which generic entry occurs creates an incentive for the parties to delay generic entry even when that entry is uncertain to occur. Because generic drugs sell for less than their branded counterparts, generic entry causes the branded company to lose more in profits than the generic company earns, with the difference accruing as consumer savings. This situation is shown in the pie chart below labeled "Expected Competition." A brand company could pay a generic to delay market entry more than it would earn by entering, and still be better off than if it faced competition, as shown in the pie chart labeled "Retained Monopoly." Under the market conditions prevailing in the pharmaceutical industry, the brand firm and its generic rival are always better off eliminating their expected competition and sharing the brand's monopoly

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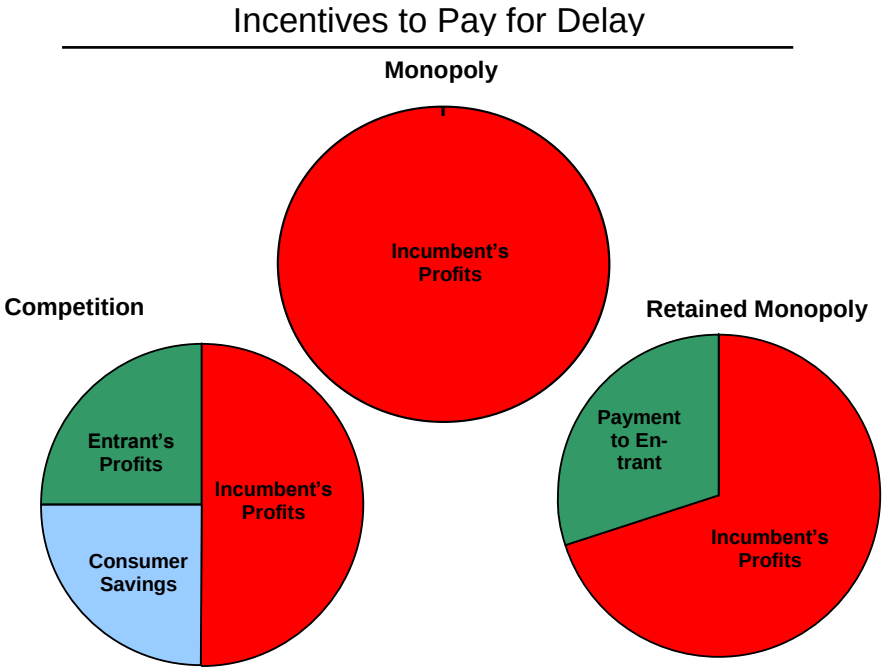
99 *See e.g.* Conn. Gen. Stat. § 17b–274 (2004) (mandating the dispensing of generic substitutes to recipients of public assistance); *In re Schering-Plough Corp.*, at 19–20 n. 37.

100 CBO, *supra* n. 96, at xiii; *see generally* Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings Papers: Microeconomics (1991); Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act*, 35 J.L. & Econ. 331 (1992); Roy Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, (FTC 1999).

101 Eric L. Cramer & Daniel Berger, *The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs*, 39 U.S.F. L. Rev. 81, 107 n. 92 (2004).

profits. [102]



Thus, when a brand-name drug manufacturer makes a substantial payment to a potential generic competitor in exchange for the generic's agreement to refrain from marketing its product until an agreed upon date, antitrust should scrutinize the agreement to determine whether these potential horizontal competitors are sharing the brand's monopoly profits, to the detriment of consumers.

B. *A Payment to Eliminate Uncertain Competition can be Anti-competitive*

As discussed above, one way to view the exclusion payment is that is purchases exclusion that could not be obtained solely through the power of the patent. An equally accurate characterization of the payment is as the purchase of "insurance" against the threat that the generic will win the patent litigation. We discuss below why the purchase of insurance against uncertain competition can be anti-competitive.

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[102] *See* Leffler & Leffler, *supra* n. 87, at 37.

The analysis of the competitive effects of a settlement, including an exclusion payment, must view the agreement from the point-in-time in which the parties entered the agreement.[103] At that point-in-time, the outcome of the patent litigation is uncertain. Indeed, the very purpose of the settlement is to eliminate that uncertainty. For that reason, and based on the market structure in which generic entry occurs, the payment from a branded drug manufacturer to a potential generic entrant in exchange for ending the litigation and setting generic entry for a future date can be characterized as the brand's payment to eliminate the chance that the generic company will win the litigation or otherwise market its product at an earlier date. There is no dispute among the courts and commentators who have examined these agreements that this is a fair characterization of the exclusion payment. The disputes center on whether such agreements are anticompetitive and whether they are within the scope of the patentee's exclusionary right.[104]

The exclusion payments themselves demonstrate the uncertainty of the litigation. Commentators have recognized that the size of an exclusion payment is proportional to the strength of generic applicant's case.[105] "The less likely the patentee is to win, the more it is willing to pay a generic to stay out of the market."[106] According to one model, "if the patentee has a 25% chance of losing, it

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103 *Valley Drug Co.*, 344 F.3d at 1306 (citing *SCM Corp. v. Xerox Corp*., 645 F.2d 1195, 1207 (2d Cir. 1981)). Were this not the case, intervening events, such as the potential entrant's plant burning down, would absolve parties that had entered clearly anticompetitive agreements not to compete from antitrust liability. Evidence of the actual effects of an agreement may be highly probative of an agreement's likely affect on competition when entered. *But see* ABA Section of Antitrust Law, *Antitrust Law Developments*, 877 (5th ed. 2002). For instance, evidence of the effect of actual generic entry on prices and market share is highly probative of the competitive conditions the parties preempted through an agreement to delay generic entry.

104 *E.g. Schering-Plough Corp*., 402 F.3d at 1075 ("[b]y entering into the settlement agreements, Schering realized the full potential of its infringement suit—a determination that the *'743 patent* was valid and that ESI and Upsher would not infringe the patent in the future."); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1047-50 (2004) (acknowledging the loss of uncertain competition from settlements including exclusion payments).

105 Thomas F. Cotter, *Symposium: The Interface Between Intellectual Property Law and Antitrust Law: Commentary: Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*," 87 Minn. L. Rev. 1789, 1808-09 (2003); Crane, *supra* n. 16, at 774 ("[t]he 'directional flow' of the settlement payment, therefore, will be affected by the probability of the plaintiff's lawsuit succeeding.").

106 Hovenkamp et al., *supra* n. 16, at 1758-59 (discussing this feature of Cotter and Crane's arguments).

[is] willing to pay up to 25% of the value of its monopoly to exclude its competitors without a trial."[107] The accuracy of the model's numbers is not important, but this feature of exclusion payments nicely illustrates their nature as the purchase of "insurance" against potential competition.[108] The greater the risk of competition, the higher the premium paid to avoid the risk.

Economic logic suggests that agreements to delay or prevent potential, albeit uncertain competition clearly are anticompetitive and harm consumers, absent significant efficiencies. Preventing potential competition causes harm to consumers in a manner similar to that caused by destroying existing competition, though discounted by the probability of entry. Consumers are always better off with the possibility of competitive entry and lower prices than they are with the certainty of no entry. Reflecting this economic reality the courts have long recognized that even agreements to delay uncertain competition have anticompetitive effects. As the Supreme Court has said, "[t]he anti-trust laws are as much violated by the prevention of competition as by its destruction."[109] A leading antitrust treatise succinctly articulates the same principle: "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition."[110]

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107 Hovenkamp et al., *supra* n. 16 at 1759.

108 *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 363 F. Supp. 2d at 534 ("[p]laintiffs' point is well-taken that the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment."); *see* George L. Priest, *Cartels and Patent License Arrangements*, 20 J. L. & Econ. 309, 327 (1977) (arguing that rational patentees won't reduce the royalty below zero unless they are cartelizing and industry).

109 *U.S. v. Griffith*, 334 U.S. 100, 107 (1948), *overruled on other grounds, Copperweld Corp. v. Indep. Tube Corp*., 467 U.S. 752, 104 (1984). Since *Board of Trade of the City of Chicago v. United States*, the rule of reason inquiry has focused on the restraint's "effect, actual or *probable*." 246 U.S. 231, 238 (1918) (emphasis added). Uncertainty about the time of entry may influence a plaintiff's ability to prove damages but does not alter the analysis of liability. *See e.g. U.S. v. Microsoft Corp.*, 253 F.3d 34, 79-80 (D.C. Cir. 2001) (*per curiam*) (distinguishing liability and remedy); *Andrx Pharm., Inc. v. Biovail Corp.*, 256 F.3d at 806, 808 (D.C. Cir. 2000) (holding plaintiff need establish only threat of injury to have standing for injunctive relief); *Microbix Biosys., Inc. v. BioWhittaker, Inc.*, 172 F. Supp. 2d 680, 694-95 (D. Md. 2000) (distinguishing damages inquiry from assessment of competitive effects for purposes of assessing liability under rule of reason), *aff'd on other grounds*, 11 Fed. Appx. 279 (4th Cir. 2001) (unpublished).

110 Herbert Hovenkamp et al., *Antitrust Law*, vol. 12, ¶ 2030b, 175 (Aspen 1999); s*ee also Blackburn v. Sweeney*, 53 F.3d 825, 828-30 (7th Cir. 1995) (finding unlawful an agreement by attorneys to refrain from advertising in one another's cities); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1 (1st Cir. 1979) (finding it unlawful for maker of snowmobiles and maker of minicycles to agree that the former would not enter the latter's market); *but see*

Because the reduction in uncertain competition itself is sufficient to demonstrate an anticompetitive effect, proving what would have happened absent the restraint is not an element of an antitrust action.[111] Even if subsequent events meant the likely effects of the agreement would not have materialized—for example, because the potential entrant's plant had burned down, it failed to obtain necessary regulatory approvals, or for some other reason—that would not alter the conclusion that when the agreement was entered into, it was likely to cause substantial competitive harm.[112]

The D.C. Circuit's opinion in *United States v. Microsoft Corp.*[113] illustrates the importance of this policy for antitrust law. Applying the rule of reason under Section 2 of the Sherman Act, the D.C. Circuit confirmed that impeding "nascent" rather than actual competition is a fully cognizable anticompetitive effect. Rejecting Microsoft's argument that the government did not establish a causal link between Microsoft's foreclosure of Netscape's and Java's distribution channels and the maintenance of Microsoft's monopoly, the court held that it could infer causation even when the exclusionary conduct is aimed at nascent competitive technologies. "Admittedly, in the former case there is added uncertainty, inasmuch as nascent threats are merely *potential* substitutes. But the underlying proof problem is the same—neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct."[114] It was not the government's burden to establish a "but for" world—to show that Java or Netscape would have become viable substitutes for Microsoft's operating system. Rather, the central question was whether "as a general matter the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power" and whether the potential entrants constituted nascent threats at the time the conduct was undertaken.[115] As the court recognized, "it would be inimical to the purpose of the Sherman

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Schildkraut, *supra* n. 104 at 1049 ("[u]ncertain competition analysis is a substantial departure from the traditional civil burdens of proof.").

111 *Ind. Fedn. of Dentists*, 476 U.S. at 461-62.

112 *See e.g. Microbix*, 172 F. Supp. 2d at 694-95 (finding an exclusive supply agreement that created a barrier to competition at the time it was entered into could be condemned under the rule of reason, even though subsequent action by the FDA made it impossible for the target of the exclusionary conduct to enter the market).

113 253 F.3d at 36.

114 *Id.* at 79 (emphasis in original).

115 *Id*.

Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will . . . ."[116]

C. *Exclusion Payments Made in the Settlement of Pharmaceutical Patent Litigation Can Harm Competition*

Applying these principles to exclusion payments made in the settlement of pharmaceutical patent litigation demonstrates that such agreements can be anticompetitive. A settlement of pharmaceutical patent litigation containing an exclusion payment effectively is a temporal market allocation arrangement, under which the brand company retains it sales for several years and shares its profit with the potential generic entrant, which, in return, refrains from selling its competing product. Here, just as in *Microsoft*, a potential generic entrant clearly constitutes a threat to a brand company.[117]

The uncertainty about whether the generic ultimately would have prevailed in the patent case does not undermine the likely anticompetitive effects of the settlements including exclusion payments. It clearly would be anticompetitive for an incumbent to pay a potential generic rival to defer entry until a specific date in the future, even if the generic's ability to obtain FDA approval was uncertain. From an economic point of view, there is no reason to treat uncertainty due to patent litigation any differently. Although some patents that are litigated through trial will be found valid and infringed, the anticompetitive harm stems from the settlement's elimination of any chance that the market will be competitive before the agreed-to generic entry date.[118] As one commentator has explained, "[t]he very fact of that uncertainty [that the patentee may win the patent litigation] suggests that exclusion payments are anticompetitive—that on average such agreements exclude at least some generics that in fact had a legal right to compete."[119]

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116 *Id.*

117 A delay in generic entry undisputedly delays consumer access to a lower-priced drug product. An agreement to delay or prevent generic entry, if proven, provides direct evidence of anticompetitive effects that makes a conventional product market analysis unnecessary. *Ind. Fedn. Dentists*, 476 U.S. at 461 ("the finding of actual, sustained adverse effects on competition . . . is legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis.") (footnotes omitted); *see also* Cramer & Berger, *supra* n. 101, at 103.

118 Hovenkamp et al., *supra* n. 16, at 1759 n. 176.

119 *Id.* at 1758; Leffler & Leffler, *supra* n. 87, at 53 ("it is anticompetitive for an incumbent manufacturer to enter into an agreement to eliminate potential competition, based on the probability that the competition would in fact have occurred.").

There is no basis for the assertion that to demonstrate the anticompetitive effect of agreements containing exclusion payments, it is necessary to show that other factors, including the loss of the patent litigation, would not have prevented generic entry in any event. Just as Microsoft's exclusionary conduct provided less competition in an expected sense, so too can agreements containing exclusion payments. Given the obvious effect that large payments to stay off the market have on a generic firm's decision about when to enter, the challenged agreements are "likely enough to disrupt the proper functioning of the price-setting mechanism of the market" that they may be deemed anticompetitive even without proof that they actually "resulted in higher prices . . . than would occur in [the conduct's] absence,"[120] based on proof that the generic would have entered the market earlier absent the payment. Indeed, as the Court of Appeals observed in *Microsoft*, to rest antitrust liability on a requirement that plaintiffs "reconstruct the hypothetical marketplace" absent the challenged conduct would merely encourage "more and earlier anticompetitive action."[121]

Moreover, there is no need to consider the outcome of the litigation because antitrust law distinguishes between effects achieved unilaterally and those achieved concertedly. A price-fixing agreement is unlawful even if a party could have raised prices unilaterally.[122] A patentee's proving infringement in litigation and its paying a potential entrant to withdraw its challenge are fundamentally different. An often-cited concurrence in *United States v. Singer Manufacturing Co.* discusses this point. Justice White found a *separate* antitrust violation in "the collusive termination of a Patent Office interference proceeding pursuant to an agreement between Singer and [its Swiss competitor]."[123] The parties entered the agreement, wrote Justice White, "to help one another *to secure as broad a patent monopoly as possible*, invalidity considerations notwithstanding."[124] Justice White pointed out that "the desire to secure broad claims in a patent may well be unexceptional – *when purely unilateral action is involved*," but does not justify the collusive agreement to terminate a PTO interference proceeding.[125] Thus, that a branded company *might have* won its patent litigations and therefore *unilaterally* precluded the generic from entering the market

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120 *Ind. Fedn. of Dentists*, 476 U.S. at 461-62.

121 253 F.3d at 79.

122 *Lee-Moore Oil Co. v. Union Oil Co. of Cal.*, 599 F.2d 1299, 1302 (4th Cir. 1979) ("the fact that [the defendant] might have caused the same damages" by unilateral conduct is "irrelevant").

123 *Singer Mfg. Co.*, 374 U.S. at 197 (White, J., concurring).

124 *Id.* (emphasis added).

125 *Id*. at 199 (emphasis added).

does not justify paying off that competitor to *guarantee* that it remains off the market.

Of course, the antitrust analysis of these agreements must also consider whether they generate any cognizable pro-competitive efficiencies. In its *Schering* decision, the FTC acknowledged hypothetical situations in which the effect of a payment from a brand to generic company would be pro-competitive because it would hasten generic entry, such as that of the "cash-[strapped] generic."[126] However, neither the FTC, nor any court that has examined these agreements has found the existence of facts sufficient to support such a situation. Moreover, unlike many patent settlements, an agreement based on an exclusion payment is typically devoid of the kind of efficiencies that can result, for example, when owners combine their conflicting intellectual property so as to produce a product that otherwise would not exist, or when a patent holder and a new entrant compromise and allow the new entrant to come to market in exchange for compensation to the patent holder.[127] For that reason, we will continue our analysis of agreements containing exclusion payments assuming that they present no cognizable pro-competitive efficiencies, but recognizing that that determination is fact-specific.[128]

IV. POLICY ISSUES SURROUNDING PHARMACEUTICAL PATENT SETTLEMENTS

Some courts and commentators have argued that settlements including exclusion payments should be allowed on policy grounds, because prohibiting them would chill litigation settlements and undermine the value of a patent's incentive to innovate. As explained below, both fears are unwarranted. Rather, Hatch-Waxman's goal of encouraging generic entry and patent policy's goal of awarding an exclusionary right commensurate with the inventive contribution[129] both caution against allowing exclusion payments.

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126 *In re Schering-Plough Corp.*, at 38-39.

127 *See* IP Licensing Guidelines, *supra* n. 9, at § 3.4 ("[t]o determine whether a particular restraint in a licensing arrangement is given *per se* or rule of reason treatment, the Agencies will assess whether the restraint in question can be expected to contribute to an efficiency-enhancing integration of economic activity.").

128 *See* Hebert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 714-18 (2004) (dismissing additional proposed hypothetical and generalized procompetitive justifications for settlements including exclusion payments).

129 *See* text accompanying *supra* n. 85-87, at 21-23.

A. *Prohibiting Exclusion Payments will not Chill Patent Settlements*

As the U.S. antitrust enforcement agencies have recognized, the general policy of the law has been to encourage settlements.[130] Therefore, some have worried that finding antitrust liability for patent settlements including exclusion payments will chill settlement activity.[131] Empirical data shows this fear is unwarranted.

To mitigate the possibility that brand-name and generic drug manufacturers might enter patent settlement agreements that could harm consumers, the FTC Generic Drug Study recommended that Congress pass legislation to require brand-name companies and generic applicants to provide copies of certain agreements to the Federal Trade Commission and the Department of Justice. Congress passed the Medicare Modernization Act, containing such a provision in December 2003.[132] As a result of that legislation, during fiscal year 2004, following the Commission's Schering decision, drug manufacturers filed 14 agreements with the FTC that resolved patent infringement litigation. None of these included a payment from the brand to the generic manufacturer in exchange for the generic's agreement not to market its product.[133]

Those data, indicating that 14 pharmaceutical patent litigation settlements were entered in a single year, fiscal year 2004, as compared to the 27 settlements entered between 1992 and 2002, suggest that a perceived prohibition on exclusion payments in settlements has not deterred parties from finding al-

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130 *Stand. Oil Co., Ind. v. U.S.*, 283 U.S. 163, 171 (1931); IP Licensing Guidelines, *supra* n. 9, at § 5.5 ("[s]ettlements involving the cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements.").

131 *See Schering-Plough Corp*., 402 F.3d at 1064 (citing *Valley Drug Co.*, 344 F.3d at 1309).

132 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461 (2003) [hereinafter MMA]; *see Medicare Prescription Drug and Improvement Act Requires Drug Companies to File Certain Agreements with the Federal Trade Commission and U.S. Department of Justice*, http://www.ftc.gov/os/2004/01/040106pharmrules.pdf (accessed Sept. 17, 2005) (containing information on the types of agreements that must be filed).

133 *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, http://www.ftc.gov/os/2005/01/050107medicareactrpt. pdf (accessed Sept. 17, 2005) (containing a summary of all agreements filed in FY 2004). Other settlement terms are possible. For example, a generic company may pay for the right to enter by taking an immediate license, in which case it would be buying the right to compete instead of being paid not to compete, or the parties could split the patent life without a payment that purchases additional protection from competition.

ternative, acceptable means to reach a settlement agreement. Moreover, of 20 final patent settlements between brand-name companies and first generic applicants identified by the FTC Generic Drug Study, only nine included exclusion payments.[134] Although settlements containing exclusion payments were prevalent in the pharmaceutical industry during this time, by no means were they the only mechanism used to achieve settlements.[135] Thus, the data indicates that legitimate patent settlements have and continue to take place in the Hatch-Waxman context.

B. *Revisiting the Merits of the Patent Litigation in the Antitrust Analysis Would Discourage Settlements*

Some have argued that the exclusionary power of the patent can be properly assessed by a plenary trial on the issues of patent validity and infringement.[136] This approach views the exclusionary power of the patent in any given situation as binary rather than probabilistic – either the patent is valid and covers the accused product, or it is not. This approach presumes that if the patent is valid and covers the accused product, patent policy allows the patentee to exclude the accused product from the market through means that would otherwise violate the antitrust laws, such as direct payment or market allocation. If the later review of the patent issues demonstrates either the patent's invalidity or non-infringement, the antitrust analysis need not consider the patent's exclusionary power and the agreement may violate the law.[137]

Such an approach disserves patentees and accused infringers equally, for they can never perform a satisfactory antitrust analysis of a settlement agreement as of the time they enter it, and obtain the predictability and certainty that the settlement was meant to convey. The antitrust analysis will depend on a later court's view of the patent merits.[138] The parties have simply traded the uncertainty of the outcome of the patent litigation, based on the patent merits,

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134 FTC Generic Drug Study, *supra* n. 43, at 31.

135 *Id*. at 27-35. The remaining two settlements do not fit into any of these three categories.

136 Crane, *supra* n. 16, at 750 (arguing that exclusion payments should be permitted when the likelihood of success of the patentee's infringement suit is high).

137 *See* Schildkraudt, *supra* n. 104, at 1040-41.

138 O'Rourke & Brodley, *supra* n. 51, at 1786. The later court's review of the patent merits will be undermined by the fact of the settlement, which changed the incentives of the generic from wishing to defeat the patent to supporting it in the interest of preserving the settlement.

for the uncertainty of the outcome of the antitrust litigation, based again on the patent merits.[139]

If the antitrust court were to find the patent valid and infringed, virtually any settlement into which the parties might enter, short of exclusion following the patent's expiration or of products falling outside the claim scope, could be deemed pro-competitive compared to continuing litigation, and, therefore, legal. On the other hand, if the antitrust court were to find the patent invalid or not infringed, a settlement that restrained the accused infringer in any way, as certainly most settlements would, would be deemed anticompetitive compared to continuing litigation and, therefore, illegal. The better approach, and the one that provides more respect for the patentee's exclusionary right, considers the exclusionary power of the patent, based on the parties' collective views on the probability of the outcome of the actual or anticipated patent litigation at the time of the agreement.

C. *Exclusion Payments Undermine the Policies of the Hatch-Waxman Act*

Congress intended the Hatch-Waxman Act to increase the flow of generic pharmaceuticals into the marketplace and the purpose and effect of exclusion payments is to stymie that flow. In the Hatch-Waxman Act, Congress struck a carefully considered balance between maintaining the incentives for innovation of new drug products and promoting significantly lower-priced generic drugs.[140] Important elements in this balance were provisions that made it easier and more lucrative for generics to challenge the validity and scope of pharmaceutical patents. The brand company patentee and the generic challenger typically litigate the patent issues before a generic enters the market.[141] Most importantly, the statue provides a powerful incentive to generics to challenge weak and narrow patents in the form of a 180-day marketing exclusivity awarded to the first generic company to take on that challenge.[142] The principal goal of these provisions is to encourage generic drug manufacturers to challenge patents and enter the market as soon as possible.

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139 *See Valley Drug Co.*, 344 F.3d at 1308 ("[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.").

140 *See* H.R. Rpt. 98-857(I) at 14-15 (June 21, 1984) (reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.)

141 *See* 35 U.S.C. § 271(e)(2) (2000).

142 21 U.S.C. § 355(j)(5)(B)(iv) (2000); MMA, *supra* n. 132, at 2461-63.

Some have justified exclusion payments in the settlement of pharmaceutical patent litigation as "a natural by-product of the Hatch-Waxman process."[143] This rationale turns the Hatch-Waxman process on it head by interpreting provisions designed to *promote* patent challenges by generics to justify payments to *avoid* patent challenges.[144] Congress recognized that exclusion payments undermine the policies of the Hatch-Waxman Act when it passed the 2003 Medicare amendments to Hatch-Waxman, which requires that patent litigation settlement agreements between brand and generic companies be reported to the antitrust agencies.[145] As the legislative history for that provision states, "the industry has recently witnessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives."[146]

V. GENERAL CONCLUSIONS

The patent-antitrust interface is and will remain one of the most complicated areas of competition policy analysis. In recent decades, American antitrust commendably has overcome its traditional hostility to patent rights and recognized that patent law, like antitrust law, is a powerful tool for promoting welfare. Nevertheless, it would be wrong to exalt patent law over other forms of property – as is the case of other property law schemes, patent law must remain fully within the reach of antitrust law, to prevent anticompetitive restrictions that harm welfare. Indeed, because a lack of competitive vigor discourages the dynamic economic rivalry that encourages business experimentation, largely exempting patent-related arrangements from antitrust scrutiny would retard, rather than encourage, the innovation that the Patent Act seeks to achieve.

Taking into account these considerations, we have explored a timely and contentious topic that implicates patent and competition policy, patent liti-

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143 *Schering-Plough Corp*., 402 F.3d at 1074-75 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)).

144 *See* Marcy L. Lobanoff, Student Author, *Anticompetitive Agreements Cloaked as "Settlements" Thwart the Purposes of the Hatch-Waxman Act*, 50 Emory L.J. 1331, 1343, 1352-55 (2001) (explaining that settlements between brand companies and first ANDA filers manipulate the 180-day exclusivity period to prevent generic entry, even though the exclusivity period was designed to encourage generic entry).

145 MMA, *supra* n. 132, at 2461-63.

146 Sen. Rpt. 107-167 at 4 (June 20, 2002).

gation settlements involving "exclusion payments" by patentees. As we have shown, barring anticompetitive exclusion payments in settlement negotiations does not discourage efficient settlements, it merely prevents collusive bargains that delay entry and harm consumer welfare. In reaching this conclusion, we took due note of the peculiar characteristics of patent property rights, namely the fact that they are more "probabilistic" in nature than other property rights.

This analysis does not derogate from the dignity of patent rights – it merely reflects the careful, issue-specific evaluation that is required to ensure that an appropriate balance is struck in jointly applying the antitrust and patent laws. In this and other areas at the patent-antitrust interface, a careful balancing of antitrust and patent considerations should yield outcomes that promote consumer welfare and innovation, consistent with the general policy goals of both legal regimes.