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Patent Settlement Agreements: Preliminary Views

Joseph F. Brodley

Maureen O'Rourke

PERSPECTIVE

PRELIMINARY VIEWS:

Patent Settlement Agreements

BY JOSEPH F. BRODLEY AND MAUREEN A. O'ROURKE

SETTLEMENTS BETWEEN competitors in patent cases raise important and sensitive antitrust issues. Patent settlement agreements may create or maintain a monopoly in technology or innovation markets and may also effectuate a monopoly or cartel in related goods markets. Indeed, absent the patent rights, certain terms of patent settlement agreements may be per se antitrust violations. Further, anticompetitive patent settlements—unlike most antitrust conspiracies—are enforceable in court, providing the parties with an effective means of preventing the cheating that is the bane of cartels. Thus, the antitrust risk that a settlement agreement may operate as a disguised cartel has long been recognized.

The antitrust enforcement issues are sensitive because patent settlements can also promote efficiencies, resolving disputes that might otherwise block or delay the market entry of valuable inventions. Settlements can reduce the expense and delay that patent litigation often entails. They enable risk averse business firms to avoid litigation uncertainty and protect against the unjustified loss of patent rights (and licensing revenues) if a court erroneously holds the patent invalid. Finally, patent settlements can promote productive technology interchange within industries (at least for non-core technologies).[1]

Thus, antitrust screening of patent settlements has an important role to play, identifying antitrust risks and balancing efficiency benefits. However, the antitrust and patent systems are in at least some surface tension because they seek to advance the social welfare in opposite ways—antitrust by fostering competition; patent law by enabling exclusion. Indeed, settlement terms that antitrust law would otherwise regard as violations may be permissible so long as the patent is valid. This is one of many factors that constrain effective antitrust scrutiny of patent settlements. Since the anticompetitive risk is most acute when patents are weak, invalid, or not infringed, any precise identification of the antitrust risk would require assessment of patent validity and scope. But these issues can only be fully resolved through patent litigation, and settlement precludes litigation. The alternative of assessing probable validity and infringement in an antitrust proceeding fails to provide a tractable or predictive legal standard.

Antitrust scrutiny of patent settlements is further constrained because patent settlements are not disclosed to enforcement agencies. To be sure, the Patent Act requires filing of interference settlements and collateral agreements with the Patent and Trademark Office (PTO).[2] But it appears doubtful that the PTO can police disclosure of collateral agreements[3] and, under the Third Circuit's decision in *United States v. FMC Corp.*, the Department of Justice lacks standing to enforce compliance.[4] The absence of effective disclosure requirements for patent settlements stands in sharp contrast to disclosure provisions for mergers, R&D joint ventures, and innovation-related production joint ventures,[5] which in the case of mergers requires notification of the transaction to the antitrust agencies or, in the case of R&D and production joint ventures, induces notification through limited antitrust immunity. Finally, defendants in settlement cases benefit from two legal presumptions that, while legitimate in themselves, impede antitrust challenge: a patent is presumed valid,[6] and courts have frequently declared that patent settlements are to be encouraged.

It is important to note, however, that the policy reasons favoring settlement of litigation generally may not be as strong in patent cases as in others. The Patent Act is imbued with the public interest, a fact reflected in its constitutional basis. Article I, section 8, clause 8 of the Constitution empowers Congress "To promote the Progress of . . . the useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." In promoting "Progress" and thereby enhancing the social welfare, the Patent Act grants exclusive rights to inventors of those inventions that meet the statute's multiple standards for protection. Generally, inventions that do not meet such standards are either protected under the far weaker state law system of trade secret[7] or not at all. Like patented inventions, this latter, unpatented and unprotected group provides a basis for further progress. Lack of competition resulting from an invalid patent or one that is not infringed costs society something, including the "Progress" the Patent Act was intended to foster. Because private settlements fail to take this public interest into account, they are inherently more troubling in the patent context than others in which the integrity of a federal system of protection—and non-protection—of innovation is not implicated.

Recent lower court decisions[8] and federal enforcement

Joseph F. Brodley is Professor and Frank R. Kenison Distinguished Scholar of Law, Boston University School of Law and Department of Economics. From January to June 2001, Professor Brodley served as Visiting Scholar at the Federal Trade Commission. Maureen A. O'Rourke is Professor of Law and Associate Dean for Administration, Boston University School of Law. *This article is based on the authors' prepared statement and Professor Brodley's testimony at the DOJ/FTC Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, May 1, 2002.*

actions[9] in the pharmaceutical industry have brought the settlement issue to the forefront of antitrust concern. The pharmaceutical industry operates under a unique regulatory structure—the Hatch-Waxman Act[10]—that heightens the risk of anticompetitive settlements. Briefly, the Hatch-Waxman Act contains several important features. It permits a generic drug manufacturer seeking FDA approval to file an Abbreviated New Drug Application (ANDA). The ANDA may incorporate the safety and efficacy data contained in the earlier application of the corresponding brand name drug as long as the generic is the brand name drug's bioequivalent. However, an ANDA filer must provide some assurance that entry of a generic substitute will not be barred by existing patent rights in the brand name product (pioneer patents). One option for an ANDA filer is to certify that the particular pioneer patent at issue is either invalid or not infringed by the generic drug. To encourage generic drug companies to challenge patents, the Act grants the first ANDA filer who makes such a certification a period of marketing exclusivity. The exclusivity period begins at the earlier of the date on which the generic drug manufacturer begins commercial marketing or the date on which a court holds the pioneer patent invalid or not infringed, and extends for 180 days.

Unintentionally, Congress created a system that can be used strategically to prevent competition and raise consumer prices. This has led to a series of recent cases in which the government or private parties have argued that brand name and generic manufacturers have made just such a strategic—and unlawful—use of the system. The most important issue in these cases centers on the effect of so-called "reverse payments" used in combination with the 180-day marketing exclusivity described above. In a reverse payment settlement, the pioneer patent holder, having brought an infringement suit against the generic producer, typically pays the generic "infringer" a large sum to defer marketing of the generic drug and to agree not to transfer its rights to the 180-day exclusivity period. By this means, the pioneer blocks all generic entry until the agreed date (the "cork-in-the-bottle" effect).[11] Some courts have held such payments to be per se antitrust violations, and have also found such agreements to be anticompetitive when they bar the generic from assigning or relinquishing the 180-day exclusivity right, or from offering other competing, non-infringing drug products.[12] The FTC has also challenged such agreements, and obtained consent judgments under Section 5 of the FTC Act.[13]

In response, pharmaceutical defendants have urged that a full rule of reason analysis is required, under which the government or private plaintiff would have to prove the probable invalidity or non-infringement of the pioneer patents. Depending on the estimated strength of the patent rights, defendants argue that reverse payments can achieve efficiencies in enabling early resolution of claims of patent invalidity and infringement. They further assert that collateral agreements delaying introduction of alleged infringing drug products by generic producers or even non-infringing substitutes, are necessary to facilitate settlements of the patent litigation.

Finally, defendants argue that patent settlements are immune from antitrust challenge under the *Noerr-Pennington* doctrine, which immunizes government petitioning.[14] The settlement, they argue, is simply a step in the prosecution of a patent infringement action. Since prosecution of a lawsuit is immune petitioning, they argue that a settlement should similarly be immune. In response, the government and private litigants assert that settlements reflect purely private conduct and involve no substantive petitioning. The settlement agreement involves no independent action by the court nor is it incidental to infringement litigation. Unlike a pre-litigation threat to enforce a patent, which has been held incidental under *Noerr*,[15] the settlement does not involve a unilateral demand for relief of the type a court could impose in an infringement case. Instead, the settlement encompasses an agreement between potential competitors that may allocate markets or contain other anticompetitive terms wholly collateral to the issue of patent infringement. Nor would judicial approval of the settlement change the analysis because it involves no substantive petitioning, but under present practice is essentially formalistic and ministerial in nature, involving only the parties to the agreement.[16]

While the pharmaceutical cases focus on a particular regulatory scheme, they raise the concern that in a world in which the extent and protection of patent and other intellectual property is rapidly increasing, patent settlements generally may require closer antitrust scrutiny. The presence of patents and the existence of a patent infringement suit does, however, make the antitrust analysis more complex than in non-patent cases in two important respects. First, the issue is often formulated as not simply whether a trade restraint reduces competition that would exist in the absence of the restraint, but whether in addition the restraint is more anticompetitive than the outcome of the patent litigation would be.[17] Second, the infringement action itself serves the vital competitive purpose of policing the validity and scope of patents where other constraining mechanisms are largely absent (apart from the examination of the invention's "patent-worthiness" by the PTO prior to the issuance of the patent)—a purpose all the more necessary in view of the multiplying number of new patents and the high casualty rate of those litigated.

Possible Approaches

We have already mentioned the difficulty of basing antitrust policy on assessments of patent validity and infringement. What other avenues are available? We suggest that the following approaches merit consideration: (1) disclosure provisions that would provide more information on the largely secret world of patent settlement agreements; (2) incentives-based analysis that would focus on whether the settlement agreement creates anticompetitive incentives; and (3) development of other indicators to identify anticompetitive settlements.

1. Disclosure Provisions. Antitrust history and the

recent pharmaceutical cases show that settlement agreements can raise significant antitrust risks. Because such agreements are largely private, the scope of the antitrust risk is unknown. Thus, a vital first step in devising antitrust policy for settlement agreements is to gain more knowledge through mechanisms for disclosure to antitrust enforcement agencies.

Some additional information may soon be forthcoming. The FTC is presently investigating generic drug competition in the pharmaceutical industry. This may provide information about current settlement agreements, but it will of course be limited to a single industry. Other steps that merit consideration include (1) empowerment of antitrust agencies to enforce Patent Act disclosure requirements for interference settlements; (2) notification to antitrust enforcement agencies of settlement agreements between generic and brand name producers of pharmaceutical drug products; and (3) notifications to antitrust agencies of patent settlement agreements in infringement cases generally.

As noted earlier, in *FMC Corp.*, the Third Circuit held that the Justice Department lacks standing to enforce compliance with Section 135 of the Patent Act, which requires disclosure of patent interference settlements to the PTO. Either through statutory amendment of Section 135 or reversal of the *FMC* case, the antitrust agencies should have standing to enforce disclosure of interference settlements, including side agreements. This is not a complete solution, however. Because the PTO is not able to police the side agreement disclosure requirement, the antitrust agencies will only rarely have knowledge of a failure to file such agreements.[18]

A second disclosure proposal, pending in Congress, focuses specifically on the pharmaceutical industry. The Leahy, Kohl, Schumer & Durbin Bill (S.754)[19] would require disclosure to the FTC and Department of Justice of agreements between a generic and brand name drug manufacturer which limit the research, development, manufacture, marketing, or selling of a generic drug product. In addition to providing the full text of the agreement, the parties would have to explain the purpose and scope of the agreement, and whether it could restrain or limit the production, manufacture or sale of the generic version of the drug. The Bill, which has been approved by the Senate Judiciary Committee, thus focuses narrowly on the issues raised by the current pharmaceutical cases, and appears amply justified in view of the antitrust problems that have been identified in recent cases and enforcement proceedings.

A third settlement notification proposal made by a former head of the Antitrust Division, Joel Klein,[20] and a similar proposal by another former head of the Division, William Baxter,[21] would require notification generally of patent settlement agreements in infringement cases meeting certain threshold criteria. This would subject patent settlements to a notification procedure which might bear some similarity to merger prenotification[22] or the more abbreviated procedures of the National Cooperative Research and Production Act. Some will argue that a notification procedure would be burdensome, but the increasing importance of patents and the need to assure that patent rights are not expanded beyond their proper scope argues in favor of this extension of reporting requirements in infringement cases.[23]

2. Incentives-Based Analysis. Patent settlements are a focal point of antitrust concern because they can distort competitive incentives among the litigants and because of the absence of any public enforcement presence. To illustrate, consider this simple example. A patent holder with a monopoly in a well defined market sues a single infringer (the "challenger") who seeks to make and sell the patented product. In the infringement action, the patent holder and the challenger confront each other as competitors for the patent right, testing its validity and scope. If the challenger prevails, the market will be opened to competition. If the patent holder prevails, its existing monopoly will be confirmed, presumably with justification. In the absence of anticompetitive collateral agreements, the incentives of the parties are correctly aligned in the public interest, and should reflect the perceived strength of their patent rights.

The Reverse Payment Cases. The basic problem in the pharmaceutical settlement cases is the skewing of the competitive incentives of the generic manufacturer. As a competitor of the pioneer patent owner, the generic has incentives that would normally be aligned with the consumer interest. The harder it competes with the pioneer in bringing its generic version of the drug to market, the better off are consumers. By allowing the generic to share the monopoly rents of the pioneer, the pharmaceutical settlements have compromised this incentive. Some would address this problem by requiring the government or private litigant to prove the invalidity or non-infringement of the patent to determine whether the expected value to consumers from continued patent litigation is higher than the expected value from the settlement agreements. But, as we have noted already, determination of patent validity is not a feasible standard for an antitrust tribunal.

A more effective antitrust approach to the reverse payment cases would be to minimize so far as possible the distortion of the generic's competitive incentives through rent sharing with the pioneer. Thus, we agree with Commissioner Leary's recent suggestion that settlement agreements in Hatch-Waxman cases should be limited to delayed entry by the generic producer (and of course may also provide for payment of royalties by the generic manufacturer). The payment or giving of any other consideration to the generic manufacturer should be at least presumptively unlawful (if not per se unlawful), with the burden of proof on the parties to justify the payment.[24]

Under this approach, the government or private enforcer would not have to prove the strength of the pioneer's patent rights because the pioneer and the generic producer—the parties who have the best information—would rely on their own assessments of validity in negotiating the date of generic entry.[25] Thus, holding the generic royalty level constant, a

strong claim of non-infringement or patent invalidity by the generic would face little entry delay, while a weak claim would face long entry delay—a result consistent with the policies underlying the patent laws and the Hatch-Waxman Act. The only way the pioneer could persuade the generic producer to extend the delay period would be by lowering the generic's royalty rate, which in itself produces some consumer benefit. But even the pioneer's offer of a royalty-free license would have limited delaying value when the generic's claims are strong in view of the diminishing present value the generic realizes from future income.

Limiting the "coin" of settlements to delayed entry and the royalty to be paid by the generic manufacturer is vastly superior to requiring proof of patent invalidity. Thus, confining the terms of settlement to the time of generic entry and the royalty to be paid by the generic removes the incentive distortion involved in reverse payments. It thereby provides the legal rule that appears most likely to lead to effective administration and minimal antitrust regulation.[26]

Additionally, the 180-day exclusivity provision in the Hatch-Waxman Act may be reformed to lessen the likelihood of anticompetitive settlements in the pharmaceutical industry. Amending the Hatch-Waxman Act to limit the generic's ability to delay the start of the 180-day exclusivity period would lessen the likelihood that a brand name manufacturer would find it economically feasible to prevent generic competition. The "cork-in-the-bottle" effect, referred to above, occurs because the particular structure of the Act permits an agreement between the brand name manufacturer and first ANDA filer to block all subsequent filers from the market. Appropriate amendment of the Hatch-Waxman Act would make a strategy aimed at implementing the cork-in-the-bottle effect less feasible.[27]

3. Other Indicators of Anticompetitive Settlements. The risk of anticompetitive settlements extends beyond the reverse payment cases. While older cases have relied heavily on intent, it would be highly advantageous to develop more objective indicators. We believe at least one is promising: the payment of trivial royalties in an industry-wide licensing arrangement involving the fixing of price or output of licensees. In addition, even the intent issue might be handled more effectively by emphasizing objective evidence of intent.

Trivial Royalty Settlements. In a trivial royalty settlement, the patent holder licenses the patent without requiring the licensee to pay a significant royalty. It is immediately apparent that the trivial royalty is a weaker case of reverse payment. But it differs from the pharmaceutical settlements in that the patent holder receives no significant other consideration from its licensees, such as deferral of entry. If the settlement involves industry-wide licensing that fixes licensee prices or output, the agreement may be a disguised cartel.

In a seminal article, George Priest has identified the trivial royalty as an important indicator of a patent cartel (to be confirmed by other evidence).[28] Priest reasons that the patent holder with a valuable patent will seek to maximize its return through a high royalty, while holding licensee profits to the competitive level. Thus, absence of significant royalties appears inconsistent with full patent exploitation because it involves a sharing of the patent rent with licensees. On the other hand, a trivial royalty is consistent with a licensee-patentee cartel. If the patent is invalid or has little value, the patent holder can maximize its profit by organizing a cartel at the licensee level, splitting the cartel return with its licensees and avoiding possible invalidation of its patent. Thus, a patent license which imposes only trivial royalties on licensees is an indicator of a possible patent-based cartel when accompanied by the fixing of licensee prices or output.[29]

Priest would confirm the cartel diagnosis by examining changes in price, output, and market share, particularly in response to variations in manufacturing costs. Stability of market shares, output, and price tend to indicate a cartel. A cartel manager would try to hold prices and market shares stable, and maintain a price umbrella over less efficient firms to avoid the disruptions and shocks that can undermine the cartel. On the other hand, a patent monopolist will seek to induce competition at the licensee level, which leads to changing market shares, fluctuations in price as manufacturing costs increase or decrease, and exit of less efficient firms.

The trivial royalty issue can also be analyzed in incentive terms. The absence of a significant royalty removes the licensee's incentive to challenge the patent owner's patent rights and to assert its own rights in a manner similar to the reverse payment. The difference is that in the trivial royalty case, the challenger is compensated by sharing in a licensee-patentee cartel. While a cartel diagnosis based on economic indicators alone becomes clear only over time, the presence of a trivial royalty could provide a useful ex ante indicator to enforcement agencies of possible anticompetitive licensing.

Intent Evidence. Intent evidence is often disfavored in modern antitrust analysis, which prefers to focus on the effects of a transaction. At the same time, the Supreme Court, and most recently, the court of appeals in *Microsoft*, recognized that when direct evidence is lacking, intent evidence may be used to prove effects.[30] Patent settlements are just such a case. The settlement may involve collateral agreements that would be per se violations in the absence of the patent rights. In such cases, the effects from an antitrust perspective will inevitably appear anticompetitive. Perhaps for this reason the patent settlement cases have placed greater weight on intent evidence than modern antitrust generally. However, following modern tendencies, appropriate intent evidence should be objective in nature, involving corporate meetings, contemporaneous business documents showing specific plans and program, and the reasons they were undertaken, rather than subjective expressions of attitude or state of mind. Such evidence will show deliberate corporate action that is likely to be profitable only because of the expected cartelization of the market. Under these circumstances, intent evidence may be particularly helpful in determining the presence of a patent cartel.[31]

Conclusion

Patent settlements can be a potent source of antitrust abuse, as evidenced by the recent pharmaceutical settlements. Effective antitrust policy is impeded by the private nature of patent settlements and the complexity of accommodating both antitrust and patent goals, including the inability of an antitrust court to determine patent validity. We have suggested here the adoption of disclosure requirements for patent settlement agreements and the use of intent as a supplemental factor when other evidence is lacking. We finally suggest, subject to further reflection and analysis, the development of objective indicators to identify cartel problems. ■

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[1] See Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 868–70 (1988).

[2] 35 U.S.C. § 135(c). An interference is "an inter parties proceeding in the PTO to determine which of two or more parties was the first to make the invention . . . If two or more applications claim the same subject matter, the applications are said to be "interfering" and the examiner, after determining patentability of the invention to each applicant, can declare an "interference" between them. . . . An interference can also be declared between a pending application and an issued patent. If the examiner does not declare the interference, the applicant can provoke an interference. An interference can relate to some or all of the claims in the application or patent." DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 127 (2d ed. 2001).

[3] Indeed, the PTO lacks standing to assert a violation of 35 U.S.C. § 135(c). *See* Charles L. Gholz, *The Law and Practice Under 35 USC 135(c) Part II*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 675, 677 (1998) (citing *Nelson v. Bowler*, 212 U.S.P.Q. 760 (1981): "[T]he PTO is merely the repository for copies of agreements filed under 35 USC § 135(c), and does not undertake to rule on whether the statute requires that a copy of a particular agreement be filed. If a party files a document and states that it is a copy of an agreement submitted in accordance with 35 USC § 135(c), the PTO's only concern is whether the copy was filed within the time limit prescribed by the statute.").

[4] 717 F.2d 775 (3d Cir. 1983) (employing the analysis set forth by the Supreme Court in *Cort v. Ash*, 422 U.S. 66 (1975), and holding that no implied right of action in favor of the U.S. exists to permit it to enforce 35 U.S.C. § 135(c)); *see also* Joel I. Klein, *Cross Licensing and Antitrust Law*, Speech Before American Intellectual Property Law Association (May 2, 1997), *available at* http://www.doj.gov/atr/public/speeches/1123.htm.

[5] See National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4305.

[6] 35 U.S.C. § 282.

[7] See Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 489–90 (1974) ("Trade secret law provides far weaker protection in many respects than the patent law. . . . [T]rade secret law does not forbid the discovery of the trade secret by fair and honest means, e.g., independent creation or reverse engineering . The holder of a trade secret also takes a substantial risk that the secret will be passed on to his competitors, by theft or by breach of a confidential relationship, in a manner not easily susceptible of discovery or proof. . . . Where patent law acts as a barrier, trade secret law functions relatively as a sieve."); *see also* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) (holding a Florida statute that prohibited a certain method of reverse engineering boat hulls preempted by the Patent Act: "The attractiveness of [the patent] bargain, and its effectiveness in inducing creative effort and disclosure of the results of that effort, depend almost entirely on a backdrop of free competition in the exploitation of unpatented designs and innovations").

[8] *See, e.g., In re* Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 682 (E.D. Mich. 2000) (holding an agreement between a brand name manufacturer and generic drug company under which the brand name agreed to pay substantial sums to the generic in return for its agreement to delay its market entry, not transfer its rights to the 180-day marketing exclusivity period under the Hatch-Waxman Act, and refrain from marketing non-infringing substitutes, a per se violation of the antitrust laws); *In re* Terazosin Hydrochloride Antitrust Litigation, 164 F. Supp. 2d 1340 (D.D.C. 2000) (also finding a per se violation under similar facts).

[9] *See, e.g.*, Abbott Labs. and Geneva Pharmaceuticals, Inc., C-3945, C-3946 (consent orders issued May 22, 2000) (FTC Commission Actions: May 26, 2000, http://www.ftc.gov); Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp., FTC Docket No. 9293 (consent order issued May 8, 2001) (FTC Commission Actions: May 11, 2001 (www.ftc.gov)); Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp., FTC Docket No. 9297 (complaint issued Apr. 2, 2001) (FTC Commission Actions: Apr. 2, 2001).

[10] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[11] *See generally* David Balto, *Pharmaceutical Patent Settlement: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2000).

[12] See cases cited *supra* note 8.

[13] The FTC obtained consent orders in the Abbott Labs and Hoechst Marion Roussel, Inc. actions cited *supra* note 9.

[14] *See generally* cases cited *supra* note 8 (rejecting the argument that the *Noerr-Pennington* doctrine sheltered the agreements at issue).

[15] *See, e.g.*, McGuire Oil Co. v. Mapco, 958 F.2d 1552, 1560 (11th Cir. 1992).

[16] For a recent case adopting the view proffered by the FTC as amicus that "petitioning" the FDA to conduct the purely ministerial and non-discretionary activity of listing a patent in its "Orange Book" was not protected under *Noerr-Pennington*, *see In re* Buspirone Patent & Antitrust Litigation, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

[17] See 12 PHILLIP AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046 (1999).

[18] See Klein, *supra* note 4.

[19] 107th Cong. 1st Sess. (2001).

[20] See Klein, *supra* note 4 (proposing notification at the outset of an infringement case so that the government could "step into the defendant's shoes" if settlement is anticompetitive, or alternatively participate in a public interest review of the settlement along with "other interested parties").

[21] See *id.* (stating that William Baxter had made a "similar proposal just last year").

[22] See Robert J. Hoerner, *Antitrust Pitfalls in Patent Litigation Settlement Agreements*, 8 FED CIR. BAR J. 113, 135 (1998) (developing a patent litigation settlement form that might be used in a notification system).

[23] The burden could be limited by threshold requirements based on market share, size of industry and economic significance of the product. *See* Klein, *supra*.

[24] Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes*, Part II, (May 17, 2001) *in* JOHN S. MILLS, HEALTH CARE AND ANTITRUST, Appendix E 103, p.1., *available at* http://www.ftc.gov/speeches/learypharmaceuticalsettlement.htm).

[25] This is not to say that introduction of the parties' internal assessments of patent validity into the antitrust suit would lead to reliable evidence on which to base estimates of patent strength. Once such assessments become evidentiary, the self interest of the parties would inevitably distort the appraisals, or—what amounts to much the same thing—lead to high selectivity in the "experts" consulted. *See* Leary, *supra* note 24.

[26] *Cf.* Joseph Farrell, Testimony at FTC/DOJ Hearings on Implications of Competition and Patent Law and Policy (2002) (antitrust agencies "rightly reluctant" to directly appraise the strength of IP rights, but instead should rely on "actual behavior in market place" to assess validity and scope of IP rights).

[27] *See generally* McCain-Schumer Greater Access to Affordable Pharmaceuticals Act, S. 812, 107th Cong. 1st Sess. (providing, *inter alia*, that the 180-day exclusivity period becomes available to the next filer if the prior filer fails to begin marketing within 90 days of FDA approval).

[28] George L. Priest, *Cartels and Patent License Arrangements*, 20 J.L. & ECON. 309 (1977).

[29] The fixing or constraining of output can take many forms, such as limiting product quality or variety, dividing or allocating markets, or constraining the timing of competition.

[30] United States v. Microsoft Corp., 253 F.3d 34, 59 (D.C.Cir. 2001).

[31] *See* Louis Kaplow, *The Patent Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1866 & n.182 (1984) (value of corporate documents in identifying patent cartel).