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Patent Settlement Agreements:

Preliminary Thoughts

by

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Settlements between competitors in patent cases raise important and sensitive antitrust issues. The issues are important because patent settlements may create or maintain monopoly in technology and innovation markets and may also effectuate a monopoly or cartel in a related goods markets. Antitrust risks are highlighted by the fact that, absent the patent rights, patent settlement agreements may be per se antitrust violations. Further, anticompetitive patent settlements – unlike most antitrust conspiracies – are enforceable in court, and by that means can prevent the cartel 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

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patent disputes that might otherwise block or delay valuable invention. Settlements can reduce the expense and delay that patent litigation often entails. They enable risk averse business firms to avoid litigation uncertainty and variance of outcome. These risks include the unjustified loss of patent rights if a court erroneously holds the patents invalid. Finally, patent settlements can promote productive technology interchange within industries (at least for non-core technologies).[2]

Thus, antitrust screening of patent settlements has an important role to play, identifying antitrust risks and balancing efficiency benefits. However, effective antitrust scrutiny is constrained by several factors. First, since the anticompetitive risk is most acute when patents are weak, invalid or not infringed, any precise identification of the antitrust risk would requires assessment of patent validity and scope. But these issues can only be fully resolved through 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 by the fact that patent settlements are not disclosed

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[2] See Robert P. Merges, Commercial Success and Patent Standards: Economic Perspectives on Innovation, 76 Cal. L. Rev. 803, 868-70 (1988).

to enforcement agencies. To be sure, the Patent Act requires filing of interference settlements and collateral agreements with the PTO.[3] But it appears doubtful that the PTO can police disclosure of collateral agreements and 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 – all of which require notification of the transactions to the antitrust agencies. Finally, defendants in settlement cases benefit from two legal presumptions that while legitimate in themselves, impede antitrust challenge: a patent is presumed to be valid and courts have frequently declared that patent settlements are to be encouraged.

Recent lower court decisions and federal enforcement actions 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 – that heightens the risk of anticompetitive settlements. This has led to a series of recent cases involving allegations that the procedures available under the Act have been

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[3] 35 U.S.C.§135.

[4] See Joel I. Klein, Cross Licensing and Antitrust Law, Speech before American Intellectual Property Law Association (May 2, 1997).

used to prevent competition and raise consumer prices.

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 provision of the Hatch-Waxman Act. As an incentive for the development of generic substitutes the Hatch-Waxman Act gives the first generic filer the exclusive right to market the generic product for six months from the date it first markets the generic drug -- whenever that may occur. 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. By this means the pioneer blocks all generic entry until the agreed date (the “cork-in-the-bottle” effect).[5] 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 even from offering other competing drug products. The FTC has also challenged such agreements, and obtained consent judgments under Section 5 of the FTC Act.

In response pharmaceutical defendants have urged that a full rule of reason analysis is required, under which the government

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[5] See generally, David Balto, Pharmaceutical Patent Settlement: The Antitrust Risks,55 Food & Drug Law J. 321 (2000).

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 reverse payment litigations.

Finally, defendants argue that patent settlements are immune from antitrust challenge under the Noerr-Pennington doctrine, which immunizes government petitioning. 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 would 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. Just as competitors could not enter into a contract to allocate markets, neither could they enter into a settlement agreement containing such provisions and receive Noerr-Pennington immunity. 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.

While the pharmaceutical cases focus on a particular regulatory scheme, they raise the concern that in a world where the extent and protection of patent and other intellectual property is rapidly increasing, patent settlements generally may require closer antitrust scrutiny.

It should be noted that the presence of patents and the existence of a patent infringement suit makes 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 would be the outcome of the patent litigation.[6] 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 issuance of the patent by the PTO) – 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 the following approaches merit considerations: (1) disclosure provisions that would

[6] See XII Areeda & Hovenkamp, Antitrust Law ¶2046 (1999).

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 teach 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. At the initiative of Congress the FTC is presently investigating 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) antitrust enforcement agency access to patent interference settlements filed with the PTO, (2) notification to antitrust enforcement agencies of settlement agreements between generic and brand producers of pharmaceutical drug products, and (3) notifications to antitrust enforcement agencies of patent settlement agreements in infringement cases generally.

As earlier noted, the Court of Appeals in FMC Corp[7] 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 enforcement agencies should have standing to enforce effective disclosure of interference settlements, and to gain access to the terms of such settlements.[8]

A second disclosure proposal, pending in Congress, focuses specifically on the pharmaceutical industry. The Leahy, Kohl, Schumer & Durbin Bill (S.754)[9] 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 inform 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

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[7] United States v. FMC Corp., 717 F2d 775 (3d Cir. 1983)

[8] See Joel I. Klein, supra.

[9] 107th Cong. 1st Sess (2001)

in view of the antitrust problems that have been identified in recent cases and enforcement proceedings.

A third settlement notification proposal made by two former heads of the Antitrust Division, William Baxter and Joel Klein, would require notification generally of patent settlement agreements in infringement cases meeting certain threshold criteria.[10] This would subject patent settlements to a notification procedure which might bear some similarity to merger prenotification[11] or the more abbreviated procedures of National Cooperative Research 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.

2. Incentives-Based Analysis

Patent settlements are a focal point of antitrust concern because they distort competitive incentives among the litigants and because of the absence of any public enforcement presence.

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[10] See Joel I. Klein, supra (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."

[11] See Robert J. Hoerner, Antitrust Pitfalls in Patent Litigation Settlement Agreements, 8 Fed Cir. Bar J.113, 135 (developing a patent litigation settlement form that might be used in a notification system).

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. The pharmaceutical settlements by allowing the generic to share the monopoly rents of the pioneer 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 in order 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 seen, 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 with the burden of proof on the parties to justify the payment,[12] if not per se unlawful.

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 in negotiating the date of generic entry.[13] Thus, holding the

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[12]Thomas B. Leary, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Part II,(Nov. 23, 2001).

[13]This is not to say that introduction of the parties' internal assessments of patent validity into the antitrust suit

generic royalty level constant, a strong patent claim of non-infringement or patent invalidity by the generic would face little entry delay, while a weak patent 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.[14]

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would lead to reliable evidence on which to base strength of patent estimates. 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.

[14] Cf. Testimony of Joseph Farrell at FTC/DOJ Hearings on Implications of Competition and Patent Law and Policy (2002) (antitrust agencies "rightly reluctant" to directly appraise the

2. Other Indicators of Anticompetitive Settlements

The risk of anticompetitive settlements of course extends beyond the reverse settlement 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. Incentives analysis is still of importance, but unlikely to be sufficient in itself. We hasten to point out that our thoughts in this area are still in process and thus our views are especially tentative here.

Trivial Royalty Settlements

In a trivial royalty settlement the patent holder licenses the patent without requiring 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 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

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strength of IP rights, but instead should rely on “actual behavior in market place” to assess validity and scope of IP rights).

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).[15] 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 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.

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

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[15] George L. Priest, Cartels and Patent License Arrangements, 20 J. L. & Econ. 309 (1977).

stable, and maintain a price umbrella over less efficient firms in order 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 cost 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.

3. 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,. 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 settlement. 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 will be objective in nature, involving corporate meetings, 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 may be particularly helpful in determining the presence of a patent cartel.[16]

[16] See Louis Kaplow, The Patent Antitrust Intersection: A Reappraisal, 97 Harv. L. Rev. 1813, 1866 & note 182 (1984)(value of corporate documents in identifying patent cartel).