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# Pharmaceutical Patent Settlement Cases: Mixed Signals for Settling Patent Litigation

In its October 2003 Report on Competition and Patent Law and Policy, the Federal Trade Commission wrote that "competition and patents are not inherently in conflict." Quoting the Federal Circuit, the Commission reaffirmed that patent and antitrust law are "actually complementary, as both are aimed at encouraging innovation, industry, and competition." Most recent commentators have agreed. Despite their consistent goals, however, tension between the means by which patents and antitrust law encourage innovation and competition ensures that patent antitrust issues are among the most confusing antitrust issues to analyze. As a result, judicial and agency opinions can provide antitrust advisors with mixed signals.

Mixed signals certainly have arisen from three recent decisions concerning the settlement of patent litigation between brand name and generic drug makers. Last June, in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), the Sixth Circuit held that an interim patent settlement in which the brand name patent holder agreed to pay a potential generic entrant to delay entry pending resolution of the lawsuit was *per se* illegal. In contrast, in September, the Eleventh Circuit in *Valley Drug Company v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), held that patent litigation settlement agreements may not be declared illegal without first considering the potential "exclusionary effect of the patent." And in December, the Federal Trade Commission in *In re Schering-Plough Corporation*, Docket No. 9297, ruled that both a *per se* and full-blown rule of reason approach were inappropriate, and inquiry into the merits of the underlying patent dispute *a la Valley Drug* was unnecessary, but found that a patent settlement agreement had anticompetitive effects under an abbreviated rule of reason approach. In all three cases, so-called "reverse payments," i.e. settlement payments flowing from the brand name patent holder to the potential generic entrant, were an important aspect of the plaintiffs' or government's case against the drug companies.

The potential for tension between the interests of patent and antitrust laws is acute in the context of patent settlement agreements. On the one hand, patents are *intended* to confer exclusionary power within the scope of the patent for the period of the patent term. On the other hand, patent settlement agreements in and out of the pharmaceutical context often are negotiated between actual or potential competitors. Thus, the parties may have the incentive to enter into agreements that, by delaying entry of the patent challenger or otherwise reducing output, allow them to split the resulting monopoly profits at consumers' expense. These incentives are present in many patent settlement negotiations, but are particularly strong in the case of patent settlement agreements between brand name and generic drug makers. Pharmaceutical patents — unlike patents in many other fields — often confer substantial market power. Moreover, as is discussed below, the Hatch-Waxman statutory regime in which pharmaceutical patent litigation has taken place heightened those incentives, in part by providing a period of generic exclusivity to the first generic entrant to challenge a brand name drug.

This article reviews the Courts of Appeal decisions in *Cardizem* and *Valley Drug*, and the Commission's decision in *Schering-Plough*, to try to make some sense of these confusing decisions. Petitions for certiorari have been

filed in both *Cardizem* and *Valley Drug*. The Supreme Court has invited the government to file a brief in the *Cardizem* case expressing its views on whether certiorari should be granted. If the Court grants certiorari, more clarity may be forthcoming in this area.

**Statutory Framework.** In 1984, Congress enacted the Hatch-Waxman Amendments, in large part to make it easier for generic drug producers to gain regulatory approval for generic equivalents of patented brand name drugs and, thus, to enter and compete. Under Hatch-Waxman, a brand name drug producer seeking FDA approval by filing a New Drug Application ("NDA") must list its patents that would be infringed by a generic producer of its new drug. The FDA publishes that information in the "Orange Book." A subsequent generic producer intending to rely on the safety and efficacy studies of the brand name drug maker may file an abbreviated new drug application ("ANDA"), which relies on the FDA's earlier determination that the active ingredients in the brand name drug are safe and effective. The ANDA must include a certification that, to the best of the applicant's knowledge, the proposed generic will not infringe any patent listed in the Orange Book as covering the brand name drug. Where a generic producer makes a "paragraph IV" certification that the relevant patent is invalid or not infringed, and the pioneer sues within 45 days, the FDA cannot approve the generic equivalent for 30 months unless before that time the court hearing the infringement case determines the patent is invalid or not infringed.

Under the 1984 version of Hatch-Waxman, the first generic producer to challenge a patent holder and submit an ANDA obtained a 180-day exclusivity period during which no other generic could compete, dating from the date on which the first generic begins marketing or the date of a court decision holding the patent invalid or not infringed, whichever is earlier. If the 180-day exclusivity period did not run, the FDA could not approve any subsequent generic applicants. This 180-day exclusivity period was intended to encourage generic entry and to compensate for the thirty-month stay accorded the patent holder. However, its structure opened the possibility that the brand name producer and the first ANDA filer could "park," or prolong indefinitely, the exclusivity period if the first filer agreed to settle and to delay marketing the generic. Thus, the unintended consequence of the exclusivity incentive was to heighten the incentives to delay generic entry of the first ANDA filer.

***In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), *petition for cert. filed Nov. 24, 2003*.** In *Cardizem*, the Sixth Circuit on interlocutory appeal held that an interim patent settlement was a *per se* violation of Section 1 of the Sherman Act. Defendant Hoechst Marion Roussel ("HMR") manufactured the heart drug Cardizem CD. Andrx filed its ANDA in September 1995 for a generic equivalent and, in December, filed a paragraph IV certification. Andrx was the first filer of an ANDA for a generic Cardizem equivalent, entitling it to the 180-day exclusivity period. In January 1996, HMR sued Andrx for patent infringement, triggering a 30-month stay of FDA's approval of Andrx's ANDA.

On September 15, 1997, the FDA tentatively approved Andrx's ANDA. Later that month, HMR and Andrx agreed that Andrx would not market generic Cardizem until it obtained a favorable, final judgment in the infringement case, or HMR entered a license agreement with either Andrx or a third party. Andrx agreed not to relinquish its 180-day exclusivity period, meaning that no other generic could receive FDA approval, and Hoechst agreed to pay Andrx $40 million per year, payable quarterly, beginning on the date that Andrx received final FDA approval.

In July 1998, the 30-month stay expired and the FDA issued its final approval of Andrx's ANDA. HMR began making quarterly payments under the settlement agreement. On September 11, 1998, Andrx filed a supplement to its previously filed ANDA which sought approval for a reformulated generic version of Cardizem CD; on the basis of this supplement, Andrx urged HMR to reconsider its infringement claims. On June 9, 1999, the FDA approved Andrx's formulated product, and HMR and Andrx entered into a stipulation settling the infringement case and terminating the settlement agreement. Shortly thereafter, Andrx began to market its product, and its 180-day period of marketing exclusivity began to run. After introduction, Andrx's Cartia XT sold at a much lower price than Cardizem CD and captured a large share of the market.

The Sixth Circuit held that the agreement was a *per se* illegal restraint of trade. "[T]he following facts," said the Court, "are undisputed and dispositive. The Agreement guaranteed to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval . . . By delaying Andrx's entry

into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer." The Court found that there was "simply no escaping" the conclusion that the Agreement was, "at its core, a horizontal agreement to eliminate competition."

The Sixth Circuit rejected the argument that the Agreement was more properly characterized as merely an attempt to enforce patent rights — the patent at issue was not due to expire for many years — or an interim patent settlement. "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." Nor was the Court convinced that this was a "novel" area of law precluding *per se* treatment.

***Valley Drug Company v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), *petition for cert. filed Feb. 12, 2004*.** In contrast to the Sixth Circuit's approach in *Cardizem*, in *Valley Drug*, the Eleventh Circuit held on interlocutory appeal that patent litigation settlement agreements *may not* be declared *per se* illegal without first considering the "potential exclusionary power of the patent." Abbott Laboratories ("Abbott") manufactured the hypertension drug Hytrin and held several patents related to terazosin hydrochloride, Hytrin's active ingredient. Geneva Pharmaceuticals ("Geneva") filed four ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications that Abbott's relevant patents were invalid or would not be infringed. Abbott sued Geneva for infringement, which invoked the 30-month stay of FDA approval. Zenith Goldline Pharmaceuticals ("Zenith") filed an ANDA for a terazosin hydrochloride drug in 1994, also making a paragraph IV certification with respect to Abbott's Hytrin patents. Zenith's ANDA also resulted in litigation with Abbott.

The two agreements challenged by the plaintiffs in *Valley Drug Company* were entered in the context of the two patent lawsuits. In the Zenith Agreement, Zenith agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until someone else introduced a generic or until one of Abbott's patents expired. Abbott agreed to pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter until the Agreement terminated.

In the Geneva Agreement, Geneva agreed not to sell or distribute any terazosin hydrochloride until a certain Abbott patent expired, someone else entered with a generic, or Geneva obtained a final judgment that Abbott's patent was either invalid or not infringed. Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Abbott agreed to pay Geneva $4.5 million each month until the agreement terminated.

The Eleventh Circuit began its analysis of whether the Agreements violated Section 1 of the Sherman Act by acknowledging that "[w]hen a firm pays its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist, competition is reduced." "This is not such a case," the Court said, because Abbott owned the '207 patent, which gave it the right to exclude others until October of 2014. "The '207 patent may have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal, which also would have prevented Geneva from marketing its terazosin hydrochloride products during this period." The Eleventh Circuit concluded that exclusionary effects of patent settlement agreements that are within the scope of the exclusionary potential of the patent may not be subject to *per se* condemnation, and remanded the case for further proceedings.

The Eleventh Circuit rejected the plaintiffs' argument that the Agreements should be analyzed under the *per se* rule because the patent was subsequently declared invalid, which the Court found inconsistent with the Supreme Court's decision in *Walker Process* and with the policy goals of the antitrust and patent laws. Moreover, exposing settling parties to antitrust liability for exclusionary effects within the scope of a patent procured in good faith would undermine patent incentives. The Court also rejected the argument that a "reverse payment," in which a patentee pays an alleged infringer to exit, compels *per se* treatment, stating that "[class action plaintiffs] have not explained why a monetary payment as part of a patent litigation settlement should be flatly prohibited as a *per se* violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with."

The Eleventh Circuit observed that the Sixth Circuit in *Cardizem* seemed to have placed

"considerable reliance" on effects of the *Cardizem* agreements that seemed to exceed the potential exclusionary power of the patent. However, stated the Court, "[t]o the extent that the Sixth Circuit suggests that a settlement of patent litigation was a *per se* violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, we respectfully disagree."

The Eleventh Circuit then proposed a new and ill-defined analysis, requiring consideration of the "effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of 'achieving a suitable accommodation between the differing policies.'" The district court must assess whether or not the settlement is more restrictive than a likely outcome of the patent litigation. However, "[a]ny provisions of the Agreements found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act."

***In re Schering-Plough Corporation, Docket No. 9197 (F.T.C. 2003).*** In *Schering-Plough,* the FTC, taking a different approach than both the Sixth and Eleventh Circuits, ruled that settlement agreements between a brand name and two generic drug makers that involved "reverse payments" and had the effect of delaying entry of a generic version of K-Dur 20, used to treat patients with low potassium, violated section 5 of the FTC Act. In August 1995, Upsher filed an ANDA for a generic version of K-Dur 20, and made a paragraph IV certification. In December, Schering sued Upsher for patent infringement. Under Hatch-Waxman, the lawsuit triggered the 30-month stay for final approval of Upsher's product. In June 1997, on the eve of trial, Schering and Upsher settled the patent litigation. The 30-month stay was scheduled to expire in a year. In the agreement, Schering agreed to make payments totaling $60 million to Upsher. Upsher agreed not to enter the market with any generic version of K-Dur 20 before September 2001, five years before the patent was due to expire. As part of the settlement agreement, Upsher licensed Schering to market six Upsher products in certain territories.

The Commission rejected both the *per se* approach applied in *Cardizem* and a full-blown rule of reason analysis based on relevant market definition, and instead, adopted an abbreviated rule of reason approach based on its recent decision in *Polygram Holding*. The Commission then looked to a variety of direct evidence on which it based its determination that the agreement was an illegal restraint of trade — including evidence in the record that generic entry was considered by the parties to be a "uniquely significant" market effect, with likely large effects on prices and sales.

The Commission found the "reverse payment" from Schering to Upsher to be of "particular significance," observing that the "[p]ossible existence of a so-called 'reverse payment' raises a red flag that distinguishes this particular litigation settlement from most other patent settlements, and mandates further inquiry." The Commission stated that "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."

The Commission sought prospective relief only against Schering Plough, stating that the "particular problems posed by reverse payments" were not so obvious when the agreements were executed. However, the Commission warned that it may be appropriate to seek disgorgement of profits in a future case.

The different approaches taken in the three decisions make it difficult to distill general lessons from them. The following is some obvious — and not so obvious — guidance for approaching patent litigation settlements. Because of the characteristics of the pharmaceutical industry, including the statutory framework, and because of the FTC's interest in that industry, the advice is most pertinent in the pharmaceutical or related context. However, since the potential for anticompetitive agreements exists in other settings as well, the first three points are important to bear in mind whenever one approaches a patent litigation settlement between actual or potential competitors. The fourth point, regarding the mandatory filing of patent settlements with the antitrust regulators, applies only to companies subject to the Hatch-Waxman Act regime.

**Avoid "Reverse" Payments.** The economic scholarship regarding "reverse payment" patent settlements sends "mixed signals" on whether or not they are necessarily anticompetitive. For example, in the most recent edition of *Antitrust Law Journal*, Marc

Schildkraut describes how using reverse payments as a guide to anticompetitive settlement agreements may be both under and over-inclusive. A number of commentators have been much more critical of reverse payments. The mixed signals from commentators suggest that the presence of a reverse payment should not trigger *per se* analysis. However, because they have been such flashpoints in the case law, care should be taken to avoid any payment that may appear to be a *quid pro quo* for delaying entry or reducing output.

**Avoid Restrictions That Go Beyond The Potential Scope Of The Patent.** Restraints on competition that go beyond the potential scope or term of the patent present significant antitrust risks, even if arguably ancillary to the settlement agreement. For example, in *Cardizem*, the settlement agreement restrained the generic company from entering with even a non-infringing generic equivalent during the pendency of the agreement. And the Eleventh Circuit in *Valley Drug*, while declining to apply the *per se* rule to the agreements at issue, commented that provisions of settlement agreements found to have "effects beyond the exclusionary effects of [the] patent" are subject to "traditional antitrust principles," including the *per se* rule.

**Notify The Court Of The Terms And Get The Settlement Approved.** Although it is unclear the extent to which the *Noerr-Pennington* doctrine insulates from antitrust challenge patent settlement agreements — particularly those that have been approved by a court — it cannot hurt to notify the court of the terms of the settlement and get the settlement approved. *Noerr-Pennington*, or petitioning, immunity, provides immunity from the antitrust laws for attempts to influence the passage or enforcement of laws. The Supreme Court has extended the right to petition the government to the courts. Moreover, there is case law that extends this immunity to activities, such as threats of litigation, that are reasonably incident to the lawsuit or other petitioning activity.

*Noerr-Pennington* has not yet had much success in immunizing pharmaceutical patent settlements. However, the pharmaceutical cases in which courts have rejected the *Noerr* argument have involved agreements that were, at best, rubber-stamped by the courts. For instance, in the *Ciprofloxacin* case, the court explained that the judge who had presided over the patent infringement case was not "even apprised of the terms before he 'so ordered' the Consent Judgment." Thus, the agreements were "private agreements between the defendants," not entitled to protection under *Noerr*.

**Notify The Antitrust Authorities If The Settlement Is Between A Brand Name And A Generic Drug Producer.** Effective January 7, 2004, brand name and generic drug manufacturers must file certain agreements with the Federal Trade Commission and Department of Justice within ten days of their execution. Agreements between a brand name manufacturer and a generic ANDA applicant with a paragraph IV certification must be filed if they concern the manufacture, marketing or sale of the brand name or generic drug, or the 180-day exclusivity period. Agreements between two generic manufacturers with paragraph IV certifications concerning the same brand name drug must be filed if they concern the 180-day exclusivity period. Failure to comply with the filing requirement carries potential civil penalties up to $11,000 per day. ■

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