Legal Backgrounder

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Ave., NW
Washington, D.C. 20036
202.588.0302

Vol. 16 No. 30 July 13, 2001

DRUG PATENT SETTLEMENTS SHOULD BE JUDGED ON A CASE-BY-CASE BASIS

by

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Settlement agreements between brand-name drug manufacturers and their generic competitors recently have drawn the attention of Congress, the Federal Trade Commission, various commentators and the plaintiffs' antitrust bar. While each of these agreements involves a unique factual context, a common factor is the actual or threatened expiration of a statutory stay which would otherwise prevent generic competition until pending patent litigation has been concluded. Under the agreements, brand-name companies which are patent holders made payments or granted other consideration to generic companies during the pendency of patent litigation, and the generic companies agreed not to launch their products until the patent litigation was resolved.

The FTC has pursued three enforcement actions, numerous civil cases have been filed, and two district court judges have concluded that such agreements are "horizontal market allocations" that constitute *per se* violations of the antitrust laws. The FTC also recently initiated an industry-wide investigation of similar settlement agreements and related matters.

Mechanical application of *per se* concepts of antitrust law is an inappropriate methodology to address these issues. The agreements were negotiated and entered into against the backdrop of a complex regulatory scheme. Moreover, the antitrust laws have traditionally presumed that, absent a showing of fraudulent, sham or otherwise abusive conduct, efforts by patent owners to exclude competitors from the market are a legitimate by-product of the limited monopolies provided by the patent laws. These recent decisions turn this presumption on its head, and create substantial uncertainty for participants in the pharmaceutical industry. The decisions are also at odds with the stated policy underlying the FDA regulations, which emphasize the importance of resolving patent challenges before any generic drug is brought to market. Application of a *per se* rule is particularly inappropriate in this setting in the absence of a finding that generic competition was in fact delayed by the agreements.

The Regulatory Background. The Hatch-Waxman Act establishes a regulatory framework for obtaining approval to market new generic drugs. The abbreviated new drug application, or ANDA, process, enables a generic drug manufacturer to rely on the safety and effectiveness tests conducted by the pioneer

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drug manufacturer in applying for FDA approval if it can show that the generic version contains the same active ingredient and is bioequivalent to the original drug. *See* 21 U.S.C. § 355(j)(2)(A).

The ANDA process also contains important protections for the patent holder — the generic drug applicant must file a "certification" regarding any patents listed in an FDA publication known as the Orange Book that claim the approved drug. 21 U.S.C. § 355(j)(2)(vii). Once the ANDA applicant certifies under Paragraph IV of this subsection that the patents listed in the Orange Book are invalid or will not be infringed by the proposed generic drug, the patent holder then has forty-five days to commence a patent infringement suit. 21 U.S.C. § 355(j)(2)(vii)(IV). FDA approval is deferred until the earliest of (i) the expiration of the patent, (ii) the expiration of a thirty month period running from the Paragraph IV certification, or (iii) such time as "the court decides that such patent is invalid or not infringed . . . ." *Id.* If the patent holder prevails, FDA approval is deferred until the expiration of the patent.

The first generic manufacturer to file a Paragraph IV certification is entitled to 180 days of marketing exclusivity vis-à-vis other generic manufacturers. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II). The "first filer" is not required to commence marketing its drug if the 30-month period expires before a judicial determination on the patent. Rather, the 180-day exclusivity period runs from the earlier of the judicial determination or the date the "first filer" begins marketing its product. *Id.* Otherwise, a "first filer" that received FDA approval prior to conclusion of the litigation would be faced with an untenable Hobson's choice either to forsake the 180-day exclusivity period or to run the risk of a crippling damage award if it does not prevail in litigation.

The Hatch-Waxman Act and the FDA regulations thus plainly contemplate the judicial resolution of the relevant patent challenges before any new generic drug is brought to market. Indeed, the FDA has recognized that "[i]t serves the public interest to permit a prudent ANDA holder in that situation to stay off the market until the litigation is resolved, thereby minimizing potential damages." *Proposed Rules: Abbreviated New Drug Applications*, 54 Fed. Reg. 28,872, 28,894 (1989)*;see also Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,352 (1994) ("Beginning the 180-day exclusivity period before the resolution of the appeals process would render the exclusivity period valueless to a prudent applicant who delayed marketing until the issues were resolved on appeal.").

Regulatory and Judicial Consideration of Hatch-Waxman Settlements. The antitrust implications of "Hatch-Waxman settlements" have been considered in the context of FTC enforcement actions and in litigation challenging three such agreements. In two of the FTC actions — arising from settlement agreements between Abbott Laboratories ("Abbott") and Geneva Pharmaceuticals, Inc. ("Geneva") and between Hoechst Marion Roussel, Inc. ("Hoechst") and Andrx Corp. ("Andrx") — the FTC negotiated consent decrees with the parties that, among other things, required court approval and notice to the FTC of any future settlement agreement in which a generic company received payments to defer marketing its product during the pendency of patent litigation. The third enforcement action, arising from agreements between Schering-Plough Corp., Upsher-Smith Laboratories, and ESI Lederle, Inc., was filed recently. Each complaint alleged that the agreements were an unreasonable restraint of trade. However, no adjudication has yet been made.

This civil litigation has resulted in two decisions that condemn the agreements as *per se* violations of Section 1 of the Sherman Act. In the first — now on interlocutory appeal to the Sixth Circuit — plaintiffs' motion for partial summary judgment was granted. *See In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000). The court concluded that the agreement was a "horizontal market allocation," an agreement to divide markets. *Id.* at 701. The court rejected the defendants' arguments that the agreement was ancillary to pro-competitive efforts to protect their respective interests in the underlying patent litigation, concluding that the agreement was a "naked restraint" that did not merit full scrutiny under the rule of reason. *Id.* at 704-706. The second decision similarly concluded that the Abbott/Geneva agreement was illegal *per se*. *See In re Terazosin Hydrochloride Antitrust Litig.*, 98-MDL-1317 (S. D. Fla. Dec. 13, 2000). Neither court examined whether the underlying patent cases raised *bona fide* disputes, nor whether the agreement had any actual effect on competition. *Id.* at 15.

Hatch-Waxman Settlements Merit Full Scrutiny Under the "Rule Of Reason". The district court decisions condemning these agreements as illegal *per se* are divorced from established antitrust precedent. Antitrust law has evinced a steady trend away from the use of formal categories and toward the use of a more nuanced economic analysis of the challenged restraint. In *California Dental Association v. FTC*, 119 S. Ct. 1604, 1617 (1999), for instance, the Supreme Court warned against the overuse of assumptions and presumptions concerning the competitive effects of business practices and emphasized that *per se* condemnation is reserved for a few well-established categories of restraints which extensive judicial experience has demonstrated to be anticompetitive under any circumstances. *California Dental* continues a long line of cases in which the Supreme Court has limited, overruled, or declined to extend previously established *per se* rules, and has cautioned lower courts against the reflexive application of *per se* rules to new forms of allegedly anticompetitive conduct.[1]

Broadly applying a *per se* rule to a novel agreement is particularly troublesome in the context of an intellectual property dispute. Special antitrust treatment of intellectual property settlement agreements dates back to the seminal decision in *Standard Oil, Co. (Indiana) v. United States*, 283 U.S. 163 (1931), which concluded that *per se* treatment was inappropriate to analyze a settlement of conflicting patent claims because the agreement settled bona fide patent disputes. *Standard Oil* thus established that "agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide [intellectual property] dispute." Herbert Hovenkamp, Antitrust Law (1998 & 1999 Supp.) ¶ 2046 at 265.

Indeed, prior to the district court decisions in *Cardizem CD* and *Terazosin Hydrochloride*, no court had ever condemned the *bona fide* settlement of an intellectual property dispute as a *per se* violation. Courts instead conducted detailed factual analyses of the context, purposes, intent, and actual effect of settlement agreements, *i.e.*, a full rule of reason analysis. *See, e.g., Standard Oil, Co. (Indiana)*, 283 U.S. at 163; *Hartford-Empire Co. v United States*, 323 U.S. 386, 400, *clarified*, 324 U.S. 570 (1945); *United States v. Singer Mfg. Co.*, 374 U.S. 174, 192-93 (1963); *Clorox*, 117 F.3d 50.

The *Cardizem CD* and *Terazosin Hydrochloride* decisions entirely ignored the long-recognized pro-competitive potential of patent settlement agreements, relying instead upon an erroneous analogy to horizontal market allocation cases. However, the fact that Hatch-Waxman settlements involve intellectual property is crucial. The patents owned by pioneer manufacturers give them a presumptively valid right to exclude would-be competitors from the market. An agreement that seeks to protect that right, while at the same time preserving the ability of the would-be competitor to pursue a judicial challenge, is fundamentally different from an agreement between two ongoing competitors to allocate the market for their products.

The *Cardizem CD* and *Terazosin Hydrochloride* courts also erred in placing virtually controlling importance on the fact that the generic companies were paid pursuant to these agreements. Settlements inherently involve compromise. In these cases, the generic companies were able to exact compensation because of procedural advantages obtained under the Hatch-Waxman framework.[2] The brand name companies faced the risk that premature entry by generic companies during the pendency of patent litigation could cause irreparable damage far beyond the ability of the generic companies to pay. Even if the patents were ultimately found to be valid and infringed, the market for the patented products could have effectively

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[1] *See State Oil Co. v. Khan*, 118 S. Ct. 275, 283 (1997) (overturning *per se* rule against vertical maximum resale price maintenance); *Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 731-35 (1988) (limiting *per se* rule against resale price maintenance); *Northwest Wholesale Stationers v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 297-98 (1985) (declining to apply the *per se* rule against group boycotts to joint activity that might enhance efficiency); *National Collegiate Athletic Ass'n v. Board of Regents of Univ. of Okla.*, 468 U.S. 85, 101, 117 (1984) (horizontal limitation of output subject to rule or reason and not *per se* illegal when related joint to economic activity); *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 70 (1977) (overturning *per se* rule against vertical territorial restraints).

[2] The Abbott/Geneva agreement was necessitated when the FDA gave Geneva approval to market a generic product solely because of a clerical error in Abbott's patent department. The Hoechst/Andrx agreement addressed the period following expiration of the 30 month stay.

been destroyed by illegitimate competition. Accordingly, the mere fact that patent holders in this situation were willing to make some payments to the generic companies, representing a small fraction of their potentially irrecoverable losses, says nothing about the strength of the underlying intellectual property claims. Indeed, the courts have as a matter of course enforced intellectual property settlement agreements involving payments to the alleged infringer. *See, e.g.*, *Metro-Goldwyn Mayer, Inc. v. 007 Safety Products, Inc.*, 183 F.3d 10 (1st Cir. 1999); *In Time Products, Ltd. v. Toy Biz, Inc.*, 38 F.3d 660 (2d Cir. 1994).

These district court decisions also appear to go well beyond the FTC's enforcement actions in which the FTC did not allege, much less find, that the agreements were illegal *per se*. Instead, the full Commission has stated that any agreement of this sort "must be examined with respect to its particular facts" — that is, under the rule of reason. Analysis to Aid Public Comment at 4, *In the Matter of Abbott Laboratories and Geneva Pharmaceuticals*, FTC Docket No. 981395 (2000). Indeed, in recently launching a major study of the competitive effects of such agreements, the FTC has emphasized that "the *Commission's experience also has suggested that there may be circumstances where the agreements between innovator and generic drug companies are procompetitive*. . . . the proposed study may identify procompetitive rationales in support of other agreements that have somewhat different terms, thereby illuminating *benign reasons* for conduct that some currently see as 'murky or unfair.'" FTC, *Agency Information Collection Activities*, Comment Request, 66 Fed. Reg. 12512, 12516 (Feb. 27, 2001) (emphasis added).

In a recent presentation, FTC Commissioner Leary likewise noted that "the issues raised by pharmaceutical patent settlements are complex, fact intensive and not susceptible to hard-and-fast rules, at least at this stage." Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes* at 13-18 (Nov. 3, 2000). Commissioner Leary conceded that "[I]t is not at all easy to distinguish between the [interim patent settlements] that are pernicious and those that are not — particularly, when the uncertain outcome of patent litigation is factored in." *Id*. at 14. Commissioner Leary further noted that the substantial uncertainty attendant to all patent litigation,[3] the tremendous damage that an alleged infringer can cause by going to market before patent litigation is resolved, and "the fact that the entrant may not be able to pay these damages," combine to provide a legitimate incentive for the parties to settle, even if the parties are relatively confident of the outcome of the litigation. *Id*. Based on these considerations, Commission Leary concluded that *per se* treatment of *bona fide* Hatch-Waxman settlements would be contrary to the long-term pro-competitive purposes of the patent system and "would cast a cloud over all patent settlements." *Id*.

Conclusion. Commissioner Leary's judgment is sound. Under the rationale of the district court decisions in *Cardizem CD* and *Terazosin Hydrochloride*, any patent settlement in which an alleged infringer agrees to cease infringing, regardless of merits of the patent claim or the actual effect on competition, would potentially be subject to *per se* condemnation. If these decisions are upheld, intellectual property owners may be forced to conclude that patent disputes cannot safely be settled without running the risk of treble damages under the antitrust laws. Regardless of the strength of their claims, and of the willingness of the alleged infringer to settle, intellectual property owners may be unable to preclude infringers from the market without expending the resources necessary to litigate their claims to a final judicial determination.

There is no need for any such *per se* rule. To date no one has pointed to evidence that any Hatch-Waxman settlement has delayed generic entry at all, much less beyond the date of a final judicial resolution of a patent litigation. Should the evidence establish such a fact, and the agreement lack legitimate business justifications, the rule of reason can serve as a basis for antitrust evaluation. Moreover, to the extent that Hatch-Waxman settlements are causing inappropriate delays in the entry of generic competition, Congress and the FDA can close any perceived "loophole" by, for instance, requiring any first-filer that receives final FDA approval to begin marketing its product within a specified time or lose its right to exclusivity. In short, there is no basis for concluding that Hatch-Waxman settlements present the sort of anticompetitive threat that would merit the creation of a new *per se* rule of antitrust liability.

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[3] "The Federal Circuit, according to its own official 1997 statistics, reversed in whole or in part 53% of the cases from district courts . . . [and] one study shows . . . reversal, in whole or in part, of almost 40% of all claim constructions." *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1476 (Fed. Cir. 1998) (Rader, J. dissenting).