Legal Backgrounder

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FTC IMPROPERLY INJECTS ITSELF INTO DRUG PATENT SETTLEMENTS

by

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Over the past year, the Federal Trade Commission (FTC) has investigated several agreements between brand-name and generic pharmaceutical manufacturers which, according to the FTC, have the effect of keeping low-cost generic drugs off the market. The FTC recently charged a major pharmaceutical maker and a generic company with entering into such anti-competitive agreements. It has also reached consent agreements resolving similar charges against other major pharmaceutical companies. With its most recent action, the FTC has begun scrutinizing more than just agreements reached pending the outcome of litigation. It has turned its focus to settlement agreements and has begun to judge the merits of underlying patent infringement claims. This LEGAL BACKGROUNDER discusses case law precedent addressing the antitrust implications of settlement agreements, the recent FTC enforcement action challenging a settlement agreement, and the need to consider the benefits of settlements in analyzing the anticompetitive effects of a settlement agreement.

Singer *and its Progeny*. Federal antitrust law is sparse on the antitrust implications of settlement agreements. It is clear that settlement of patent or copyright litigation, in and of itself, does not violate the antitrust laws. Courts encourage settlement of patent infringement litigation, which tends to be complex and drawn out. "Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931). Yet, settlement agreements with anticompetitive effects can violate the Sherman Act.

U.S. v. Singer, 374 U.S. 174 (1963) is the principal U. S. Supreme Court case to discuss the antitrust implications of settlement agreements. In *Singer*, American, Swiss, and Italian companies used cross-licensing agreements and transfers of patents to keep Japanese competition out of the U.S. market. The particular settlement in *Singer* involved an agreement to resolve interfering or blocking patents. The Court examined all of the parties' actions, including the settlement agreement, and determined that the entire course of conduct was sufficient to establish liability under Sections 1 and 2 of the Sherman Act.

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Justice White added in a concurrence that, apart from the conspiracy, the settlement of the patent interference alone also constituted a *per se* violation of the Sherman Act or, at least, was "presumptively bad." *See id.* at 197-99. (The vote on the Court's decision was 8-1. Justice White's separate concurrence was, therefore, not necessary to the outcome.) This statement has become the source of subsequent discussion and litigation over the sufficiency of a settlement agreement — of any kind — for antitrust liability. *See e.g.* David A. Balto, *Pharmaceutical Patent Settlements The Antitrust Risks*, 55 FOOD DRUG L.J. 321 (2000).

Whether settlements violate antitrust laws is an issue suffuse with complexity. But, "*Singer* makes [it] clear that it is not the mere act of settlement but the intent of the parties in entering into that settlement and their actions pursuant thereto that, in law, constitute such a violation. It is ... the anti-competitive intent or purpose of the parties which is the critical factor." *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1221 (1976). Courts faced with this issue have considered the intent of the parties in entering the agreement, the amount of judicial supervision involved in the settlement, the availability of *Noerr-Pennington* protection, and other conduct of the parties beyond the settlement agreement itself. *See United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *In re New Mexico Natural Gas Antitrust Litigation*, 1982-1 Trade Cases 64685, 1982 WL 1827 (D.N.M. 1982); *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1221 (1967). But no court has yet provided a comprehensive framework for analyzing whether a particular settlement agreement violates the Sherman Act.

Recent FTC Actions. Over the past two years, the FTC has brought enforcement actions against three sets of pharmaceutical companies. While the facts in each are similar and involve the same legislative scheme regarding the marketing of generic drugs, each case differs, and collectively they represent the FTC's attempt to expand its enforcement powers towards the outer limit of established law.

Hoechst Marion Roussell, Inc. and Adrx Corporation. In March 2000, the FTC brought an enforcement action against Hoechst Marion Roussel, Inc. ("HMRI") and Andrx Corporation ("Andrx"). The FTC charged both companies with violations of Section 5 of the FTC Act, and specifically, for entering into an agreement in restraint of trade. HMRI manufactured the drug Cardizem, used to treat hypertension. Andrx, a potential competitor, was in the process of gaining approval to market a generic version of Cardizem. Upon Andrx's application to the FDA for approval of its generic drug, HMRI filed a patent infringement suit against Andrx. In late July 1997, the two companies entered into an agreement where, among other things, Andrx agreed not to enter the market with a generic version of Cardizem until entry of judgment in the patent suit. The agreement was *not* a settlement agreement, since the parties anticipated a judicial resolution to the patent litigation. In exchange for Andrx's agreement not to enter the market, HMRI agreed to pay Andrx $10 million per quarter, beginning upon final FDA approval of Andrx's product, and continuing until the end of the infringement suit or HMRI's decision to license the formula for Cardizem to Andrx or a third party.

Abbott Laboratories and Geneva Pharmaceuticals, Inc. In May 2000, the FTC brought a similar action against Abbott Laboratories ("Abbott") and Geneva Pharmaceuticals, Inc. ("Geneva"). The facts were essentially the same as those in the case against HMRI and Adrx. In June 1996, Abbott sued Geneva for patent infringement of its brand-name drug Hytrin. While the suit was continuing, Geneva obtained FDA approval to market its generic form of Hytrin. Just as Geneva was about to enter the market with a generic competitor of Abbott's product, Geneva and Abbott negotiated an agreement whereby Geneva agreed not to enter the market with a generic competitor of Hytrin until either the patent litigation was resolved (including review by the Supreme Court) or another company produced a generic competitor of Hytrin. In return, Abbott agreed to pay Geneva $4.5 million per month in non-refundable payments until a district court judgment in the parties' patent infringement dispute was rendered.

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Schering-Plough Corporation and Upsher-Smith Laboratories. Building on its earlier enforcement actions, *Hoechst* and *Abbott*, the FTC initiated yet another enforcement action this year against two pharmaceutical companies — Schering-Plough Corporation and Upsher-Smith Laboratories. (The FTC also brought a separate claim against Schering, American Home Products and ESI Lederle Incorporated, a division of American Home Products.) Like the other cases, Schering-Plough sued Upsher-Smith for patent infringement when Upsher-Smith applied for FDA approval of a generic product competitive with Schering-Plough's brand name drug. But unlike the earlier cases, the parties were able to negotiate a *settlement* agreement on the eve of trial that was dispositive of the underlying patent dispute. In exchange for a payment of $60 million, Schering-Plough received licenses to market five Upsher-Smith products and Upsher-Smith's agreement not to enter the market for a period of time.

The FTC's Analysis in *Schering-Plough*. The major difference among the FTC's enforcement actions against Schering-Plough/Upsher-Smith ("*Schering*"), HMRI/Andrx, and Abbott/Geneva is the FTC's attack in *Schering* is on the *settlement* agreement itself. By questioning the validity of the settlement agreement, the FTC ventured into a more ambiguous area of established law. In both its complaints against HMRI/Andrx and Abbott/Geneva, the FTC highlighted the fact that the challenged agreement was *not* for purpose of settling the patent litigation. *See HMRI/Andrx* Complaint, ¶ 23 (Docket No. 9293); *Abbott/Geneva* Complaints, ¶27 (Docket Nos. C-3945 and C-3946). Furthermore, as to Abbott/Geneva, the FTC criticized the parties' actions because the court handling the patent litigation, was not made aware of the parties' agreement. *See Abbott/Geneva* Complaint, ¶28 Docket No. 9293; May 2000 Statement of Chairman Robert Pitofsky, et al. re Abbott Laboratories and Geneva Pharmaceuticals, Inc. But in *Schering*, the court *was* made aware of the agreement reached *and* the agreement resolved the pending litigation. The FTC did not explain, or even note, that distinction in its complaint in *Schering*. Nor did the FTC challenge whether the settled parties' infringement claim was a *bona fide* dispute.

Moreover, in the *Schering* complaint, the FTC infers anticompetitive intent from its assertion that "the $60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering." *Schering-Plough/Upsher-Smith* Complaint, ¶45 (Docket No. 9297) (currently pending before a FTC administrative law judge). The FTC drew this conclusion from the *ex post* observation that "Schering never sold four of the five licensed products, made minimal sales of the fifth, and has no expectation of making additional sales of any of the five products." *Id.* at ¶46. The complaint reveals no attempt to analyze the license agreement from an *ex ante* perspective.

Nor does the FTC appear to account for parties' varying risk preferences in inferring anticompetitive intent. The amount of money exchanged in litigation settlements often reflects more than the expected (or risk-neutral) value of the underlying disputed property or contract because risk preferences vary. A low probability of a devastating outcome at trial may prompt some parties to settle, whereas others may be risk-neutral or even risk-seeking.

The FTC Did Not Account for the Benefits Resulting from Settlement. The most disturbing aspect of *Schering* is the FTC's disregard for the benefits a settlement can produce. It does not consider the value to the parties and to the federal courts of settling rather than taking a complex patent infringement case all the way through trial to final judgment. While the Supreme Court has rejected the pursuit of social welfare goals as a sole justification for otherwise *per se* conduct when the restraint serves a purely economic self-interest,[1] settlements do not merely promote economic self-interest, but can also result in major cost-savings and other benefits to society. *Cf. U.S. v. Brown University*, 5 F.3d 658, 676-78 (3d Cir. 1993). The potential for realizing such benefits militates in favor of using a rule of reason, rather than a *per se*, analysis of such settlements. *Id*.

[1]*See National Society of Professional Engineers v. United States*, 435 U.S. 679, 695-6 (1978); *FTC v. Indian Federation of Dentists*, 476 U.S. 447, 462-63 (1986); *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 427 (1990).

A complex patent infringement case generates huge out-of-pocket costs associated with discovery and a protracted trial. Most of these costs are generally borne by the parties to the litigation. But, the public also bears out-of-pocket costs when a court assembles and supervises a jury during a long trial. Moreover, the opportunity costs borne by the parties and the public are likely to be even greater than the out-of-pocket costs. Major patent litigation can often approach the level of "bet-your-company litigation" and absorb large amounts of executive time and attention that could be better used in operating the business. Jurors also suffer opportunity costs. Many jurors must forego their income while on jury duty or, even if compensated by their employers, are unable to complete projects and possibly sacrifice career enhancement opportunities as well as family involvement. The productivity of employees-jurors is also lost during a trial — a cost borne by employers. More generally, the public may suffer from the lost opportunity to resolve other cases more quickly because they had to stand in the queue behind the patent infringement action.

Settlement can also avoid the costs and uncertainty surrounding the appeal of patent infringement actions. The U.S. Court of Appeals for the Federal Circuit (the appeals court that handles all appeals in patent infringement actions) reports a reversal rate of 16% of patent appeals from the district courts. *See* Table B-8 of Judicial Business of the United States Courts 2000 at http://www.uscourts.gov/judbus2000/appendices/b08sep00.pdf. Presumably many of those reversals resulted in a new trial — where costs would continue to mount for the parties, jurors and the public.

Conclusion. The FTC's enforcement action in *Schering*, based solely upon the parties' settlement agreement and the consideration exchanged therein, appears to eschew a rule of reason antitrust analysis for a conclusory *per se* or at least a severely truncated competition analysis. In so doing, the FTC has ignored the courts' admonition that the mere act of settling does not violate the antitrust laws. *See Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1221 (1976). More is required. The FTC should look to the intent of the parties, the anticompetitive effects, the benefits produced by the settlement, and weigh the benefits against the anticompetitive effects. In other words, the FTC should have conducted, as the Supreme Court recently instructed the FTC in *California Dental Association v. FTC*, 526 U.S. 756 (1999), a "rule of reason" analysis to determine whether the antitrust laws had been violated.

With the *Schering* complaint, the FTC has expanded its power include the policing of settlement agreements and to perform judicial functions, (i.e., judge the merits of the underlying patent infringement actions) — functions that heretofore had been within the exclusive province of the federal courts. Neither of these tasks falls within the traditional expertise of the FTC. The most troubling aspect of the FTC's enforcement action in *Schering* though is its disregard for the social benefits that the settlement of litigation can produce. In ignoring those benefits, the FTC also ignores the directive of the Supreme Court to limit, rather than expand, the categories of *per se* offenses of the antitrust laws. *See Business Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717, 724 (1988).

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