Legal Backgrounder

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202.588.0302

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FTC ADMINISTRATIVE JUDGE REJECTS COMMISSION'S VIEW OF DRUG PATENT SETTLEMENTS

by

Geraldine M. Alexis and Zorah Braithwaite

In a 122-page initial decision filed on June 27, 2002, Administrative Law Judge Michael Chappell ("ALJ") rejected the Federal Trade Commission's ("FTC") attempt to expand its powers to police agreements settling litigation. The ALJ concluded that the FTC had failed to adequately investigate the pro-competitive benefits and legitimate business objectives underlying a settlement agreement entered into between Schering Plough Corporation ("Schering") and Upsher-Smith Laboratories ("Upsher-Smith") to resolve a patent infringement suit. The FTC's prosecution of the case was insufficient to convince the ALJ that Schering and Upsher-Smith's agreement resulted in anticompetitive harm. This LEGAL BACKGROUNDER will discuss the ALJ's decision and the unusual appeals procedure Schering will face with the FTC. It will also offer a suggestion for the reform of the FTC's appeals process.

BACKGROUND

In March 2001, the FTC issued a Complaint against Schering and Upsher-Smith[1] alleging that Schering paid Upsher-Smith $60 million to delay the entrance of a generic substitute to Schering's brand name drug K-Dur 20, a potassium supplement. Though Schering received five licenses to market a niacin-based product as part of the agreement, the FTC claimed that those licenses were merely a sham to disguise the fact that Schering was in fact paying Upsher-Smith $60 million to delay the entry of its generic substitute into the market. The FTC based this allegation upon the fact that Schering did not market or use four of the five licenses it "purchased" from Upsher-Smith.

Schering and Upsher-Smith elected to proceed with a trial before an administrative law judge rather than enter into a consent agreement with the FTC.[2]

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[1]The FTC also brought a separate claim against Schering, American Home Products (AHP), and ESI Lederle Incorporated, a division of American Home Products.

[2]ESI Lederle signed a consent agreement with the FTC which prohibits AHP from entering into certain types of agreements with other drug makers and requires AHP to provide the FTC with notice prior to entering into other types of agreements. The consent order, approved in April 2002, expires in 2012.

Geraldine M. Alexis and **Zorah Braithwaite** are a partner and an associate, respectively, with the law firm Bingham McCutchen LLP in its San Francisco office.

ANALYSIS

No court has provided a comprehensive framework for analyzing litigation settlement agreements under the antitrust laws. The few courts that have examined this issue have considered the intent of the parties in settling, 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.[3] The FTC's charges against Schering and Upsher-Smith pushed the limits of established law regarding the antitrust implications of settlement agreements. Even the FTC's own precedent did not support its position in *Schering*. Unlike the Commission's past cases against pharmaceutical companies that entered into agreements delaying entry of generic substitutes pending the outcome of the underlying patent infringement litigation, *Schering* involved an attack upon a settlement agreement that disposed of the underlying patent infringement claims.[4]

The FTC was unable to sustain its burden of proof in *Schering* primarily because it did not follow a rule of reason approach to the case. The ALJ criticized the FTC for failing to define the relevant market properly, ignoring legitimate business reasons for the agreement, assuming that the settled parties' infringement claim was not a bona fide dispute, and failing to consider the pro-competitive benefits that the settlement produced — all critical aspects of a rule of reason analysis.

Not a Per Se Violation. The ALJ rejected the FTC's theory that Schering and Upsher-Smith entered into a *per se* illegal agreement to allocate the "temporal market," and that "temporal market allocation" led to a reduction in output of the relevant product. The FTC's theories of *per se* illegality could not succeed because they were based upon the underlying premise that Schering's patent at issue in the infringement case was invalid. If Schering's patent was deemed valid, Schering could legitimately prevent Upsher-Smith and other manufacturers from entering the market with K-Dur 20's formulation until the expiration of its patent. Only if Schering's patent was deemed invalid could there be some truth to the allegation that the settlement agreement illegally delayed entry of a valid, non-infringing K-Dur 20 generic from entering the market.

During the trial, the FTC acknowledged that its experts were unable to predict the outcome of the underlying patent infringement litigation, and hence, could not presume the invalidity of Schering's patent. Therefore, it would be impossible to assert that the settlement agreement was *per se* illegal. Barring a clear indication that Schering's patent infringement claim had no merit, the FTC should have engaged in a rule of reason analysis of the settlement agreement. The FTC was required to prove the relevant market and show that the anticompetitive harms in that market resulting from the agreement outweighed the pro-competitive and public policy benefits of settling an infringement suit.

Incorrect Market Definition. The ALJ found the FTC's definition of the relevant product market to be too narrow and unsupported by the evidence presented. The FTC attempted to define the relevant product market as K-Dur 20 mEq. However, the evidence revealed that K-Dur 20 was only one of many potassium chloride products on the market — all of which are considered therapeutically equivalent to one another. Among other factors supporting a broader potassium chloride supplement market definition was the evidence that customers viewed K-Dur 20 and other potassium chloride products as interchangeable. Schering and Upsher-Smith also viewed other potassium chloride product suppliers as their relevant competitors. K-Dur 20 did not possess any unique characteristics which would make it a separate market,

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[3]*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).

[4]A similar settlement agreement reached between Schering and ESI Lederle was forged under active judicial supervision.

or even a sub-market of the greater potassium chloride supplement market.

Rule of Reason Analysis — Anticompetitive Effects. In order to ascertain the parties' intent in entering into an agreement, a court must examine the facts relating to the making of the agreement as they existed at the time the agreement was entered into. In other words, the analysis must be *ex ante*. At the time Schering and Upsher-Smith were contemplating the settlement agreement, the evidence showed that Schering was seriously considering a foray into the niacin market. It had negotiated a deal with another company, Kos, for the license of a niacin product, but the deal ultimately fell through.

The FTC sought to show that there was no legitimate business reason associated with the settlement agreement. The basis for the FTC's claim was the *ex poste* presumption that the $60 million payment from Schering to Upsher-Smith was unrelated to the value of the products licensed to Schering because Schering never sold four out of the five licensed products, and made minimal sales from the fifth. To support this theory, the FTC's posited two tests: (1) the "revealed preference" test and (2) the "market test" — both of which analyzed the parties' incentives from an *ex poste* perspective. Instead of examining the reasons why Schering turned down the Kos contract — that the financial commitment was not commensurate with the profit split contemplated under the contract — the FTC used its "revealed preference" test to jump to the conclusion that Schering's withdrawal from the Kos deal revealed Schering's unwillingness to make an up-front payment for a niacin product. Similarly, the "market test" was unsupportable because it did not examine the factors the parties considered in making their decision about the sale and purchase of the niacin licenses. The FTC used the "market test" to conclude that, because no other company had made Upsher-Smith an offer as large as that made by Schering, Upsher-Smith's niacin product did not have sufficient value to support the large up-front payment made by Schering. In other words, the FTC asserted that Schering paid for something other than the five licenses it received, namely, Upsher-Smith's agreement not to enter the market.

Rule of Reason — Pro-competitive Benefits. The ALJ concluded that the FTC did not demonstrate any anti-competitive effects, and therefore the companies did not need to prove pro-competitive benefits. Nevertheless, it was clear the settlement agreement presented numerous benefits. Aside from the public policy benefits of settling litigation, such as preservation of judicial and parties' resources, avoiding the costs and uncertainty of litigation and possible appeal, there were other benefits unique to the Schering/Upsher-Smith agreement. As a result of this particular agreement, Upsher was able to come to the market five years earlier with its competitive product.[5]

APPEAL TO THE COMMISSION: DUE PROCESS CONSIDERATIONS

The FTC has requested a review of the ALJ's initial decision. The Commission's appeals process is an unusual (and perhaps unique) procedure in the federal government whereby the FTC is permitted to act as judge, jury, and prosecutor in the same case. It is difficult to imagine a system more favorable to the FTC, and unfavorable to defendants. The appeal of the initial decision will be heard by the full Commission, the same Commission that issued the Complaint against Schering and Upsher-Smith. The Commission does not require itself to give any deference to the ALJ's findings of fact and has the right to review the record *de novo*. Only after the Commission has issued its decision can the parties move the case to a judicial venue and appeal to a federal Court of Appeals. Yet, ironically, the Court of Appeals must give deference to the Commission's (not the ALJ's) findings of fact.

[5]Similarly, Schering's agreement with ESI Lederle would have allowed ESI to come to market with its generic substitute of K-Dur 20 two years before its patent would have expired.

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Until five years ago, the slow pace of the cases through the Commission ensured that by the time the parties appealed to the Commission again, individual Commissioners other than the ones who issued the initial complaint would be sitting on the Commission. As a result, there was arguably some modicum of due process. After the Commission adopted "fast-track procedures" in 1996, cases move through the system more quickly, and often the very same Commissioners who issued the complaint would sit in judgment upon the complaint they voted to issue.

The administrative appeals process in *Schering* places the Commission in an awkward position. Either it will affirm the ALJ's decision, thereby indicating that it was wrong in issuing the Complaint, or it will overrule the ALJ's decision, and find an antitrust violation in the face of some very clear evidence of legitimate business activity, pro-competitive benefits, and public policy considerations.

Congress could return fairness to the FTC appeals process by eliminating this bizarre procedure that, at a minimum, gives the appearance of denying the parties before the Commission the same due process afforded to defendants when the Department of Justice charges a defendant with antitrust wrongdoing. The Justice Department, which acts only as a prosecutor, and not as a judge, must file its case in federal court and seek adjudication by an Article III judge.

There is no sound reason to treat parties who have the misfortune of being in an industry that traditionally falls within the FTC's jurisdiction to be treated any differently. The FTC's long-standing justification for preserving its anachronistic procedures is its superior expertise in antitrust law compared to that of an Article III trial judge. Not only is that position an insult to federal judges, it is simply not true. Federal trial judges have tackled complex antitrust issues in industries such as credit card networks when the Justice Department has brought suit and performed admirably. Moreover, defendants in those judicial proceedings can rest assured that, regardless of the outcome, they have received due process.

The current structure of the appeals process within the Commission will not guarantee Schering due process. Despite the ALJ's clear findings of legitimate business activity and pro-competitive benefits, Schering will not receive the benefit of the ALJ's conclusions. Instead, Schering must trust the Commission to review the record objectively. A procedure that conditions the outcome of a decision upon the Commissions' willingness to admit that it was wrong when it issued the Complaint lacks fundamental fairness.

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