ARNOLD & PORTER LLP

CLIENT ADVISORY

Court Allows Pharmaceutical "Product Hopping" Antitrust Case to Proceed

JUNE 2006

Washington, DC
+1 202.942.5000

New York
+1 212.715.1000

London
+44 (0)20 7786 6100

Brussels
+32 (0)2 517 6600

Los Angeles
+1 213.243.4000

San Francisco
+1 415.356.3099

Northern Virginia
+1 703.720.7000

Denver
+1 303.863.1000

On May 26, Judge Kent Jordan of the federal court in Delaware denied a motion to dismiss the "product hopping" antitrust cases challenging Abbott Laboratories' repeated reformulation of its cholesterol drug TriCor.[1] While Judge Jordan's opinion deals only with pleading standards, it is noteworthy because it is the first judicial analysis of when pharmaceutical reformulations may be considered impermissibly exclusionary. The opinion also contains a discussion of "sham litigation" claims based on assertions of inequitable conduct.

FACTUAL ALLEGATIONS OF THE COMPLAINTS

Abbott sold TriCor capsules, its branded version of fenofibrate, and listed the '726 patent (licensed from Fournier) in FDA's Orange Book. Two generic companies sought to introduce generic versions of fenofibrate and filed Abbreviated New Drug Applications (ANDAs) with Paragraph IV certifications. Abbott and Fournier sued the generics for infringement of the '726 patent. The generics won summary judgment based on claim construction and non-infringement.

While the capsule infringement litigation was pending, Abbott filed an NDA for a tablet (rather than capsule) formulation of TriCor, adding a new indication. Abbott listed several additional patents in the Orange Book covering the new tablet formulation. The TriCor tablet NDA relied upon bioequivalence with the original capsule formulation and upon data from trials of the capsule to support the additional indication for the drug.

After the NDA for the new TriCor tablet was approved, Abbott removed all TriCor capsules from the market by buying them back from pharmacies. The company also changed the code for TriCor capsules in the National Drug Data File ("NDDF") to "obsolete." The change in NDDF status prevented pharmacists from substituting generic capsules for prescriptions of TriCor tablets. Faced with no market for its generic fenofibrate capsules, one of the generics, Teva, launched its product as a brand name drug.

[1] *Abbott Labs., Inc. v. Teva Pharm. USA Inc.*, 2006 WL 1460077 (D. Del. May 26, 2006)

Following FDA approval of Abbott's tablet reformulation, Teva and Impax submitted ANDAs for the reformulated TriCor tablets. Abbott and Fournier again sued the generics. In that patent case, Judge Jordan granted partial summary judgment of non-infringement. Abbott and Fournier then dismissed the remaining infringement claims.

While the tablet infringement litigation was pending, Abbott again submitted new NDAs for TriCor tablets, this time containing slightly different dosages of fenofibrate. The change in dosage had the effect of preventing pharmacists from substituting the now-approved Teva and Impax generic tablets for the new reduced dosage Abbott tablets. This reformulation did not add any new indications, but the label for the new tablet dosage no longer indicated that it had to be taken with food. Teva and Impax were again left with a generic tablet formulation with no extant brand-name equivalent.

ANTITRUST CLAIMS AND MOTION TO DISMISS

After Abbott and Fournier dismissed their most recent infringement claims, a number of parties—the generics, classes of direct and indirect purchasers, and individual purchasers—sued the companies on federal and state antitrust grounds. The gist of the allegations was that Abbott and Fournier monopolized or attempted to monopolize a market for fenofibrate through an overall scheme involving product reformulations, removal of old formulations from the market, and "sham" infringement litigations. Abbott and Fournier moved to dismiss the complaints. They argued, among other things, that changes to the TriCor formulations, and actions taken to support those changes, could not support antitrust claims.

THE RULING: ANALYTIC FRAMEWORK FOR PRODUCT REFORMULATIONS

The court disagreed with Abbott and Fournier. It rejected their argument that "any product change that introduces an improvement, however minor, is per se legal under the antitrust laws." Slip op. at 14. Instead, the court appears to suggest the following analytic framework:

- Determine whether the monopolist's introduction of a new product "prevents consumer choice." Slip op. at 17. If there is an "open market where the merits of any new product can be tested by unfettered consumer choice," (id. at 18), Judge Jordan suggests that "judicial deference" is warranted, and no weighing of benefits versus harm is necessary to find the new product lawful. Id. at 17. If, however, the "introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate." Id.
- That "greater scrutiny" is a traditional rule of reason analysis, under which the plaintiff must first demonstrate the anticompetitive effect of the conduct. The plaintiff need not demonstrate that competitors were totally foreclosed from the market. It is sufficient to demonstrate that generics "cannot produce generic substitutes for the current TriCor formulation, which is alleged to be their cost-effective means of competing in the pharmaceutical drug market." Id. at 20-21.
- The burden then shifts to the reformulator to present a procompetitive justification for the conduct. The court offers no particular examples of what those justifications might be, and it is unclear whether Judge Jordan would accept any product improvement at the cost of eliminating consumer choice.
- Finally, the burden shifts back to the plaintiff to either rebut the justification or demonstrate that the anticompetitive harm outweighs the procompetitive benefit.

WHERE DOES THIS LEAVE PHARMACEUTICAL REFORMULATORS?

Motions to dismiss will be difficult to win if the old product is removed from the market. The court's reasoning suggests that a pharmaceutical reformulator will

rarely, if ever, win a motion to dismiss an antitrust case if it has removed the old product from the market as Abbott and Fournier are alleged to have done. The premise of Judge Jordan's opinion is that the "removal" of the old product from the market deprived consumers of choice, leading to a full-blown rule of reason analysis best left to the jury, or at least to a later stage of the litigation.

The key to prevailing may be to show that consumers in fact had a choice. Judge Jordan's premise that the defendants' actions deprived consumers of choice seems questionable. Even according to the complaints, nothing stopped the generics from selling their presumably lower-priced versions of the old formulations, as Teva in fact did with the capsule formulation. And nothing would have stopped HMOs, for instance—among the most sophisticated and influential of "consumers" (always a difficult term to define in the pharmaceutical arena)—from taking actions to advise doctors to prescribe those lower-priced products. While Judge Jordan gave short shrift to the argument that a company need not take actions to facilitate competition—here, either continuing to sell a product that has been succeeded by a new formulation, or continuing to list a product that is no longer sold in various databases—another court might be more open to the argument that a company has no duty to facilitate free-rider competitors. *See Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370 (7th Cir. 1986), *cert. denied*, 480 U.S. 934 (1987). Arguments that could succeed as applied to other industries however, may not hold as much sway in the politically-charged atmosphere surrounding pharmaceuticals.

Think long and hard about removing the old product from the market. The result in the case might have been different had the defendants not "obsoleted" the old product. It may be difficult to justify a decision not to sell a product if consumers still have demand for the product and sales of the product remain profitable. A decision to recall and destroy existing inventories of the old product may also be difficult to justify. Health and safety considerations, however, may dictate in favor of removing the old product from the market. Concurrent availability of old and new products could, for instance, lead to consumer confusion and ultimately, health risks. Imagine, for example, a situation in which the old formulation of a product, while effective, had significant adverse side effects, but a new formulation retained the efficacy and eliminated the side effects. Health and safety considerations that lead to a decision to remove a product from the market should, of course, be amply supported by your documents.

Do more than think long and hard about the advantages of the new product. Assume that a jury is going to be deciding whether the new product is better than the old. Do not assume that because PTO issues a new patent, or because FDA approves the new formulation, the new product will necessarily be considered better. Where advantages are real, write about them early and often. If no documents in your files reflect those advantages, you may run the risk that a court or jury will find them pretextual.

Where is the dividing line between acceptable conduct and impermissibly exclusionary conduct? One troublesome aspect of the opinion is its failure to set forth a clear dividing line between conduct that we believe should be considered lawful and conduct that may be open to challenge. Take, for example, a situation in which a pharmaceutical company introduces a successor product at a price 30 percent lower than the predecessor product, vigorously promotes it, stops selling the predecessor product, and notifies databases that it is no longer selling the predecessor product. The market for the predecessor product dries up because few see any benefit to buying a more expensive drug that offers no advantages. Judge Jordan's analysis—which appears to chide the defendants for "an effort to game the rather intricate FDA

rules to anticompetitive effect"—does not on its face suggest any difference between this conduct and the conduct challenged in the TriCor complaint. As the Solicitor General of the United States recently suggested in an amicus brief to the Supreme Court, a "subjective and standardless test for Section 2 liability" could "'chill the very conduct the antitrust laws are designed to protect.'" Brief for the United States as Amicus Curiae, *Weyerhaeuser Co. v. Ross Simmons Hardwood Lumber Co., Inc.*, No. 05-381, at 7, 20 (May 2006) (quoting *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 226 (1993)).

A NOTE ON SHAM LITIGATION

Most of the plaintiffs in these cases also claimed that Abbott's and Fournier's patent infringement litigations against the generics were "sham" under the standards of *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (PRE) because, among other reasons, Abbott and Fournier knew that some of the patents asserted were unenforceable due to inequitable conduct before the PTO. Abbott and Fournier argued that inequitable conduct cannot be the basis for a sham litigation claim, because that would enable antitrust plaintiffs to "improperly circumvent the intentional fraud requirement set forth in" *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.,* 382 U.S. 172 (1965).

The court rejected that argument, finding (as has the Federal Circuit in *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998)) that *PRE* and *Walker Process* are alternative theories that may be used to overcome *Noerr-Pennington* immunity for filing a lawsuit. The court stated that a sham litigation claim based on inequitable conduct is "predicated on the objective and subjective reasonableness for bringing the lawsuit, rather than on the conduct before the Patent Office." Slip op. at 28. The court finds plaintiffs' allegations—which it characterizes as stating that "any reasonable litigant in Defendants' position, knowing that the patents were unenforceable, would not have pursued the litigation"—to be sufficient. Id. at 29.

The opinion is ambiguous on the question of what it means to "know" that a patent is unenforceable. Under *PRE*, we believe that the appropriate inquiry (if indeed such sham litigation claims can be stated given *Walker Process*, which we question) is whether a reasonable litigant would have believed that it could succeed on the merits of the patent case—either by demonstrating that the misrepresentation was not material or by otherwise convincing a court that the patent should not be held unenforceable due to inequitable conduct. That, in fact, may be the meaning of Judge Jordan's statement. We suspect, however, that antitrust plaintiffs bringing sham litigation cases based on inequitable conduct findings will argue that the language of Judge Jordan's opinion means that a finding of inequitable conduct almost inevitably leads to a finding that the underlying patent suit was "objectively baseless." Plaintiffs are likely to argue that the patent holder will necessarily have been found to have known of and intended the misconduct before the PTO, and therefore the patent holder necessarily must have "known" of the unenforceability of the patent.

For further information about this decision, or to discuss its implications, please contact:

Cathy Hoffman
202.942.5123
Cathy.Hoffman@aporter.com

Ken Letzler
202.942.5921
Kenneth.Letzler@aporter.com