HOW OFTEN WILL THE FTC USE ITS RECENTLY REAFFIRMED AUTHORITY TO COMPEL DISGORGEMENT?

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The U.S. District Court for the Eastern District of Pennsylvania recently granted the Federal Trade Commission's ("FTC") request to compel a branded pharmaceutical company to disgorge $448 million in profits. The court held that the company obtained the profits by pursuing unfounded patent claims against potential generic drug competitors in "sham litigation." The profits which the court found were obtained by the defendant through sham litigation are to be paid to the FTC and thereafter returned to consumers. The court rejected arguments that a recent Supreme Court opinion limiting securities law sanctions implied limitations on the FTC's disgorgement authorities. Nevertheless, the recent turnover in commissioners at the FTC leaves in question how often the FTC will exercise its disgorgement powers.

THE UNDERLYING DISPUTE

AbbVie, Inc. ("AbbVie"), and certain of its subsidiaries, as well as Besins Healthcare, Inc. ("Besins"), jointly own a patent covering AndroGel, a brand-name, transdermal testosterone replacement drug. The FTC alleged that AbbVie and Besins unlawfully maintained their monopoly in the U.S. market for transdermal testosterone replacement drugs by pursuing sham patent litigation against two generic drug companies. A party litigating patent claims against a competitor is ordinarily immune from antitrust claims, pursuant to the First Amendment and the *Noerr-Pennington* [1] doctrine, which includes litigation within the First Amendment's protection for petitioning the government for relief. However, there is no such protection where the litigation is "a mere sham to cover….an attempt to interfere directly with the business relationships of a competitor." [2] This "sham litigation" exception encompasses situations in which (i) a defendant intends to cause the ongoing conduct of a governmental process like litigation — as opposed to a successful outcome of the process — to restrain competition, and (ii) no reasonable person could realistically expect success on the merits of the claim. [3]

The court had found that AbbVie and Besins had no reasonable prospect of prevailing on their patent claim because, although the generic product used the same active ingredient as the patented branded product, it used a different penetration enhancer than the only such enhancer covered by the patent. Thus, the composition of the generic medication was sufficiently different from AndroGel as to be outside the literal scope of the patent. Further, according to the court, the branded companies were estopped by the prosecution history from asserting that the generic drugs were sufficiently similar to fall within the doctrine of equivalents. The district court also found that the defendants intended to use the pendency of the litigation to delay entry by the generics.

The FTC alleged that the sham litigation had allowed AbbVie and Besins to generate higher profits on AndroGel than would have been the case if the sham patent litigation had not kept one or more generics out of the market. Not only did the branded AndroGel avoid losing share to the generic products, but it avoided the price decline that typically occurs in the market for a pharmaceutical once a general version is introduced.

THE ORDER OF DISGORGEMENT

Section 13(b) of the Federal Trade Commission Act (the "Act") provides that the FTC may sue in federal court to enjoin any conduct that is violating or is about to violate the Act. The district court is authorized to enter temporary restraining orders, preliminary injunctions, and final injunctions against such conduct. The Eastern District of Pennsylvania held that Section 13(b) of the Act, in its general authorization of equitable relief, is broad enough to encompass disgorgement without any specific reference to such a remedy. Quoting to a Supreme Court interpretation of similar provisions in the Fair Labor Standards Act, the court stated:

> When Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historical power of equity to provide complete relief in the light of statutory purposes.

"This language," the district court said, "in our view is equally applicable here to the FTC Act." Absent the availability of disgorgement, the court reasoned, a monopolist would "be able to retain its ill-gotten gains and simply face an injunction against future wrong-doing, but even then only if the wrong-doing is continuing or likely to continue." [4]

The district court rejected the defendants' argument that the Supreme Court's opinion in *Kokesh v. SEC* [5] restricted the FTC's authority to seek disgorgement. In *Kokesh*, the U.S. Securities and Exchange Commission ("SEC") had sought to compel an alleged securities law violator to disgorge profits received in the 14 years preceding the filing of the SEC's complaint. The relevant securities statute, similar to Section 13(b), stated only that the SEC had the power to obtain injunctive relief or mandatory civil penalties. The Supreme Court held that, since disgorgement is a penalty, the five-year statute of limitations in 28 U.S.C. § 2462 relating to "an action, suit or proceeding for the enforcement of any civil fine, penalty or forfeiture" applied to the SEC's disgorgement claim. Further, in a footnote the Supreme Court stated, "Nothing in this opinion should be interpreted as an opinion on whether courts possess authority to order disgorgement in SEC enforcement proceedings or on whether courts have properly applied disgorgement principles in this context." Relying in part of that footnote, the defendants in *AbbVie* argued that disgorgement was beyond the FTC's authority because Section 13(b) authorizes only injunctive relief. The district court, however, declined to read the *Kokesh* opinion as preventing it from granting the "well-established equitable relief of disgorgement." [6]

In ordering disgorgement, "a court may exercise its equitable power only over the property causally related to the wrongdoing." [7] This involves a two-step process in which the government must establish a reasonable approximation of the profits resulting from the violation and then the burden shifts to the defendant to show that the government's approximation of profits is unreasonable. Then the court may add prejudgment interest. In this instance, that required the court to determine when each generic entrant would have entered the market absent

the sham litigation, how quickly each entrant would have grabbed market share from the monopolist, how quickly prices would have fallen, and how long the monopolist's market position continued to benefit from the effects of the sham litigation. Resolving those factual questions, the court determined that the defendants' additional profits resulting from the sham litigation were $448 million and ordered disgorgement of that amount.

HOW OFTEN WILL THE FTC ASSERT ITS DISGORGEMENT AUTHORITY?

In 2012, with a majority of Democratic members, the FTC withdrew its Policy Statement on Monetary Equitable Remedies in Competition Cases, which the FTC had unanimously adopted in 2003. [8] The 2012 Withdrawal Notice suggested an intent to pursue disgorgement or restitution more frequently in competition cases. The 2003 Policy Statement had stated that the FTC "do not view monetary disgorgement or restitution as routine remedies for antitrust cases." [9] The 2003 Policy Statement set forth three principles that the FTC would employ in deciding whether to seek restitution or disgorgement in antitrust cases: (1) it would seek such relief only when the underlying antitrust violation is clear, based on existing precedent; (2) it would seek such relief only when there is a reasonable basis for calculating the amount of the remedial payment; and (3) it would consider the value of seeking monetary relief in light of any other available remedies, including private rights of action.

In withdrawing the 2003 Policy Statement by a 3–2 majority, the three Democratic members in 2012 stated that the 2003 Policy Statement took an "overly restrictive view of the Commission's options for equitable remedies." They reasoned that disgorgement and restitution serve both to deprive wrongdoers of the benefit of their wrongdoing and to restore victims to the position they would have enjoyed absent the wrongful conduct. "[W]hile disgorgement and restitution are not appropriate in all cases, we do not believe they should apply only in 'exceptional cases' as previously set out in the [2003] Policy Statement." Indeed, "competition cases may often be appropriate candidates for monetary equitable relief." The assertion of a claim for monetary equitable relief, according to the 2012 Withdrawal Notice, would be evaluated on a case-by-case basis, guided by existing case law regarding such remedies. [10]

Then-Commissioner Ohlhausen, a Republican, dissented from the Withdrawal Notice, endorsing the 2003 Policy Statement's three factors for evaluating the pursuit of monetary equitable relief. [11] Later, in February 2017, as then-Acting Chairman, Ohlhausen declared, "Time and again [after the 2012 Withdrawal Notice, the FTC] elected to forego administrative litigation in conduct matters in favor of federal court, which is where the money is," since monetary equitable relief can be obtained only in federal district court and not in FTC administrative proceedings. [12] She favored the adoption of new guidelines similar to the 2003 Policy Statement. Further, Commissioner Ohlhausen and then-Commissioner Joshua Wright, also a Republican, jointly issued a statement regarding their concurrence in the FTC's acceptance of a consent order in *FTC v. Cephalon, Inc.*, [13] which included disgorgement. While expressing their concern about the lack of a policy statement regarding the circumstances in which the FTC will seek disgorgement, they explained that they endorsed a disgorgement remedy in that case because it would meet the factors set forth in the withdrawn 2003 Policy Statement. [14] Commissioner Wright further explained that optimal deterrence of anticompetitive conduct (while avoiding over-deterrence of potentially pro-competitive behavior) means that disgorgement should not be imposed for misconduct with a high probability of detection and punishment or for conduct with plausible efficiency justifications.

Five new commissioners have now been confirmed by the Senate, three Republican and two Democratic. [15] What position the new commissioners will take regarding disgorgement remains to be seen. Some indication may

be available, however, from the FTC's handling of a July 31, 2018 consent decree in an administrative proceeding against alleged collusion among therapist staffing companies with respect to the compensation they pay to therapists. According to the complaint, after a home health agency advised the staffing companies that it was reducing the rate it was paying to the staffing companies, two staffing companies colluded to reduce their pay rate to the therapists they contracted with to provide services. The complaint was resolved through an agreed order requiring the parties to cease and desist from colluding on compensation. [16] Although the matter was resolved in an administrative proceeding and not in federal court where the FTC's equitable powers under Section 13(b) are available, Commissioner Chopra filed a statement noting that the conduct at issue "was a clear violation of law" and that his fellow commissioners were preparing to resolve the matter in a manner "that does not include any notice or restitution to those targeted by this unlawful conduct, nor any admission of liability." He opined, "While in some situations this may be appropriate, the Commission would benefit from hearing from the public on whether it should follow this approach on this and future matters, especially those involving our country's growing 'big economy.'" [17]

EUROPEAN LAW ALSO RECOGNIZES THE CONCEPT OF PROTECTING A DOMINANT MARKET POSITION THROUGH VEXATIOUS LITIGATION BUT DOES NOT PROVIDE FOR DISGORGEMENT

In Europe, the European Union courts recognize that "sham litigation" or "vexatious litigation" may constitute, in wholly exceptional circumstances, an abuse of a dominant position contrary to Article 102 of the Treaty on the Functioning of the European Union (the equivalent of Section 2 of the Sherman Act). In its seminal *ITT Promedia v. Commission* judgment, the General Court of the European Union ("CGEU") clarified that "wholly exceptional circumstances" arise: (i) where the litigation cannot reasonably be considered as an attempt to establish the rights of the claimant and would therefore serve only to "harass" the opposite party, and (ii) where the litigation is part of a plan whose aim is to eliminate competition. [18] This approach has been recently confirmed in *Protégé International Ltd v Commission*, [19] where the GCEU noted that the two conditions of *ITT Promedia* should be interpreted restrictively in order not to jeopardize the application of the general principle of European Union law on access to justice and that the conditions are cumulative. National competition authorities in the European Union have also employed the same approach for a pattern of complex conduct to exclude competitors that included patent-related litigation before civil and administrative courts. [20] The key piece of evidence in identifying vexatious litigation was the absence of genuine interest in receiving judicial relief.

Nevertheless, with respect to patent litigation in the pharmaceutical sector in the European Union, the European Commission (the "Commission") in *Astra Zeneca* and then the GCEU refused to apply *ITT Promedia* and to characterize the contested conduct as vexatious litigation, notwithstanding the fact that there was a pattern of litigation related to the supplementary protection certificates ("SPC") from which Astra Zeneca benefited in order to prevent or delay generic competition to its ulcer treatment drug, Losec. Astra Zeneca had submitted misleading information to national patent offices in order to acquire SPCs, which extended the patent protection for Losec and then defended those in court. Although there was the theoretical possibility that both of the *ITT Promedia* conditions were satisfied in *Astra Zeneca*, the Commission chose to put forward a separate type of abuse of dominant position, relying on the initially misleading representations made by Astra Zeneca before the patent offices which led to the granting of the SPCs. [21] This approach was upheld by the GCEU. [22]

It should be noted that in *ITT Promedia*, as well as in *Protégé International*, the GCEU referred to "wholly exceptional circumstances" instead of the usual reference to "exceptional circumstances," indicating that the finding of an abuse in the context of intellectual property litigation is likely to be more difficult. This also suggests that the conditions for "vexatious" litigation will be more strictly interpreted than for other types of abuse (e.g., unilateral refusals to deal). This cautious approach at the European Union level has been clearly illustrated in *Astra Zeneca*, where both the Commission and the CGEU declined to put forward a theory of harm based on vexatious litigation but rather opted for another type of abuse to challenge Astra Zeneca's conduct. As a result, in the context of intellectual property litigation, the two prongs of the *ITT Promedia* test are likely to be interpreted and applied restrictively so as to not frustrate the general principle of access to courts.

In Europe, "vexatious litigation," if proven to amount to an abuse of dominant position, would result in the imposition of a fine up to 10% of the global turnover of the dominant company in the last financial year. Notably, fines are not intended to amount to a disgorgement of profits *per se*. The fines may be more or less than the actual profit made by the entity engaging in the vexatious litigation.

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[1] E. R.R. Presidents Conference v. Noerr Motor Freight, 365 U.S. 127 (1961); United Mine Workers v. Pennington, 381 U.S. 657 (1965).

[2] *Noerr*, 365 U.S. at 144.

[3] Prof'l Real Estate Inv'rs v. Columbia Pictures Indus., 508 U.S. 49, 60–67 (1993).

[4] *See also* FTC v. Cephalon, Inc., 100 F. Supp. 3d 433, 439 (E.D. PA 2015).

[5] 137 S. Ct 1635 (2017).

[6] Slip op. at 79. The U.S.D.C. for the M.D. Fla. had earlier rejected the *Kokesh* argument in a case under Section 13(b) in a case involving the FTC's consumer protection mission. FTC v. J. William Entr., LLC, 283 F. Supp. 3d 1259 (M.D. Fla. 2017).

[7] Slip op. at 81, quoting Commodity Futures Trading Comm'n v. Am. Metals Exch. Corp., 991 F.2d 71, 78–79 (3rd Cir. 1993). *Cf.* FTC v. Magazine Sols. LLC, 432 Fed. App'x 155, 158 (3rd Cir. 2011). (In consumer protection cases, the courts have upheld restitution up to the gross revenue resulting from the improper conduct.).

[8] Statement of the Commission, Effecting the Withdrawal of the Commission's Policy Statement on Monetary Equitable Remedies in Competition Cases, 77 Fed. Reg. 47070 (Aug. 7, 2012), withdrawing Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45,820 (Aug. 4, 2003) [the "Withdrawal Notice"].

[9] *Policy Statement on Monetary Equitable Remedies in Competition Cases*, 68 Fed. Reg. at 45, 82.

[10] 77 Fed. Reg. at 47070-02.

[11] *Id.* at 47071-2.

[12] M. K. Ohlhausen, *The FTC's Path Ahead* (Feb. 3, 2017), https://www.ftc.gov/system/files/documents/public_statements/1070123/gcr_the-ftc_path_ahead.pdf.

[13] FTC v. Cephalon, Inc., Stipulated Order, Civil Action No. 08-cv-2141 (E.D. Pa., June 17, 2015), https://www.ftc.gov/system/files/documents/cases/150617cephalonstip.pdf.

[14] Separate Statement of Commissioners Maureen Ohlhausen and Joshua D. Wright in *Cephalon* (May 28, 2015), https://www.ftc.gov/system/files/documents/public_statements/645501/150528cephalonohlhausenwright1.pdf. *See also* Dissenting Statement of Commissioner Joshua D. Wright in Cardinal Health, Inc., Fed No. 101-0006 (April 17, 2015), https://www.ftc.gov/system/files/documents/public_statements/637771/150420cardinalhealthwright.pdf.

[15] Commissioner (formerly Acting Chairman) Ohlhausen remains with the FTC until her term expires in September 2018 or her nomination as a judge in the U.S. Court of Federal Claims remains pending. Christine S. Wilson has been confirmed to take her seat at the FTC.

[16] In the Matter of Your Therapy Source LLC, FTC Docket No. 1710134, Complaint, www.ftc.gov/system/files/documents/cases/1710134_your_therapy_source_complaint_7-31-18.pdf and Decision and Order, www.ftc.gov/system/files/documents/cases/1710134_your_therapy_source_decision_and_order_7-31-18.pdf.

[17] Statement of Commissioner Chopra, https://www.ftc.gov/system/files/documents/public_statements/1396706/1710134_your_therapy_source_statement_of_commissioner_chopra_7-31-18.pdf.

[18] Case T-111/96 ITT Promedia NV v. Comm'n (1998) ECR II-2937.

[19] Case T-119/09 Protégé Int'l, ECLI:EU:T:2012:421.

[20] *See, e.g.*, Decision of the Italian Competition Authority of January, 11 2012, in Case A431-Ratiopharm/Pfizer, Bulletino note 2/2012, annulled by the Regional Administrative Court of Lazio, I, decision No. 7467 (September 3, 2012), but reaffirmed by Council of State, order No. 2790 (May 22, 2013).

[21] Decision of the European Commission of June 15, 2005, in Case COMP/A.37.507/F3, Astra Zeneca, 2006 O.J. (L 332).

[22] Case T-321/05, Astra Zeneca v. Comm'n [2010] ECR II-2805.

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