IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION, Plaintiff,	:	CIVIL ACTION
v.	:	No. 2:08-cv-2141
CEPHALON, INC., Defendant.	:	

Goldberg, J. **April 15, 2015**

MEMORANDUM OPINION

This case emanates from several Hatch-Waxman "reverse payment" settlement agreements entered into between Defendant Cephalon, Inc. ("Cephalon") and four generic drug companies.[1] Presently before me is Cephalon's motion to preclude the Federal Trade Commission ("FTC") from seeking disgorgement of Cephalon's past profits for the years 2007 through 2012.[2] For reasons that follow, I will deny Cephalon's motion.

I. BACKGROUND AND PROCEDURAL HISTORY

Cephalon owned U.S. Patent No. RE 37,516 ("the RE '516 patent") which claimed a specific formulation of modafinil and covered Cephalon's flagship drug, Provigil. This patent, combined with a number of regulatory exclusivity periods Cephalon obtained, had the potential to protect Provigil from competition through April 6, 2015.

[1] Barr Pharmaceuticals, Inc.; Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc.; Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc.; and Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc.

[2] Disgorgement "wrests ill-gotten gains from the hands of a wrongdoer. It is an equitable remedy meant to prevent the wrongdoer from enriching himself by his wrongs." Edmonson v. Lincoln Nat. Life Ins. Co., 725 F.3d 406, 415 (3d Cir. 2013) (citing S.E.C. v. Huffman, 996 F.2d 800, 802 (5th Cir. 1993)).

On December 24, 2002, the first day allowed by law, the four generic drug manufacturers sought permission from the Food and Drug Administration to market generic versions of Provigil. In doing so, these generics were required by the Hatch-Waxman Act to make a certification regarding the RE '516 patent. All four generic drug manufacturers certified that the RE '516 patent was either invalid or not infringed by their proposed generic drugs.

These certifications — technical acts of infringement under the Hatch-Waxman Act — prompted Cephalon to file a lawsuit for patent infringement against the four generic drug manufacturers. Between late 2005 and early 2006, all four of these cases settled with Cephalon paying the generics millions of dollars in return for, among other agreements, promises from each of the generics to drop their invalidity contentions and not market a generic version of Provigil until April 6, 2012.

These settlements (commonly referred to as "reverse payments") drew immediate antitrust scrutiny from private plaintiffs and, as relevant here, the FTC. In February 2008, the FTC filed suit challenging the settlements under Section 5(a) of the Federal Trade Commission Act ("FTC Act") (15 U.S.C. § 45(a)). The FTC's amended complaint requested injunctive relief pursuant to Section 13(b) of the FTC Act to prevent Cephalon from enforcing the existing settlements and from engaging in similar agreements in the future. The complaint's prayer for relief also requested "such other equitable relief as the Court finds necessary to redress and prevent recurrence of Cephalon's violation of Section 5(a) of the FTC Act."

Following a bench trial in 2011 in a related matter, I found that Cephalon's RE '516 patent was invalid on several grounds and unenforceable due to Cephalon's inequitable conduct during the patent procurement process. Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011).

Generic Provigil entered the market in early 2012. On August 29, 2012, this case and the related private plaintiff matters were stayed pending proceedings before the United States Supreme Court that would potentially resolve a split amongst the Circuit Courts of Appeals regarding the standards applicable to reverse payment settlement claims. On June 17, 2013, the United States Supreme Court issued its decision in FTC v. Actavis, Inc., 133 S.Ct. 2223 (2013) which held that courts should apply the "rule of reason" approach when reviewing reverse payment settlement agreements.

In light of the Actavis decision, a status conference was held on July 11, 2013. During this conference, the FTC indicated that it would "potentially be looking for some redress of the consumer harm that's been caused by the years and years of delayed generic entry." (Tr. 36, July 11, 2013.) Following the status conference, the parties were ordered to submit a discovery and scheduling plan and propose "the scope of additional fact and expert discovery that should be permitted." In its July 31, 2013 proposed scheduling plan, the FTC stated that it was seeking to supplement its economic expert's report to "address appropriate equitable monetary remedies." Cephalon contends, and the FTC does not dispute, that July 2013 was the first time that the FTC indicated that it intended to seek equitable monetary remedies.

On September 20, 2013, Cephalon filed a "Motion to Dismiss for Lack of Subject Matter Jurisdiction" arguing that the FTC's complaint should be dismissed on the grounds that the entry of generic Provigil rendered the FTC's requested injunctive relief moot and that the FTC's proposed monetary equitable remedy was inappropriate. On July 29, 2014, I denied Cephalon's motion and explained that:

> Cephalon argues that the Court "should deny the FTC's belated request for monetary relief" because: (1) the FTC did not include a specific prayer for disgorgement in its complaint, (2) the FTC has often stated that it did not intend to seek monetary relief, and (3) an FTC policy statement in place for most of this

> litigation (though now withdrawn) would have counseled against seeking equitable monetary relief. These arguments address only the propriety of certain relief, not the Court's power to grant it . . . Cephalon may or may not be right that the FTC is not entitled to any of the relief it currently seeks. But to try to answer this question on a motion challenging the Court's subject-matter jurisdiction "confuses mootness with the merits." Chafin v. Chafin, 133 S. Ct. 1017, 1024 (2013).

FTC v. Cephalon, Inc., 36 F. Supp.3d 527, 529 n.2 (E.D. Pa. July 29, 2014).

On December 3, 2013, an amended Pretrial Scheduling Order was entered which allowed the parties to serve supplemental expert reports regarding "[a]nalyses of monetary and non-monetary remedies to account for changed factual circumstances or the standard recently set forth by the United States Supreme Court in Federal Trade Commission v. Actavis, Inc., 133 S.Ct. 2223 (2013)." Pursuant to this Order, the FTC served a supplemental expert report which included disgorgement calculations. Cephalon then served a supplemental expert report responding to these calculations.

On January 28, 2015, Cephalon filed a motion to preclude the FTC from seeking disgorgement. Cephalon now argues that preclusion is warranted because the FTC lacks statutory authority to seek disgorgement and, alternatively, even if the FTC is authorized to seek disgorgement in some cases, it should not be permitted to do so in this case as a matter of equity.

II. DISCUSSION

A. Statutory Authority

Cephalon first contends that the statute under which the FTC brought this case – Section 13(b) of the FTC Act – does not permit the FTC to seek "equitable monetary relief." This section states that whenever the FTC has reason to believe that a party has violated a provision of law enforced by the FTC, it "may bring suit in a district court of the United States to enjoin any such act or practice . . . [and] in proper cases the [FTC] may seek, and after proper proof, the court

may issue, a permanent injunction." 15 U.S.C. § 53(b). Cephalon notes that Section 13(b) does not explicitly include equitable monetary relief and urges that "injunction" may not be construed to include disgorgement or other equitable relief.[3]

The FTC counters that courts have uniformly concluded that Section 13(b) grants district courts authority to order monetary equitable relief. The weight of precedent supports this position. See FTC v. Ross, 743 F.3d 886, 890-92 (4th Cir. 2014) (Section 13(b) confers power to award "monetary consumer redress"); FTC v. Bronson Partners, LLC, 654 F.3d 359, 365 (2d Cir. 2011) ("Section 13(b) permits a court to order ancillary equitable relief, including monetary relief"); FTC v. Freecom Commc'ns, Inc., 401 F.3d 1192, 1202 n.6 (l0th Cir. 2005) ("[Section] 13(b)'s grant of authority to provide injunctive relief carries with it the full range of equitable remedies, including the power to grant consumer redress"); FTC v. Gem Merch. Corp., 87 F.3d 466, 470 (11th Cir. 1996) ("We conclude that section 13(b) permits a district court to order a defendant to disgorge illegally obtained funds"); FTC v. Pantron I Corp., 33 F.3d 1088, 1102 (9th Cir. 1994) (Section 13(b) permits courts to grant monetary relief); FTC v. Sec. Rare Coin & Bullion Corp., 931 F.2d 1312, 1314-15 (8th Cir. 1991) (Section 13(b) empowers district courts to grant equitable monetary relief); FTC v. Amy Travel Serv., Inc., 875 F.2d 564, 571-72 (7th Cir.

[3] Cephalon also contends that Congress' deliberate omission of disgorgement from Section 13(b) is underscored by a separate provision – Section 19 – which permits the district court to hear suits to enforce cease-and-desist orders and, where appropriate, to award "such relief as the court finds necessary to redress injury to consumers [including] the refund of money or return of property." 15 U.S.C. § 57b(a)(2) & (b). Cephalon urges that Section 19 reflects a legislative determination that monetary relief is only appropriate in a limited set of circumstances and not "in suits under Section 13(b) for more general violations of the FTC Act."

However, Section 19 expressly provides that "[n]othing in this section shall be construed to affect any authority of the Commission under any other provision of law." Id.; see also FTC v. Bronson Partners, LLC, 654 F.3d 359, 367 (2d Cir. 2011) (rejecting argument that the "language of Section 19 limits Section 13(b) to its terms"); FTC v. Sec. Rare Coin & Bullion Corp., 931 F.2d 1312, 1315 (8th Cir. 1991) ("There can be no inference from this language that Congress intended in section 19 to restrict the broad equitable jurisdiction granted to the district court by section 13(b)"). In light of the foregoing, I decline to adopt Cephalon's reading of Section 19.

1989) (Section 13(b) includes grant of power to order restitution); FTC v. Sw. Sunsites, Inc., 665 F.2d 711, 717-18 (5th Cir. 1982) ("Section 13(b) carries with it the authorization for the district court to exercise the full range of equitable remedies traditionally available to it.")

Additionally, in dicta of a non-precedential opinion, the United States Court of Appeals for the Third Circuit expressed agreement with the Second, Fourth, Fifth, Seventh, Eighth, Ninth, Tenth and Eleventh Circuits. FTC v. Magazine Solutions, LLC, 432 F. App'x 155, 158 n. 2 (3d Cir. 2011).

In determining that Section 13(b) grants district courts the authority to order monetary equitable relief, courts have relied upon Porter v. Warner Holding Co., 328 U.S. 395 (1946) and Mitchell v. Robert DeMario Jewelry, Inc., 361 U.S. 288 (1960). In Porter, the Court held that "[u]nless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction." Porter, 328 U.S. at 398. The Supreme Court reaffirmed this principle in Mitchell and held "[u]nless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied." Mitchell, 361 U.S. at 291.

According to Third Circuit precedent, Porter and Mitchell have "charted an analytical course that seems fairly easy to follow . . . a district court sitting in equity may order restitution unless there is a clear statutory limitation on the district court's equitable jurisdiction and powers." United States v. Lane Labs-USA Inc., 427 F.3d 219, 225 (3d Cir. 2005). The Third Circuit has also noted that "[n]umerous courts have followed this approach in opining about a court's power to order restitution or disgorgement under several different statutes that granted open-ended enforcement powers to the courts." Id. at 225 (citing, as an example, FTC v. Gem

Merch. Corp., 87 F.3d 466 (11th Cir. 1996) in which the court found disgorgement to be appropriate under Section 13(b)).

Cephalon counters that Meghrig v. KFC W., Inc., 516 U.S. 479 (1996) makes clear that the foregoing reading of Porter and Mitchell is incorrect. Cephalon urges that Meghrig demonstrates that a district court's equitable authority may be limited absent an explicit statutory disclaimer of certain equitable remedies. In Meghrig, the Supreme Court refused to interpret a citizen suit provision of the Resource and Conservation and Recovery Act (RCRA) as allowing courts to order restitution even though the statute did not contain an express disclaimer of such remedies. Id. at 481. In reaching this conclusion, the Court determined that Congress did not intend to permit recovery of past cleanup costs in light of the RCRA's "elaborate enforcement provision," statutory purpose and private nature[4] as well as the existence of a related statute which did contain an explicit provision authorizing the recovery of such costs. Id. at 484-87.

Contrary to Cephalon's contention, the Meghrig Court did not abandon the general rule established by Porter and Mitchell that the equitable discretion of the courts is limited only when that is the necessary and inescapable inference of the statutory scheme. Rather, the Court found that the particular attributes of the RCRA noted above created such an inference.

The FTC also correctly notes that the Third Circuit rejected the broad reading of Meghrig that Cephalon now advances. See Lane Labs 427 F.3d at 230-32. In doing so, the Third Circuit stated that there is no "indication, either in Meghrig or since, that the Court has abandoned the holdings of Porter and Mitchell." Lane Labs, 427 F.3d at 232; see also United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 496 (2001) (citing Porter for the proposition that courts

[4] The RCRA provided for citizen suits not enforcement actions by the government. As the Court noted in Porter, a court's equitable powers "assume an even broader and more flexible character" when the public interest is involved than when "only a private controversy is at stake." Porter, 328 U.S. at 398.

sitting in equity have discretion to fashion remedies "unless a statute clearly provides otherwise").

Nothing in the FTC Act creates a necessary and inescapable inference that a district court's equitable power under Section 13(b) is limited. Eight Circuit Courts of Appeals have reached this conclusion. I find that the FTC is permitted to seek disgorgement in cases brought pursuant to Section 13(b).

B. Equitable Considerations

Cephalon also argues that, based on equitable principles, even if Section 13(b) allows disgorgement, the FTC should not be permitted to pursue this remedy.

First, Cephalon urges that the FTC should be precluded as a matter of equity from seeking disgorgement because that remedy was not mentioned in its prayer for relief. However, the FTC did request "such other equitable relief as the Court finds necessary to redress and prevent recurrence of Cephalon's violation of Section 5(a) of the FTC Act." I find that this language is sufficient to encompass disgorgement as "Rule 8(a)(3) of the Federal Rules of Civil Procedure does not require that the demand for judgment be pled with great specificity." Sheet Metal Workers Local 19 v. Keystone Heating & Air Cond., 934 F.2d 35, 40 (3d Cir. 1991); Sheet Metal Workers' Local 19 v. Herre Bros., 201 F.3d 231, 249 (3d Cir. 1999) (finding the phrase "[s]uch other relief as the Court deems just and reasonable" broad enough to encompass the remedy of specific performance).

Cephalon similarly argues that the FTC should be precluded from seeking disgorgement because of repeated statements made by the FTC throughout this litigation that it would not pursue monetary remedies. Cephalon asserts that "all remedies that are governed by equitable principles" must be pursued by the government with "reasonable promptness," United States v.

Olds, 426 F.2d 562, 566 (3d Cir. 1970), and that the FTC changed its position "simply because it became strategically convenient" to do so after generic Provigil entered the market. However, changed circumstances may necessitate a change in relief. See Kirby v. U.S. Gov't, Dep't of Hous. & Urban Dev., 745 F.2d 204, 207 (3d Cir. 1984). The FTC persuasively argues that the finding that Cephalon procured its patent by fraud as well as the entry of generic Provigil into the market in 2012 are "dramatic changes in circumstances since it brought its case" and necessitate a change in the relief requested.

The Third Circuit has recognized that courts may award any relief "appropriate under the circumstances ... even [if] the complaint did not request [such] relief. . . . Indeed, so long as a cause of action for equitable relief is 'in fact inherent in the [pleadings], such relief may be granted.'" Massachusetts Mut. Life Ins. Co. v. Curley, 459 F. App'x 101, 109-10 (3d Cir. 2012) (alterations in original) (citing Kahan v. Rosenstiel, 424 F.2d 161, 174 (3d Cir. 1970) (holding the phrase "further relief as may be just" sufficient to encompass injunctive relief where such relief is inherent in the pleadings)).

Cephalon next contends that disgorgement is only permissible upon the showing of a "clear violation" of law. Cephalon asserts that disgorgement is limited to instances of "conscious wrongdoing" because the purpose of the remedy is to strip a defendant of wrongful gain. Cephalon cites the Restatement (Third) of Restitution and Unjust Enrichment § 3 for this proposition which states "[l]iability to disgorge profits is ordinarily limited to cases of what this Restatement calls 'conscious wrongdoing.'"

According to Cephalon, this principle was "firmly reflected" in the FTC's own 2003 Policy Statement in effect at the time the complaint was filed. Cephalon references the following passage of the FTC Policy Statement: "[t]he Commission will ordinarily seek monetary

disgorgement only when the violation is clear. A violation is 'clear' for this purpose when, based on existing precedent, a reasonable party should expect that the conduct at issue would likely be found to be illegal." See Federal Trade Comm'n, Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45820, 45821 (Aug. 4, 2003).

Cephalon has not however pointed to any precedent establishing that a showing of a clear violation is a prerequisite to seeking disgorgement. Moreover, the 2003 Policy Statement referenced above explicitly states that the FTC had warned pharmaceutical companies that it would consider the entire range of remedies "including possibly seeking disgorgement of illegally obtained profits" in connection with reverse payment schemes. Id. at 45822. As such, I find Cephalon's reliance on the Restatement and the FTC's Policy Statement as suggesting that a "clear violation" is a necessary prerequisite unpersuasive.[5]

Lastly, Cephalon argues that disgorgement is inappropriate because it would be duplicative to the relief which consumers may obtain in the private plaintiff actions. Certainly, there is no way to predict the outcome of the private plaintiff's antitrust lawsuits. Moreover, the FTC explains that any award obtained pursuant to its proposed disgorgement remedy would be placed in a Consumer Relief Fund and would be used to satisfy any claims in the private plaintiff

[5] Nonetheless, assuming such a rule does apply, I will consider Cephalon's argument that it would be inequitable to allow disgorgement because the FTC conceded that it could not show a "clear violation." In support, Cephalon points to a letter the FTC submitted on November 27, 2009 which responded to questions I raised about the standard applicable to reverse payment settlements. In that letter, the FTC stated that "[i]f the Court adopts the [scope of the patent] standard articulated by the Second and Federal Circuits at the pleadings stage . . . , the FTC's complaint . . . would fail to state a claim and should be dismissed." According to Cephalon, this statement establishes that the FTC believed that there was no clear violation under the then-governing "scope of the patent" standard and, therefore, disgorgement should not be permitted. This argument seems misplaced as the Supreme Court has rejected the scope of the patent standard. The FTC also contests that it conceded there was no clear violation and correctly notes that Cephalon's fraudulent conduct, if proven, is a clear violation of the antitrust laws under any standard. As such, even if a "clear violation" is a necessary prerequisite to seeking disgorgement, Cephalon's argument fails.

cases. Therefore, I find that Cephalon's concerns about duplicative recovery do not preclude the FTC from seeking disgorgement.

III. CONCLUSION

For the reasons expressed herein, Cephalon's motion to preclude the FTC from seeking disgorgement is denied. An appropriate Order follows.