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

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

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.

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)

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 reasonablI

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