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

APOTEX, INC., Plaintiff,	:	CIVIL ACTION
v.	:	No. 2:06-cv-2768
CEPHALON, INC., et al., Defendants.	:	

ORDER

AND NOW, this 15th day of March, 2011, upon consideration of "Apotex's Combined Motion and Memorandum for Summary Judgment of Non-Infringement of the '346 Patent," (doc. no. 299), "Defendant Cephalon, Inc.'s Cross-Motion for Summary Judgment on Apotex's '346 Patent Claims and, in the alternative, Motion to Dismiss under FED. R. CIV. P. 12(b)(1)," (doc. no. 315), and the respective responses thereto, we find as follows:

Background

1) This lawsuit (hereinafter referred to as the "Apotex Litigation") is one of several consolidated cases collectively named In re Modafinil.[1] This multi-party litigation emanates from the settlement of a patent infringement suit in late 2005 - early 2006, in the District of New Jersey, between Cephalon, a brand name drug manufacturer, and four (4) generic drug manufacturers (Barr, Mylan, Teva and Ranbaxy, hereinafter "the Generic Defendants"). The

[1] King Drug Company of Florence, Inc., et al. v. Cephalon, Inc., et al., 2:06-cv-1797 - The King Drug Direct Purchaser Class Action; Vista Healthplan, Inc., et al. v. Cephalon, Inc., et al., 2:06-cv-1833 - The Vista Healthplan End Payor Class Action; Apotex, Inc. v. Cephalon, Inc., et al., 2:06-cv-2768 - The Apotex Litigation; and Federal Trade Commission v. Cephalon, Inc., 2:08-cv-2141 - The F.T.C. Litigation.

settled patent suit revolved around the proposed sale of a generic version of Provigil®, a sleep disorder drug. The gist of the controversy as it generally pertains to the consolidated cases in In re Modafinil, is that the four (4) settlement agreements in the patent infringement suit constitute unlawful, anti-competitive conduct under the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2.

2) The Apotex Litigation commenced on June 26, 2006, with the filing of the original complaint, which raised patent claims regarding Cephalon's RE'516 patent for Provigil® and antitrust claims against Cephalon and the Generic Defendants relating to the settlements noted above. Since that time, the original complaint has been consolidated with a separate complaint filed by Apotex regarding a second Cephalon patent - U.S. Patent No. 7,297,346 (hereinafter "the '346 patent"), also relating to Provigil®. Thereafter, Apotex filed an amended complaint and second amended complaint which sets forth patent and antitrust claims. On January 20, 2010, we granted Apotex's motion to bifurcate the patent claims from the antitrust claims. On February 23, 2010, Cephalon's motion to dismiss the patent claims on the '346 patent for lack of subject matter jurisdiction was denied.

3) Before the Court is Apotex's motion for summary judgment on Count V of the second amended complaint which alleges non-infringement on Cephalon's '346 patent. Cephalon has filed a cross-motion for summary judgment, or in the alternative, a motion to dismiss, alleging lack of subject matter jurisdiction.

Standard of Review

4) Under Federal Rule of Civil Procedure 56(c), summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the

affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to summary judgment as a matter of law." FED. R. CIV. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In order to defeat a motion for summary judgment, disputes must be both (1) material, meaning concerning facts that will affect the outcome of the issue under substantive law, and (2) genuine, meaning the evidence must be such that a reasonable jury could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

5) A party moving for summary judgment has the initial burden of supporting its motion with evidence that would be admissible in a trial. Id. at 250 n. 4. If this requirement is satisfied, the burden shifts to the non-moving party to "set out specific facts showing a genuine issue for trial." FED. R. CIV. P. 56(e)(2).

6) The non-moving party cannot avert summary judgment with speculation or conclusory allegations such as those found in the pleadings, but rather, must present evidence from which a jury could reasonably find in its favor. Ridgewood Bd. of Edu. v. N.E. for M.E., 172 F.3d 238, 252 (3d Cir. 1999). In reviewing a motion for summary judgment, the court does not "make credibility determinations, and must view facts and inferences in the light most favorable to the party opposing the motion." Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1127 (3d Cir. 1995).

Motions for Summary Judgment

7) For the purposes of efficiency, we incorporate our February 23, 2010, Memorandum Opinion, wherein we denied Cephalon's motion to dismiss Apotex's patent claims on the '346 patent. There, in the context of a Rule 12(b) motion, we addressed this Court's subject

matter jurisdiction over claims on the '346 patent.

8) Apotex has moved for judgment that its ANDA No. 77-667 does not infringe the '346 patent. Apotex asserts it is entitled to a judgment of non-infringement based upon correspondence from Cephalon dated July 23, 2010, wherein Cephalon acknowledges that Apotex's ANDA does not infringe.

9) Despite this concession, Cephalon opposes Apotex's motion and has filed its own cross-motion for summary judgment claiming that the Court lacks subject matter jurisdiction to enter a judgment on the merits of Apotex's '346 non-infringement claim. Cephalon agrees that Apotex's product does not infringe the '346 patent, but posits that because Apotex does not need a declaratory judgment of non-infringement on the '346 patent to trigger the first-filer exclusivity, there is no case and controversy, and thus, no subject matter jurisdiction.

10) The correspondence from Cephalon to Apotex states:

> Based on presently available information, Cephalon does not contend that the particular formulation of the generic modafinil drug product identified at module 2.3.P.1 (Bates No. ANDA-MOD-0000103) in ANDA No. 77-667 infringes the '346 patent, either literally or under the doctrine of equivalents.

(Apotex Memo., Ex. E.)

11) Based on a plain reading of this correspondence and Cephalon's admissions in their motion for summary judgment, there is no dispute of material fact as to whether or not Apotex's proposed generic product infringes on the '346 patent. (Cephalon Memo., p. 2.) Because we find that Apotex's ANDA does not infringe, the only remaining issue is whether the Court has jurisdiction to enter that judgment.

12) Before addressing this question, we note that the Court has extensively reviewed and

addressed the issue of subject matter jurisdiction at the motion to dismiss stage in this litigation. Cephalon's current motion for summary judgment, or in the alternative, motion to dismiss, does not allege any new facts differentiating the case at this stage from the motion to dismiss stage, but rather focuses on the fact that Apotex allegedly does not need a judgment on the '346 patent in order to obtain FDA approval. Cephalon maintains that because Apotex does not need such a judgment, this Court has no subject matter jurisdiction. We disagree with Cephalon's reasoning for several reasons.

13) First, Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278 (Fed. Cir. 2008), which is controlling on this issue, does not support Cephalon's position. There, the Federal Circuit found that there was a case and controversy such that a subsequent Paragraph IV ANDA filer could pursue a declaratory judgment on two patents, even though the patent holder had only sued the ANDA filer on one of the two patents. Id. at 1287. The Court reasoned that this conclusion was consistent with the Hatch-Waxman framework because only a judgment on both patents would effectuate the court-judgment trigger under 21 U.S.C. §355(j)(5)(B)(iv)(II) (2000). Id. at 1288. Despite the fact that the FDA makes its own triggering decisions on a case by case basis and could choose to grant approval based upon a court-judgment on only one of the patents, the Caraco Court found that a judgment on all Orange Book listed patents was necessary. Caraco, at 1287-97; see also, Dr. Reddy's Labs., Inc. v. Thompson, 302 F.Supp.2d 340, 359 (D.N.J. 2003).

14) Here, the facts are strikingly similar to Caraco in that Apotex is seeking a judgment of non-infringement on both the RE'516 patent and the '346 patent, but Cephalon only contests infringement on the former. Apotex's challenge fits squarely within the Hatch-Waxman

framework in that they need a judgment on both patents pursuant to the statute to effectuate the court-judgment trigger. Both Teva and Barr, Generic Defendants in the antitrust portion of this case, have filed Paragraph IV certifications on both the RE'516 patent and the '346 patent. (Apotex Statement of Facts Regarding Subject Matter Jurisdiction, ¶ 16.) Therefore, because neither Teva nor Barr have relinquished those certifications on either patent and neither are marketing a generic version of Provigil® because of the settlement agreements, Apotex needs a court-judgment on both patents to trigger the 180-day exclusivity period. The triggering of that exclusionary period is what allows Apotex to then seek FDA approval of its ANDA.

15) Furthermore, we reject Cephalon's argument that judgment on the RE'516 patent is sufficient to trigger the 180-day exclusivity, and therefore, there is no subject matter jurisdiction over the '346 patent. Cephalon's basis for that argument is that pursuant to its settlement agreements with the Generic Defendants, a judgment in Apotex's favor on the RE'516 patent will trigger the 180-day time period. Cephalon may be correct that the settlement agreements do suggest that such a judgment may allow the Generic Defendants to enter the market place, thus, triggering the 180-day exclusivity based on the market trigger pursuant to 21 U.S.C. §355(j)(5)(B)(iv)(I) (2002). However, Cephalon ignores the "or" that was placed between subsection (I) for the market trigger and subsection (II) for the court-judgment trigger in the statute. While Cephalon may be technically correct that a judgment on the RE'516 patent will trigger the 180-day time period pursuant to the market trigger, there is nothing precluding Apotex from pursuing the "or" - the court-judgment trigger. Apotex is not bound by the terms of settlement agreements Cephalon entered into with other companies, and we

will not construe such agreements to preclude a non-party from pursuing a statutorily permitted judgment. Indeed, a plain reading of the statute reflects that judgments on all Orange Book patents for which there are Paragraph IV certifications filed by first filers, who are not commercially marketing the drug, are necessary to effectuate the court-judgment trigger. 21 U.S.C. §355(j)(5)(B)(iv) (2002).

16) Therefore, for the reasons stated above and explained in detail in our February 23, 2010, Memorandum Opinion, this Court does have subject matter jurisdiction over Apotex's non-infringement claim on the '346 patent.

17) Cephalon also argues that the Food and Drug Administration's (hereinafter "FDA") current import ban from two of Apotex's Canadian manufacturing plants renders Apotex's claims non-justiciable. Cephalon posits that Apotex's common good manufacturing practices violations are a barrier to FDA approval and not the lack of judgment on the '346 patent. Therefore, Cephalon argues that Apotex's claim is not ripe.

18) A case is ripe when the issues are fit for judicial decision and withholding court consideration would be a hardship to the parties. Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967), *overruled on other grounds by* Califano v. Sanders, 430 U.S. 99 (1977). In the ANDA context, withholding consideration of a declaratory judgment action has the "immediate and substantial impact" of forestalling the generic's ability to activate the 180-day exclusivity period through a court-judgment trigger. Caraco, 572 F.3d at 1294-95. That hardship is exactly what creates ripeness in the ANDA context.

19) Here, as previously stated, Apotex's situation is analogous to that of the generic company in Caraco. Withholding court consideration would have the immediate impact of preventing

Apotex from the possibility of activating the 180-day exclusivity period with a court-judgment. Therefore, Apotex's declaratory judgment is ripe and is not moot.

20) The fact that the FDA may or may not approve Apotex's ANDA because of the current import ban is of no consequence to this analysis. Apotex needs the court-judgment to trigger the 180-day exclusivity period, which then allows the FDA to consider Apotex's ANDA for final approval. Apotex cannot seek FDA approval without first triggering the exclusivity period. If and when Apotex proceeds before the FDA, what the FDA then chooses to do is entirely speculative. For instance, at the time when the FDA will consider final approval for Apotex's ANDA, the manufacturing issues relied upon by Cephalon may have been resolved and the import ban lifted. Additionally, at that time, Apotex could amend its ANDA to include a different manufacturing facility, and/or the FDA could render a decision on Apotex's ANDA based on many other conceivable factors. Attempting to hypothesize what the FDA may or may not do is certainly not a basis for dismissal of this action. The current harm to Apotex is its inability to seek approval from the FDA, and that is what makes this case ripe for decision.

WHEREFORE, it is hereby **ORDERED** that Apotex's motion for summary judgment (doc. no. 299) is **GRANTED** and Cephalon's motion for summary judgment, or in the alternative, motion to dismiss (doc. no. 315) is **DENIED. IT IS FURTHER ORDERED** that judgment is entered in favor of Apotex on Count V of the second amended complaint and against Cephalon.

BY THE COURT:

/s/ Mitchell S. Goldberg

MITCHELL S. GOLDBERG, J.