NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SCHERING CORPORATION, et al., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., et al., Defendants.	Civil Action No.: 09-6383 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of a motion for partial summary judgment filed by Plaintiffs, Schering Corporation and MSP Singapore Company LLC (collectively, "Schering"), on March 11, 2011, seeking dismissal of Defendant Mylan Pharmaceuticals, Inc.'s ("Mylan") Fifth Separate Defense and Fourth Counterclaim. The Court has considered the parties' submissions in support of and in opposition to the present motion and decides the matter without oral argument pursuant to Rule 78 of the Federal Rules of Civil Procedure. For the reasons set forth below, Schering's motion is granted.

I. BACKGROUND

The following facts are undisputed, except where noted. On December 16, 2009, Schering filed a Complaint alleging that Mylan's filing of an Abbreviated New Drug Application infringed two of Schering's patents, specifically United States Patent Nos. RE37,721 ("the '721 patent") and 5,846,966 ("the '966 patent") (collectively, the "patents-in-suit"). (Schering's Local

Civ. R. 56.1 Stmt. of Uncontested Facts in Support of Their Mot. for Summ. J. ["SOF"] ¶¶ 3–6.) On March 2010, Mylan filed an Amended Answer, asserting as its Fifth Separate Defense and Fourth Counterclaim that the patents-in-suit are unenforceable for inequitable conduct by Schering during patent term extension proceedings. (SOF ¶ 8.) Mylan specifically alleges that during the pendency of the patent term extension application for the '721 patent, Schering violated the disclosure obligations set forth by the United States Patent and Trademark Office ("PTO") and thereby committed fraud on the agency. (Am. Answer at 50.) The facts underlying these allegations began a number of years before said application was filed.

On February 4, 1993, Schering disclosed a compound called SCH48461 in Example 9 of International Published Patent Application WO 93/02048 ("the '048 PCT"). (Mylan's Stmt. of Add'l Facts ¶ 1.) Mylan asserts that "[f]ollowing ingestion by a mammal, natural metabolism of SCH48461 by the body results in the formation of compounds encompassed by at least claims 1, 2, 5, and 7 of the '721 patent."[1] (Id. at ¶ 2.) In September of 1993, Schering filed a patent application with the PTO that ultimately led to the issuance of the '721 patent. (SOF ¶ 3.) Specifically, an initial patent, United States Patent No. 5,757,115 ("the '115 patent"), issued on June 16, 1998, and that patent was reissued on May 28, 2002 as the '721 patent. (Id.) On December 17, 2002, Schering filed an application for extension of the term of the '721 patent pursuant to 35 U.S.C. § 156 and 37 C.F.R. §§ 1.170–1.791. (Id. at 11.) In 2006, the PTO granted the patent term extension. (Id. at 12–13.)

On June 9, 2010, Schering filed a reissue application for the '721 patent. (Mylan's Stmt.

[1]Schering disputes this issue of fact, but argues that it is not material to the instant motion. (Schering's Response to Mylan's Stmt. of Add'l Undisputed Facts ¶ 2.)

of Add'l Facts ¶ 16.) As part of its declarations accompanying the reissue application, Schering stated that "at least Claim 1 of [the '721 patent] is potentially inherently anticipated by the International published application [of the '048 PCT]." (Id. at ¶ 17.) Schering informed the PTO that because of the "potential invalidity of claims 1, 2, 5, and 7 of both the '721 reissue patent and the '115 patent, in the present reissue application, applicants have amended and narrowed the claims of the '721 reissue patent to exclude compounds 4A, 4B, 4E and 4F, as well as any other putative metabolites of the Example 9 compound (and any other of the exemplified compounds) of the '048 PCT publication." (Id. at ¶ 19.)

II. LEGAL STANDARD

A court shall grant summary judgment under Rule 56(c) of the Federal Rules of Civil Procedure "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to present evidence that a genuine issue of material fact compels a trial. Id. at 324. In so presenting, the non-moving party must offer specific facts that establish a genuine issue of material fact, not just "some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986). Thus, the non-moving party may not rest upon the mere allegations or denials in its pleadings. See Celotex, 477 U.S. at 324. Further, the non-moving party cannot rely on unsupported assertions, bare allegations, or speculation to defeat summary judgment. See Ridgewood Bd. of Educ. v.

N.E. ex rel. M.E., 172 F.3d 238, 252 (3d Cir. 1999). The Court must, however, consider all facts and their reasonable inferences in the light most favorable to the non-moving party. See Pennsylvania Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995).

III. DISCUSSION

Mylan alleges that during the pendency of the '721 patent term extension proceedings, "one or more of the named inventors of the '721 patent knew that certain metabolites which formed in vivo after administration of prior art compound SCH48461 fell within the scope of at least Claims 1, 2, 5, and 7 of the '721 patent" (Mylan's Stmt. of Add'l Facts ¶ 3), and that Schering's failure to disclose such information constituted inequitable conduct before the PTO, rendering the subject patent, and related patents, unenforceable. Schering responds that even if the inventors or Schering's attorneys had such knowledge, a fact which Schering disputes,[2] Schering had no duty to disclose such information in connection with those proceedings.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), a patentee can obtain an extension of the ordinary patent term if the patent claims an invention which is subject to a regulatory review period before its commercial marketing or use. 35 U.S.C. § 156. The Hatch-Waxman Act "has two general purposes: (1) to increase the availability of low-cost drugs by expanding a generic drug approval procedure; and (2) to further encourage new drug research by restoring some of the patent term lost while drug

[2]Mylan's contention that Schering's attorney "knew" that the '721 patent was invalid is based on the attorney's statement in connection with the June 9, 2010 reissue application that because of the "potential invalidity of claims 1, 2, 5, and 7" Schering sought to narrow those claims to exclude the prior art compounds. (Mylan's Br. in Opp'n to Pls.' Mot. for Partial Summ. J. ["Mylan's Opp'n Br."] at 6, Decl. of Lance Soderstrong, Ex. 9 at SPV00182686.) Schering responds that the attorney's use of "potential" qualifies any conclusive statement regarding validity. (Pls.' Reply Br. In Support of Their Mot. for Partial Summ. J. at 4 n.2.)

products undergo testing and await FDA pre-market approval." Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 396 (Fed Cir. 1990). A patentee is entitled to a term extension if the following requirements are met:

> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;
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> (2) the term of the patent has never been extended under subsection (e)(1) of this section;
>
> (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use;
>
> (5)(A) except as provided in subparagraph (B) or (C),[3] the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

35 U.S.C. § 156(a).

In applying for a patent term extension, the applicant has a "duty of candor and good faith" toward the PTO, which involves a duty to disclose "material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding . . . ." 37 C.F.R. § 1.765(a). Information is material "where there is a substantial likelihood that the [PTO] . . . would consider it important in determinations to be made in the patent term extension proceeding." Id. "[I]f it is determined that fraud on the [PTO] was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding," the

[3]Subparagraphs (B) and (C) are inapplicable here.

patent is not eligible for an extension. Id. at § 1.765(c).

Mylan contends that Schering knowingly failed to inform the PTO that the claims at issue in the patent term extension proceedings for the '721 patent were invalid, violating the duty of good faith and candor set forth in § 1.765 and rendering the '721 patent unenforceable due to inequitable conduct.[4] (Mylan's Opp'n Br. 9.) Mylan argues that Schering did more than simply "fail[] to provide material prior art" to the PTO, but rather that counsel for Schering "perpetrat[ed] a fraud" on the PTO by seeking an extension of the term of a patent that he knew to be invalid. (Id.) Mylan's Fifth Separate Defense and Fourth Counterclaim, however, do not facially allege common law fraud. Instead, those allegations are explicitly based on the doctrine of inequitable conduct (see Am. Answer at 50–53, 89–91.), which is an equitable defense that is "a broader, more inclusive concept" than common law fraud, Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069 (Fed. Cir. 1998).

To prove inequitable conduct, the accused infringer must first establish by clear and convincing evidence "that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]." Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1356 (Fed. Cir. 2008) (quoting Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1363 (Fed. Cir. 2007)). However, "even if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable." Id.

[4]Mylan also alleges that Schering's inequitable conduct with respect to the '721 patent term extension proceedings renders the '966 patent unenforceable under the doctrine of "infectious unenforceability." (Am. Answer at 50.)

Here, Schering argues that Mylan's inequitable conduct defense and counterclaim must fail as a matter of law because information regarding the validity of the '721 patent was not "material" to the patent term extension proceedings under the first prong of the inequitable conduct analysis.

Section 1.765 of the Code of Federal Regulations explicitly defines what information is material to patent term extension proceedings. Information is material "where there is a substantial likelihood that the [PTO] . . . would consider it important in determinations to be made in the patent term extension proceeding." 37 C.F.R. § 1.765(a). The determinations to be made in the patent term extension proceeding are limited to those delineated in 35 U.S.C. § 156, and that provision does not provide for any inquiry as to patent validity.[5] Instead, the inquiry under § 156 is limited to more ministerial questions, like whether the patent has expired, whether previous term extensions have been granted, and the extent to which the product was subject to regulatory review prior to its commercial marketing or use. This is so because Congress expected the term extension process to be an "administratively simple" proceeding, in which the "determination as to whether a patent is eligible for extension . . . may be made solely on the basis of the representations made in the application for extension," such that "a final

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[5]The PTO directly addressed this issue in its notice of final rulemaking, responding to the following public comment:

> Comment: It has been suggested that § 1.765 should be clarified as to whether the duty of disclosure extends to prior art discovered since issuance of the patent.
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> Reply: Section 1.765(b) specifically states that an attorney, agent or patent owner has no duty to transmit information which is not material to the determination of entitlement to the extension sought.

Rules for Extension of Patent Term, 52 Fed. Reg. 9386, 9392 (Mar. 24, 1987).

determination to refuse a patent term extension because of fraud or a violation of the duty of disclosure is expected to be rare." Rules for Extension of Patent Term, 52 Fed. Reg. at 9392. These simple proceedings stand in contrast to patent prosecution and reissue proceedings, during which the PTO conducts an in depth review of patentability, and the patent applicant has an express "duty to disclose to the [PTO] all information known to that individual to be material to patentability," as defined in 37 C.F.R. § 1.56.

Thus, even assuming that counsel for Schering knowingly failed to disclose potentially invalidating prior art to the PTO in connection with the term extension proceedings for the '721 patent, such information was not material those proceedings. Mylan cannot show that there was a "substantial likelihood" that the PTO would consider the information "important" to its determinations, as validity questions are not among the statutorily mandated inquiries to be made during patent term extension proceedings. Other courts addressing this issue have reached the same conclusion. See Pfizer Inc. v. Ranbaxy Laboratories Ltd., 405 F. Supp. 2d 495, 512 (D. Del. 2005), aff'd in relevant part, 457 F.3d 1284 (Fed. Cir. 2006) (holding that a failure to disclose information that was "not relevant to the patent's scope" did not render the term extension invalid because the information was not "material such that it was required to be disclosed during the application process for the patent term extension"); United Sweetener USA, Inc. v. Nutrasweet Co., 760 F. Supp. 400, 420 (D. Del. 1991) (denying a claim of inequitable conduct for a failure to disclose "the patent's invalidity in light of prior art" because the court "cannot imagine that, without so specifying, Congress intended that a patentee, in seeking an extension under § 155, justify ab initio the original grant of the patent."). That counsel allegedly "knew" that the subject patent was invalid would not command a different result in this case than

if counsel had merely failed to disclose information material to patentability, as the relevant statute and rule simply do not require the disclosure of such material or the communication of any "knowledge" of the legal conclusions that could be drawn therefrom.[6] Indeed, the rule explicitly provides that an applicant "an attorney, agent or patent owner has no duty to transmit information [provided by third parties] which is not material to the determination of entitlement to the extension sought." 37 C.F.R. § 1.765(b) (emphasis added).

Mylan further argues that the "duty of candor and good faith" described in § 1.765(a) creates a disclosure obligation that transcends the precise requirements identified therein. Mylan argues that Schering had a duty of candor and good faith to disclose the potentially invalidating prior art to the PTO, even if the relevant rules and statutes did not expressly require it to do so. While the Court agrees that patent term extension applicants owe the PTO a duty of candor and good faith, the mere existence of such a duty, without more, would provide little guidance as to what the applicant would be required to disclose. This duty should therefore be read in conjunction with the disclosure obligations expressly provided thereafter. Indeed, where the PTO has required the disclosure of material related to patentability, such as in prosecution and reissue proceedings, it has explicitly provided so. See 37 C.F.R. § 1.56. Section 1.765 contains no such requirement. Furthermore, to the extent that the "duty of good faith" could be read to encompass fraud or other related claims that are independent of § 1.765's disclosure obligations, see 37 C.F.R. § 1.765(c) ("if it is determined that fraud on the [PTO] was practiced or attempted or the duty of disclosure was violated . . .") (emphasis added), such claims are not implicated

[6]The Court notes that this is not a case in which a term extension was sought for a patent that had actually been held invalid.

here, as Mylan's Fifth Separate Defense and Fourth Counterclaim allege only disclosure violations.[7] Thus, in view of the specific allegations at issue in this motion, the Court does not interpret the duty of candor and good faith identified in § 1.765 to require the disclosure of potentially invalidating prior art relating to the '721 patent. The Court therefore concludes that the Schering's alleged failure to disclose such information during the term extension proceedings would not support a finding of inequitable conduct. As such, no genuine issue of material fact exists, and Schering is entitled to summary judgment on Mylan's Fifth Separate Defense and Fourth Counterclaim.[8]

IV. CONCLUSION

For the foregoing reasons, Schering's motion for partial summary judgment is granted. An appropriate Order accompanies this Opinion.

DATED: May 17, 2011

/s/ Jose L. Linares
JOSE L. LINARES
UNITED STATES DISTRICT JUDGE

[7]The Court notes, however, that to the extent that Mylan's Fifth Separate Defense and Fourth Counterclaim could be construed as alleging common law fraud based on Schering's alleged failure to comply with the disclosure obligations set forth in 35 U.S.C. § 156(a) and 37 C.F.R. § 1.765, such a claim of fraud would likewise require a showing of materiality and would thus fail for the same reason as Mylan's inequitable conduct claims. See Nobelpharma, 141 F.3d at 1069–70.

[8]Having so ruled, the Court declines to consider Schering's alternative arguments in support of its motion.