IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY, LTD., a Japanese Corporation, and TAP PHARMACEUTICAL PRODUCTS, INC. a Delaware Corporation, Plaintiffs and Counterclaim-Defendants, vs. TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES, LTD., an Israeli Corporation, Defendants and Counterclaim-Plaintiffs.	Civil Action No. 06-33-SLR

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION FOR LEAVE TO AMEND ANSWER, DEFENSES, AND COUNTERCLAIMS TO ASSERT INEQUITABLE CONDUCT

CONNOLLY BOVE LODGE & HUTZ LLP
Arthur G. Connolly, III (#2667)
The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19801
(302) 658-9141

Attorneys for Plaintiffs
Takeda Pharmaceutical Company, Ltd. and
TAP Pharmaceutical Products, Inc.

Of Counsel:
Eric J. Lobenfeld
Tedd W. Van Buskirk
Arlene L. Chow
HOGAN & HARTSON L.L.P.
875 Third Avenue
New York, NY 10022
(212) 918-3000

Philippe Y. Riesen
HOGAN & HARTSON L.L.P.
Shinjuku Center Building, 46th Floor
25-1 Nishi-Shinjuku 1-chome
Shinjuku, Tokyo 163-0646
Japan
(81) 3-5908-0470

Attorneys for Plaintiff Takeda Pharmaceutical Company, Ltd.

William F. Cavanaugh, Jr.
Stuart E. Pollack
Chad J. Peterman
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorneys for Plaintiff TAP Pharmaceutical Products, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

NATURE AND STAGE OF THE PROCEEDING 1

PRELIMINARY STATEMENT 1

SUMMARY OF ARGUMENT 3

STATEMENT OF FACTS 4

ARGUMENT 4

TEVA'S MOTION SHOULD BE DENIED AS FUTILE BECAUSE ITS PROPOSED AMENDMENTS CANNOT WITHSTAND A MOTION TO DISMISS UNDER RULE 12(b) 4

A. Teva Confuses a Patentee's Duty of Disclosure During a Patent Term Extension With a Patent Applicant's Duty of Disclosure During Prosecution 5

B. Teva Fails to Assert Any Legal Support for Its Assertion That a Failure to Disclose Data Relating to Patentability During a Patent Term Extension Proceeding Amounts to Inequitable Conduct 8

CONCLUSION 10

TABLE OF AUTHORITIES

Cases

Cowell v. Palmer Twp., 263 F.3d 286 (3d Cir. 2001) 5

Foman v. Davis, 371 U.S. 178 (1962) 5

Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392 (Fed. Cir. 1990) 6

In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410 (3d Cir. 1997) 5

Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V., 464 F.3d 1339 (Fed. Cir. 2006) 5

Oran v. Stafford, 226 F.3d 275 (3d Cir. 2000) 5

Pfizer, Inc. v. Ranbaxy Labs., Ltd., 457 F.3d 1284 (Fed. Cir. 2006) 8, 9

Pfizer, Inc. v. Ranbaxy Labs., Ltd., 405 F. Supp. 2d 495 (D. Del. 2005), *rev'd in part*, 457 F.3d 1284 (Fed. Cir. 2006) 9

Shane v. Fauver, 213 F.3d 113 (3d Cir. 2000) 5

United Sweetener USA, Inc. v. Nutrasweet Co., 760 F. Supp. 400 (D. Del. 1991) 8

Statutes and Rules

35 U.S.C. § 156 (2000) 6

37 C.F.R. § 1.56(a) 6

37 C.F.R. § 1.720 6

37 C.F.R. § 1.720(a) 9

37 C.F.R. § 1.765(a) 5

37 C.F.R. § 1.765(b) 5, 7

Fed. R. Civ. P. 15(a) 4

H.R. Rep. No. 98-857, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48) 6, 7

Rules for Extension of Patent Term, 52 F.R. 9386, 9392 (Mar. 24, 1987) 7

Plaintiffs Takeda Pharmaceutical Company, Ltd ("Takeda") and TAP Pharmaceutical Products, Inc. ("TAP") submit this memorandum in opposition to Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.'s (collectively "Teva") motion for leave to amend their Answer, Defenses and Counterclaims to assert post-grant inequitable conduct during a patent term extension proceeding. Teva's proposed amendment is futile and should be denied.

NATURE AND STAGE OF THE PROCEEDING

Plaintiffs filed this action on January 17, 2006 alleging infringement of five Takeda patents, including the '098 patent. Plaintiffs allege that Teva's amendment of Abbreviated New Drug Application ("ANDA") No. 77-255 to include a Paragraph IV certification constitutes infringement under 35 U.S.C. §271(e)(2). On January 24, 2007, the Court approved a stipulation dismissing three of the five patents, leaving the '098 patent and U.S. Patent 5,045,321. In its Answer, Teva denies infringement and asserts affirmative defenses and counterclaims of non-infringement and invalidity. Teva now moves for leave to amend its Answer to add affirmative defenses and counterclaims of unenforceability based on alleged inequitable conduct: (1) during prosecution of the application that resulted in the '098 patent; and (2) during the later petition for an extension of the term for the '098 patent. Plaintiffs oppose the motion as to its second respect as futile.

PRELIMINARY STATEMENT

This is a patent case. Plaintiff TAP markets PREVACID®, a drug of the "proton pump inhibitor" ("PPI") class used for treating gastric ulcers in the United States. Its active ingredient is lansoprazole, a compound discovered and patented by Plaintiff

Takeda. That patent, the '098 patent, is one of several TAP and Takeda listed in the *Orange Book* as covering PREVACID®. PREVACID® is one of several highly successful PPI's and was among the top 10 selling drugs in the U.S. in 2006, with sales in excess of $4 billion.

Not surprisingly, given PREVACID's® commercial success, Teva wants to get in on the action. Teva filed ANDA No. 77-255 on August 27, 2004 seeking permission to market lansoprazole capsules upon expiration of the *Orange Book* patents. But Teva apparently changed its mind and, on December 5, 2005, filed a "Paragraph IV" certification alleging that five of the listed patents were either invalid or would not be infringed by Teva's generic lansoprazole capsules. In response to Teva's notice of Paragraph IV certification, Plaintiffs commenced this action.

Seven months ago, Teva first raised the issue of alleged inequitable conduct in connection with the '098 patent term extension during a September 20, 2006 discovery conference before the Court. (Disc. Hr'g Tr., D.I. 59 at 18-20, Sept. 20, 2006.) The Court, skeptical of the relevance of the patent term extension to the validity of the '098 patent, questioned whether a patentee's duty of candor to the PTO lasted "forever and ever and ever and ever." (D.I. 59 at 26.) Nevertheless, the Court invited Teva to submit by letter any support for its position that a patentee has an ongoing post-grant duty of disclosure in petitioning for a patent term extension. (D.I. 59 at 24.) Teva waited seven weeks, until November 9, 2006, before submitting its letter. (D.I. 72.) Takeda promptly responded (D.I. 74.). Within three weeks of the fact discovery cutoff, Teva now seeks leave to amend its Answer to add two claims: (1) inequitable conduct during

prosecution; and (2) inequitable conduct based on an alleged duty of disclosure during patent term extension proceedings.

Without conceding that there is any merit to Teva's first proposed amendment, Plaintiffs do not object to Teva adding an affirmative defense and counterclaim of inequitable conduct during prosecution. Those allegations, while late in the day, state a claim for relief. Plaintiffs only object to Teva's second amendment to add a charge of inequitable conduct with respect to Takeda's petition for a patent term extension.

SUMMARY OF ARGUMENT

1. Takeda and TAP respectfully submit that the Court should deny Teva's motion as to alleged inequitable conduct in connection with the patent term extension of the '098 patent. As noted by Teva, Plaintiffs do not oppose Teva's proposed amendment as to alleged inequitable conduct during prosecution of the '098 patent.

2. Teva's motion should be denied as futile because its proposed allegations cannot withstand a motion to dismiss. Teva mistakenly conflates a ***patentee's*** duty to disclose information ***material to entitlement to the extension sought*** in petitioning for a patent term extension with a ***patent applicant's*** duty to disclose information ***material to patentability*** during patent prosecution. As understood by the PTO and the courts, a patentee has no affirmative duty to disclose information ***material to patentability*** during a patent term extension proceeding. This is because by definition, the duty ends when the patent issues. Also, Teva admits that there is no case law directly supporting its novel theory, yet it seeks to inject these allegations anyway.

STATEMENT OF FACTS

Takeda spent years developing lansoprazole, the active ingredient in PREVACID®. In doing so, it sought to develop a novel compound that was more effective than prior art PPI's in anti-ulcer and cytoprotective action. During its development, Takeda synthesized and tested hundreds of compounds, using various experimental models to assess the profile of the compounds. Because the indomethacin-induced gastric antral ulcer model mimicked the human ulcer (as opposed to the other experimental models used by Takeda), Takeda submitted results from the indomethacin-induced gastric antral ulcer in its patent application.

As a new and nonobvious compound, the '098 patent issued without any office action by the Examiner. Had she relied on superiority or unexpected results over prior art compounds in her determination of patentability, she would have likely stated such reliance in a Statement of Reasons for Allowance. Significantly, the Notice of Allowability cited no specific reason for allowance. (*See* U.S.P.T.O. Notice of Allowability, '098 prosecution history, May 16, 1986.)

ARGUMENT

TEVA'S MOTION SHOULD BE DENIED AS FUTILE BECAUSE ITS PROPOSED AMENDMENTS CANNOT WITHSTAND A MOTION TO DISMISS UNDER RULE 12(b)

Federal Rule of Civil Procedure 15(a) provides that leave to amend "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). The Supreme Court has outlined the reasons by which a district court, in its discretion, may deny leave to amend. They include: "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice

to the opposing party by virtue of allowance of the amendment [or] futility of amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Cowell v. Palmer Twp.*, 263 F.3d 286, 296 (3d Cir. 2001); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997).

A proposed amendment is futile if it would not withstand a Rule 12(b)(6) motion to dismiss. *Oran v. Stafford*, 226 F.3d 275, 291 (3d Cir. 2000); *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000); *Burlington Coat Factory*, 114 F.3d at 1434-35. A party whose motion for leave to amend is challenged on futility grounds must "demonstrate that its pleading states a claim on which relief could be granted, and it must proffer sufficient facts supporting the amended pleading that the claim could survive a dispositive pretrial motion." *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339, 1355-56 (Fed. Cir. 2006) (denying leave to amend antitrust and unfair competition counterclaims in patent infringement case). Teva's proposed amendment to add an affirmative defense and counterclaim of unenforceability due to inequitable conduct during patent term extension proceedings should be denied because it fails as a matter of law.

A. Teva Confuses a Patentee's Duty of Disclosure During a Patent Term Extension With a Patent Applicant's Duty of Disclosure During Prosecution

A patentee's duty of disclosure in a patent term extension proceeding applies solely to "material information adverse to a determination of ***entitlement to the extension sought*** . . . ." 37 C.F.R. § 1.765(a) (emphasis added). The rule specifically states that there is "***no*** duty to transmit information which is not material to the determination of entitlement to the extension sought." 37 C.F.R. § 1.765(b) (emphasis added). The requirements for entitlement to a patent term extension do not include a duty to submit

information relating to information or test results after the grant of the patent. *See* 35 U.S.C. § 156 (2000); 37 C.F.R. § 1.720. Instead, the basic requirements for patent term extensions are: (a) "[t]he patent claims a product or a method of using or manufacturing a product" as defined; (b) "[t]he term of the patent has never been previously extended"; (c) a compliant application has been submitted; (d) "[t]he product has been subject to a regulatory review period . . . before its commercial marketing or use"; (e) "[t]he product has received permission for commercial marketing or use . . ."; (f) the application is submitted within sixty days of the grant of permission; (g) the application is submitted before the term of the patent expires; and (h) "[n]o other patent term has been extended for the same regulatory review period for the product." 37 C.F.R. § 1.720. There is simply no requirement concerning patent validity.

Conversely, a patent applicant's duty of disclosure before the PTO during prosecution is notably different. Rule 56 defines an applicant's duty to disclose as follows: "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be ***material to patentability*** as defined in this section." 37 C.F.R. § 1.56(a) (emphasis added).

This difference in language in the respective regulations was purposeful and consistent with the different purposes of the two proceedings. Under the Hatch-Waxman Act, patent term extensions were meant "to further encourage new drug research by restoring some of the patent term lost while drug products undergo testing and await FDA pre-market approval." *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 396 (Fed. Cir. 1990) (citing H.R. Rep. No. 98-857, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N.

2647, 2647-48). They were not intended as a vehicle to reopen prosecution on the merits, re-examine patent validity, or impose on a patentee an ongoing duty of disclosure of information material to ***patentability*** for an already issued patent.

The PTO's comments in promulgating its rules further support the different duty with respect to patent term extensions. The PTO recognized that "Congress expected that [a patent term extension] would be an administratively simple proceeding." Rules for Extension of Patent Term, 52 F.R. 9386, 9392 (Mar. 24, 1987). "Since 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, a final determination to refuse a patent term extension because of fraud or a violation of the duty of disclosure is expected to be rare." *Id.* As noted above, those representations do not include anything about patent validity or enforceability. Further, in response to a comment asking whether the duty of disclosure extends to prior art discovered since the issuance of the patent, the PTO simply restated the rule: "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.***" *Id.* (emphasis added). The plain language of the rule and the PTO's comments support the conclusion that the duty of disclosure for patent term extensions is limited to information relevant to the requirements of the extension—including whether the patent covers the "product" subject to the delay in regulatory approval (***i.e.***, requirement "(a)")—and does not include, as Teva suggests, a reexamination of patent validity.

In the only case to squarely address this issue, this Court concluded that a patentee's duty of disclosure during a patent term extension proceeding bears no

connection to a patent applicant's duty during prosecution: "we 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." *United Sweetener USA, Inc. v. Nutrasweet Co.*, 760 F. Supp. 400, 420 (D. Del. 1991) (granting motion to dismiss claim that alleged inequitable conduct during patent term extension proceedings would render patent unenforceable). Noting the presumption of validity of patents, the Court concluded that matters relevant to the original patent application are irrelevant to a petition for a patent term extension. *Id.* "[W]e cannot see that a patentee should have to challenge the validity of its own patent in seeking an extension under § 155." *Id.* Despite its clear applicability here, Teva would have the Court ignore *United Sweetener* on the basis it was decided in 1991 and not appealed. At best, all Teva can say is that it is not aware of any *Federal Circuit* decision adverse to its position. But so far as Plaintiffs are aware, the Court is free to follow its own prior decisions too.

B. Teva Fails to Assert Any Legal Support for Its Assertion That a Failure to Disclose Data Relating to Patentability During a Patent Term Extension Proceeding Amounts to Inequitable Conduct

Teva cannot cite any support for its assertion that alleged inequitable conduct before the PTO during prosecution is somehow relevant to entitlement to a patent term extension. As noted above, this Court, in one of the only decisions on the issue, has directly rejected Teva's contention. *See id.* Teva admits the lack of case law in direct support of its assertion. (Def.'s Mem. at 12.) Teva also admits that *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006) does not squarely address the issue. (Def.'s Mem. at 12.) As a result, Teva resorts to a misplaced attempt to contort the holding of *Pfizer* to create a basis for its position.

First, the main issue in *Pfizer* with respect to the patent term extension was whether the patent in fact covered the product, Lipitor® (*i.e.*, requirement "(a)"). *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 405 F. Supp. 2d 495, 511 (D. Del. 2005), *rev'd in part on other grounds*, 457 F.3d 1284. The first requirement for a patent term extension is that "[t]he patent claims a product or a method of using or manufacturing a product." 37 C.F.R. § 1.720(a). This is not an issue here because Teva admits that the '098 patent covers lansoprazole, the active ingredient in PREVACID®. Second, in *Pfizer*, the defendant argued that the patent term extension was invalid because during the extension proceeding, Pfizer failed to disclose statements made in connection with the prosecution of foreign counterparts and a subsequent U.S. patent. *Pfizer*, 405 F. Supp. 2d at 512. These statements allegedly related to the ***construction of the claims*** of the extended patent, and therefore to requirement "(a)." The Court evaluated Pfizer's statements in its claim construction but found them irrelevant. *Id.* at 506; 457 F.3d at 1291 (affirming the district court's finding). Thus, they were not material to Pfizer's entitlement to a patent term extension. *Pfizer*, 405 F. Supp. 2d. at 512; 457 F.3d at 1291. Here, any subsequent test data allegedly relates only to ***patentability*** are, *a fortiori*, completely irrelevant to Takeda's entitlement to a patent term extension.[1]

[1] In addition to being futile, Teva's proposed amendment will cause undue delay and prejudice. Pursuant to the Court's Scheduling Order of March 21, 2006, the close of fact discovery is April 12, 2007. (D.I. 26 at ¶ 2(b).) With the close of fact discovery less than three weeks away, Teva seeks to add alleged inequitable conduct during the '098 patent term extension, an issue it first raised with the Court seven months ago during the September 20, 2006 discovery conference. As of that date, Teva was aware of the facts on which it based its proposed claim regarding the patent term extension. Nevertheless, it waited seven months before moving to amend. By the time this motion is decided, fact discovery will be closed, and the parties will be in the midst of expert discovery. Reopening fact discovery would unduly delay expert discovery and delay the case from proceeding to trial.

CONCLUSION

For the foregoing reasons, Takeda and TAP respectfully submit that Teva's Motion for Leave to Amend Its Answer, Defenses, and Counterclaims to include a claim of inequitable conduct concerning the patent term extension of the '098 patent should be denied.

CONNOLLY BOVE LODGE & HUTZ LLP

April 6, 2007

By: /s/ Arthur G. Connolly, III

Arthur G. Connolly, III (#2667)
The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19801
(302) 658-9141
Attorneys for Plaintiffs
Takeda Pharmaceutical Company, Ltd. and
TAP Pharmaceutical Products, Inc.

Of Counsel:
Eric J. Lobenfeld
Tedd W. Van Buskirk
Arlene L. Chow
HOGAN & HARTSON L.L.P.
875 Third Avenue
New York, NY 10022
(212) 918-3000

Philippe Y. Riesen
HOGAN & HARTSON L.L.P.
Shinjuku Center Building, 46th Floor
25-1 Nishi-Shinjuku 1-chome
Shinjuku, Tokyo 163-0646
Japan
(81) 3-5908-0470

Attorneys for Plaintiff Takeda Pharmaceutical Company, Ltd.

William F. Cavanaugh, Jr.
Stuart E. Pollack
Chad J. Peterman
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorneys for Plaintiff TAP Pharmaceutical Products, Inc.

#531726v2

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 6, 2007, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and caused the foregoing document to be served upon the following counsel of record in the manner indicated:

VIA ELECTRONIC MAIL:
Karen L. Pascale, Esq.
Young Conaway Stargatt & Taylor LLP
The Brandywine Building
1000 West St., 17th Floor
Wilmington, DE 19899

VIA ELECTRONIC MAIL
John L. North, Esq.
Jeffrey J. Toney, Esq.
Jeffrey D. Blake
Sutherland Asbill & Brennan LLP
999 Peachtree Street
Atlanta, GA 30309-3996

/s/ Arthur G. Connolly, III
Arthur G. Connolly, III (#2667)