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

TEVA'S REPLY IN SUPPORT OF ITS MOTION FOR LEAVE TO AMEND ANSWER, DEFENSES, AND COUNTERCLAIMS TO ASSERT INEQUITABLE CONDUCT

Plaintiffs' opposition to Teva's motion rests on the misguided notion that a patentee's duty of disclosure in seeking a patent term extension applies only to information concerning the basic requirements set forth in 37 C.F.R. § 1.720. The PTO, Congress, and federal courts each have interpreted the duty more broadly. For instance, in promulgating its patent term extension rules, the PTO expressly stated that a patentee must disclose information relating to the validity of the patent:

> *Comment*: It has been suggested that § 1.740(a)(8) [which sets out some of the formal filing requirements for the extension petition] be modified by adding the requirement for a copy of any decision by a court of competent jurisdiction, which decision is adverse to the validity of the patent.
>
> *Reply*: This suggestion has not been adopted because *the patent owner or agent has a duty of disclosure under 37 C.F.R. § 1.765 which would reasonably include the obligation to bring such a decision to the attention of the Office.*

52 F.R. 9386, 9390 (March 24, 2987) (emphasis added).

The legislative history of the Hatch-Waxman Act also demonstrates that Congress anticipated that patentees seeking a patent term extension would be required to disclose any knowledge that their patent was not valid and enforceable. "The Committee expects that those requirements would subject the applicant to at least the same duty of disclosure, and the penalties and loss of rights for violation of the duty of disclosure, which governs all patent application proceedings before the Patents and Trademarks Office." H.R. Rep. No. 98-857 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2674.

Further, as discussed in Teva's motion, the Federal Circuit in *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006) examined the materiality of withheld information relating to claim construction. *See* 3/23/07 Motion (D.I. 104), at p. 12. Plaintiffs' analysis of *Pfizer* ignores the fact that the court could have stated that a petitioner for a patent term extension would only have to disclose information related to claim construction if that information affected whether the claim covers the drug being sold (as required by 37 C.F.R. § 1.720(a)), but it chose not to do so. The *Pfizer* court held only that the withheld information was not material because it did not affect the construction itself. *See* 457 F.3d at 1290. In other words, the *Pfizer* court declined to adopt Plaintiffs' narrow rule that information only has to be disclosed if it relates to a specific requirement of 37 C.F.R. § 1.720.

Despite the positions of the PTO, Congress and courts, Plaintiffs attempt to rewrite 37 C.F.R. § 1.765(a) from a duty to disclose "material information adverse to **a determination of entitlement to the extension sought**" to a duty to disclose "material information adverse to **the requirements of 37 C.F.R. § 1.720**". This is improper. The PTO had the opportunity to define the duty of disclosure in section 1.765(a) as it saw fit, and it chose not to craft the duty as narrowly as the Plaintiffs. The reason for this is quite simple. The patent term extension process

is *ex parte*, and the PTO must rely on a heightened duty of disclosure to ensure that parties disclose **all** information that affects a patentee's entitlement to a patent term extension.

Taking the allegations pled in Teva's proposed twelfth affirmative defense and thirteenth counterclaim as true, which the Court should do in considering a motion for leave to amend, Teva has set forth a factual issue as to whether Takeda violated its duty of disclosure in seeking the patent term extension on the '098 patent. See *CC Investors Corp. v. Raytheon Co.*, 74 U.S.P.Q.2d 1152, 1156 (D. Del. 2005) ("Under this standard, leave to add a counterclaim, 'should be denied only if it appears beyond doubt that the defendants can prove no set of fact supporting their claim that entitled them to relief.' In making this determination, the Court 'must accept as true the allegations in the complaint and all reasonable inferences that can be drawn therefrom.'") (internal citations omitted). During prosecution, Takeda represented that the effectiveness of the claimed compound exhibited superior anti-ulcer activity up to and exceeding 20 times better than the prior art. Despite becoming aware of test results contradicting its asserted basis for patentability, Takeda failed to disclose them to the PTO.[1] *See* 3/23/07 Motion (D.I. 104), at pp. 5-7.

This information, uncovered by Teva during discovery, demonstrates Plaintiffs' knowledge that the '098 patent is invalid or was obtained through inequitable conduct; thereby creating an issue of fact concerning the propriety of the patent term extension that would

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[1] Plaintiffs' statement that "Had [the examiner] 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" is incorrect. *See* 4/6/07 Opposition (D.I. 107), at p. 4. Examiners enjoy discretion in deciding whether to include their reasons for allowing a patent to issue and are not required to identify on which statements they relied in allowing an application. 37 C.F.R. § 1.104. As such, why the examiner allowed the application and the information the examiner relied upon in doing so remain questions of fact. *See Miller Products Co., Inc. v. Velteck Assocs., Inc.*, No. 01-35-KAJ, 2003 U.S. Dist. LEXIS 18673, at *15, n.9 (D. Del. Oct. 9, 2003).

withstand a motion to dismiss. Indeed, the existence of a factual issue is demonstrated by Plaintiffs' efforts in their opposition to explain why only test results from the indomethacin-induced gastric antral ulcer model were submitted to the PTO. *See* 4/6/07 Opposition (D.I. 107), at p. 4. Teva thus seeks to add its unenforceability claim relating to the patent term extension to this action and have the opportunity to prove that claim at trial.

Plaintiffs' claims of undue delay and prejudice ring hollow. Teva suspected Takeda's improper activities early in this case. Rather than basing claims on suspicions, Teva sought discovery and asserted its claims now that it has the facts to support detailed allegations. Those facts, such as the alleged reason for submitting only indomethacin-induced gastric antral ulcer model data, were uniquely within the possession of Takeda. Now that they have come out, Plaintiffs will not need additional fact discovery. Tellingly, Plaintiffs failed to identify for the Court any discovery that would be necessary for Plaintiffs to respond to this defense and counterclaim. Indeed, if the addition of an inequitable conduct defense on these facts would prejudice Plaintiffs, it begs the question why did Plaintiffs consent to the addition of Teva's defenses and counterclaims relating to the inequitable conduct that occurred during the prosecution of the '098 patent. The straight-forward answer to that question is that no additional discovery is needed and no prejudice exists.

For the foregoing reasons, Teva respectfully submits that its Motion for Leave to Amend its Answer, Defenses and Counterclaims should be granted.

April 13, 2007

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on April 13, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on April 13, 2007, I caused a copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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