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REPLY TO Wilmington Office

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The Honorable Sue L. Robinson
United States District Court
844 King Street
Wilmington, DE 19801

Re: *Takeda Pharmaceutical Co. Ltd. and TAP Pharmaceutical Products Inc. v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, C.A. No. 06-33-SLR

Dear Chief Judge Robinson:

We represent Plaintiffs Takeda Pharmaceutical Co. Ltd ("Takeda") and TAP Pharmaceutical Products Inc. ("TAP") in the above-referenced action. We respectfully submit this letter in response to Defendants Teva Pharmaceuticals USA, Inc.'s and Teva Pharmaceutical Industries, Ltd.'s (collectively "Teva") letter dated November 9, 2006. This letter responds to Part A of Teva's letter regarding Teva's Request Nos. 10, 11, 15-19 and 38-39. TAP and Teva are further discussing the issues raised in Part B of Teva's letter. Therefore, we do not address that portion of Teva's letter and ask the Court to allow the parties to resolve these issues.

As an initial matter, Plaintiffs stress that Teva's inquiry focuses on the '098 patent directed to the compound lansoprazole per se, the active pharmaceutical ingredient in Prevacid®. That patent issued on December 9, 1986, while the last of the asserted formulation patents issued on July 18, 1995. Thus, Plaintiffs have already produced R&D documents relating to lansoprazole dating more than eight and a half years after issuance of the '098 patent. But Plaintiffs have quite reasonably drawn the line at July 18, 1995.

In its quest for a theory of obviousness, Teva is engaged in a fishing expedition seeking to obtain every R&D document, including all tests, data and analyses carried out by Takeda -- regardless of when they were created. That is simply unreasonable. Just as post-grant testing and data have no bearing on Takeda's entitlement to a patent term extension as explained below, they are similarly irrelevant to any issue raised by Teva. Obviousness is measured *at the time the invention was made* -- not two decades after the fact as Teva would have it.

Teva is similarly mistaken in its interpretation of the duty of disclosure with respect to patent term extension proceedings. Teva asserts that "information that called into question the validity of the '098 Patent" would be relevant to the patent term extension proceeding. But the plain language of the PTO's rule states that the 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 duty of disclosure does not, as Teva argues, extend to information regarding post-grant testing. *See* 35 U.S.C. § 156 (2000) (stating the requirements for a patent term extension); 37 C.F.R. § 1.710, 1.720 (same).[1]

Teva conflates a patent *applicant's* duty to disclose information material to patentability with a *patentee's* duty of disclosure of information material to a determination of entitlement to the term extension sought. Under Hatch-Waxman, patent term extensions were meant as a reasonable means for pharmaceutical patentees to restore some of the patent term lost to the FDA approval process. Extensions were not designed 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. That is evident from the different language used by the PTO in its respective regulations. Rule 56 defines a patent applicant's duty of disclosure 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). But for patent term extensions, the PTO limited the duty of disclosure to "material information adverse to a determination of *entitlement to the extension sought* . . . ." 37 C.F.R. § 1.765(a) (emphasis added). This difference in standards is meaningful and consistent with the general purpose of patent term restoration: "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).

The PTO's comments in connection with its rulemaking also support this different duty for patent term extensions. The PTO noted that "Congress expected that it would be an administratively simple proceeding," and "[s]ince the determination as to whether a patent is

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[1] The basic requirements for a patent term extension 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 no requirement concerning patent validity.

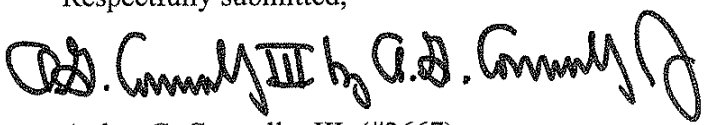
eligible for extension . . . may be made solely on the basis of the representations made in the application for extension, a final determination to refuse a patent term extension because of fraud or a violation of the duty of disclosure is expected to be rare." Rules for Extension of Patent Term, 52 F.R. 9386, 9392 (Mar. 24, 1987). Further, in answering a comment of whether the duty of disclosure extends to prior art discovered since the issuance of the patent, the Office simply reiterated 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, and does not include, as Teva suggests, a reexamination of patent validity.

Teva's reliance on *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 405 F. Supp. 2d 495 (D. Del. 2005), *rev'd in part on other grounds*, 457 F.3d 1284 (Fed. Cir. 2006) is also misplaced. First, the main issue with respect to the patent term extension in *Pfizer* was whether the patent-at-issue in fact covered the product, Lipitor®. *Id.* at 511. Here, Teva admits that the extended '098 patent covers lansoprazole, the active ingredient in Prevacid®. Second, Ranbaxy argued that the patent term extension was invalid because during the term extension proceeding, Pfizer failed to disclose statements made in connection with the prosecution of foreign counterparts and a subsequent U.S. patent. *Id.* at 512. These statements allegedly related to *construction of the claims* of the extended patent. The Court evaluated these statements in its claim construction and found them to be irrelevant to the patent's scope. *Id.* at 506. Thus, they were similarly irrelevant to Pfizer's entitlement to a patent term extension. *Id.* at 512. Here, subsequent test data allegedly relating to *patentability* are, *a fortiori*, irrelevant to a Takeda's entitlement to a patent term extension.

On a separate note, we write in response to Your Honor's request at the teleconference today with respect to Plaintiffs' discovery of Teva's Board of Directors meeting minutes. (Doc. Req. No. 34.) We believe that these notes may shed light on Teva's decision to file ANDA 77-255 and its Paragraph IV certification that, in Teva's opinion, the patents-in-suit are invalid, unenforceable or will not be infringed by Teva's proposed lansoprazole product. Accordingly, these materials squarely pertain to Plaintiffs' allegations that (1) Teva acted "without a reasonable basis for a good faith belief that it would not be liable for infringing" the patents-in-suit and (2) Teva's disregard of its duty to exercise due care by making baseless assertions of invalidity. Plaintiffs are not seeking wholesale production of such minutes, only those portions concerning the ANDA and other issues involved in this case.

Thank you for your consideration.

Respectfully submitted,



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