IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY, LIMITED and TAP PHARMACEUTICAL PRODUCTS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 06-33 (SLR)
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

PLAINTIFFS' MOTION FOR CLARIFICATION OF FINAL JUDGMENT ORDER

PRELIMINARY STATEMENT

The Prevacid® capsule and Prevacid® SoluTab™ products are Takeda's best-selling products, with over $2 billion in combined U.S. annual sales. This Court has enjoined Teva from marketing products containing lansoprazole (the active ingredient in all Prevacid® products) until expiration of the ′098 basic compound patent and its pediatric exclusivity. (Final Judgment Order, D.I. 186, ¶ 5.) Teva is presently offering its customers its generic Prevacid® capsule and SoluTab™ products for sale starting on November 10, 2009. But Teva's planned launch on November 10, 2009 is one day too early; that date violates the Court's Final Judgment Order, as well as the clear dictates of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Instead, Teva's earliest possible launch should be on November 11, 2009.

As is evident from the combined annual sales figures for the Prevacid® capsule and SoluTab™ products, premature market entry of Teva's products—even by one day—bears significant financial ramifications for Plaintiffs. Accordingly, in order to ensure Teva's compliance with the Court's Final Judgment Order, Plaintiffs respectfully seek a revised Final

Judgment Order that expressly sets forth November 11, 2009 as the earliest possible date that Teva may obtain FDA approval – in essence, market entry for its generic lansoprazole products.

NATURE AND STAGE OF THE PROCEEDINGS

Patent owner Takeda and former exclusive licensee TAP[1] (collectively, "Plaintiffs") brought this lawsuit under the Hatch-Waxman Act, alleging that Teva's Abbreviated New Drug Application ("ANDA") No. 77-255 for generic Prevacid® capsules, 15 and 30 mg, infringes U.S. Patent No. 4,628,098 ("′098 patent) and 5,045,321 ("′321 patent"). Teva conceded infringement of the ′098 Patent. This case was tried to the Court from October 29 through November 6, 2007 on the issue of infringement of the ′321 patent, and Teva's challenges based on obviousness (as to the ′098 and ′321 Patents) and inequitable conduct (as to the ′098 Patent).[2] On March 31, 2008, the Court issued its Memorandum Opinion, finding the ′098 patent valid and enforceable and the ′321 patent not infringed but valid. (D.I. 182) On April 15, 2008, the Court issued a Final Judgment Order. (D.I. 186) The Final Judgment Order states in paragraph 5: "Pursuant to 35 U.S.C. § 271(e)(4)A), the effective date of any Food and Drug Administration approval of Teva's ANDA 77-255 [with respect to Prevacid® capsule] and ANDA No. 78-730 [with respect to Prevacid® SoluTab™] shall be no earlier than the date of expiration of claim 10 of the ′098 patent and any pediatric exclusivity that applies to the ′098 patent, if applicable."

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1 TAP no longer exists. Takeda Pharmaceuticals North America, Inc, Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. currently hold all of the exclusive U.S. rights in the ′098 patent.

2 In a related case (C.A. No. 07-331-SLR) tried to the Court earlier this year, Plaintiffs also brought a lawsuit under the Hatch-Waxman Act, alleging that Teva's ANDA No. 78-230 for generic Prevacid® SoluTab™, 15 and 30 mg, infringes U.S. Patent No. 5,464,632. The outcome of that case remains before the Court.

STATEMENT OF FACTS

Takeda owns the ′098 patent. That patent, covering the basic compound lansoprazole present in Plaintiffs' Prevacid® capsule and SoluTab™ products, expired on May 10, 2009. At the time that the Court entered its Final Judgment Order in April of 2008, Plaintiffs' submission to the FDA for pediatric exclusivity was still pending. Subsequent to the issuance of the Court's Final Judgment Order, the FDA granted pediatric exclusivity in July of 2008, thereby extending Plaintiffs' market exclusivity for an additional 6 months beyond the ′098 patent expiration. Accordingly, the FDA's Orange Book (that captures the relevant dates the FDA works off of in determining when it may approve an ANDA application) shows the ′098 patent's expiration as May 10, 2009 and expiration of the ′098 patent's pediatric exclusivity as November 10, 2009. Teva is presently offering its customers its generic Prevacid® capsule and SoluTab™ products for sale starting on November 10, 2009.[3] In short, Teva is offering its generic Prevacid® products one day too early.

ARGUMENT

Plaintiffs respectfully seek clarification of the Court's Final Judgment Order so that it expressly refers to November 11, 2009 as the earliest possible date that Teva may obtain FDA approval for commercial release of its generic lansoprazole products. Teva's present, planned launch date of November 10, 2009 is improper and violates the FDCA.

The FDCA determines precisely when the FDA may permit a generic's market entry.

[3] Plaintiffs have attempted, without success, to seek clarification from Teva's counsel with respect to Teva's intended launch date. *See* Exhibits A and B. Indeed, Teva's present refusal to directly respond to Plaintiffs' inquiries is consistent with its actions earlier this month with respect to C.A. No. 07-331-SLR, Plaintiffs' infringement case against Teva involving the ′632 patent's orally-disintegrating tablet technology and generic Prevacid® SoluTab™. At that time, Plaintiffs asked Teva to confirm that it would not launch at risk in the event of an infringement decision adverse to Teva; Teva did not meaningfully respond.

The FDCA states that "the period during which an [ANDA] application ***may not*** be approved . . . shall be extended by a period of six months ***after the date*** the patent expires (including any patent extensions)." 21 U.S.C. § 355a(b)(1)(B)(i)(II) (emphasis added). Significantly, the FDCA is couched in the negative. The FDA may not approve an ANDA application until ***after the date*** of expiration of the patent and any patent extensions, *i.e.* until ***the day after*** expiration of the patent extension. Stated differently, the Orange Book captures the time period for which the FDA is barred from approving an ANDA; that period runs up to and through the date of expiration of the patent extension, in this instance, November 10, 2009.

Indeed, Teva is well aware of the FDA's practice in this regard. By way of example, with respect to Teva's generic risperidone product, U.S. Patent No. 4,804,663 expired on December 29, 2007. Pediatric exclusivity extended the term of that patent until June 29, 2008. The FDA issued an approval letter granting Teva permission to market its generic on June 30, 2008, the day after the expiration of the pediatric exclusivity for U.S. Patent No. 4,804,663. *See* Exhibit C, attached hereto.

In sum, because the ′098 patent's extension expires on November 10, 2009, the plain language of the FDCA means that the FDA may not approve Teva's ANDA until ***after*** November 10, 2009. November 11, 2009 is the earliest date that Teva may obtain FDA approval for its generic lansoprazole products; that date is the earliest date that Teva may launch its generic Prevacid® products.

Accordingly, in order to ensure that Teva complies with the Court's Final Judgment Order, Plaintiffs respectfully request a revision of paragraph 5 **from:**

> Pursuant to 35 U.S.C. § 271(e)(4)A), the effective date of any Food and Drug Administration approval of Teva's ANDA 77-255 and ANDA No. 78-730 shall be no earlier than the date of expiration of claim 10 of the ′098 patent and any pediatric exclusivity that applies to the ′098 patent, if applicable.

to:

> Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any Food and Drug Administration approval of Teva's ANDA No. 77-255 and ANDA No. 78-730 shall be no earlier than ***November 11, 2009***, the date ***after*** expiration of claim 10 of the ′098 patent and the pediatric exclusivity that applies to the ′098 patent.

See Plaintiffs' Proposed Revised Final Judgment Order, attached hereto as Exhibit D (emphasis added).

Plaintiffs submit that resolution of this discrete issue now—with such tremendous financial ramifications at stake—ultimately promotes judicial economy compared to prolonged, burdensome motion proceedings that would attempt to rectify, after-the-fact, damage due to Teva's premature launch. Determination and resolution of the amount of damages due to Teva's one day head-start would require the Court to engage in complex economic analysis. In short, resolution of this motion before November 10, 2009 ultimately saves time for the Court.

CONCLUSION

For the reasons discussed above, Plaintiffs hereby move the Court for an Order (in the form attached as Exhibit D) revising the Final Judgment Order (D.I. 186) to expressly set forth November 11, 2009 as the earliest possible date that Teva may obtain FDA approval – in essence, market entry for its generic lansoprazole Prevacid® products.

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October 29, 2009
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CERTIFICATE OF SERVICE

I hereby certify that on October 29, 2009, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on October 29, 2009 upon the following individuals in the manner indicated:

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