IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM ORDER

At Wilmington this 9th day of November, 2009, having reviewed the parties' submissions regarding plaintiffs' request for clarification (D.I. 191) with respect to the court's Final Judgment Order (D.I. 186), and having conducted an emergency hearing in connection with said request;

IT IS ORDERED that the effective date of any Food and Drug Administrative approval of defendants' ANDA No. 77-255 and ANDA No. 78-730 shall be no earlier than November 11, 2009, for the reasons that follow:

1. Background. Plaintiff Takeda Pharmaceutical Company Ltd. ("Takeda") is the owner of U.S. Patent No. 4,628,098 ("the '098 patent").[1] The '098 patent expired on May 10, 2009; however, the Food and Drug Administration ("the FDA") granted an additional six months of pediatric exclusivity, extending Takeda's market exclusivity

[1]Plaintiff TAP Pharmaceutical Products Inc., the previous owner of the '098 patent, no longer exists. Takeda currently holds all of the exclusive U.S. rights in the '098 patent.

through November 10, 2009. The '098 patent is directed to lansoprazole, a compound within the family of proton pump inhibitors. The Orange Book of the FDA lists the '098 patent in connection with Prevacid®, proprietary to Takeda. Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva") filed ANDA No. 77-255 and ANDA No. 78-730 ("the ANDAs") with the FDA, seeking approval to market generic versions of Prevacid® ("the ANDA products"). In its ANDAs, Teva conceded infringement of the '098 patent, but challenged the patent on grounds of invalidity and enforceability.

2. Upon notification of the ANDAs, Takeda brought a patent infringement suit against Teva pursuant to the Hatch-Waxman Act, alleging infringement of, inter alia, the '098 patent. On March 28, 2008, the court concluded that the '098 patent was valid and enforceable. (D.I. 182) The court's Final Judgment Order states, in relevant part, "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." (D.I. 186 at ¶ 5)

3. Takeda's request for clarification. Takeda contends that Teva plans to introduce the ANDA products on November 10, 2009. Takeda argues that this action would be in contravention of the court's Final Judgment Order, because the pediatric exclusivity period of the '098 patent does not lapse until November 11, 2009, i.e., after the final day of exclusivity on November 10, 2009. In response, Teva relies upon

several cases that have purportedly recognized a generic manufacturer's ability to commence marketing on the date that the pediatric exclusivity period expires.

4. Legal Standard and Analysis. The "precise question at issue"[2] here is whether Takeda's 6-month period of pediatric exclusivity for Prevacid® "overlaps" with the 180-day marketing exclusivity period to which Teva is entitled pursuant to 21 U.S.C. § 355(j)(5)(B)(iv) and, if so, which of these parties gets the benefit of the single day of overlap.

a. The statute itself is informative:

> If a 180-day period under section 355(j)(5)(B)(iv) of this title overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 355(j) of this title entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended . . . .

21 U.S.C. § 355a(m). In other words, Teva apparently suffers no prejudice if I resolve the question in favor of Takeda.[3]

b. The question remains whether the date of expiration of Takeda's pediatric exclusivity is the date Teva can launch its generic product. Because the Federal Circuit has not addressed this question precisely, I have looked to analogous situations. Under the Federal Rules of Civil Procedure, for example, certainly a party does not lose its right to file a paper on the last day allowed for such a filing. In our

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[2]*Hi-Tech Pharmacal Co., Inc. v. United States FDA*, 587 F. Supp. 2d 13, 20 (D.D.C. 2008).

[3]Takeda, on the other hand, alleges that its revenue for Prevacid®, which generates $2 billion annually in the United States alone, would be substantially diminished by allowing Teva entry to the market even one day too early.

everyday lives, products are not taken from the grocery shelves on their expiration date, and we can still drive to the DMV on the expiration date of our car registration or of our drivers' license. So why should the situation at bar be any different, particularly since Teva is protected by statute?

c. Teva has directed the court to the ambiguous language from a handful of cases to arrive at its inconsistent answer. Starting with the Federal Circuit case, *Janssen Pharmaceutica, N.V. v. Apotex, Inc.,* 540 F.3d 1353 (Fed. Cir. 2008), the question before the Federal Circuit was not the date when the first ANDA filer (Teva) could commercially launch its generic product (described by the Court in a footnote as the expiration date of the pediatric exclusivity period),[4] because Teva did not yet have FDA approval, but whether another generic manufacturer (Apotex) could launch before the expiration of Teva's 180-exclusivity period. In describing the latter date, the Court explained that "the earliest Apotex will be able to enter the market is **181** days after the expiration of the '663 patent." *Id.* at 1360 (emphasis added).

d. The district court in *Hi-Tech Pharmacal Co., Inc. v. United States FDA*, 587 F. Supp. 2d at 14, was asked to review the FDA's determination that Hi-Tech had forfeited its 180-day period of marketing exclusivity. Although the district court itself stated that the patentee's "six-month period of pediatric exclusivity . . . ran from April 28, 2008 **through** October 28, 2008," *id.* at 20 (emphasis added), it related (without analysis) that the "FDA [had] indicated that, at the earliest, it would take final action with respect to these issues on October 28, 2008 - the first day that generic COSOPT could

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[4]540 F.3d at 1362 n.7.

possibly be marketed." *Id.* at 15. Indeed, in earlier filed opinions in related cases, the courts discuss expiration dates without analysis and, frankly, without consequence because the dates are not really at issue. *See, e.g., Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1320 (Fed. Cir. 2007); *and Hi-Tech I*, 587 F. Supp. 2d 1, 6 (D.D.C. 2008).

e. In sum, the language upon which Teva relies emerges from a series of related cases, none of which address the precise question at issue. Given the lack of a precise ruling on the issue, and consistent with a common sense approach to the issue, I conclude the following: (1) there should be no overlap between the expiration of a patent's exclusivity period and the commencement of a generic's period of marketing exclusivity; and (2) Takeda should continue to get the benefit of its exclusive rights until the day after the patent and its related period of exclusivity expires.

5. Clarification. Accordingly, the court clarifies that, by its Final Judgment Order (D.I. 186), November 11, 2009 is the earliest effective date upon which Teva may launch its commercial generic product.

United States District Judge