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**DOCKET NO. 2007N-0389**

**COMMENTS REGARDING 180-DAY GENERIC DRUG EXCLUSIVITY FOR GRANISETRON HYDROCHLORIDE INJECTION**

Sun Pharmaceutical Industries, Ltd. ("Sun"), by counsel, submits the following comments in response to Gary J. Buehler's letter dated October 11, 2007, which established Docket No. 2007N-0389 for comments regarding 180-day generic drug exclusivity for granisetron hydrochloride injection.

## I. Introduction

On June 1, 2004, Teva Parenteral Medicines ("Teva") filed ANDA No. 77-165 for its generic granisetron hydrochloride injection drug product. This ANDA contained a "paragraph III" certification to the earliest-expiring granisetron patent (the '808 patent), a "section viii" method-of-use certification to the next-expiring patent (the '340 patent) and a "paragraph IV" certification to the latest-expiring patent (the '548 patent). To date, the patentee, Hoffmann-La Roche Inc. ("Roche"), has not initiated a patent infringement action against Teva. Nor has Teva filed a declaratory judgment action seeking patent certainty. Teva received tentative approval on August 6, 2005, and it anticipates receiving final approval on December 29, 2007, when the '808 patent expires. At the moment, therefore, Teva has no legal authority to launch its generic product.

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By letter to the FDA dated September 28, 2007, Teva asked for confirmation that it is entitled to 180-day exclusivity for its generic granisetron hydrochloride injection drug product. It appears that Teva is concerned that the FDA might conclude that such exclusivity has been forfeited because Teva was not able to market its product within 30 months of the ANDA filing. According to Teva, however, a plain reading of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003), does not support a finding of an exclusivity forfeiture under these circumstances.

Sun supports Teva's position. As demonstrated below, Teva has not forfeited its 180-day exclusivity under the MMA, nor will Teva forfeit such exclusivity if it immediately markets its drug product once the FDA approves Teva's ANDA.

## II. The MMA Prevents Generics From Parking Their Right To Exclusivity Through A "Failure To Market"

Congress passed the Hatch-Waxman Act of 1984 to promote innovation and competition in the pharmaceutical industry. This Act "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990).

To encourage early ANDA applicants, the Hatch-Waxman amendments provide for a 180-day marketing exclusivity period for the first ANDA applicant to make a successful paragraph IV certification. *See Mylan v. Pharms. v. Merck Co.*, 2005 WL 2850137, at *1-2 (M.D. Pa. Oct. 28, 2005). The first generic applicant qualifies for the 180-day exclusivity period even where the patentee elects not to sue the ANDA applicant for patent infringement based on the paragraph IV certification. *Inwood Labs. v. Young*, 723 F. Supp. 1523, 1526 (D.D.C. 1989).

Over time, Congress became concerned that ANDA applicants with 180-day exclusivity were intentionally delaying entry into the market by "parking" their exclusivity—*i.e.*, by not marketing their generic drug products immediately upon receiving a favorable litigation outcome concerning the challenged patents and final approval from the FDA.[1] When an ANDA applicant with market exclusivity intentionally delays its launch of a generic drug product, this

[1] *See, e.g., Patent Challenge Provisions of the Medicare Reform Bill*, S. Cong. Rec., S16105 (December 8, 2003) (statement by Sen. Orrin Hatch); Press Release of Sen. Gregg (June 5, 2003), at http://lists.essential.org/pipermail/ip-health/2003-June/004871.html; *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace, Before the S. Comm. in the Judiciary*, 108th Cong. 5 (June 17, 2003) (statement by Hon. Timothy Muris, FTC Chairman); Senate Cong. Rec. S8190, (June 19, 2003) (statement of Sen. McCain); *Examining the Senate & House Versions of the "Greater Access to Affordable Pharmaceuticals Act," Before the S. Comm. on the Judiciary,* 108th Cong. 4, 21-22 (Aug. 1, 2003) (statements of FTC Chairman Timothy Muris and Sen. Orrin Hatch).

action necessary postpones consumer savings resulting from generic drug competition. Accordingly, in 2003, Congress provided in the MMA a provision requiring forfeiture of exclusivity when market entry is unduly delayed or "parked."

Under the MMA, "[t]he 180-day exclusivity period . . . shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant." 21 U.S.C. § 355(j)(5)(D)(ii). The statute defines six possible "forfeiture events." The forfeiture event at issue here is a "failure to market." The pertinent statutory language is as follows:

> (I) *Failure* to market
>
> The first applicant *fails* to market the drug *by the later of*--
>
> (aa) the earlier of the date that is--
>
> > (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
> >
> > (BB) 30 months after the date of submission of the application of the first applicant; or
>
> (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), *at least 1 of the following has occurred*:
>
> > (AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
> >
> > (BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

> (CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

21 U.S.C. § 355(j)(5)(D)(i)(I) (emphasis added). The general intent of this forfeiture provision was to encourage generic companies to launch immediately (*e.g.*, within 75 days) upon receiving final approval, or a favorable patent litigation outcome—whichever occurs later.[2]

## III. Teva Has Not Forfeited Its 180-Day Exclusivity

A plain reading of the MMA demonstrates that Teva has not yet forfeited its 180-day exclusivity. The MMA sets forth a three-step analysis to determine the "failure to market" forfeiture date:

- First, the FDA must ascertain the date resulting from application of subsection (aa).
- Second, the FDA must ascertain the date resulting from application of subsection (bb).
- Finally, the FDA must compare these two dates, and the "later" date is the date by which the ANDA applicant must market its generic drug product to avoid forfeiture.

As Teva correctly explains in its submission, the FDA cannot even determine the "failure to market" forfeiture date at this point in time, let alone find that this date already has passed.

According to Teva, the pertinent date under subsection (aa) is November 28, 2006—*i.e.*, 30 months after Teva filed its ANDA. Again, however, this date has no force or effect with regard to exclusivity forfeiture unless it is "later" than the date resulting from application of subsection (bb).

The FDA cannot ascertain the date resulting from application of subsection (bb) until "*at least 1* of the [three events discussed in that subsection] has occurred." These three events include: (1) a final decision by a court that the patent is invalid or not infringed; (2) a signed court settlement order or consent decree that enters final judgment that includes a finding that the patent is invalid or not infringed; or (3) the patent information is withdrawn by the holder of the application. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

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[2] *See, e.g., Patent Challenge Provisions of the Medicare Reform Bill*, S. C. R., S16105 (December 8, 2003) (statement of Sen. Orrin Hatch); Press Release of Sen. Gregg (June 5, 2003), at http://lists.essential.org/pipermail/ip-health/2003-June/004871.html.

As Teva correctly explains in its submission, *none* of these three events has occurred. Teva's ANDA has not yet resulted in related patent litigation, and Roche has not withdrawn any of the patent information it submitted in connection with its NDA. Consequently, the FDA cannot yet find that the subsection (aa) date of November 28, 2006 date is "later" than the date resulting from application of subsection (bb). Put simply, there currently is no "failure to market" forfeiture date pertaining to Teva's ANDA.

The FDA has no authority to ignore the phrase "the later of" and read the MMA as requiring an exclusivity forfeiture based solely on the subsection (aa) date where, as here, the paragraph IV certification has not yet resulted in litigation. *See, e.g., Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (repeating the well-established principle of statutory construction requiring statutes to "be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant"). Under a plain reading of the statute, there can be no exclusivity forfeiture based on a "failure to market" until "at least 1" of the three events listed in subsection (bb) actually occurs. Further, as discussed below, a "failure to market" cannot be deemed to have occurred until the generic applicant had the ability and freedom to market its generic drug product.

## IV. Teva Will Not Have Failed To Market Its Generic Drug Product If It Launches That Product Immediately Upon Receiving Final Approval

Sun recognizes that the MMA does not directly address when an ANDA applicant forfeits its exclusivity if the paragraph IV certification does not result in litigation and the NDA applicant has not withdrawn its submitted patent information. And perhaps Congress needs to revisit this statutory language to address this type of situation. Nevertheless, the FDA should have no concerns from a public policy perspective about confirming an ANDA applicant's 180-day exclusivity if the ANDA applicant follows through with its representation to market its generic drug product immediately upon receiving final approval of its ANDA.

Teva would not run afoul of Congress' intent to prevent exclusivity "parking" if, as Teva represents, it markets its generic granisetron drug product immediately upon receiving final approval. In that situation, there would be no "*failure* to market" because Teva would have marketed its generic drug product as soon as it had the freedom and ability to do so, *i.e.*, when the '808 patent expires. 21 U.S.C. § 355(j)(5)(D)(i)(I) (emphasis added). Statutory terms are to be interpreted consistent with their natural and clear meaning given the context of the statute.[3] Black's Law Dictionary defines "failure" as: "An omission of an *expected* action, occurrence or performance." BLACK'S LAW DICTIONARY, 631 (8th ed. 2004) (emphasis added). One cannot expect an ANDA applicant to market its generic drug product until the drug product has been approved for marketing and the applicant is free from a patent preventing marketing. It logically

[3] *See, e.g., SEC v. Nat'l Sec., Inc.*, 393 U.S. 453, 466 (1968); *City of New York v. Beretta U.S.A. Corp.*, 401 F. Supp. 2d. 244, 264 (E.D.N.Y. 2005) ("the meaning of particular phrases must be determined in context," and "the canons of construction cannot be used to avoid plain meaning").

follows that an ANDA applicant cannot forfeit exclusivity by failing to market its generic drug product unless and until the applicant actually obtains the freedom and ability to market its product.

From a policy perspective, Teva certainly should not be deemed to have failed to market its ANDA product unless it delays marketing its generic granisetron drug product, thus "parking" its exclusivity, *after* receiving final approval and/or a license from Roche to go to market. Teva currently lacks the freedom and ability to market its generic granisetron drug product and, therefore, it should not be deemed to have forfeited exclusivity based on a *failure* to market. Otherwise, Teva would be punished for a failure beyond its control. Accordingly, it would make no sense to deem an immediate launch by Teva after final approval a "failure to market" exclusivity forfeiture event.

Moreover, Teva's approach of launching immediately upon final approval would be consistent with the policy underlying the Hatch-Waxman amendments of encouraging early entry of generic drugs. Teva's generic granisetron hydrochloride injection drug product would be brought to market nearly 12 years before the scheduled expiration of the '548 patent in May 2019, thus providing a substantial financial benefit to consumers. Significantly, this is not a situation in which an ANDA applicant with exclusivity intends to delay its market launch, or "park" its exclusivity, more than 75-days after receiving final approval. To find that Teva forfeited its 180-day exclusivity period simply because, to date, Roche has decided not to file suit for infringement of the '548 patent in response to Teva's paragraph IV certification would ignore the public policy of encouraging generic companies like Teva to challenge pharmaceutical patents and pave the way for early entry of low-cost generic drugs into the marketplace.

## V. Conclusion

For all of the following reasons, Teva should not be deemed to have failed to market its generic granisetron product, and should be entitled to 180-day exclusivity if it markets its product immediately after receiving final approval of its ANDA.

Respectfully submitted,

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cc: Charles B. Klein