IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC., AVANIR HOLDING COMPANY, AND CENTER FOR NEUROLOGIC STUDY, Plaintiffs, v. ACTAVIS SOUTH ATLANTIC LLC, ACTAVIS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., IMPAX LABORATORIES, INC., WOCKHARDT, LTD., WOCKHARDT USA, LLC, WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., AND WATSON PHARMA, INC., Defendants.	C.A. No. 11-704-LPS (CONSOLIDATED)

DEFENDANTS' BRIEF IN SUPPORT OF AN ORDER
TO DELIST U.S. PATENT NO. RE38,115

Pursuant to the April 30, 2014 Order (D.I. 489), as amended (D.I. 492, 494, 495), Defendants submit this brief requesting the Court to order Plaintiffs to delist U.S. Patent No. RE38,115 ("the '115 patent") from the Orange Book entry for Nuedexta®.

I. ISSUE PRESENTED

The Hatch-Waxman Act provides that a generic company is entitled to "an order requiring the [brand] to . . . delete the patent information" in the Orange Book if a listed patent does not claim "the drug for which the application was approved." 21 U.S.C. § 355(j)(5)(C)(ii)(I). Here, the Court ruled that the listed '115 patent does not claim Nuedexta. *See* D.I. 488 at 31-38; D.I. 489 at ¶ 6. Accordingly, Defendants are entitled to an order requiring Plaintiffs to delete the '115 patent from the Orange Book entry for Nuedexta.

II. FACTS

On September 6, 2011, Par filed an Answer with a counterclaim "seek[ing] an order that requires Plaintiffs to delete the '115 patent from the Orange Book entry for NUEDEXTA®, because the '115 patent fails to claim the drug NUEDEXTA® . . . ." D.I. 10 at 12 (C.A. No. 11-cv-705-LPS); *see also id.* at 14 (demanding same); D.I. 36 at 14-16 (C.A. No. 11-cv-757-LPS) (Impax's Answer). On April 30, 2014, the Court issued a Memorandum Opinion and Order ruling, among other things, that "Nuedexta® does not meet the 'therapeutically effective' limitation of the '115 patent." D.I. 488 at 31-38; D.I. 489 at ¶ 6. The Court also requested additional briefing on whether it "should grant Defendants' request to 'delist' the '115 patent . . . ." D.I. 489 at ¶ 6.

Plaintiffs and Defendants agree that the '115 patent must be delisted from the Orange Book entry for Nuedexta®. In fact, on May 16, 2014, Avanir unilaterally submitted a letter asking the FDA to delist the '115 patent. *See* FDA Letter (Ex. A). Before Avanir's letter, Defendants offered to resolve the counterclaim with a consent judgment. *See* Proposed Consent Judgment and Order (Ex. B). Plaintiffs, however, rejected Defendants' proposal, and sent a draft stipulation seeking a *quid pro quo*: dismissal of the delisting counterclaims in exchange for voluntarily delisting the '115 patent. *See* Proposed Stipulation and Order (Ex. C). During one of several meet-and-confers, Par's counsel explained that Plaintiffs' stipulation was unacceptable because the FDA may reject Plaintiffs' unilateral request to delist a patent that is the subject of a paragraph IV certification, like the '115 patent.

On May 19, 2014, Plaintiffs informed Par that Avanir asked the FDA to delist the '115 patent, and that Plaintiffs would proceed with the scheduled briefing. To minimize expenditure of judicial resources, Par proposed—and Plaintiffs rejected—a stay on the briefing until the FDA notifies Avanir whether the delisting request has been accepted.

At this juncture, an order should be entered to resolve the issue.

III. DISCUSSION

A. Legal Standards

The Hatch-Waxman Act provides a single method for delisting an Orange Book patent:

> If an owner of the patent or the holder of the approved application . . . for the drug that is claimed by the patent . . . brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to . . . delete the patent information submitted by the holder . . . on the ground that the patent does not claim either--
>
> (aa) the drug for which the application was approved . . . .

21 U.S.C. § 355(j)(5)(C)(ii)(I). After a government study on "anticompetitive practices" exposed "brands' submission of inaccurate patent information to the FDA," "Congress responded to these abuses by creating a mechanism, in the form of a legal counterclaim, for generic manufacturers to challenge patent information a brand has submitted to the FDA." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012) (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)). "According to the statute, a successful claimant may obtain an order requiring the brand to 'correct or delete' its patent information." *Id.* at 1684 (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)).

B. Avanir's unilateral delisting request is an empty gesture.

Without a court order, Defendants believe Avanir will not be able to delist the '115 patent.[1] The FDA will likely decline Avanir's unilateral request because there is no statutory

[1] This is confirmed by the Orange Book for Nuedexta, which indicates the FDA rejected Avanir's request to delist the '115 patent. The electronic Orange Book for Nuedexta currently shows that Avanir's delisting request has been received. *See* Orange Book (Ex. D) ("Y" under "Delist Requested" column). The "Y" means: "Sponsor has requested patent be delisted. ***This patent has remained listed*** because, under Section 505(j)(5)(D)(i) of the Act, a first applicant may retain eligibility for 180-day exclusivity based on a paragraph IV certification to this patent for a certain period." Orange Book Data Files (Ex. E) (emphasis added). Finally, the '115 patent is ***not*** in the list of delisted patents. *See* Delisted Patent List (updated "Daily") (Ex. F).

provision regarding delisting Orange Book patents without a counterclaim. In fact, recent case law indicates that the FDA may refuse to accept any such unilateral delisting requests for a patent after paragraph IV certification. *See Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) ("A potential bug in the system is the ability of the brand manufacturer, after a generic has filed a paragraph IV certification, to announce that in fact the challenged patent is not one that protects the drug at issue and to ask the FDA to 'delist' the patent, thus purporting to pull the rug from under the paragraph IV certification."). The *Teva* court ultimately ruled that it is improper for the FDA to grant a unilateral request to delist a patent after paragraph IV certification. *See id.* at 1318 (finding nothing "that changes the structure of the statute such that brand companies should be newly able to delist challenged patents"). Accordingly, the FDA will likely deny Avanir's unilateral request to delist the '115 patent without an accompanying order proving that the request was made pursuant to a successful delisting counterclaim, which provides the statutory keys for Avanir to delist the '115 patent.

The Federal Circuit recently required such an order to effectuate a generic's successful delisting counterclaim. On remand from the Supreme Court's *Caraco* case, the Federal Circuit agreed it needed to issue "an appropriate order granting relief under 21 U.S.C. § 355(j)(5)(C)(ii)(I) . . . ." *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 688 F.3d 766, 768 (Fed. Cir. 2012). And that is precisely what it did to ensure the brand complied:

> IT IS ORDERED THAT:
>
> Novo Nordisk is hereby directed by mandatory injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(I)(bb) to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the '358 patent by submitting to FDA an amended form FDA 3542 for Prandin that accurately describes the scope of claim 4 of the '358 patent in section 4.2b. The description shall be clearly limited to use of repaglinide in combination with metformin to treat non-insulin dependent diabetes mellitus.

Id. at 768-69. Here, Defendants request a similar order to ensure the '115 patent is in fact

delisted:

> IT IS ORDERED THAT:
>
> Avanir Pharmaceuticals, Inc. is hereby directed by mandatory injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(I)(aa) to correct within twenty (20) days from the date of this Order and Injunction its improper listing of the '115 patent by submitting to FDA a request enclosing this Order and Injunction to delete the '115 patent from the Orange Book entry for NUEDEXTA®.

C. Without an order, Plaintiffs can freely relist the '115 patent.

Without the order provided in the statute and requested by Defendants, Plaintiffs have no barrier against relisting the '115 patent if they can successfully delist it. Defendants cannot accept Plaintiffs' offer to moot their delisting counterclaims with a letter to the FDA that has not yet—and may never be—approved. Even if the FDA accepts the delisting request, nothing bars Plaintiffs from relisting the '115 patent at some point in the future. The Federal Circuit likely recognized this potential loophole, and closed it by issuing an Order and Injunction to ensure compliance with 21 U.S.C. § 355(j)(5)(C)(ii)(I). *See Novo Nordisk*, 688 F.3d at 768-69. Defendants ask for the same treatment here.

D. Avanir cannot object to an order compelling what it has agreed to do.

Avanir agrees that the '115 patent was improperly listed, and filed a voluntary request to delist it. *See* FDA Letter (Ex. A). If Plaintiffs have no issue with delisting the '115 patent, how could they object to an order requiring them to do the same thing? Assuming Avanir's FDA request is not an empty gesture, Defendants' requested order will require a simple resubmission. If, however, FDA declines to delist the '115 patent, Plaintiffs should welcome an order that allows them to accomplish what they were unable to do alone.

IV. CONCLUSION

For the reasons stated above, Defendants respectfully request an order requiring Plaintiffs to delete the '115 patent from the Orange Book entry for Nuedexta®.

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DATED: May 20, 2014