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August 14, 2014

The Honorable Leonard P. Stark
United States District Court
For the District of Delaware
822 North King Street
Wilmington, DE 19801

*VIA ELECTRONIC FILING*

Re: *Avanir Pharms., Inc., et al. v. Actavis South Atlantic LLC, et al.*, C.A. No. 11-704 (LPS) (Consolidated) (D. Del.)

Dear Chief Judge Stark:

Plaintiffs Avanir Pharmaceuticals, Inc., Avanir Holding Company and Center for Neurologic Study (collectively "Plaintiffs"), and Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. ("Par") jointly submit this letter in response to the Court's request for a joint status report addressing the status of Par's delisting counterclaim. (D.I. 514.) The parties are available for a status conference should the Court determine that such a conference would be helpful.

Plaintiffs' position:

In accordance with the Court's June 17, 2014 Order (D.I. 507), Avanir informed the FDA of this Court's request that the FDA provide its views relating to Par's pending delisting counterclaim and Avanir's pending request to delist the '115 patent from the Orange Book. To date, the FDA has not taken further action with respect to the '115 patent, which remains listed in the Orange Book with a notation that delisting has been requested.

Plaintiffs maintain that Par's delisting counterclaim should be dismissed as moot. Plaintiffs have already requested that the FDA delist the '115 patent from the Orange Book. *See* D.I. 497 at 3. This is the sole relief contemplated by the delisting statute that underlies Par's counterclaim. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). Indeed, Plaintiffs cannot do more to delist the '115 patent—nor does the statute require the FDA to do more. The parties have previously explained that the FDA cannot remove the '115 patent from the Orange Book due to Par's potential 180-day regulatory exclusivity as the first

ANDA filer on the '115 patent.[1] *See* D.I. 498 at 3-4; D.I. 500 at 2-3. Since Avanir has already requested delisting of the '115 patent, and the statute does not provide any remedy against the FDA, there is nothing further to adjudicate with respect to Par's delisting counterclaim.

Par argues that the Court should order Avanir to delist the '115 patent because "without an order, the FDA is powerless to delist the '115 patent." Par's argument is wholly fallacious. It makes no difference whether Avanir's request to the FDA for delisting is done voluntarily or pursuant to a Court order. The result is identical–the FDA cannot remove a patent from the Orange Book that is the subject of potential regulatory exclusivity, as is the case here. Thus, Par's requested order is an exercise in futility.

Additionally, Par now admits that it has done nothing to comply with the Court's June 17, 2014 Order to inform the FDA of this Court's request for the FDA's input. If Par actually believed that the FDA would delete the '115 patent if only Avanir resubmitted its request with a Court order, Par would have called the FDA to confirm this. Par did not. Instead, Par took no action and attempted to excuse its failure to comply with the Court's Order by representing that it was unaware of any procedure it could use to communicate with the FDA regarding Avanir's delisting request. But Par's professed excuse rings hollow as it has already communicated with the FDA on this very issue. *See* D.I. 511, Ex. A (Par's affidavit of its conversations with the "Orange Book staff at the [FDA]" regarding Avanir's delisting request). Thus, there is no reason why Par could not have contacted the FDA, other than that it already knows, and does not like, the answer the FDA would give—the FDA will not delist the '115 patent because of Par's potential regulatory exclusivity.

Accordingly, and for the reasons set forth in Plaintiffs' briefing (D.I. 497, 500), Plaintiffs submit that Par's delisting counterclaim should be dismissed as moot.

Par's position:

Par disagrees with Plaintiffs' interpretation of the Oral Order on August 7, 2014 (D.I. 514) as calling for supplemental, duplicative, and argumentative briefing regarding Par's delisting counterclaim. To the extent this briefing was not invited, Par moves to strike it, but is forced to rebut Plaintiffs' baseless allegations below.

Par's delisting request has been fully briefed and is ripe for final disposition. *See* D.I. 497, 498, 499, 500. On June 17, 2014, the Court issued an Order stating, in relevant part: "The parties shall make reasonable efforts to inform the Food and Drug Administration (FDA) of the pending request for delisting and of this Court's request that the FDA provide its views relating to the pending request." D.I. 507, ¶ 3. On June 19, 2014, Par's counsel proposed a "joint letter to the FDA," which Plaintiffs ignored. Ex. A. Having received no response, during a meet-and-confer on July 7, 2014 about other issues, Par raised the issue of compliance with the Order. After hanging up during the middle of the call, Plaintiffs rejoined the call, and refused to explain what they did—if anything—to comply with

[1] The FDA maintains the listing to require other ANDA filers to certify against the patent. This prevents second-filers from gaining final FDA approval before the first filer gets the benefit of its 180-day exclusivity. In other words, the '115 patent remains in the Orange Book for Par's benefit.

paragraph 3 of the Order. Stating that the Order does not require joint action, they refused to produce copies of any FDA correspondence related to the Order, refused to state whether a letter had been sent to the FDA, and concluded that Par did not need to know what Plaintiffs had done. Instead, Plaintiffs summarily affirmed that they followed the Order without further explanation. Now, Avanir accuses Par of "do[ing] nothing to comply with the Court's June 17, 2014 Order." Avanir's accusation is misplaced. Putting aside Par's efforts to jointly approach the FDA, there was nothing left to do after Avanir represented that it had complied with the Court's Order. Other than the FDA's website acknowledgement of Avanir's delisting request, Par is unaware of any further FDA response.

For the reasons explained in Par's briefing (D.I. 498, 499), the delisting request is not moot. Indeed, Plaintiffs admit that the '115 patent remains listed in the Orange Book. The remedy in 21 U.S.C. § 355(j)(5)(C)(ii)(I) is not, as Plaintiffs argue, satisfied with a unilateral letter from the NDA holder. As explained by the Supreme Court, "[a]ccording to the statute, a successful claimant may obtain ***an order*** requiring the brand to 'correct or delete' its patent information." *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)) (emphasis added). Here, Par requests "an order" because the FDA is unable to delist the '115 patent without it. Indeed, the only means of delisting a patent is through 21 U.S.C. § 355(j)(5)(C)(ii)(I). Therefore, without an order, the FDA is powerless to delist the '115 patent because there is no statutory basis to delist with just a letter from Avanir. *See* D.I. 505, Ex. A ¶ 6 ("FDA policy bars New Drug Application holders from unilaterally delisting an Orange Book patent after paragraph IV certification of the same patent."). If, indeed, Plaintiffs believe they have already complied with the statutory requirement, they cannot be heard to complain about a second act of compliance—this time with a Federal Court Order—with the delisting statute.

Final determination of the delisting counterclaim is necessary to proceed with an appeal of this action. *See* D.I. 513-1 (dismissing the appeal because there is no final decision regarding Par's delisting counterclaim). Accordingly, Par requests an order pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I) (*see* D.I. 498 at 5 (Par's proposed language)), which would also result in a final judgment, allowing the parties to appeal.

Respectfully,

*/s/ Maryellen Noreika*

Maryellen Noreika (#3208)

MN/lm
cc: Clerk of Court (Via Hand Delivery)
All Counsel of Record (Via Electronic Mail)
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