IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC., AVANIR HOLDING COMPANY, AND CENTER FOR NEUROLOGIC STUDY, Plaintiffs, v. PAR PHARMACEUTICAL, INC, PAR PHARMACEUTICAL COMPANIES, INC, AND IMPAX LABORATORIES, INC. Defendants.	)	C.A. No. 11-704 (LPS) (CONSOLIDATED)

PLAINTIFFS' RESPONSIVE BRIEF REGARDING
DELISTING OF THE '115 PATENT

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I. INTRODUCTION

Defendants' request is moot. They request "Plaintiffs to delete the '115 patent from the Orange Book entry for Nuedexta®." D.I. 498 at 5. But Plaintiffs have already done so. *See* D.I. 497, Ex. A ("We write to request that U.S. Patent No. RE38,115 be delisted from . . . the Orange Book.") Thus, Plaintiffs have already given Defendants exactly what they ask for.

II. ARGUMENT

A. Whether the FDA Removes the '115 Patent From the Orange Book Is Irrelevant

Defendants correctly point out that the FDA might ***not*** actually delist the '115 patent, but this irrelevant. As explained in the *Teva* case that Defendants cite, if the FDA removed a patent from the Orange Book that was subject to a Paragraph IV challenge, it could result in harm to the first ***generic company*** who filed a Paragraph IV certification. *Teva Pharm. USA v. Sebelius*, 595 F.3d 1303, 1305-06 (D.C. Cir. 2010). This is because removal of a patent from the Orange Book can, under certain circumstances, cause a generic company to lose its 180-day marketing exclusivity. Here, Plaintiffs are at a loss to understand why Par seeks delisting of the '115 patent, when its continued listing would be intended to protect Par's own interest in regulatory exclusivity against other generics. Nonetheless, the exclusivity considerations set forth in *Teva* are not present here because Par is not entitled to any exclusivity from the '115 patent. Instead, Defendants are enjoined from launching their product until 2026 – ten years ***after*** the expiration of the '115 patent.

In any event, what the FDA does or does not do with Plaintiffs' request is irrelevant to Defendants' counterclaims. The statutory remedy is limited to requiring the patent ***holder—i.e.,*** Plaintiffs—to correct or delete patent information: "the applicant may assert a counterclaim seeking an order requiring the ***holder*** [of the NDA] to correct or delete the patent information."

21 U.S.C. § 355(j)(5)(C)(ii)(I) (emphasis added). The statute does ***not*** mandate that the FDA delist the '115 patent. Since Plaintiffs have already done what is called for by the statute, Defendants' counterclaims are moot. *See* D.I. 497 at 3.

B. Defendants' Proposed Relief Will Not Change Anything

Defendants apparently seek an order requiring Plaintiffs to send ***another*** letter to the FDA again requesting delisting of the '115 patent. D.I. 498 at 5. Such an order would be futile.[1] The FDA has received Plaintiffs initial request and will either delist the patent or not. A second letter will not change anything. Indeed, neither Defendants nor Plaintiffs have identified any case where a patent was actually removed from the Orange Book as a result of a delisting counterclaim.[2]

Defendants' citation to *Novo* does not support Defendants' requested relief. *Novo Nordisk A/S v. Caraco Pharm. Labs.*, 688 F.3d 766 (Fed. Cir. 2012). In *Novo*, the generic applicant asserted a counterclaim seeking correction of a patent use code in the Orange Book, not seeking deletion of a patent from the Orange Book. There, the patent holder disputed that it had to correct the use code information. Thus, the parties litigated the counterclaim. The generic applicant prevailed, and the court issued an order requiring the patent holder to submit a corrected use code to the FDA. Despite Defendants' attempt to imply otherwise, the *Novo* Court did ***not*** require the holder to submit the Court's order when submitting its corrected use code to the FDA. Indeed, Defendants have failed to cite any legal authority supporting their speculation

[1] Defendants question how Plaintiffs could object to a court order requiring Plaintiffs to do what has already been done. The answer is simple—subject matter jurisdiction is a constitutional requirement, and it is not present here.

[2] Defendants argue that the "Y" in the "Delist Requested" column means that the FDA has denied Plaintiffs' request. Not so. The "Y" means what it says – a request to delist has been made and the FDA has not yet acted upon it. It is not a decision one way or another.

that the FDA would delist the ’115 patent if only Plaintiffs would resubmit their delisting request with an order from this Court in Defendants’ favor on their counterclaims.

C. Plaintiffs Do Not Agree That the ’115 Patent “Must Be Delisted”

Defendants argue that “Plaintiffs … agree that the ’115 patent must be delisted.” D.I. 498 at 2. Not so. Defendants have made no showing that this Court’s Opinion meets the standards for a delisting counterclaim. Moreover, Plaintiffs could have sought to maintain the ’115 patent listing pending appeal. Plaintiffs chose instead to seek deletion of the ’115 patent in order to moot Defendants’ counterclaim and avoid wasting the Court’s and the parties’ time because ***whether the ’115 patent is listed in the Orange Book does not matter anymore***. Plaintiffs prevailed on the ’282 and ’484 patents and Defendants are enjoined from launching their product until 2026. The ’115 patent is now entirely irrelevant as is this briefing.[3]

III. CONCLUSION

For the reasons set forth herein and in D.I. 497, Par’s and Impax’s delisting counterclaims should be dismissed for lack of subject matter jurisdiction.

[3] Defendants also argue that there should not be a “loophole” that would allow Plaintiffs to relist the ’115 patent “at some point in the future.” D.I. 498 at 5. That is not a loophole. If future clinical trials or other evidence shows that the ’115 patent covers Nuedexta®, Plaintiffs would be ***required*** under FDA regulations to relist the ’115 patent in the Orange Book, regardless of whether or not the delisting occurred pursuant to a court order. *See* D.I. 497 at 1-2. Moreover, this possibility is insufficient to confer subject matter jurisdiction. *See Texas v. United States*, 523 U.S. 296, 300 (1998).

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CERTIFICATE OF SERVICE

I hereby certify that on May 23, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 23, 2014, upon the following in the manner indicated:

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