IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| SANOFI, et al., | : | |
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| Plaintiffs, | : | |
| | : | |
| v. | : | Civil Action No. 15-415-RGA |
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| LUPIN ATLANTIS HOLDINGS SA, et al., | : | |
| | : | |
| Defendants. | : | |

**MEMORANDUM ORDER**

Defendant Sandoz, having exhausted legitimate means to seek a postponement of a trial scheduled for April 24, 2017 (D.I. 23), now seeks to dismiss the case against it for lack of subject matter jurisdiction. (D.I. 156). Sandoz's view is that it should be able to decide when, if ever, the trial takes place. For the reasons that follow, I **DENY** Sandoz's motion.

Sanofi owns various patents that it asserts covers its branded drug, Multaq. Some of them were listed in the Orange Book, and, after Sandoz filed ANDA No. 205744 seeking FDA approval to market a generic version of Multaq, Sanofi filed suit. The result was a trial in June 2016. I eventually found in favor Sanofi, and against Sandoz, on the '167 and '800 patents, and on September 22, 2016, enjoined Sandoz from commercializing the proposed ANDA generic before April 16, 2029. (No. 14-264-RGA, D.I. 336, ¶¶ 14-15). Sandoz has appealed from that judgment. (*Id.*, D.I. 339).

Meanwhile, on August 18, 2015, Sanofi was issued another patent, the '900 patent, which Sanofi listed in the Orange Book as covering Multaq. On December 23, 2015, Sanofi filed the instant suit against Sandoz, asserting the '900 patent, which also expires on April 16, 2029. (No.

15-1207, D.I. 1, ¶ 20). That case, along with similar cases against two other generics, is now proceeding under the above caption.

Sandoz made a "Paragraph IV" certification in relation to the '900 patent on February 17, 2016. (D.I. 157, p. 4). On October 7, 2016, Sandoz and the other two defendants requested a stay of this case pending resolution of the multiple appeals from the earlier trial. (D.I. 144). I denied the request for a stay on October 14, 2016. (D.I. 150). On October 28, 2016, Sandoz changed the Paragraph IV certification to a "Paragraph III" certification. (D.I. 159-1). On December 8, 2016, the instant motion was filed.

The basis for Sandoz's motion is simple. A Paragraph IV certification creates subject matter jurisdiction. A Paragraph III certification does not, because it represents that the generic will not market its product before the relevant patents expire. Thus, the parties agree that, since there was a Paragraph IV certification by Sandoz on the '900 patent, the Court has had subject matter jurisdiction over the case against Sandoz. (D.I. 157, p. 7; D.I. 167, p. 2). Thus, I think the precise issue raised here is whether a generic who has filed a Paragraph IV certification divests the district court of jurisdiction by the mere act of converting the Paragraph IV certification to a Paragraph III certification.

I see two arguments in the briefing that are germane and therefore need to be considered.

One is a purely legal statutory interpretation argument. What exactly is the basis for subject matter jurisdiction in the first place? The other is a mootness argument. Under what circumstances can the unilateral actions of one party divest a court of jurisdiction?

The statutory interpretation argument, as I understand it, is not entirely settled. *See* Stephen R. Auten & Jane S. Berman, ANDA LITIGATION 149–74 (Kenneth L. Dorsney et al. eds., 2nd ed. 2016) (discussing related topics). Nonetheless, I am not deprived of jurisdiction

under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 1338(a) because it is sufficient that the case was initially certified under Paragraph IV. *Cf. Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *4–5 (D. Del. Mar. 1, 2012) (finding that the absence of a Paragraph IV certification does not, as a matter of law, automatically deprive the court of subject matter jurisdiction under both 35 U.S.C. § 271(e)(2) and 28 U.S.C. § 2201). It also appears that 28 U.S.C. § 2201 may confer jurisdiction. *Cf. id. at* *5 ("[S]o long as there is an actual controversy, that is, there is a sufficient allegation of immediacy and reality, the exercise of jurisdiction over such an action is within the discretion of the district court." (internal quotations omitted)).

I do not think Sandoz's mootness argument has any merit.

The standard for deciding whether Sandoz's actions have mooted this case are straightforward.

> A case becomes moot when interim relief or events have eradicated the effects of a defendant's act or omission, and there is no reasonable expectation that the alleged violation will recur. In cases where a defendant voluntarily ceases the challenged practice, it is necessary for the court to determine whether "there is no reasonable expectation that the wrong will be repeated." As a result, "'a defendant claiming that its voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the alleged wrongful behavior could not reasonably be expected to recur.'"

*Ferring B.V. v. Watson Labs, Inc.-Fla.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014) (citations omitted).

First, the record makes clear that Sandoz's Paragraph III certification is a matter of convenience and expedience on Sandoz's part. It is asserted, without contradiction, that Sandoz's conversion to Paragraph III certification is "wholly revocable." (D.I. 164, p.1). Indeed, Sandoz admits, "Of course Sandoz could, and very well might, convert its Paragraph III certification back to a Paragraph IV at some future date under certain circumstances." (D.I. 167, p. 5). In my opinion, this is essentially a concession that the case is not moot. Sandoz argues

that any generic that from the outset gives a Paragraph III certification could later change the certification to Paragraph IV. (D.I. 167, p. 5). I assume this is true, but the difference is that the statutory structure shows that there is no jurisdiction over an initial Paragraph III certifier, whereas there is jurisdiction over an initial Paragraph IV certifier. The specific facts leading to the finding that the case was moot in *Ferring* are not analogous here. *See Ferring*, 764 F.3d at 1388–91. Unlike in *Ferring*, Sanofi makes an adequately supported argument that Sandoz would reconvert back to Paragraph IV. *See id.* at 1391 ("Ferring makes no argument that Apotex would file an infringing ANDA in the future"). There is thus a "reasonable expectation that the wrong will be repeated." *Id.* Defendant has not met its "formidable burden of showing that it is absolutely clear the alleged wrongful behavior could not reasonably be expected to recur." *Id.*

Second, Sandoz cites exactly one case, *AstraZeneca AB v. Anchen Pharms Inc.*, 2014 WL 2611488 (D.N.J. June 11, 2014), where a court had decided the instant issue in favor of the generic.[1] In *AstraZeneca*, the court noted the argument that the generic was "free to change its certification back to Paragraph IV at any time." *Id.* at *5. The court's opinion recites no facts that would indicate the likelihood in that case of there being a change back. Instead, the court noted that the circumstances in an ANDA case were quite different from cases in other areas of the law. Mootness is a fact-bound issue; therefore I do not see the decision in *AstraZeneca* as being inconsistent with what I decide here, because the facts are significantly different.

Third, Sanofi relies upon the recent decision of another judge of this court in *AstraZeneca AB v. Aurobindo Pharma Ltd.*, Civ. Act. No. 14-664-GMS (D. Del. Sept. 15, 2016) (D.I. 359).

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[1] Sandoz cites stipulated dismissals in support of its argument. First, as a general rule, I attribute no precedential or persuasive weight to stipulated dismissals. Second, under different circumstances, a change from Paragraph IV certification to Paragraph III certification might raise no specter of a later reversal.

Sandoz (commendably) brought this decision up in its Opening Brief, distinguishing it as being raised on the eve of trial. I do not think there is a material difference between bringing the issue up in the middle of expert discovery, as in this case, and right before trial, as in *Aurobindo*.[2] The timing of the motion is merely a consideration in deciding whether "there is a reasonable expectation that [the branded company] may well again at some future time be required to assert its interest in the [patent-in-suit]." *Id.* at 2 n.3.[3] I believe the instant case is indistinguishable on any meaningful basis from *Aurobindo*.

Thus, I will deny Sandoz's motion. (D.I. 156).

IT IS SO ORDERED this 26 day of January 2017.

Richard G. Andrews
United States District Judge

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[2] If changing from Paragraph IV to Paragraph III were all that was required to divest the court of jurisdiction, presumably, assuming the generic were willing to pay some sanctions, it could moot the case after completion of the trial but before issuance of the decision if it did not like the way the trial had gone.

[3] I do not agree with Sanofi that the appeal of the earlier trial and this lawsuit are necessarily either both moot or both not moot. For example, even if this lawsuit were moot, Sandoz could win on appeal, and subsequent events, such as its codefendants succeeding in invalidating the '900 patent, would offer the probability of Sandoz being able to get FDA approval and to launch its generic long before 2029. Of course, Sandoz's pursuit of the appeal is compelling evidence of its desire to pursue launch of its generic product long before 2029.