IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. AUROBINDO PHARMA LTD., et al. Defendants.	)	C.A. No. 14-664-GMS (CONSOLIDATED)

ORDER

WHEREAS, on October 8, 2014, the court consolidated actions filed by AtraZeneca AB ("AstraZeneca") alleging the defendants'[1] Abbreviated New Drug Applications ("ANDAs") would infringe U.S. Patent No. RE44, 186 ("the RE'186 patent");

WHEREAS, on June 4, 2015, Mylan filed a petition for inter partes review ("IPR") of the RE'186 patent;

WHEREAS, on May 2, 2016, the Patent Trial and Appeal Board instituted IPR for all of the claims of the RE'186 patent and must issue a final ruling by May 2, 2017;

WHEREAS, the case is currently scheduled to begin trial on September 19, 2016;

WHEREAS, presently before the court is defendants Wockhardt BIO AG and Wockhardt USA LLC (collectively, "Wockhardt") Motion to Dismiss for Lack of Subject Matter Jurisdiction (D.I. 351)[2];

[1] The defendants are Mylan Pharmaceuticals Inc. ("Mylan"); Amneal Pharmaceuticals LLC ("Amneal"); Aurobindo Pharma Ltd. and Aurobindo Pharma U.S.A., Inc. (collectively, "Aurobindo"); Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"); Wockhardt Bio AG and Wockhardt USA LLC (collectively, "Wockhardt"); and Actavis Laboratories FL, Inc. and Watson Laboratories, Inc (collectively, "Actavis").

[2] AstraZeneca and Sun have stipulated as follows: "AstraZeneca and Sun, by their undersigned counsel, hereby stipulate and agree, subject to the approval of the Court, that they will be bound by the Court's decision on

WHEREAS, the court, having considered the instant motion, the response,[3] and the applicable law, concludes that Wockhardt has not demonstrated that a dismissal for lack of subject matter jurisdiction is appropriate in this case;[4]

IT IS HEREBY ORDERED that Wockhardt's Motion to Dismiss is DENIED.

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the Wockhardt Motion to Dismiss as if Sun had filed its own motion to dismiss, on the grounds set forth in D.I. 352, that was opposed by AstraZeneca, on the grounds set-forth in D.I. 355." (D.I. 357.)

[3] In seeking dismissal for lack of subject matter jurisdiction, Wockhardt argues that by converting to a Paragraph III certification, it is no longer engaged in the "highly artificial act of infringement" that confers subject matter jurisdiction under 35 U.S.C. § 271(e)(2). (D.I. 352 at 2.) Wockhardt asserts AstraZeneca's claims of infringement no longer present a real or immediate controversy to establish subject matter jurisdiction pursuant to Article III of the Constitution, because Wockhardt does not seek approval until the expiration of the Reissue Patent on July 21, 2023. (*Id.*) Thus, Wockhardt asserts that the court now lacks subject matter jurisdiction with respect to the infringement claims against Wockhardt. (*Id.*)

The court, however, agrees with AstraZeneca and finds subject matter jurisdiction remains because the conduct at issue is capable of repetition, yet evading review. Courts are not deprived of subject matter jurisdiction for mootness where "(1) the challenged action is in its duration too short to be fully litigated prior to cessation or expiration, and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again." *Fed. Election Comm'n v. Wisconsin Right to Life, Inc.*, 551 U.S. 449, 462 (2007) (quoting *Spencer v. Kemna*, 523 U.S. 1, 17 (1998)).

Both circumstances are present here. First, it would be unlikely that AstraZeneca could obtain complete judicial review of its claims before a generic party converted from its initial Paragraph IV certification. The court finds that a patent owner would be prevented from fully litigating its claims of infringement if every time a Paragraph IV filer amended its certification from IV to III, or some other designation, the court was determined to be deprived of subject matter jurisdiction. Second, there is circumstantial, if not direct, evidence that supports the conclusion that there is a reasonable expectation that the same controversy involving these parties will recur. First, on August 25, 2016, a mere two days after the court denied Wockhardt's and the other IPR Defendants' motion to stay this action, Wockhardt notified the Food and Drug Administration of its election to amend its certification from Paragraph IV to Paragraph III. (D.I. 352, Ex. A.) Following this, in a letter to the court dated September 2, 2016, (D.I 347), Wockhardt requested that the court dismiss AstraZeneca's suit against it. Next, in its letter brief in opposition to Wockhardt's Motion to Dismiss, AstraZenca reports that Wockhardt has refused to covenant or agree to stipulations precluding it from re-converting its FDA submission back to Paragraph IV and attacking the RE' 186 patent in subsequent IPR proceedings. (D.I. 355.) Perhaps the most telling evidence is Wockhardt's own words which can be found in its amended Paragraph III Certification transmitted to the FDA on August 25, 2016: "Wockhardt Bio AG has already submitted a *Paragraph IV* certification in its original ANDA # 206000 for Saxagliptin Hydrochloride Tablet; Oral; Eq. 2.5 mg Base and Eq. 5 mg Base dated Jul 31, 2013 for the US Patent No. 7,951,400 expiring on Nov 30, 2028. Wockhardt Bio AG *maintains* the already submitted *Paragraph IV* certification for said patent." (D.I. 352, Ex. A) (emphasis added).

When taken together, the reasonable inference to be drawn from the cited evidence supports the conclusion that there is a reasonable expectation that Astra Zeneca may well again at some future time be required to assert its interests in the RE '186 patent, both in U.S. District Court and before the USPTO, against Wockhardt. Thus, Wockhardt's motion is denied.

Date: September 15, 2016

UNITED STATES DISTRICT JUDGE