IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SANDOZ INC.,

Plaintiff,

v.

AMGEN INC., et al.,

Defendants.
_____/

No. C-13-2904 MMC

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS; DISMISSING COMPLAINT WITHOUT LEAVE TO AMEND; VACATING HEARING

Before the Court is the "Motion by Defendants, Amgen Inc. ["Amgen"] and Hoffman-La Roche Inc. ["Roche"] to Dismiss for Lack of Subject-Matter Jurisdiction or, Alternatively, to Decline to Exercise Declaratory Judgment Jurisdiction," filed August 16, 2013. Plaintiff Sandoz Inc. ("Sandoz") has filed opposition, to which defendants have replied, and Sandoz, with leave of court, has filed a surreply. Having read and considered the papers filed in support of and in opposition to the motion, the Court deems the matter suitable for determination on the parties' respective written submissions, VACATES the hearing scheduled for November 15, 2013, and rules as follows.

BACKGROUND

The Food and Drug Administration ("FDA") has approved the use of "Enbrel," an Amgen product, to treat specified illnesses; Enbrel is a "human tumor necrosis factor (TNF) receptor" known as "etanercept." (See Compl. ¶ 14; Winters Decl., filed August 16, 2013,

Ex. 22.) Amgen takes the position that etanercept is covered by U.S. Patent No. 8,063,182 ("the '182 patent") and U.S. Patent No. 8,163,522 ("the '522 patent"). (See Compl. ¶ 2; Winters Decl. Exs. 22, 26.) Roche is the owner of, and Amgen is the exclusive licensee under, the two subject patents. (See Compl. ¶¶ 21-22, 29-30.)

Sandoz alleges it is presently conducting clinical trials to test a "biologic drug containing etanercept" (see Compl. ¶ 3), and "intends to file an FDA application for licensure of its etanercept product as biosimilar to Enbrel" upon completion of the clinical trials (see Jankowsky Decl., filed September 19, 2013, ¶ 14).[1]

In its complaint, Sandoz seeks declaratory relief, specifically, a declaration that its assertedly biosimilar product does not infringe any claim of either the '182 patent or the '522 patent and that the subject patents are invalid and unenforceable.

DISCUSSION

Defendants contend the instant action is premature for two separate but related reasons, and, consequently, is subject to dismissal. In particular, defendants argue, (1) a district court lacks statutory authority to consider a patent dispute involving a biosimilar product until after such time as an application for FDA approval of the biosimilar product has been filed, and (2) as a factual matter, a cognizable case or controversy does not presently exist. As set forth below, the Court agrees.

Sandoz's claims for declaratory relief are brought pursuant to 28 U.S.C. § 2201, under which a district court "may declare the rights and other legal relations of any interested party seeking such declaration" in a "case of actual controversy within its jurisdiction." See 28 U.S.C. § 2201(a). The district court's discretion to enter such declaratory judgment is, however, subject to certain limitations, and, as to "actions brought with respect to drug patents," the limitations set forth in "section 351 of the Public Health Service Act." See 28 U.S.C. § 2201(b).

[1]A "biosimilar is a drug product designed to be similar to a previously approved biologic drug (a 'reference product') in its quality, safety, and efficacy." (See Roth Decl., filed September 19, 2013, ¶ 4); see also 42 U.S.C. § 262(i)(2) (defining "biosimilar" products).

Section 351 of the Public Health Service Act, 42 U.S.C. § 262, provides the FDA with authority to license biological products that are "biosimilar to a reference product," see 42 U.S.C. § 262(k), and sets specific limitations on the timing of any litigation arising from the filing of an application for such license. See 42 U.S.C. § 262(l); see also 28 U.S.C. § 2201(b). Specifically, with limited exceptions not applicable here, neither a reference product sponsor, such as Amgen,[2] nor an applicant, such as Sandoz, may file a lawsuit unless and until they have engaged in a series of statutorily-mandated exchanges of information. See 42 U.S.C. §§ 262(l)(2)-(6).

Here, Sandoz does not contend, and cannot contend, it has complied with its obligations under §§ 262(l)(2)-(6), because, as it concedes in its complaint and opposition, it has not, to date, filed an application with the FDA. Rather, citing § 262(l)(8), Sandoz argues § 262 "provides [declaratory judgment] actions can be filed by either party upon the biosimilar manufacturer's notice of commercial marketing, which Sandoz has given here." (See Pl.'s Opp'n, filed September 19, 2013, at 24:9-10.) The Court, for several reasons, is not persuaded.

First, as set forth in the section on which Sandoz relies, a "notice of commercial marketing" is required to be given by the applicant to the reference product sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [§ 262] subsection (k)." See 42 U.S.C. § 262(l)(8)(A). Here, Sandoz cannot, as a matter of law, have provided a "notice of commercial marketing" because, as discussed above, its etanercept product is not "licensed under subsection (k)." See id. Second, even after an applicant provides a "notice of commercial marketing," it cannot bring an action for declaratory relief until, at a minimum, it has complied with its obligations under § 262(l)(2)(A). See 42 U.S.C. §§ 262(l)(9); see also 28 U.S.C. § 2201(b).

Moreover, Sandoz has not, at this time, established a "real and immediate injury or

[2]A "reference product sponsor" is a "sponsor of the application for the reference product." See 42 U.S.C. § 262(l)(1)(A). In this instance, the "reference product sponsor" is Amgen, the entity that previously obtained a license for Enbrel.

threat of future injury that is caused by the defendants." See Prasco, LLC v. Medicis Pharmaceutical Corp., 537 F.3d 1329, 1338-39 (Fed. Cir. 2008) (setting forth requisite showing by declaratory relief plaintiff to establish "case or controversy"). Here, defendants state they have never advised Sandoz they intend to sue Sandoz, and are not in a position to consider the propriety of such action until after Sandoz has "prepared an [application] for approval to launch a product in the U.S." (see Mot. at 5:9-11, 6:1-3; see also id. at 18:8-11); no evidence to the contrary has been offered. Nor has Sandoz submitted evidence demonstrating defendants, by some means other than an express threat to sue, have subjected Sandoz to an "immediate" threat of injury. See Prasco, 537 F.3d at 1339 (holding patentee "can cause such an injury in a variety of ways"; providing examples). Although Sandoz points to public statements by Amgen that its patents cover etanercept,[3] and that it defends the patents it owns (see, e.g., Compl. ¶¶ 51-60), such statements do not suffice to show an "imminent threat," see Prasco, 537 F.3d at 1339; see also id. at 1338 (holding "mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury").

Finally, Sandoz's allegation that it intends in the future to file an application with the FDA is insufficient to create a case or controversy. See Benitec Australia, Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1346 (Fed. Cir. 2007) (holding "fact that [declaratory judgment plaintiff] may file an [application for drug] in a few years does not provide the immediacy and reality required for a declaratory judgment"); Telectronics Pacing Systems, Inc. v. Ventritex, Inc., 982 F.2d 1520, 1527 (Fed. Cir. 1992) (affirming dismissal of declaratory judgment action brought by patentee where accused "device had only recently begun clinical trials, and was years away from potential FDA approval").

Accordingly, the instant action is subject to dismissal.

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[3]As noted, Amgen markets etanercept under the brand name "Enbrel."

CONCLUSION

For the reasons stated, defendants' motion to dismiss is hereby GRANTED, and the complaint is hereby DISMISSED without prejudice and without leave to amend.

IT IS SO ORDERED.

Dated: November 12, 2013

MAXINE M. CHESNEY
United States District Judge