IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, *Plaintiffs*, v. AMGEN INC., *Defendant*.	Civ. No. 17-1407- CFC, Consol.

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MEMORANDUM OPINION

February 12, 2020
Wilmington, Delaware

CONNOLLY, UNITED STATES DISTRICT JUDGE

This action arises under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), 42 U.S.C. § 262. Plaintiffs Genentech, Inc. and City of Hope (collectively "Plaintiffs") have sued Defendant Amgen Inc. ("Amgen") based on Amgen's submission of an Abbreviated Biologics License Application ("aBLA") seeking approval to market Mvasi, a biosimilar of Genentech's drug product Avastin. Pending before me is Plaintiffs' Motion for Leave to File a Second Amended and Supplemental Complaint. D.I. 263.

I. LEGAL STANDARDS

Whether to grant or deny a motion for leave to amend is within the district court's discretion. *Foman v. Davis*, 371 U.S. 178, 182 (1962). Under Federal Rule of Civil Procedure 15(a)(2), "[t]he court should freely give leave when justice so requires." The Third Circuit has adopted a liberal approach to the amendment of pleadings to ensure that "a particular claim will be decided on the merits rather than on technicalities." *Dole v. Arco Chem. Co.*, 921 F.2d 484, 486–87 (3d Cir. 1990). Nevertheless, leave to amend should be denied where amendment is futile, made in bad faith, or causes undue delay or prejudice. *Oran v. Stafford*, 226 F.3d 275, 291 (3d Cir. 2000); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). In addition, leave should be denied when the amendment "relates only indirectly, if at all, to the original complaint and the alleged cause of

action arose out [of] an entirely unrelated set of facts and related to a defendant not implicated in the original complaint." *Bohm v. Straw*, 2013 WL 100441, at *14 (W.D. Pa. Jan. 8, 2013) (*quoting Nottingham v. Peoria*, 709 F. Supp. 542, 544 (M.D. Pa. 1988)). In such circumstances, the unrelated claims "will not promote judicial economy or the speedy disposition of the dispute between the parties." *Id.* at 14.

II. DISCUSSION

Amgen objects to many but not all of Plaintiffs' proposed amendments. To the extent Amgen does not object to the proposed amendments, I will grant Plaintiffs' motion for leave to amend. *See* D.I. 263 at 3 (discussing "housekeeping" amendments).

Amgen objects to four categories of proposed amendments. It has specific objections to each category, but objects generally to all the proposed amendments as untimely and prejudicial.

I will not deny Plaintiffs' motion based on its general objections. Plaintiffs filed their motion on February 22, 2019, the last day amendments could be made under the then-operative Scheduling Order, and several months before fact and expert discovery were set to close. *See* D.I. 260. Moreover, Amgen has now launched its biosimilar, Mvasi, and the trial date has been postponed until

November 2020. *See* D.I. 504; D.I. 585; D.I. 613. This leaves Amgen's specific objections to each category of proposed amendments, which I address in turn.

A. Section 271(g) Claims

Plaintiffs propose to add claims for declaratory and legal relief under 35 U.S.C. § 271(g) for eight of the method patents asserted in the First Amended Complaint. *See* D.I. 263-1, Ex. A ¶¶ 48, 68, 134, 144, 153, 167, 185, 214. Plaintiffs state that these claims arise out of Amgen's alleged "use or sale of its massive Mvasi stockpile," D.I. 301 at 5, and that "[n]o additional facts are required to establish infringement [of these claims] (or a defense thereto)," *id.* at 5 n.5. Amgen argues that leave to add these new claims should be denied on futility grounds. Specifically, Amgen argues that the new claims fail to state a claim under § 271(g), because (1) they do not allege "the importation of a product of a patented process practiced abroad," D.I. 293 at 18; and (2) they do not allege that Plaintiffs lack "an adequate remedy separate from § 271(g)," *id.* at 19. Both of these arguments lack merit.

First, § 271(g) does not require the importation of a product. Section 271(g) provides in relevant part that "[w]hoever without authority imports into the United States *or* offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, *or* use of the product occurs during the term of

such process patent." 35 U.S.C. § 271(g) (emphasis added). The use of the disjunctive makes clear that importation is not required to establish infringement liability under § 271(g).

Second, § 271(g) does not require a showing that no remedy separate from § 271(g) exists under the Patent Act. Again the relevant language in the statute is clear: "In an action for infringement of a process patent, no remedy may be granted for infringement on account of *the noncommercial use or retail sale* of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product." 35 U.S.C. § 271(g) (emphasis added). The proposed amended claims do not allege infringement based on noncommercial use or retail sales. Instead, they allege that Amgen infringes under § 271(g) by "making and/or using ABP 215 in the United States." D.I. 263-1, Ex. A ¶¶48, 68, 134, 144, 153, 167, 185, 214. Thus, § 271(g) does not require Plaintiffs to allege the lack of an adequate remedy under other provisions in the Patent Act.

Accordingly, I will grant Plaintiffs leave to add their proposed § 271(g) claims.

B. The Repatha Claim

The First Amended Complaint alleges that Amgen's manufacture of its cancer drug Mvasi infringes U.S. Patent No. 8,574,869 (the "#869 patent"). The

#869 patent claims a method for prevention of disulfide bond reduction by, following fermentation, sparging pre-harvested or harvested cell culture fluid. '869 patent at 107:44-49. The proposed amended complaint adds a claim, based on information obtained during discovery, that Amgen's manufacture of the cholesterol drug Repatha also infringes the #869 patent. Plaintiffs argue that adding the Repatha claim to this litigation will avoid unnecessary waste, because the claims involve similar issues regarding validity and infringement. I disagree.

The drug at issue in the Abbreviated Biologics License Application that gave rise to this BPCIA action is Mvasi, not Repatha. Plaintiffs suggest that adding claims related to Repatha would not greatly expand the scope of this case, but the scope of this case for the Mvasi drug alone is already substantial by any measure. Plaintiffs' initial complaint had 47 counts based on 24 patents, prompting the Honorable Gregory M. Sleet, then presiding, to describe the case as "unwieldly." *See* Minute Entry (Apr. 11, 2018). Judge Sleet's description was prescient. The case has to date involved more than 11 days of in-person discovery conferences, three days of *Markman* hearings, several motions, and a preliminary injunction ruling. To expand the scope of the case after two years of intense litigation to add claims that concern a different drug, a different disease, and a different manufacturing process would undermine the Court's previous efforts to drive the case to a reasonable and efficient conclusion. Accordingly, I will deny Plaintiffs

leave to add their proposed claims related to Repatha. *See Bohm*, 2013 WL 100441, at *14 (denying leave to amend where the addition of unrelated claims "will not promote judicial economy or the speedy disposition of the dispute between the parties").

C. Actual Infringement of the #269 Patent

The First Amended Complaint alleges that Amgen will infringe U.S. Patent No. 7,060,269 (the "#269 patent") in the future when its customers prescribe and/or administer Mvasi to cancer patients. According to Plaintiffs, discovery showed that Amgen has already infringed the #269 patent during clinical trials undertaken for foreign regulatory approvals. Thus, the proposed amended complaint adds a claim for past infringement of the #269 patent. Amgen asks the court to deny this amendment as futile, because the allegations in the proposed amended complaint are "barebones." D.I. 293 at 14.

A claim for infringement need only provide "fair notice of what the claim is and the ground upon which it rests." *Disc Disease Sols. Inc. v. VGH Sols.*, Inc., 888 F.3d 1256, 1260 (Fed. Cir. 2018) (internal ellipses omitted) (quoting *Erickson v. Pardus*, 551 U.S. 89, 93 (2007)). The proposed amended complaint satisfies this standard, alleging use of a specific product (Mvasi) in a particular manner (during clinical trials) that infringed a specific claim (Claim 2) of the #269 patent. *See* D.I.

293-1 ¶¶ 85–92. Accordingly, I will grant Plaintiffs leave to add their proposed claim for past infringement of the #269 patent.

D. Conditional Amendments

For the stated purpose of "avoid[ing] delay should the Court deny Plaintiffs' pending motion to dismiss Amgen's counterclaims" (i.e., the motion at C.A. No. 17-1407, D.I. 128), Plaintiffs propose adding two claims and one patent that were not identified during the parties' pre-litigation "patent dance" exchanges. D.I. 263 at 3. Specifically, Plaintiffs propose adding U.S. Patent No. 9,714,293 (the "#293 patent"), claim 4 of the #869 patent, and claim 81 of U.S. Patent No. 9,441,035 (the "#035 patent). D.I. 263 at 3.

Yesterday, I granted in part and denied in part Plaintiffs' motion to dismiss Amgen's counterclaims. D.I. 626. It is unclear whether and, if so, in what way, my decision to grant in part and deny in part Amgen's motion to dismiss affects Plaintiffs' request to add to the case the proposed allegations concerning the #293 and #869 patents. It is also unclear whether the case management limitations Judge Sleet and I placed on the parties to make it possible to actually litigate this case would allow for the addition of the proposed allegations concerning those patents. Accordingly, I will deny Plaintiffs' motion insofar as it seeks to amend the First Amended Complaint to add allegations relating to the #293 and #869 patents, but will permit Plaintiffs to raise the issue of adding the proposed

allegations concerning those patents at the next status conference convened by the Court. I will deny the proposed addition of the #035 patent as moot, since the parties entered into a stipulated judgment of noninfringement for the #035 patent. *See* D.I. 484.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' motion for leave to file a second amended and supplemental complaint (D.I. 263) is granted in part and denied in part.

The Court will issue an Order consistent with this Memorandum Opinion.