IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM ORDER

Pending before the Court is a motion by Plaintiffs Genentech, Inc. and City of Hope (collectively, "Genentech") to amend the Protective Order entered on November 5, 2018. (D.I. 291). Genentech argues that the amendment it seeks is necessary so that it can use discovery obtained in this patent infringement action to initiate a new patent infringement action against Defendant Amgen Inc. ("Amgen"). (*Id.*). For the following reasons, the motion is DENIED.

1. In November 2016, Amgen filed Biologics License Application No. 761028 (the "BLA") seeking approval of ABP 215 (trademark name "Mvasi"). Mvasi is a biosimilar to Genentech's drug product Avastin. On September 14, 2017, the Food and Drug Administration (the "FDA") approved Amgen's BLA. It is

undisputed that the manufacturing facility identified in the BLA is located in Thousand Oaks, California.

2. Genentech filed the current patent infringement action in October 2017.

3. In August 2018, Amgen filed Supplemental Biologics License Application No. 761028-003 (the "sBLA"), seeking approval to manufacture Mvasi at a Rhode Island facility. (D.I. 291-1, Ex. 2 at ¶ 2).

4. Genentech asserts that amendment of the Protective Order is required so that Genentech can use discovery obtained in this litigation to initiate a new patent infringement action against Amgen. (D.I. 291 at 1). Genentech's proposed complaint for the new patent infringement action alleges 26 counts of patent infringement. (D.I. 291-1, Ex. 2). All but one of the counts in the proposed complaint allege that the manufacture of Mvasi at the Rhode Island facility infringes 14 different patents held by Genentech (the "Mvasi Claims"). (*See Id.* at ¶¶ 23-232, 243-88). The one non-Mvasi claim alleges that Amgen's manufacture in Rhode Island of the drug product Repatha infringes U.S. Patent No. 9,493,744 (the "Repatha Claim"). (*Id.* at ¶¶ 233-42).

5. The Court finds that the Protective Order it entered on November 5, 2018 (D.I. 291) does not preclude Genentech from using information obtained in this action to file the Mvasi Claims in a new patent infringement action. Paragraph 28 of the Protective Order states: "Confidential Discovery Material produced by a

Party ... may be used by a Receiving Party only for purposes of this Litigation or *future United States patent infringement litigation between the Parties arising from Defendant's filing of Biologics License Application No. 761028.*" (D.I. 209 at ¶ 28 (emphasis added)). The proposed complaint is for a future United States patent infringement litigation between the parties; and the Mvasi Claims set forth in that proposed complaint arise from Amgen's filing of the Biologics License Application No. 761028.

6. Genentech ties all the Mvasi Claims to Amgen's filing of Supplemental Biologics License Application No. 761028-003. (D.I. 291-1, Ex. 2). The applicable FDA regulations define a "supplement" as "a request to approve a change in an approved license application." 21 C.F.R. § 600.3(gg); *see also* 21 C.F.R. § 601.12 (requiring applicants to file a supplement when there are changes to the "product, production process, quality controls, equipment, facilities, responsible personnel, or labeling *established in the approved license application*" (emphasis added)). Because the Mvasi Claims are based on Amgen's filing of the sBLA, and the sBLA is a request to approve a change in the BLA, the Mvasi Claims arise from Amgen's BLA. There is, therefore, no need to amend the Protective Order for Genentech to use discovery obtained in this litigation to pursue the Mvasi Claims.

7. With respect to the Repatha Claim, Genentech bears the burden of demonstrating that the Protective Order should be modified. *Phillips Petroleum Co.*

v. Rexene Prods. Co., 158 F.R.D. 43, 46 (D. Del. 1994). Courts have discretion to modify the terms of a protective order if the moving party demonstrates "good cause." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994). In *Pansy*, the Third Circuit identified eight factors that may be considered in evaluating whether good cause exists: (1) whether disclosure will violate any privacy interests; (2) whether the information is being sought for a legitimate purpose; (3) whether disclosure will cause embarrassment to a party; (4) whether the information to be disclosed is important to public health and safety; (5) whether sharing the information among litigants will promote fairness and efficiency; (6) whether the party benefitting from the order is a public entity or official; (7) whether the case involves issues important to the public; and (8) the parties' reliance on the order. *Invista North Am. S.a.r.l. v. M & G USA Corp.*, 2014 WL 1908286, at *9 n. 14 (D. Del. Apr. 25, 2014) (citing *Pansy*, 23 F.3d at 787-91).

8. Applying the *Pansy* factors, I find that Genentech has failed to establish good cause to amend the Protective Order. In making its motion, Genentech focused exclusively on the Mvasi Claims. (*See* D.I. 291 at 1-2). But as noted above, the Protective Order does not prohibit Genentech from bringing the Mvasi Claims in a new patent infringement case. Genentech made no attempt to apply any *Pansy* factor to the Repatha Claim.

9. Against Genentech's weak, if not non-existent, showing of good cause, the Court balances Amgen's interest in protecting the confidentiality of the material in question. For discovery in this action, Amgen was expected to produce confidential business information related to the design, development, manufacturing, and sale of a drug that is likely to generate billions of dollars in revenue. (D.I. 161-1, Ex. 1 at 38). In order to facilitate this discovery, the parties crafted a Protective Order that all believed would protect the confidentiality of the documents produced. The Court reviewed and signed the Protective Order and understood that the parties would rely on the terms of the Order. "[T]he ability to rely on the Protective Order is essential in cases involving the disclosure of highly confidential business information." *In re Intel Corp. Microprocessor Antitrust Litig.*, 2008 WL 4861544, at *19 (D. Del. Nov. 7, 2008). Under these circumstances, Amgen's reliance on the Protective Order outweighs Genentech's interest in using discovery from this litigation to pursue the Repatha Claim. Thus, Genentech has failed to demonstrate good cause to modify the Protective Order.

NOW, THEREFORE, at Wilmington this 26th day of March, 2019, it is HEREBY ORDERED that Genentech's motion to amend the Protective Order (D.I. 291) is DENIED.

UNITED STATES DISTRICT JUDGE