IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 16-666-SLR-SRF
AMGEN INC. and AMGEN MANUFACTURING LTD.,	:	
Defendants.	:	

LETTER DATED JUNE 2, 2017
FROM MICHAEL P. KELLY, ESQ. TO THE HONORABLE SHERRY R. FALLON

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Dear Judge Fallon:

Amgen asks the Court to require AbbVie to produce information of marginal relevance that is confidential by statute and whose disclosure is prohibited. Amgen further compounds the problem by seeking information pertaining to patents and theories not at issue in this case. Amgen chose the scope of this case—by limiting the case to just 10 of more than 60 patents it infringes—and should not now be allowed discovery on patents it chose to exclude. *See Amgen Inc. v. Hospira, Inc.*, No. 1:15-cv-839-RGA, D.I. 47 at 39-40 (D. Del. May 8, 2016) (denying Amgen discovery on patents it could have included in the biosimilars suit but did not). Because Amgen's request is contrary to the BPCIA and goes well beyond the scope of this case, it should be denied.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") outlines a series of pre-litigation exchanges that culminate in litigation. The exchange process begins when the FDA accepts the biosimilar's application for review, at which point, the biosimilar applicant must provide to the innovator its confidential biosimilar application ("aBLA") and confidential details about its manufacturing process (42 U.S.C. § 262(l)(2)). Based on this confidential information, an innovator must identify the patents for which a claim of infringement could reasonably be asserted and provide this list of patents, also known as the 3A list, to the biosimilar. 42 U.S.C. § 262(l)(3)(A). A biosimilar then provides a statement to the innovator explaining why, in its opinion, it does not infringe the listed patents or why the listed patents are invalid. 42 U.S.C. § 262(l)(3)(B) (hereinafter, "3B statement"). After reviewing this statement, the innovator provides a response to the biosimilar's infringement and invalidity positions. 42 U.S.C. § 262(l)(3)(C) (hereinafter, "3C statement"). These exchanges make up the patent exchanges that Amgen originally requested in its Request for Production No. 25 ("All documents … produced by, served by or received by AbbVie in any Third Party Proceeding, including … any list provided under 42 U.S.C. § 262(l)(3)(A), any statement provided under 42 U.S.C. § 262(l)(3)(B) or any statement provided under 42 U.S.C. § 262(l)(3)(C)."). Amgen has since clarified that it is only seeking 3B and 3C statements. D.I. 78 at 1.

In addition to outlining the pre-litigation exchange process, the BPCIA states that "[n]o person that receives confidential information … shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the [biosimilar] applicant." 42 U.S.C. § 262(l)(1)(C). Additionally, the "confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the [biosimilar] applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the [biosimilar] application." 42 U.S.C. § 262(l)(1)(D). Lastly, the statute makes clear that "[b]y providing the confidential information [to the innovator and any outside counsel] the [biosimilar] applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than" determining "whether a claim of patent infringement could reasonably be asserted." 42 U.S.C. § 262(l)(1)(D), (E).

Amgen seems to recognize that it cannot access a biosimilar's confidential information as it now agrees that "it does not want the infringement contentions or any confidential information of the other applicants." D.I. 78 at 1. But this purported concession does not begin to solve the confidentiality problem. 3B and 3C statements, which may each be thousands of pages long,[1] are based on a biosimilar's confidential information and are intertwined with that information. Amgen notes that during the exchanges in this case, AbbVie took the position that the validity arguments in the contentions were not confidential, but neglects to mention that Amgen asserted a unilateral right to prohibit AbbVie from disclosing even redacted contentions to unrelated third parties. *See* May 9, 2017 Hr'g Tr. at 161:18-162:7. The biosimilar companies are likely to assert confidentiality over even non-confidential or marginally confidential information, and AbbVie will be in the untenable position of having to defend a confidentiality designation it may not even believe in.[2]

This is precisely why AbbVie's compromise proposal noted that it would need to give notice and an opportunity for any third party to object or intervene. *See* D.I. 78 at Ex. B ("[W]e will need to give notice and an opportunity to object/intervene to any such third parties."). The BPCIA expressly states that the confidential information disclosed during the statutory exchange "is, and shall remain, the property of the [biosimilar] applicant" and the innovator or the outside counsel cannot "use the confidential information, for purposes other than those subparagraph (D) [*i.e.*, determining whether a claim of patent infringement can be brought against a biosimilar]." 42 U.S.C. 262 § (l)(1)(E). And, if AbbVie violated the statute, there are specific penalties:

> The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider *immediate injunctive relief* to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

42 U.S.C. 262 § (l)(1)(H) (emphasis added). Therefore, AbbVie cannot produce these documents without consent from third parties.

Nothing in the BPCIA suggests that Congress intended for Courts to allow—much less require—disclosure of patent exchange materials to third parties in litigation. Thus, it is very likely that Amgen's request will create ancillary litigation with third party biosimilar manufacturers. Nearly a dozen companies have expressed their intent to pursue an adalimumab biosimilar. Requiring each of these companies to disclose their patent exchange materials will result in wave after wave of complex and time-consuming disputes.

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[1] Between the parties, almost 4500 pages of contentions were exchanged before the start of this case. *See* D.I. 60 at 1 ("Amgen served nearly 3,000 pages of contentions (called "3B Statements"); D.I. 65 at 1 ("AbbVie produced nearly 1,500 pages of detailed infringement and validity contentions to Amgen as part of the pre-litigation exchanges.").

[2] This is *not* a mere hypothetical. AbbVie can represent that it is aware that a biosimilar company has taken the position that all aspects of a 3B statement—including validity contentions—would be confidential, and could not even be shared with other attorneys at the innovator's company (beyond the one required by statute), much less third parties. If the Court wishes, AbbVie can provide additional details *in camera*.

The marginal (or nonexistent) relevance of the patent exchange materials completely fails to justify the burden required to produce them. To begin with, Amgen's allegedly limited request for validity and invalidity contentions of the patents-in-suit and related patents goes well beyond the scope of this case. Amgen seeks contentions for patents *not in suit*. Amgen, not AbbVie, chose to limit this case to just 10 of the more than 60 patents at issue. Amgen cannot now seek discovery on patents that it could have included in this case. *Amgen,* D.I. 47 at 39-40. But more importantly, Amgen has failed to establish why statements regarding unasserted patents are relevant to this case. *See Wyeth v. Impax Labs, Inc.* 248 F.R.D. 169, 171 (D. Del. 2006) (denying a Defendant's request where it had "not demonstrated why it is entitled to documents from [another litigation] involving matters not at issue in this litigation."). Amgen merely states that because it has limited its request to "the patents-in-suit and those that share a common priority with the patents-in-suit," it has adequately justified its request. D.I. 78 at 2. However, "[t]he mere fact that [two litigations] involve similar patents is not itself sufficient for a finding of relevancy pursuant to Rule 26." *Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, 662 F. Supp. 2d 375, 382 (D. Del. 2009); *see also Pfizer Inc. v. Teva Pharms. USA, Inc.*, 2009 WL 1587893, *1-2 (D.N.J. 2009) (denying motion to compel on unasserted claims); *Devex Corp. v. General Motors Corp*., 275 F. Supp. 310, 313 (D. Del. 1967) (limiting scope of response to that which pertained to claims at issue). Rather, a party must make a particularized showing why its broad discovery request is warranted. Amgen's request could require production of information concerning literally scores of patents that are not part of this lawsuit. Because Amgen has failed to establish the relevance of its broad request, it should be denied.

Even exchange materials concerning the patents-in-suit would be of little or no relevance. Such materials would not be evidence generated by percipient witnesses of the parties. They would be prepared by and exchanged between counsel. A major purpose of the BPCIA exchanges is to allow the parties to negotiate and potentially resolve which patents are relevant, which, if any, might be licensed, and which must be litigated.

Further, Amgen offers no persuasive justification for why it should have access to invalidity contentions made by another biosimilar company. Amgen is one of the largest pharmaceutical companies in the world. As it has repeatedly told this Court, it compounded 2700+ pages of invalidity contentions on its own. Amgen does not need to piggyback off the work of others, when the underlying information is equally available to it. As for AbbVie's responsive contentions, while Amgen is correct that the exchange documents themselves will not become public once litigation is filed against the biosimilar, the positions AbbVie takes are likely to be public in this very Court. At minimum, at that stage, all relevant parties will be in front of this or another court, which will allow a more orderly consideration of whether and how discovery of related litigation materials should proceed.

Amgen's request implicates complex issues of third party confidentiality under the BPCIA that will needlessly multiply the proceedings in this case, and the relevance of the materials it seeks is limited, at best. It should be denied.

Respectfully submitted,

/s/ Michael P. Kelly

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cc: Counsel of Record (via electronic mail)