IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD	:	
v.	:	CIVIL NO. 17-cv-01065-MSG-RL
BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC.	:	

MEMORANDUM OPINION CONCERNING Doc. No. 138

The defendants (collectively, "Boehringer") have moved to compel the production of prelitigation disclosures from another suit between the plaintiffs (collectively, "AbbVie") and Amgen, as well as settlement agreements that AbbVie concluded with potential biosimilar competitors to its drug, Humira. Doc. No. 138 at 2[1] ("BI. Mot."). I have reviewed the parties' submissions and will grant Boehringer's motion, with provision for the parties' counsel to meet and confer about confidentiality terms.

The 3B and 3C contentions are discoverable.

AbbVie and Amgen engaged in prelitigation disclosures and litigation under the Biosimilar Price Competition and Innovation Act ("BPCIA") starting in 2016. The case concerned seven of the eight patents in suit in this case. *Id.* AbbVie and Amgen settled the case in 2018. *Id.* at 3; *see* Doc. No. 138-2 (press release). The prelitigation disclosures[2] in the Amgen case spelled out the parties' contentions regarding validity and infringement.

[1] Page references are to the page numbers assigned by the ECF system.
[2] The disclosures at issue are so-called 3B and 3C statements, named after the BPCIA section calling for the disclosures. *See* 42 U.S.C. § 262 (l)(3)(B)-(C).

AbbVie argues that the "BPCIA provides a carefully balanced mechanism for parties to make a confidential and informal exchange of positions to facilitate potential agreement on the scope of litigation." Doc. No. 140 at 2-3 ("AV Opp."). AbbVie also argues that Boehringer fails to establish the "relevance and proportionality of the BPCIA exchanges under Rule 26." *Id.* at 3. AbbVie particularly objects to providing Amgen's contentions, questioning how Amgen's contentions could be relevant, since they have no tendency to make a fact of consequence to this litigation more or less likely. *Id.* at 4 (citing to Fed. R. Evid. 401).

The BPCIA requires a biosimilar applicant (such as Amgen, in the previous litigation) to disclose confidential information about its drug to the reference product sponsor (in both the Amgen case and in this one, AbbVie). 42 U.S.C. § 262 (l)(1)(B)(i), (l)(2). The purpose is to permit the reference product sponsor to figure out which patents it claims are infringed by the biosimilar drug. *Id.* at § 262 (l)(1)(D), (l)(2). The disclosures by the biosimilar applicant are to be kept confidential and used by the reference product sponsor only for the purpose intended under the statute. *Id.* at § 262 (l)(1)(C) and (D). The information may be disclosed with the consent of the biosimilar applicant, which must not be unreasonably withheld. *Id.* at § 262 (l)(1)(C). Amgen has consented to the disclosure sought by Boehringer, subject to court order and the maintenance of confidentiality.[3]

[3] Amgen's counsel, in an email dated June 19, 2018, wrote that

> Amgen agrees that AbbVie would not need Amgen's permission to produce the (3)(B) and (3)(C) statements in the BI Litigation, if ordered to do so by the Magistrate Judge, as long as AbbVie complies with the requirements of the Protective Order entered in the earlier *AbbVie v. Amgen* lawsuit, including by redacting any confidential Amgen information. Further, Amgen would not object to the production of the (3)(B) and (3)(C) statements in the BI Litigation, if the Magistrate Judge orders their production, as long as confidential Amgen information is redacted in compliance with the earlier Protective Order. Amgen would expect AbbVie to give Amgen an

Once the biosimilar applicant's information has been turned over to the reference product sponsor, the sponsor must give the applicant a list of patents it claims are infringed by the biosimilar. *Id.* at § 262 (l)(3)(A). The applicant then provides a claim-by-claim, detailed explanation of its contentions about the patents that it argues are invalid or not infringed (or both). *Id.* at 262 (l)(3)(B).[4] The sponsor then provides the applicant a detailed explanation of why the patents identified by the applicant under § 262 (l)(3)(B) are valid and infringed. *Id.* at § 262(l)(3)(C). These last two conflicting sets of contentions – the so-called 3B and 3C contentions – are what Boehringer seeks. The BPCIA has much to say about the confidentiality of the biosimilar applicant's (Amgen) information disclosed under 42 U.S.C. § 262(l)(1) but does not provide for separate or additional confidentiality for the contentions required under § 262(l)(3)(B) and (C).

The 3C contentions by AbbVie are statements by a party that may be used against the party, provided they are relevant. Fed. R. Evid. 801(d)(2)(A). Since seven of the eight patents in suit were also part of the Amgen case, it is likely that the 3C contentions are relevant, at least in part, under Fed. R. Evid. 401's liberal standard of relevance.

The 3B contentions by Amgen likely are relevant to supply the context of the 3C contentions. Producing the 3C contentions without the 3B contentions would be like producing a transcript of one side of a telephone conversation, or producing the answer to a complaint without the complaint. The exercise seems fruitless. Both sides of the dialogue are relevant and admissible, for different reasons. If the party statement is

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opportunity to review its redactions before producing the statements to BI to ensure compliance with the Protective Order with respect to Amgen confidential information.

Doc. No. 138, Exhibit 7 (ECF 138-7 at 2). These are reasonable conditions.

[4] The exchange of information can result in the parties dropping claims that they think are not worth pursuing, in light of the additional information provided.

relevant, it is admissible non-hearsay when used against the party making the statement. Fed. R. Evid. 801(d)(2)(A). The other side of the dialogue is relevant and admissible not for its truth, but because it makes the party statements understandable by putting them in context. *See United States v. Hendricks*, 395 F.3d 173, 184 (3d Cir. 2005) (a cooperating witness' side of a taped conversation was not hearsay because it was not introduced for its truth, but to place the defendant's side of the conversation in context).

The 3B and 3C disclosures are reasonably relevant to this case. They can be disclosed with minimal burden, provided reasonable confidentiality protections are followed. The minimal burden of production is far outweighed by the potential probative value of the disclosures to resolution of the issues in this case. *See* Fed. R. Civ. Pro. 26(b)(1). AbbVie will produce the requested 3B and 3C disclosures, subject to the terms of the current protective order entered in this case, and subject to its confidentiality obligations under the protective order in the *Amgen* case, as described in footnote 3, *supra*. The parties' counsel will meet and confer to iron out the terms of disclosure, which should include review by outside counsel only. If they cannot agree I will impose terms.

The settlement agreements are discoverable.

Boehringer also moves to compel the production of settlement agreements that AbbVie reached with Amgen, Samsung Bioepis, and Mylan, companies who seek to market a biosimilar drug in competition with adalimumab. BI. Mot. at 2. I find that the settlement agreements are likely to be relevant to Boehringer's invalidity and unenforceability defenses, are easily identifiable and producible without undue burden, are within the control of AbbVie and not accessible to Boehringer, and are routinely

produced in patent litigation, with adequate confidentiality protections. *See Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, 2017 WL 132265, at *1 (E.D. Tex. Jan. 12, 2017) ("Courts have frequently ordered the production of such agreements, subject to appropriate guarantees of confidentiality[]") (collecting cases); Fed. R. Civ. Pro. 26(b)(1) (listing factors that must be considered when ruling on the scope of discovery). That is not the end of the analysis, however.

AbbVie cites to the opinion in *Spear v. Fenkell*, 2015 WL 3947559, at *2 (E.D. Pa. June 26, 2015), arguing that Boehringer has not borne its burden to make a particularized showing that the settlement agreements are likely to be relevant to a permitted purpose under Fed. R. Evid. 408. Rule 408(a) bars the introduction of agreements, conduct, or statements made as part of compromise negotiations. The rule excepts such evidence for "another purpose," and provides examples, though the examples are not meant to be exclusive. Fed. R. Evid. 408(b). *Spear* was an ERISA case decided under Third Circuit law.[5] There is a legitimate question whether the heightened standard explained in *Spear* is applicable in this patent case, subject as it is to Federal Circuit law. BI Mot. at 3 n.2 (citing to *Blue Gentian, LLC v. Tristar Prods., Inc.,* 2017 WL 5203044 at *3 (D.N.J. Mar. 21, 2017) ("federal circuit law governs disputes over the discoverability" of a settlement agreement in a patent case).

[5] AbbVie misunderstands the holding in *Spear*. *See* AV Opp. at 6-7. *Spear* explained that the Second Circuit requires proof that a settlement agreement is collusive before it will be admitted. 2015 WL 3947559, at *1 (citing to *Grant Thornton v. Syracuse Sav. Bank,* 961 F.2d 1042, 1046 (2d Cir. 1992)). That is not the standard applied in *Spear*, which was drawn from District Court precedent within the Third Circuit. *See id.* at *2 ("the 'heightened' and 'particularized' showing of relevance under *Methacton Scho. Dist.* and *Felicetti* means that Stonehenge bears the burden of showing that the settlement agreement is likely to be admissible for a permitted purpose, under Rule 408. The standard is less demanding than the showing of collusion required under *Grant Thornton* and *Mars Steel Corp.*").

Given the frequency with which courts have ordered the production of settlement agreements in patent cases, *see Allergan*, 2017 WL 132265, at *1, and cases cited, it may be that the discovery rule in the Federal Circuit is less demanding than that described in *Spear*. Nevertheless, the Federal Circuit has rejected discovery of settlement agreements where there has been no showing of the "materiality of the settlement agreement[,]" being "mindful, as was the district court, of the policy in favor of protecting settlement negotiations from being admitted as evidence, thus serving to encourage settlements." *Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1308 (Fed. Cir. 2001) (citations omitted).

Boehringer's main contention is that the settlement agreements are relevant to the "'nexus' between the alleged commercial success of Humira and the allegedly inventive features of the asserted patents." BI Mot. at 6 (citing to *Pfizer Inc. v. Apotex Inc.*, 731 F. Supp. 2d 754, 759 (N.D. Ill. 2010)). Commercial success of a product incorporating a patented invention can be used to show that the patented invention was non-obvious. This would tend to favor the patent's validity. There is no doubt that Humira was commercially successful. But AbbVie must show more: that the patents in suit – which do not include the original Humira patent – are part of the reason for Humira's success. The terms of the settlement agreements may be relevant to show whether the patents in this case contributed materially to Humira's commercial success. *Pfizer*, 731 F. Supp. 2d at 759.

Boehringer also argues that the settlement agreements may be relevant to its unclean hands defense. BI Mot. at 6. The unclean hands defense alleges that AbbVie created a "patent thicket" of "overlapping and non-inventive patents for the purpose of . . . delaying competition." *Id.* (citation omitted). AbbVie denies that an unclean hands

defense can comprehend concepts of anti-competitive behavior in this fashion, and denies the substance of the claim, but the defense is pled and has not been the subject of a motion to dismiss. There is precedent holding that a settlement agreement is discoverable in a patent case when it is relevant to establish wrongful anti-competitive behavior. *See Key Pharmaceuticals, Inc. v. ESI-Lederle, Inc.*, 1997 WL 560131, at *3 (E.D. Pa. Aug. 29, 1997) (settlement agreements were discoverable in a patent case where wrongful anti-competitive behavior was alleged).

Whether the settlement agreements will be admissible under Fed. R. Evid. 408 depends in large measure on the claims that wind up being tried, the theory of evidence under which the settlement agreements are proffered, and whether the theory of admissibility falls under the exclusionary provisions of Rule 408(a) or the admissible purposes described in 408(b).[6] Boehringer has made enough of a showing, at this point, to warrant discovery of the settlement agreements.

AbbVie will produce the settlement agreements subject to the protective order entered in this case, and subject to review by outside counsel only. I will not impose the added layer of protection requested by AbbVie, creating a special cadre of lawyers who alone are authorized to see the settlement agreements. Such a system promises to be

[6] Whether evidence of commercial success – or its absence – goes to "prove or disprove the validity . . . of a disputed claim" within the meaning of Rule 408 is a question that calls into play the divergent meanings of "claim" in different legal contexts. Patent claims refer to something different than the ordinary meaning of the word "claim" in the Rules of Procedure and Evidence, where the word is typically used to refer to the allegations of a pleading. Additionally, the focus of Rule 408(a) is on the particular claim that was settled, not future, similar claims. *See* Rule 408(a)(1) and (2) (referring to "*the* claim") (emphasis supplied). That does not mean the policy of Rule 408(a) should not be extended to similar future claims, but the extension of that policy may clash with other policies emphasizing transparency in matters that affect the public welfare. The duration of the monopoly granted to an important and widely used medication may implicate such a policy. As for Rule 408(b), Boehringer seeks to prove "undue delay," not to "negat[e]" a claim of undue delay, as permitted in Rule 408(b). Allegations of a scheme to delay the introduction of a biosimilar drug may come within the meaning of the exception, but the argument is not so routine or obvious that its correctness should be assumed without examination. Resolution of these admissibility issues will benefit from a better defined record during motions *in limine* or trial.

unworkable. *See Allergan*, 2017 WL 132265, at *2 ("Creating a group of 'litigation' counsel and a separate group of 'settlement' counsel" should only be done in cases of "exceptional need"). The parties will meet, confer, and agree about the details of disclosure. If the parties cannot fashion agreeable confidentiality protections, they will advise me by letter and I will impose terms.

BY THE COURT:

s/Richard A. Lloret
RICHARD A. LLORET
U.S. MAGISTRATE JUDGE