AbbVie Inc. et al v. Boehringer Ingelheim International GMBH et al Doc. 100

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD	:	
v.	:	**CIVIL NO. 17-1065-MSG**
BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC.	:	

MEMORANDUM AND ORDER
CONCERNING DOC. NO. 69.

AbbVie[1] has moved under Fed. R. Civ. Pro. 26(b)(2)(C) for a protective order[2] staying responses to eight third-party subpoenas issued by Boehringer.[3] Doc. No. 69 ("AV Mot."). Boehringer has responded. Doc. No. 76 ("BI Res."). AbbVie filed a reply. Doc. No. 84 ("AV Rep.").

The third party subpoenas seek information related to three clinical studies related to adalimumab, known as HUMIRA, the drug at the center of this case. The three studies are the ARMADA study, which concerned rheumatoid arthritis (number DE009), a continuation of the ARMADA study (number DE009X), and the ATLAS study, which concerned ankylosing spondylitis (number M03-607). AbbVie Mot. at 4. AbbVie argues that these subpoenas are duplicative of information already requested from AbbVie, are unduly burdensome, and seek irrelevant information. *Id.* AbbVie also

[1] Collectively the plaintiffs will be referred to as "AbbVie," and the defendants as "Boehringer."
[2] AbbVie has standing to move for a protective order concerning these third-party subpoenas. *See Aetrex Worldwide, Inc. v. Burten Distribution, Inc.*, 2014 WL 7073466, at *4 (D.N.J. 2014).
[3] The subpoenas were issued to Florida Medical Clinic, Dr. Charles Birbara, Regents of University of California, University of Alabama Birmingham, Denver Arthritis Clinic, Brigham and Women's Hospital, Arthritis and Osteoporosis Center, and Altoona Center.

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claims that the subpoenas jeopardize AbbVie's "key relationships" with customers and clinical investigators. *Id*. Boehringer disputes AbbVie's contentions. BI Mem. at 6-9.

> Rule 26(c) places the burden of persuasion on the party seeking the protective order. . . [T]he party seeking the protective order must show good cause by demonstrating a particular need for protection. Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not satisfy the Rule 26(c) test.

Cipollone v. Liggett Grp., Inc., 785 F.2d 1108, 1121 (3d Cir. 1986). "Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure.[4] The injury must be shown with specificity." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation and citation omitted).

Four factors guide the evaluation of good cause: "relevance, need, confidentiality and harm." *Mannington Mills, Inc. v. Armstrong World Industries, Inc.*, 206 F.R.D. 525, 529 (D.Del. 2002) (citing to *Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1323 (Fed. Cir. 1990). "[E]ven if the information sought is relevant, discovery is not allowed where no need is shown, or where compliance is unduly burdensome, or where the potential harm caused by production outweighs the benefit." *Id*.

1. Relevance

Relevance is a forgiving standard, even when evaluating evidence to be admitted at trial. Fed. R. Evid. 401. During discovery the question is whether the information sought is "relevant to any party's claim or defense and proportional to the needs of the case . . ." Fed. R. Civ. Pro. 26(b)(1). Boehringer explains that the clinical trial documents it seeks from third parties may be relevant to its public use defense. BI Res. at 6-7; *see*

[4] *Pansy* concerned a sealing order relating to a settlement agreement, but the court made it clear that the same standards apply to protective orders preventing or controlling discovery during litigation. 23 F.3d at 786.

35 U.S.C. § 102(b) (2000). The documents are also directed to obtaining documents AbbVie is unlikely to have, and to check the completeness of the discovery produced by AbbVie. *Id*. at 7-9.

The public use defense is available if an "invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005) (quoting 35 U.S.C. § 102(b)) (emphasis omitted). Boehringer's theory of relevance is that details about the use of the drug during the clinical trial process may establish the defense. How the clinical trials were conducted – "the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed on members of the public who observed the use; and commercial exploitation" – may bear on a public use defense. *Id*. at 1380 (citing to *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1574 (Fed.Cir. 1995)).

AbbVie argues that the "proper focus of any public use inquiry was on the party in control of the clinical trials," not the patients. AV Rep. at 2 (citing *Dey, L.P. v. Sunovion Pharmaceuticals, Inc.*, 715 F.3d 1351, 1358 (Fed. Cir. 2013)). AbbVie overstates the holding in *Dey*. The Federal Circuit held only that patient "clinical trial at-home use of the formulation of Batch 3501A without an affirmative confidentiality obligation" did not doom Dey's patents. *Id*. at 59. The decision did not hold that communications with patients were categorically irrelevant. Instead, it held only that the district court could not "discount the relevance of the study participants' limited knowledge of Batch 3501A's formulation or . . . sidestep disputed factual questions about the nature of the allegedly public use[,]" because "a reasonable jury could conclude that if members of the public are not informed of, and cannot readily discern, the claimed features of the

invention in the allegedly invalidating prior art, the public has not been put in possession of those features." *Id*. This is a far cry from holding that communications between health care providers and participants in a clinical study are irrelevant.

Boehringer's theory of relevance is not make-weight. Details of the clinical testing process and protocols, and communications with patients, are reasonably calculated to produce relevant evidence concerning a public use defense. *See* Fed. R. Civ. Pro. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case . . . [i]nformation within this scope of discovery need not be admissible in evidence to be discoverable.").

2. Need

"Need is enhanced when information is uniquely available from the party from whom it is sought. The corollary is that need is diminished when the information is available elsewhere." *Avago Technologies U.S., Inc. v. IPtronics Inc.*, 309 F.R.D. 294, 299–300 (E.D.Pa., 2015) (quoting *American Standard Inc. v. Pfizer Inc.*, 828 F.2d 734, 743 (Fed. Cir. 1987)). Need is especially salient when a subpoena to third parties covers information available from a litigant. AbbVie contends that the clinical trial information is available from AbbVie, and has been requested by Boehringer. AV Mot. at 1. A review of the subpoenas, compared to Boehringer's requests for production, reveal that there is considerable overlap, although not exact congruence. *Id*. at 2-3.

Boehringer argues that the discovery seeks information related to patent invalidity – their "public use" defense. BI Res. at 7-8. Boehringer points out that the subpoenas seek information that AbbVie has refused to produce, and that some of the

information is unlikely to be in AbbVie's possession. *Id*. at 8. The discovery will also serve as a check on whether AbbVie has produced all relevant information. *Id*.

3. Confidentiality

AbbVie argues that the discovery sought by Boehringer will require disclosure of patient records protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, 110 Stat. 1936. AV Mot. at 5. This will mean extensive redactions, a significant burden on the eight subpoenaed parties. *Id*. AbbVie points out that "[r]elevant patient data – without HIPAA protected patient identifying information – is summarized in the clinical study reports that AbbVie has already produced to Boehringer." *Id*. Boehringer argues that the records are likely to have already been "anonymized." BI Res. at 10.

There is no allegation here that trade secrets or other, competitively vital, confidential information is at stake. *See, e.g., American Standard*, 828 F.2d at 743. The burden of HIPAA redactions is a routine concern in any case involving health care records. It is better accommodated as part of the analysis of harm, below.

4. Harm

AbbVie relies on *Joy Technologies, Inc. v. Flakt, Inc.*, 772 F.Supp. 842, 849 (D.Del. 1991) as authority for the entry of a protective order "to avoid the potential for harassment of these third party customers." AV Mot. at 4. The third parties who received the discovery requests from Joy were Flakt's customers for flue gas desulfurization ("FGD") systems, the patents for which were at issue in the case. 772 F.Supp. at 843, 849. It is a stretch to call the eight third parties in this case "customers," in the same sense. The eight subpoenaed parties in this case are researchers and health care providers who cooperated with AbbVie in clinical trials of HUMIRA. None of the

entities subpoenaed appear to be drug wholesalers or retailers, although as health care providers they may prescribe adalimumab to patients. There is no indication that Boehringer and AbbVie are seriously competing for sales to these third parties. AV Mot. at 1.There is no indication that the third-parties are presently participating in AbbVie trials. *Id*.

The harm that AbbVie posits is that researchers may grow wary of participating in clinical trials with AbbVie if they have to respond to discovery spawned by lawsuits involving the products they research. *Id*. Quantifying such future harm would be difficult, if not impossible, and AbbVie does not attempt to do so. *Id*. On its face the harm cannot be particular to AbbVie. AbbVie is not the only drug manufacturer whose clinical trial partners may face discovery demands during litigation. This cannot be the first instance when a researcher had to produce documents during litigation. Those who conduct drug research are typically sophisticated, and doubtless anticipate the possibility that litigation may erupt, sooner or later. Where there is litigation, there is discovery. The risk of having to respond to discovery is or should be factored into the cost of doing clinical trials, either up front or by way of indemnification. In short, the circumstances in this case are not close to those in *Joy Technologies*.

It is of course true that responding to a subpoena is inevitably a burden, and often an onerous one. When discovery is sought from a non-party, a court may take into account whether the discovery can be obtained from a fellow litigant, rather than from a bystander. *See Avago Techs. U.S., Inc. v. IPtronics, Inc.*, 309 F.R.D. 294, 297 (E.D. Pa. Sept. 15, 2015) (citation omitted). Limiting the scope of discovery required from third parties to that which cannot be obtained from a litigant tends to put the costs of litigation squarely on those actually engaged, forcing them to evaluate more closely the

relative benefits and burdens of any given discovery request. Limits on third party discovery may "secure the just, speedy, and inexpensive determination" of the case. Fed. R. Civ. Pro. 1. A given case may present circumstances that weigh in favor of, or against, limiting third party discovery.

The alternative to third-party compliance proposed by AbbVie is that Boehringer wait until it evaluates documents AbbVie has produced, then make a showing that the third-parties are likely to have relevant documents that have not been produced by AbbVie. This proposal seems likely to result in much work and time spent in order to get to largely the same place: Boehringer seeking to subpoena third-parties, and AbbVie claiming that subpoenas to third-parties are unnecessary and might chill a willingness to engage in future drug trials with AbbVie.

5. Weighing the various factors

The documents sought are reasonably calculated to lead to relevant evidence. While Boehringer has not introduced independently developed evidence that demonstrates a high likelihood that a public use defense will emerge from the third-party discovery, its relevance theory is legally grounded, and not chimerical. The subpoenas appear to be relatively focused. BI Mem. at 7 (the subpoenas are limited to those "involved in clinical trials conducted more than one year before the filing dates" of the patents in suit.). AbbVie has refused to produce a variety of documents relating to the recruitment of patients and public disclosures relating to the studies. *Id*. at 8. The subpoenas directed to production of these documents are reasonably designed to elicit information that would bear on Boehringer's public use defense.[5] None of the third-

[5] Boehringer makes the point that one of the purposes of third-party discovery is to serve as a check on the completeness of the discovery provided by a party. BI Res. at 9. There has been no motion by Beohringer

parties have filed a motion to quash. The burden of production seems proportional to the stakes in this case.

Preventing a breach of patient confidentiality is an administrative burden, in this case, not an existential risk to one of the parties. Harm to the business relationship between AbbVie and the subpoena recipients is speculative.

In the end a protective order denying a litigating party access to third-party records is not the norm, but an exception, and the party seeking such a protective order bears the burden of demonstrating "good cause." *Pansy*, 23 F.3d at 786. AbbVie has not borne its burden to demonstrate "with specificity" that compliance with the subpoenas "will work a clearly defined and serious injury" to AbbVie. *Id; see Cipollone*, 785 F.2d at 1121 ("broad allegations of harm, unsubstantiated by specific examples or articulated reasoning" do not suffice; Rule 26(c) requires a "particular and specific demonstration of fact" rather than "conclusory statements") (citations and quotations omitted).

For the reasons outlined above, it this 23rd day of May, 2018, **ORDERED** that AbbVie's motion is **DENIED.** Pursuant to my oral order of May 10, 2018, the third-parties will respond to the subpoenas within 14 days of the date of this order, unless any third party negotiates or seeks a later deadline for good cause.

BY THE COURT:

s/Richard A. Lloret
HONORABLE RICHARD A. LLORET
United States Magistrate Judge

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to compel AbbVie to produce documents. It is doubtful that a corroborative venture of this sort could ever be more than an adjunct rationale for otherwise relevant and proportional third-party discovery.