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 AND ORDER CONCERNING
DOC. NO. 72

Defendants (collectively "Boehringer") have moved to compel plaintiffs (collectively, "AbbVie") to produce documents sought in Boehringer's Second Set of Requests for Production of Documents and Things (RPD) concerning research and development underlying AbbVie's asserted patents. Boehringer's Motion (BI Mot.) at 1 (Doc. No. 72). AbbVie has responded (Doc. No. 77) (AV Res.), and Boehringer has replied to the response (Doc. No. 87) (BI Rep.).

I. The Nature of the Dispute.

This is a discovery dispute about the scope of a request for research and development documents concerning adalimumab (HUMIRA), several patents for which are the subject of this case. Boehringer seeks an order directing AbbVie to "search for R&D [research and development] materials in all custodial and non-custodial data sources reasonably likely to contain that information without regard to the six-year default temporal limitation in Paragraph 4(e) of the Delaware Default Standard for

Discovery [DDSD 4(e)(e)]."[1] *Id*. Boehringer argues that "[c]ourts routinely grant discovery of this nature in patent cases because it directly impacts the issues of prior art and patent validity." BI Mot. at 1.

AbbVie argues that DDSD 4(e) provides that discovery should be limited to six years before the filing of the complaint, except for discovery related to conception and reduction to practice or asserted prior art. AV Res. at 1. AbbVie contends it has already produced more than DDSD 4(e) requires. *Id.* (describing the various categories of document produced regardless of date). AbbVie complains that Boehringer "conflates ***thirty-seven*** different document requests as all purportedly seeking documents 'related to' R&D underlying the inventions claimed in the patents-in-suit." *Id.* at 2 (bold and italics in AV Res.) (citing to BI Mot. at 1). As an example, AbbVie points to RPD 60, which asks for discovery about "any steps taken by AbbVie or any Third Party to increase the antibody titer of adalimumab." *Id.* AbbVie contends that this language covers a wide range of research and development relating to adalimumab, regardless of whether the "steps" are covered by any of the contested patents, and regardless of whether the research and development occurred after the '867 patent's effective filing date.[2] *Id*. AbbVie makes the same point about RPD 55, which would require production of all research and development relating to "the selection of the cell expression system used to express any adalimumab[,]" regardless of whether the research had any significance to the patents at issue in this case. *Id*.

[1] The text of the rule reads "[a]bsent a showing of good cause, follow-up discovery shall be limited to a term of 6 years before the filing of the complaint, except that discovery related to asserted prior art or the conception and reduction to practice of the inventions claimed in any patent-in-suit shall not be so limited."

[2] U.S. Patent No. 9,090,867, titled "Fed-Batch Method of Making Anti-TNF-Alpha Antibody," which was issued by the USPTO on July 28, 2015. Complaint at 23, ¶ 77 (Doc. No. 1).

AbbVie argues that the relief Boehringer seeks would force AbbVie to "search every location that potentially may contain decades-old documents unrelated to any of the patents-in-suit[,]" and that Boehringer has not demonstrated "good cause" for exceeding the time limit in DDSD 4(e). *Id.* at 2. AbbVie contends that merely showing the relevance or importance of the discovery is not enough to show "good cause," under DDSD 4(e). *Id.* at 6 (citing to *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, No. CV 14-878-LPS-CJB, 2016 WL 859229, at *3 (D. Del. Mar. 3, 2016) ("if the possible existence of some other relevant, non-produced documents was always enough to demonstrate good cause to abandon the Default Standard's requirements, the Standard would be worth little.").

Boehringer replies that DDSD 4(e) exempts discovery concerning conception and reduction to practice; the requested discovery is "limited to R&D before the filing dates of the asserted patents[;]" and the breadth of the search is a function of AbbVie asserting 157 claims. BI Rep. at 2. Boehringer points out that "the entire scope of discovery that Boehringer seeks to compel through this motion would be responsive to Request No. 32, which seeks documents "concerning the research and development of the alleged invention(s) of the patents-in-suit, including, but not limited to, documents concerning the conception and reduction to practice of any of the alleged inventions of the patents-in-suit." *Id.* at n.3.

II. Discussion.

At a surface level the dispute is over the delimitation of the phrases "research and development" and "conception and reduction to practice." At bottom the dispute is an iteration of the usual problem of discovery: how to balance the need for information against the burden of searching for the information. The parties agree that the phrase

"research and development" implicates a larger universe of documents than the phrase "conception and reduction to practice." Boehringer is concerned that a search limited to "conception and reduction to practice" will "exclude critical documents relevant to Boehringer's invalidity defenses. For example, failed experiments that contradict the teachings of subsequent patents-in-suit or discussions relating to the state of the art that demonstrate the obviousness of the asserted claims." BI Mot. at 1-2. AbbVie resists a search for broad ranging research and development documents unrelated to the patents-in-suit, and seeks sanctuary in a more limited search for documents "related to the conception and reduction to practice of the inventions claimed in the patents-in-suit." AV Res. at 1-2. The wrangle over the implications of the two phrases also extends to whether the time limit in DDSD 4(e) should be enforced or relaxed.

Boehringer argues that its request for "research and development" documents should be exempted from DDSD 4(e)'s time and subject matter constraints because there is "good cause." BI Mot. at 1-2. The "good cause" proposed is that this case is unusual, given the number of patents and claims at issue, and the evolution of a "patent thicket" over a lengthy period of time. *Id.* at 5. Boehringer also argues that research and development documents are routinely discovered in patent cases across the country. BI Rep. at 1. As an example, Boehringer points to the Northern District of California's local rule, which requires production of research and development documents as part of mandatory discovery. *Id.* at 1 (citing to Exhibit H at 5 (a copy of the ND Ca. local rule)).

The problem with the argument is that it amounts to a rewrite of Delaware's local rule. There is no obvious limiting principle to such a "good cause" exception. Such an exception likely would come into play any time a complaint is filed more than a few

years after the conception of the patent. That is sure to be a large percentage of patent cases, regardless of whether a case is "typical" or "complex."

AbbVie's argument, that such a generalized search goes beyond the patents actually at issue in this case, finds a logical home in the text of DDSD 4(e). The rule exempts discovery "related to asserted prior art or the conception and reduction to practice of the inventions claimed in any patent-in-suit . . ." from the otherwise applicable time limitation of six years before the filing of a complaint. The time limit exemption does not apply to the more generalized category of "research and development" documents, unless they are "related to" prior art or conception and reduction to practice.

Conception and reduction to practice are milestones in the larger continuum of research and development. Conception marks the point at which an invention is complete and eligible for a patent. *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67-68 (1998). The date of conception informs the time frame for application of the "on-sale" bar, *id.*, and may determine the time frame for evaluating "prior art." *See Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 968 (Fed. Cir. 2014). Reduction to practice is an evidentiary signal that conception is sufficient to justify patent protection. *Pfaff*, 525 U.S. at 68. Tying the time limit exemption in DDSD 4(e) to "conception and reduction to practice" has the benefit of tethering discovery closely to the inventions actually at issue in a case.

Limitations on discovery always carry a risk of leaving behind useful information. The question is the value of the discovery that might be missed, weighed against the burden of searching for it. DDSD 4(e) strikes such a balance by imposing a time limit on most discovery, but exempting from the time limit information that relates to prior art,

conception, and reduction to practice. For evidence that does not relate to prior art, conception, or reduction to practice, the time limit may be excused for "good cause." Boehringer's proposed "good cause" exception would swallow the rule. I do not agree with Boehringer that the time limits under DDSD 4(e) should be disregarded. Nevertheless, the language of DDSD 4(e) lends itself to a broader scope of discovery than AbbVie seems to acknowledge.

The phrase "related to," used in DDSD 4(e), is undefined. The phrase must mean at least "relevant," as defined under Fed. R. Evid. 401, although it may mean more. Evidence is relevant if it has "any tendency to make a fact [of consequence to the determination of the action] more or less probable than it would be without the evidence." *Id.* "Any tendency" is a liberal standard.

"Conception" and "reduction to practice" are facts of consequence under this particular legal standard.[3] Research and development information that leads in a plausible and logical fashion to "conception and reduction to practice" is "related to" these two facts of consequence. It makes the existence of the facts of consequence more likely. Information that tends to contradict or disprove the existence of "conception or reduction to practice" also is "related to" those facts of consequence.[4] Events at some remove from the moments of "conception and reduction to practice" may be "related to" either one, because such events may form part of a logical chain that tends to affirm or negate the likelihood of conception or reduction to practice.[5]

[3] As is "prior art," under DDSD 4(e), but the parties' dispute focuses for the most part on conception and reduction to practice.

[4] An email in which a manager wrote "this process is interesting, but we will never be able to turn it into anything useful," is "related to" conception and reduction to practice, because it has a tendency to make less likely the existence of either event.

[5] The rule's generality does not solve the practical problem of how to define document search terms to include relevant documents and exclude irrelevant documents. The parties have not asked me to rule on

III. Conclusion and Order.

Boehringer acknowledges that RPD No. 32 defines the universe of documents it is asking for. RPD No. 32 asks for documents "concerning the research and development of the alleged invention(s) of the patents-in-suit, including, but not limited to, documents concerning the conception and reduction to practice of any of the alleged inventions of the patents-in-suit." I will use this request as a basis for ordering some relief,[6] while denying Boehringer's motion in large part.

For the reasons described above, it is on this 6th day of June, 2018, **ORDERED** that

1) Boehringer's motion (Doc. No. 72) is **DENIED**, except as follows;

2) Boehringer's motion is **GRANTED in part**:

> A) For the six-year period preceding filing of the complaint in this action, AbbVie shall promptly respond to RPD No. 32.
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> B) For the time preceding the six-year period described in paragraph 2(A), AbbVie shall promptly produce documents concerning the research and development of the alleged invention(s) of the patents-in-suit that relate to asserted prior art and to the conception and reduction to practice of any of the alleged inventions of the patents-in-suit.
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> C) The search shall be limited to the 50 custodial sources previously identified by AbbVie.

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disputed search terms, but have couched their dispute in terms of the language of the overarching legal rule. I will order the parties to meet and confer over search terms and an expedited time frame for discovery.

[6] In its reply, Boehringer for the first time asked that certain arguments and evidence be precluded at summary judgment and trial if AbbVie "cannot conduct the requested search in a timely fashion[.]" BI Rep. at 3. I permitted AbbVie to file a sur-reply addressing this argument. *See* Oral Order of 6/5/2018; AbbVie sur-reply (Doc. No. 113). I will deny Boehringer's request for sanctions. *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269 (Fed. Cir. 2011), relied upon by Boehringer, does not justify such a sanction. There, the district court excluded certain proposed expert testimony at trial because it was based on evidence not disclosed during discovery. *Id.* at 1286. Trial is a long way off. There has been no showing that proposed trial evidence has been undisclosed in discovery.

3) Counsel shall meet and confer on or before June 20, 2018 for the purpose of (A) agreeing upon an expedited time frame for the discovery required under this order, and (B) agreeing upon additional search terms, if needed to implement this Order. If the parties cannot agree, they may schedule a conference call with my chambers to discuss whether a hearing is needed.

4) Boehringer's request for sanctions (*see* Doc. No. 87) is **DENIED.**

BY THE COURT:

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