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 CONCERNING MOTION TO ENFORCE (DOC. 233)

INTRODUCTION

The defendants (collectively, "Boehringer") have moved for entry of an Order enforcing my Order of June 4, 2018, which directed the plaintiffs (collectively, "AbbVie") to respond promptly to Boehringer's Second Set of Requests for Production of Documents and Things, No. 36-37, and 40-43. *See* Doc. No. 233 ("Pl. Mot."). AbbVie has opposed the Motion to Enforce, contending that it has complied with the Order. *See* Doc. No. 242 ("Def. Opp.").

Some context is helpful. AbbVie refused to produce documents pertaining to Boehringer's "unclean hands" defense. Boehringer filed a motion to compel. Doc. No. 71. I granted the motion by Order dated June 4, 2018 and directed AbbVie to produce the documents identified by Boehringer's requests for production ("RFP") 36-37, 40-43. Doc. No. 112. AbbVie produced some documents in response to my Order, but Boehringer identified a number of deficiencies. Doc. No. 233-1, at 5-7 (Boehringer's deficiency letter of August 17, 2018). These are the deficiency categories Boehringer identified:

• AbbVie's patenting program designed to mitigate biosimilar entry;

• Incentives employed by AbbVie to increase the patent coverage for Humira®, including, but not limited to, the Humira® Idea Submission Program purportedly launched in December 2010 and referenced at ABV-BI00658341;

• Strategies underlying the document titled "Humira IP Discussion" dated January 25, 2011 and carrying Bates numbers ABV-BI00658329-47;

• Strategies to mitigate biosimilar competition involving at least George Avgerinos, Andy Brookes, William Chase, Azita Gerhardt, Richard Gonzalez, John Landgraf, Li-Hong Malmberg, Peter Moesta, Perry Siatis, and Glenn Warner;

• Brainstorm meetings concerning the mitigation of biosimilar competition, including, but not limited to, the meeting held October 4-5, 2010 in Worcester and sponsored by John Landgraf and Peter Moesta;

• Strategies underlying Chairman and Chief Executive Officer Richard Gonzalez's statements in the presentation titled "Abb Vie Long-Term Strategy" dated October 30, 2015, concerning AbbVie's "Broad U.S. Humira Patent Estate";

• Strategies underlying Chairman and Chief Executive Officer Richard Gonzalez's statements during AbbVie's 2015 third quarter earnings call on October 30, 2015 that AbbVie's patent portfolio will "cover not only our commercial formulation but also other related information that biosimilar companies might employ";

• Strategies underlying Chief Financial Officer William Chase's statements on June 11, 2014 at the Goldman Sachs Healthcare Conference that AbbVie' s intellectual property strategy "is designed to make it more difficult for a biosimilar to follow behind you and come up with a very, very similar biosimilar" because the "less similar, the greater likelihood of a difference in efficacy; or, very importantly, a difference in safety";

• Strategies underlying Chief Financial Officer William Chase's statements on June 13, 2017 at the Goldman Sachs Global Healthcare Conference that even if Amgen had "prevail[ed] and knock[ed] down every claim" of the 61 patents at-issue, then the market would recognize biosimilar competition would not occur prior to 2022;

• Strategies underlying the documents referenced in AbbVie's clawback letters dated May 4 and June 4, 2018;

• Groups, programs, or initiatives within AbbVie created to further biosimilar mitigation efforts;

• AbbVie's consultation with McKinsey & Co. and the Boston Consulting Group to mitigate biosimilar competition;

• Internal meetings and conferences directed to generating patent applications, including those applications directed to existing and common technology platforms;

• Strategies underlying AbbVie's effort to obtain patent protection over product quality-related attributes and processes;

AbbVie responded to the deficiency letter. Doc. No. 233-1, at 9 (AbbVie's responsive letter of August 30, 2018). Boehringer's motion followed. Doc. No. 233. Beyond this dispute, the parties have been engaged in broad ranging discovery disputes for quite some time, as a scan of the docket will indicate.

DISCUSSION

AbbVie makes four arguments:

- AbbVie contends that Boehringer's August 17, 2018 deficiency letter, and its motion to enforce, are attempts to broaden the scope of their requests for documents, after the deadline for serving discovery requests had passed. Def. Opp. at 1.
- AbbVie also argues that documents sought in the deficiency letter and motion "do not relate to Boehringer's unclean hands defense as pled, much less the specific RFPs subject to Beohringer's motion to compel." *Id.* at 5.
- AbbVie contends that Boehringer's deficiency letter and motion are attempts to require "additional custodial searches despite the Court's denial of previous such attempts, [and] apply new search terms in

contravention of the District of Delaware Default Standard . . .” *Id.* at 1; *see id.* at 4-7.

- Finally, AbbVie points out that it has produced many documents in compliance with the June 4, 2018 Order, and argues that it has complied with the Order of June 4, 2018. *Id.* at 2.

I will address AbbVie’s arguments one at a time, in the order I have mentioned them.

1. The deficiency categories are within the scope of the requests.

Boehringer makes a showing that the litany of documents identified in its deficiency letter of August 17, 2018 all fall within the scope of their Requests No. 36-37, and 40-43, to which the June 4, 2018 Order required AbbVie to respond promptly. *See* “Appendix A” to Pl. Mot., at 1-6 (Doc. No. 233-2). Appendix A is a chart that compares the classes of unproduced documents identified in the letter of August 17, 2018 with the six document requests that were the subject of the June 4, 2018 Order.

AbbVie argues that Boehringer’s showing is insufficient. Def. Opp. at 3-4. As an example, AbbVie explains that Boehringer claims that its deficiency category of documents “relating to ‘AbbVie’s patenting program designed to mitigate biosimilar entry’ is relevant to ‘marketing and promotion by AbbVie of any formulation containing . . . Humira®’ (RFP No. 36).”*Id.* at 4. AbbVie contends that there is “no tie between AbbVie’s marketing of HUMIRA® and any alleged patenting program designed to mitigate biosimilar entry.” *Id.* AbbVie concludes that the “Court ordered AbbVie to comply with the RFPs that were the specific subject of the motion – not with Boehringer’s expansion of the RFPs in its motion to compel.” *Id.* at 5.

AbbVie's argument is unconvincing. Boehringer described the missing information as "AbbVie's patenting program designed to mitigate biosimilar entry." Appendix A, at 1; August 17, 2018 letter (Doc. No. 233-1, at 5). In its Appendix A, Boehringer recapitulated the six requests that were the subject of my June 4, 2018 Order, and compared these requests with the litany of deficiency categories listed in its August 17, 2018 letter:

Appendix A

RFP Nos. 36-37, 40-43: Documents and Things Concerning the Following Categories						
Exemplary withheld documents identified in Boehringer's August 17, 2018 letter to AbbVie	**Marketing and promotion by AbbVie of any formulation containing adalimumab, including Humira®, including, but not limited to, U.S. marketing or promotional materials and brand plans (36)**	**Financial analyses, sales, revenues, costs, profits, and projections concerning any AbbVie adalimumab or any formulation containing adalimumab, including Humira® (37)**	**Economic or market impact (whether actual, anticipated, direct, or indirect) to AbbVie or any Third Party resulting from AbbVie's enforcement of the patents-in-suit or any related U.S. patent (40)**	**AbbVie's adalimumab "patent estate" (*see, e.g.*, Andrew Pollack, Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions, N.Y. TIMES, (July 16, 2016), https://www.nytimes.com/2016/07/16/business/makersof-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html) (41)**	**October 30, 2015 presentation by AbbVie's Chairman and Chief Executive Officer titled "AbbVie Long Term Strategy," including, but not limited to, any documents referenced or used to prepare the foregoing or any drafts thereof (42)**	**Any presentation given at any conference or materials provided to AbbVie shareholders relating to AbbVie's intellectual property strategy for Humira® (43)**
AbbVie's patenting program designed to mitigate biosimilar entry	✓	✓	✓	✓	✓	✓

Doc. No. 233-2, at 1. AbbVie's argument only explicitly discusses an alleged mismatch between the first deficiency category and the first of the requests, RFP 36. To be convincing, AbbVie would have to explain why this deficiency category is not covered by *any* of the requests. AbbVie has not done so. Based on my own examination, it seems obvious that documents fitting within the description "AbbVie's patenting program designed to mitigate biosimilar entry" would fit comfortably within requests 37, 40, 41, 42 and 43. I will explain why.

It seems clear enough that AbbVie did have a "patenting program designed [at least in part] to mitigate biosimilar entry"[1] that might have an impact on Humira® sales. It is hard to imagine that there was no "financial analyses, sales, revenues, costs, profits,

[1] I will refer to this as the "patenting program," for short.

and projections concerning . . . Humira®" (RFP 37) conducted as part of that patenting program. A company of AbbVie's sophistication would be unlikely to undertake such a patenting program without counting the costs and benefits.

Similarly, it stands to reason that such a patenting program would have considered the "economic or market impact . . . to AbbVie or any Third Party resulting from enforcement of the patents-in-suit." (RFP 40). Such a patenting program clearly concerned AbbVie's "patent estate," as described in a New York Times article in 2016 (RFP 41). It also seems reasonable that such a patenting program would have informed the Chairman's presentation of "AbbVie Long Term Strategy" (RFP 42), as well as presentations or materials given at conferences, or to shareholders, "relating to AbbVie's intellectual property strategy for Humira®" (RFP 43). In sum, AbbVie did not demonstrate a mismatch between the first deficiency description and requests 37, 40-43. My own examination convinces me there is no significant mismatch.

Getting back to AbbVie's explicitly voiced criticism, relating to RFP 36, it is reasonable to believe that documents concerning AbbVie's patenting program included information concerning the "marketing and promotion by AbbVie of any formulation containing adalimumab, including Humira®." After all, the patenting program was designed (by Boehringer's plausible account) to preserve Humira's® market share beyond the core patent's expiration date.

I am convinced that AbbVie's "scope" argument is not a sound basis for refusing to turn over documents covered by the Order. I will not go through every one of Boehringer's listed deficiency categories and explain why Boehringer justly contends that the category is a "fit" with one or more of its requests for production. I have examined the back-and-forth contained in the parties' filed papers, as well as their

correspondence, and I find that Boehringer has supplied a reasonable explanation of the "fit" between Boehringer's deficiency categories and its requests for production.

I reject AbbVie's "scope" argument. I will turn to AbbVie's other arguments.

2. The requested documents are within the scope of Boehringer's defense.

AbbVie argues that "Boehringer's unclean hands defense relates to AbbVie's ***patent*** strategy, not to every aspect of its biosimilar strategy." Def. Opp. at 4 (AbbVie's emphasis). Thus, AbbVie argues, "Boehringer's multiple requests directed to, for example, any AbbVie strategy to 'mitigate biosimilar entry,' 'strategies to mitigate biosimilar competition,' and 'AbbVie's consultation with McKinsey & Co. and the Boston Consulting Group' would include documents related to AbbVie's consideration of whether to develop its own biosimilar products and AbbVie's evaluation of the regulatory framework for biosimilar products." Def. Opp. at 4.

The first example provided by AbbVie is the argument's undoing. AbbVie says that documents relating to its "strategy to 'mitigate biosimilar entry'" would exceed the scope of Boehringer's unclean hands defense, which relates to "***patent*** strategy." *Id.* (AbbVie's emphasis). But the documents Boehringer actually described in its August 17, 2018 deficiency letter were those relating to "AbbVie's ***patenting program*** designed to mitigate biosimilar entry." Appendix A, at 1; Doc. No. 233-1, at 5 (my emphasis). AbbVie has omitted the crucial qualifier in Boehringer's deficiency category, a qualifier that makes AbbVie's argument nonsense. AbbVie has set up a "straw man" to knock it

down.[2] This is unhelpful, to put it politely. It convinces me that I need not spend inordinate time on AbbVie's objection.

As for AbbVie's two other examples,[3] they do not argue that the documents described by the deficiency categories are wholly divorced from the scope of the defense. They just argue that the deficiency categories may include some documents that do not directly relate to the defense. At this point, so be it. Appropriately designed search techniques may mitigate this concern, but the time for wrangling over the contours of the requests, or of the deficiency categories noted by Boehringer, is past. AbbVie chose to fight the "unclean hands" discovery to the last ditch. I am declaring the fight over. AbbVie will produce the documents. The parties may fight over the viability of the unclean hands defense at summary judgment, with all the available and potentially relevant facts. That is where the fight belongs, and that is how it will be conducted.

In accordance with Federal Rule of Civil Procedure 26(b)(1), I make the following findings:

- the requests mentioned in my Order of June 4, 2018, and the categories noted in Boehringer's deficiency letter of August 17, 2018, are relevant to the defense of unclean hands.
- The document production requested is proportional to the needs of the case.
- The issue at stake is the "unclean hands" defense, which is an important, not peripheral, part of this case.

[2] "A variation of *ignoratio elenchi*, known under the name of the straw man fallacy, occurs when an opponent's point of view is distorted in order to make it easier to refute." Hansen, Hans, "Fallacies", *The Stanford Encyclopedia of Philosophy* (Summer 2018 Edition), Edward N. Zalta (ed.), URL = <https://plato.stanford.edu/archives/sum2018/entries/fallacies/>. (Accessed 2/8/2019 at 10:21 a.m.).
[3] Those being 'strategies to mitigate biosimilar competition,' and 'AbbVie's consultation with McKinsey & Co. and the Boston Consulting Group,' Def. Opp. at 4, pulled from Boehringer's litany of deficiencies.

- The amount in controversy in this case is vast, and the unclean hands defense, if substantiated, is potentially dispositive.
- The discovery will be important to the resolution of the unclean hands defense.
- AbbVie has far better access to, and knowledge of, its documents than does Boehringer.
- Given the parties' resources, and the documents' importance, I find that the likely benefits of the discovery outweigh any burden and expense.[4]

As for the discovery taking lots of time, I disagree. AbbVie has already elected to spend its time resisting discovery. It litigated and lost, twice. Months will not be absorbed with compliance. AbbVie will engage in rapid and punctilious compliance with my Order.

I reject AbbVie's contention that the requests and deficiency notices exceed the scope of the unclean hands defense.

3. If more custodial searches are required to comply with my Order of June 4, 2018, AbbVie will accomplish the searches.

AbbVie contends that Boehringer's deficiency letter and motion are attempts to require "additional custodial searches despite the Court's denial of previous such attempts, [and] apply new search terms in contravention of the District of Delaware Default Standard . . ." *Id.* at 1; *see id.* at 4-7. I will not speculate on Boehringer's agenda. My focus is on my Order of June 4, 2018, and on AbbVie's non-compliance. The short answer to AbbVie's argument is that I reject it. AbbVie will conduct whatever new searches of whichever new custodians are needed to comply fully and in good faith with

[4] AbbVie has not introduced evidence of the volume, time, or particular difficulties attending compliance.

my Order of June 4, 2018, and to remedy the deficiencies noted in Boehringer's August 17, 2018 letter.

I have no doubt that AbbVie, with its vast resources and superb attorneys, can accomplish this duty with efficiency and dispatch. I will direct that counsel meet and confer promptly about how best to manage the remedial discovery. Counsel may discuss whether additional custodians and search terms are necessary, and if so, who those custodians are and what the search terms will be. I caution, however, that the meet and confer is not an opportunity for AbbVie to throw more wrenches into the gears.

4. The fact that AbbVie has supplied documents responsive to my June 4, 2018 Order does not cure its deficiencies.

AbbVie points out that it has produced many documents in compliance with the June 4, 2018 Order, and argues that it has complied with the Order of June 4, 2018. *Id.* at 2. The fact that AbbVie produced some documents in compliance with the Order does not excuse the failure to produce others. The argument is rejected.

CONCLUSION

I will enter an Order directing AbbVie to comply with my June 4, 2018 Order and to remedy the deficiencies noted in Boehringer's August 17, 2018 letter.

BY THE COURT:

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