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.	:	

ORDER RESOLVING DISPUTES OVER DEPOSITION TOPICS

The parties have a number of discovery disputes relating to the scope of depositions under Fed. R. Civ. Pro. 30(b)(6). They have submitted a chart outlining their positions, item by item, and have provided "preliminary statements"[1] as a preface to the chart. The chart and the preliminary statements are collectively identified in this Order as the "Chart." A copy of the chart is being filed under seal contemporaneously with this Order, because the parties have indicated there is confidential information contained in the Chart. By this Order I resolve the various disputes described in the Chart. The references to dispute category and topic number follow the Chart from start to finish.

Where I have quashed a deposition notice as disproportionate, I have considered the factors identified in Fed. R. Civ. Pro. 26(b)(1). Given the volume of discovery already turned over by both parties, and the length of time this litigation has already proceeded, I am particularly concerned that the burden and expense of additional, voluminous

[1] The preliminary statements are in the nature of a commentary on the chart itself. I will address the parties' contentions as distilled in the chart, and will not address the preliminary statements.

discovery will outweigh its likely benefits. I am also concerned that much of the information sought through broadly drawn 30(b)(6) notices will not be of significant importance in resolving the issues in the case.

On this 17th day of January, 2019, it is **ORDERED**, as follows:

I. Research & Development Dispute

Topic 5: The topic is limited to research and development that resulted in the approved BLA formulation, even if experiments were on a different formulation, as long as the experimentation was reasonably related to the research and development of the approved BLA formulation.

Topic 6: The topic is limited to the purification processes Boehringer has used, is using, or will use in the production of BI695501: Protein A chromatography, cation exchange chromatography, anion exchange chromatography, and hydrophobic interaction chromatography. AbbVie will produce a witness to testify concerning this same scope under Boehringer's parallel deposition Topic No. 7.

Topic 9: The scope of the topic is limited to the analytical characterization of acidic species and oligosaccharide composition of BI695501 and any research and development reasonably related to the same.

Topic 10: The scope of the topic is limited to the analytical characterization of BI695501: N-linked oligosaccharide composition of BI695501.

Topics 11 & 12: The topics are limited to host cell proteins, proteases, procathepsin L. and cathepsin L. AbbVie will produce the same discovery in response to Boehringer's parallel topics.

Topic 13: The topic is limited to the stability testing of the product that is the subject of BLA No. 761058, including studies on the degradation pathways for BI 695501 and forced degradation studies; experimental protocols; experimental testing data; stability tests performed on BI 695501; and the individuals involved in these studies and tests.

Topic 17: The topic is limited to the dosing regimen for the adalimumab product that is the subject of BLA No. 761058.

Topic 19: The topic is limited to the approved label for the product that is the subject of BLA No. 761058 for use in patients with rheumatoid arthritis and ankylosing spondylitis, as well as any changes made to the label as they relate to the formulation and instructions for use to treat rheumatoid arthritis and ankylosing spondylitis for the adalimumab product that is the subject of BLA No. 761058 that have been submitted to the FDA for approval.

Topic 24: The topic is limited to any studies or investigations by or for Boehringer concerning methods of viral inactivation for production of BI 695501, including when the studies or investigations occurred; the results; and the identities of the persons involved, along with their roles.

Topic 38: The topic is limited to facts concerning the approved indications for the adalimumab product that is the subject of BLA No. 761058 for use in patients with rheumatoid arthritis and ankylosing spondylitis.

II. Batch Records Dispute

Topic 14: The deposition notice is quashed as disproportionate.

Topic 15: The deposition notice is quashed as disproportionate.

III. Secondary Considerations Dispute

Topic 21: The deposition notice is quashed as disproportionate. AbbVie may reformulate the topic to focus directly on the patents-in-suit.

Topics 33: The deposition notice is quashed as disproportionate. AbbVie may supply a detailed notice that identifies with specificity which secondary indicia it is relying on, which patent claims have a nexus to the indicia, and the facts supporting its claims of secondary indicia. At that time AbbVie may reissue a notice of deposition with a reformulated topic limited to the scope of its notice. Boehringer also will supply a 30(b)(6) witness to testify concerning its Topic 30.

Topic 34: The deposition notice is quashed as disproportionate.

Topic 35: The deposition notice is quashed as disproportionate.

Topic 36: The topic as defined by AbbVie is sustained.

Topics 39, 40: The deposition notices are quashed as disproportionate.

Topic 44: The topic is limited to any attempts to copy any of the Patents-in-Suit.

IV. Unclean Hands Dispute

Topic 1: The scope of this topic as defined by AbbVie is sustained. Boehringer seeks to litigate an unclean hands defense predicated on its "patent thicket" theory. This theory, by definition, raises issues concerning patents that are not in suit. If patents not in suit will be used as evidence in support of Boehringer's unclean hands defense, AbbVie is entitled to inquire exactly which patents constitute the wrongful "thicket," and to get an account from Boehringer of the factual details that make these patents probative of an unclean hands defense.

AbbVie is also entitled to inquire about the extent to which these patents formed a consideration in Boehringer's decision to bring a biosimilar product to

market. If Boehringer's decision-makers did not consider these "thicket" patents, or their effect on the potential success of the biosimilar product, when deciding to bring their biosimilar product to market, this would tend to undercut the nexus between AbbVie's purported "unclean hands" and the patents-in-suit.

Boehringer contends that AbbVie has "consistently refused to provide discovery on these unasserted patents[.]" If there have been discovery lapses by AbbVie, Boehringer may pursue its remedies.[2] Boehringer also contends that the topic as defined by AbbVie may trench on attorney-client privilege. Boehringer will bear the burden of establishing that information sought by AbbVie during the deposition is subject to the privilege. If so, there are adequate means to protect against encroachment on the privilege.

Topic 3: The topic is limited to Boehringer's capability to manufacture and supply Cyltezo.

Topics 41-50: The deposition notices are quashed as disproportionate.

V. Affirmative Defenses Dispute

Topic 45: The topic is limited to Boehringer's Fourth and Ninth affirmative defenses. Boehringer raised the defenses, so AbbVie is entitled to inquire about the factual bases for the defenses in a manner it deems appropriate. Boehringer contends that written discovery is a more appropriate device for ascertaining the factual bases for such defenses. Even if this is true, it is not at all uncommon for a party reasonably to insist on a 30(b)(6) deposition, even when the ground has

[2] AbbVie has consistently maintained that the "patent thicket" theory is defective as a matter of law, but has not moved to strike the defense. Given that strategic decision, AbbVie cannot avoid responding to discovery on the subject. Having raised the "patent thicket" defense in the first place, Boehringer cannot avoid identifying which patents are in the "thicket" and why these patents are part of the "thicket." Neither can Boehringer claim that patents in the "thicket" are not proper subjects of discovery.

already been plowed by written discovery, in order to pin down an opponent's position.

VI. Other Issues

Topic 2: The parties will meet and confer in an effort to resolve the issue.

Topic 43: The deposition notice is quashed as disproportionate.

BY THE COURT:

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