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. 326

RICHARD A. LLORET **March 29, 2019**
U.S. MAGISTRATE JUDGE

Introduction

The plaintiffs (collectively, "AbbVie") have moved to compel deposition testimony. Doc. No. 326 ("AV Mot."). AbbVie argues that the defendants' (collectively, Boehringer) attorney improperly directed Dr. Dougherty and Mr. Blanarik not to answer certain questions at their depositions. *Id.* at 1. In addition, AbbVie contends that various witnesses were not properly prepared to testify about their designated topics. AV Mot. at 3-5.

According to AbbVie, the questions directed to Dr. Dougherty "related to the status of formulations for the accused product, BI 695501." *Id.* at 1. AbbVie alleges that information about alternative formulations of Boehringer's product developed by Boehringer may reveal information relevant to secondary considerations of non-obviousness, such as copying or commercial success. AV Mot. at 2. As for Mr. Blanarik, the questions "related to the launch and release of the accused product, BI 695501." *Id.*

at 1. AbbVie contends that directing the witnesses not to answer was inappropriate, as there was no protective order filed or granted. *Id.* at 1-2.

Boehringer contends that it "did not instruct Dr. Dougherty not to answer about 'the status of formulations for the accused product,' as AbbVie asserts." Doc. No. 336, at 2 n.2 ("BI Opp."). Boehringer also argues that before the depositions commenced, it had "agreed to designate a witness to testify regarding formulations considered in the course of development of the accused aBLA product, but objected to discovery of unaccused potential future products." *Id.* at 1. Boehringer contends that "potential launch-related information" sought from Mr. Blanarik should be off-limits, for reasons described in its earlier motion (Doc. No. 243) objecting to AbbVie's Interrogatory No. 21. *Id.* at 3. Finally, Boehringer asserts that its designated witnesses were properly prepared to testify. *Id.* at 3-5.

Discussion

Fed. R. Civ. Pro. 30(c)(2) prohibits instructing a deposition witness not to answer a question except to preserve a privilege, enforce a limitation ordered by the court, or present a motion to terminate or limit the deposition under R. 30(d)(3). Boehringer was not preserving a privilege, but claims it was enforcing a limitation that it had sought through a motion previously filed with the court that had not been decided. BI Opp. at 1-2. Boehringer did not file a motion to terminate or limit the depositions.[1] Under the

[1] Boehringer refers to the dilemma presented because I had ordered the parties not to submit any more briefing on the subject of R. 30(b)(6) topics. BI Opp. at 2 (referring to Doc. No. 261). The Order of October 31, 2018 was entered in connection with disputes about the content of a chart I had requested summarizing the positions of the parties on the scope of R. 30(b)(6) depositions. *See* Doc. No. 261. A subsequent Order of December 27, 2018 (Doc. No. 324) provided the parties with a process for litigating over instructions not to answer questions at a deposition. Under this Order AbbVie filed its motion (Doc. No. 326) and Boehringer filed its response (Doc. No. 336). I have since resolved the dispute over R. 30(b)(6) topics. Doc. No. 359. AbbVie has filed objections to the Order, which are currently pending before Judge Goldberg. Doc. No. 396.

circumstances I find that Boehringer acted in good faith, and that the purpose of the rule will not be subverted by deciding the motion on its merits.

Turning to the merits, AbbVie does not elaborate on its argument that questioning Dr. Daugherty about unaccused formulations might uncover evidence of copying, from which favorable inferences might be drawn about the non-obviousness of its inventions. AV Mot. at 2. The argument is that evidence that one of AbbVie's inventions or discoveries has been copied might tend to rebut a contention that prior art made AbbVie's patents obvious, and therefore invalid. AbbVie has made no showing that copying has taken place in connection with the accused product. Nor has there been any showing that copying would be more likely in connection with the development of unaccused but related products.

It is possible that evidence of copying may turn up, but the possibility is disproportionate to the value of such evidence, even if uncovered. "[P]roof of copying is currently best viewed as only a weak form of circumstantial proof of non-obviousness." 3 Moy's Walker on Patents, at 9-130 (West, 4th Ed. 2012); *see Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000) ("a showing of copying is only equivocal evidence of non-obviousness in the absence of more compelling objective indicia of other secondary considerations."). In the context of biosimilar litigation under the BPCIA, an inference of non-obviousness from copying evidence is likely to be even less compelling than usual. *Cf. Santarus, Inc. v. Par Pharmaceutical, Inc.*, 720 F. Supp. 2d 427, 455 (D. Del. 2010) (copying is "not compelling evidence of non-obviousness" due to the nature of the ANDA process in Hatch-Waxman cases), *aff'd in part, rev'd in part on other grounds, Santarus, Inc. v. Par Pharmaceutical, Inc.*, 694 F.3d 1344, 1347 (Fed. Cir. 2012); *Purdue Pharma*

Products L.P. v. Par Pharmaceutical, Inc., 377 F. App'x 978, 983 (Fed. Cir. 2010) (not precedential) ("we do not find compelling Purdue's evidence of copying in the ANDA context where a showing of bioequivalency is required for FDA approval."). A kind of "copying" is, in a sense, the foundation of the BPCIA process. An applicant must show biosimilarity to a reference drug to qualify for the aBLA pathway to approval. The inference as to non-obviousness from evidence of copying in this context would be feeble, at best.

AbbVie also contends that discovery of unaccused products will bear on Humira's commercial success, a recognized secondary consideration.[2] AV Mot. at 2. It is not immediately apparent how discovery of non-public information about products that may or may not be marketed by Boehringer in the future will reflect in any useful way on the commercial success of Humira. Neither is it immediately apparent why AbbVie needs additional proof of the overwhelming commercial success of Humira. The parties have from time to time bandied about the annual revenues generated by Humira – an estimated $13 billion per year. There is no legitimate dispute that Humira has been commercially successful. Additional, marginal evidence on the subject would not be worth the trouble it takes to collect.

I will deny AbbVie's motion, insofar as it seeks to re-depose Dr. Daugherty. The likely probative value of the inquiry AbbVie seeks is negligible and is outweighed by the likelihood of unfair harm to Boehringer through the disclosure of sensitive competitive information.

[2] The inference is that commercial success is a consequence – at least in part – of a non-obvious invention that introduced a previously unavailable and useful product to consumers.

As for questions about future launch plans, I ruled on AbbVie's motion to compel an answer to their Interrogatory No. 21, which concerned launch plans. *See* Doc. No. 429 (Order of February 25, 2019). I have also ruled on related R. 30(b)(6) deposition topics. *See* Doc. No. 359 (Order of January 17, 2019), at 5, Topic 41 (concerning launch plans). The Order of January 17, 2019 is presently before Judge Goldberg, who will rule on AbbVie's objections. As I have previously denied a deposition on launch plans (Topic 41, Order of January 17, 2019), I will deny the motion to re-depose Mr. Blanarik. If my Order as to Topic 41 is upended, or good cause for the deposition can be shown after proceeding with the written discovery permitted in my Order of February 25, 2019 concerning Interrogatory No. 21, AbbVie may file a motion to reconsider this denial.

As for the alleged failure to properly prepare Fed. R. Civ. Pro. 30(b)(6) witnesses, the resolution of the dispute over deposition topics may go far to resolve the dispute over whether to re-depose Drs. Buske, Happersberger, and Studt. I will deny AbbVie's motion with leave to reinstate the motion after Judge Goldberg's ruling. After Judge Goldberg's ruling and before filing a motion to reinstate the motion to compel, counsel for AbbVie should meet and confer with counsel for Boehringer to discuss depositions (or re-depositions) that may be warranted.

BY THE COURT:

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