

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVERATIV INC., BIOVERATIV
THERAPEUTICS INC., and BIOVERATIV
U.S. LLC,

Plaintiffs,

v.

CSL BEHRING LLC, CSL BEHRING
GMBH, and CSL BEHRING LENGNAU
AG,

Defendants.

Civil Action No. 17-914-RGA

ORDER

I had an oral argument on June 25, 2020, about some unresolved motion in limine issues. (D.I. 311). Upon review of the transcript, and in view of the scheduled trial, I wanted to reduce my rulings to an order.

1. The dispute about how to determine plasma FIX activity is moot. (*Id.* at 8:4-22).
2. In regard to Shapiro III, the parties can point out, using some combination of expert testimony and the face of the patent, that Shapiro III was before the Patent Office. I take it that Shapiro III will be introduced into evidence, and that what is introduced into evidence will have the correct date of publication. No one can bring up any evidence that one or more submissions of the inventors contained the wrong date. No one can comment on the face of the patent having the wrong date in any way to suggest less than diligent patent examination. In terms of whether Shapiro III is prior art or not because of an identity of inventors, nothing in the prosecution history is relevant to that argument.

3. The third dispute is the most difficult. We had a productive discussion of the issues on June 25th. (D.I. 311 at 26-48). The parties have, at my request, submitted a follow-up letter. (D.I. 308). The relevant background, stated at a high level, is that: (1) Bioverativ's asserted patent claims (which include a partial limitation of "an FcRn binding partner [that] comprises Fc or albumin," *e.g.*, '091 pat. claim 1 at 79:30-32) have a priority date of July 9, 2010; (2) Defendant CSL wants to present a "derived obviousness" invalidity case, in which the "derived" part of the obviousness package is information the Bioverativ inventors obtained from CSL scientists in the 2009-10 time period relating to a "FIX albumin fusion protein" (D.I. 311 at 44:10-12); and (3) Plaintiff wants to respond that in about 2005, there were interactions between CSL scientists and Bioverativ (then Syntonix) scientists during which a "FIX FcRn binding partner" (*id.* at 36:7-9) was disclosed to CSL, which is supposed to rebut the CSL case by showing that what the CSL scientists presented in 2009-10 was "exactly comparable" (*id.* at 37:1-3) to what CSL had learned from Syntonix in 2005.

The parties have been unable to reach agreement on CSL's derived obviousness defense and Bioverativ's evidence regarding the 2005 interactions between Syntonix, and CSL (D.I. 308), although they are not too far apart.

The parties disagree about the relevance of the 2005 discussions. At oral argument, CSL stated that the 2005 interactions are not probative of the issues in this case because there was no conception earlier than the priority date of the provisional patent application of July 2010. (D.I. 311 at 46:6-8). Bioverativ does not argue for an earlier priority date, but disputes who invented the albumin portion of the claim element "FcRn binding partner comprises Fc or albumin." (*Id.* at 44:25-45:3). Bioverativ reiterated this at oral argument, highlighting that the claims refer to a

FIX FcRn binding partner polypeptide, which it contends is what was disclosed in 2005 to CSL and led to the development of the invention. (*Id.* at 44:25-45:17).

So, to put it in a chronological nutshell, the proffers of evidence are that: (1) in 2005, Bioverativ disclosed to CSL a FIX FcRn binding partner where the partner was Fc; (2) in 2009-10, CSL disclosed to Bioverativ a FIX FcRn binding partner where the partner was albumin; and (3) later in 2010, Bioverativ patented a FIX FcRn binding partner where the partner was Fc or albumin.

I think that the argument that the 2005 interactions are irrelevant because the conception date is July 9, 2010 ignores that the claimed methods are a joint invention of multiple claim elements from multiple inventors. Although the claimed methods were not fully conceived until July 9, 2010, an inventor's conception of a particular claim element can occur beforehand. CSL conceded as much. (D.I. 311 at 46:17-22). I thus do not think it is appropriate to exclude evidence of the 2005 interactions on the basis of relevance alone.

At oral argument, I asked the parties whether they might come to some agreement whereby they could take the various accusations of theft out of the case, to avoid any unfair prejudice. (D.I. 311 at 48:16-17). CSL proposes that both sides be permitted to present evidence of their interactions with each other, while complying with my directive to avoid accusations of copying and other wrongdoing. As long as Bioverativ does not accuse CSL of "copying" or "misuse," CSL agrees that it will not argue that the named inventors "copied" CSL, and Bioverativ can point to the 2005 interactions to avoid a "one-sided" story. (D.I. 308).

CSL further asserts that it would be highly prejudicial to preclude CSL from trying its derived obviousness defense. (*Id.* at 2). CSL argues that it cannot present its derived obviousness case as a "traditional" §103 defense, stating that the claim was disclosed as a derived

obviousness defense and all of the discovery taken in the case is premised on that disclosure. (*Id.*). CSL further argues that its derived obviousness defense relies on different evidence than CSL's other § 103 defenses, including "largely" upon evidence that could not otherwise qualify as prior art under § 102.¹ CSL contends that it would be "significantly prejudiced if a key invalidity argument were to be taken out of the case at this stage." (*Id.*).

Bioverativ disagrees, arguing that copying is "inherent" in derived obviousness and infers wrongdoing. (*Id.* at 3). Thus, in Bioverativ's view, for CSL to propose that it can present derived obviousness while Bioverativ cannot use the word "copied" in rebuttal is unbalanced. (*Id.*). Bioverativ proposes that both parties drop their "copying" accusations from the case. (*Id.* at 2).

I want to avoid prejudicing either party by precluding the party from bringing in prior art evidence. CSL contends that it would be so prejudiced if I precluded the derived obviousness defense.

To address Bioverativ's concerns and avoid prejudicing Bioverativ by making its rebuttal "unbalanced," I make the following rulings. First, all accusations of copying, misuse, or other references to stealing information would certainly be unfairly prejudicial and are unequivocally excluded.² Second, the parties' proposed jury instructions on derived obviousness state that "derived" information is subject matter "communicated" to the named inventors. (D.I. 283 at 68-69). There is no reference to or requirement of "copying" in these instructions. I expect the final jury instructions to remain uninflamatory. Third, to address any further concerns about

¹ CSL gives an example of evidence that could not otherwise qualify as prior art under § 102: "[T]he defense relies on testimony (and contemporaneous notes) from inventor Dr. Peters regarding information he learned from CSL presentations about animal testing of CSL's FIX-albumin fusion proteins." (D.I. 308 at 2).

² To be crystal clear, counsel need to prepare their witnesses to avoid any testimony that approaches or crosses the line.

limiting any such inference, I will consider, upon request, additional language to make clear there is no accusation of wrongdoing against either side.

While I would like the case to be without even a hint of copying accusations, as I stated at oral argument, I am hesitant to omit what CSL views as a key argument to its defense or the underlying evidence that would otherwise be precluded. And, in line with that ruling, I will also not bar discussion of the 2005 exchanges of information, but without talk of NDAs or the like. Both sides can tell their story. (*See* D.I. 308 at 1-2).

With the above understanding, each side's evidence has probative value that is not substantially outweighed by the risk of unfair prejudice.

IT IS SO ORDERED this 11th day of August 2020.

/s/ Richard G. Andrews
United States District Judge