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

MEMORANDUM ORDER

Before me are five motions submitted by Bioverativ and CSL Behring regarding Defendants' alleged infringement of patents by the accused pharmaceutical product Idelvion. This order will address Defendants' Motion to Exclude Certain Opinions of Dr. Robert Sidonio and Dr. Matthew Lynde (D.I. 213) and Defendants' Motion to Exclude Certain Opinions of Dr. Rodney Camire and Dr. E. Sally Ward (D.I. 215). I have reviewed the parties' briefing and related papers. (D.I. 217, 227, 237). I heard oral argument on February 21, 2020. After full consideration of the briefing, the motions are resolved as follows.

I. BACKGROUND

Plaintiffs Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC filed this lawsuit against Defendants CSL Behring LLC, CSL Behring GmbH, and CSL Behring Lengau AG on July 7, 2017, asserting infringement of U.S. Patent Nos. 9,670,475 ("the '475 patent"), 9,623,091 ("the '091 patent"), and 9,629,903 ("the '903 patent") (collectively, "the

Asserted Patents"). (D.I. 1). Defendants move to exclude certain opinions of Plaintiffs' experts Dr. Robert Sidonio and Dr. Matthew Lynde regarding convoyed sales and patient compliance with prescribed dosing regimens. (D.I. 217). Defendants also seek to exclude Dr. Camire's and Dr. Ward's opinions regarding (1) reliance on material that Plaintiffs allege is "incorporated by reference" into the Asserted Patents' specification and (2) the use of the phrase "representative subspecies." (*Id.*).

II. LEGAL STANDARD

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The Third Circuit has explained:

> Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the methods and procedures of science' rather than on 'subjective belief or unsupported speculation; the expert must have good grounds for his or her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in *Daubert* that Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.
>
> By means of a so-called "*Daubert* hearing," the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury. *See Daubert* ("Faced with a proffer of

> expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) of the Federal Rules of Evidence whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.").

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404-05 (3d. Cir. 2003) (cleaned up).

Qualification refers to the requirement that the witness possess specialized expertise. "We have interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert." *TQ Delta, LLC v. 2Wire, Inc.* 373 F. Supp. 3d 509, 516 (D. Del. 2019) (citing *Schneider*, 320 F.3d at 404-05); *see also Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003). "Rule 702's liberal policy of admissibility extends to the substantive as well as formal qualifications of experts." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). The Third Circuit has "eschewed imposing overly rigorous requirements of expertise and ha[s] been satisfied with more generalized qualifications." *Id.*

An expert is qualified to provide testimony if he/she "possess[es] at least ordinary skill in the pertinent art." *Sonos, Inc. v. D & M Holdings Inc.*, 297 F. Supp. 3d 501, 508 (D. Del. 2017). An expert who lacks the literal qualifications of one ordinarily skilled in the art, but who otherwise has sufficient relevant technical experience that will assist the trier of fact to understand the evidence, may still be qualified to testify in the pertinent art. *See, e.g.*, *Tesco Corp. v. Weatherford Int'l, Inc.*, 750 F. Supp. 2d 780, 795 (S.D. Tex. 2010) ("Even if he does not have specific experience studying or working with pipe handling devices, his three degrees in engineering and his experience in oil fields sufficiently qualify Dr. Wooley as an expert on the subject matter of this case. Rule 702 does not require [ ] extreme specificity of expertise…."); *Int'l Gamco, Inc. v. Multimedia Games Inc.*, 732 F. Supp. 2d 1082, 1088 (S.D. Cal. 2010) ("While Ms. Spielman may lack the context in which these patents and technologies at issue are

designed and implemented… the main component of the [ ] patent and its technologies at issue is clearly the distributed computing system," with which the expert did have experience.).

"[I]t is not necessary that the expert have expertise in the precise technology that is the subject of the patent or patents in suit." *Sonos*, 297 F. Supp. 3d at 510; *see also TQ Delta,* 373 F. Supp. 3d at 527-28 (denying the defendant's motion to exclude patentee's technical expert, the court stated, "Defendant attempts to define the pertinent art too narrowly. I determine that [the expert] has sufficient experience with communications systems, including DSL, to offer specialized testimony that would be helpful to the jury."). "However, the level of expertise may affect the reliability of the expert's opinion." *In re Paoli*, 35 F.3d at 741.

III. DISCUSSION

a. Opinions of Dr. Sidonio and Dr. Lynde

Defendants move to exclude opinions of Plaintiffs' damages expert, Dr. Matthew Lynde, and infringement expert, Dr. Robert Sidonio, regarding convoyed sales and patient compliance with prescribed dosing regimens. (D.I. 217 at 26). Defendants argue that Dr. Lynde's opinions that non-infringing uses of Idelvion are convoyed sales upon which Plaintiffs can recover damages are based on an incorrect "but for" legal test. (*Id.*). Defendants also state that Dr. Lynde's damages calculation is based on Dr. Sidonio's assumption that 100% of Idelvion patients comply with their prescribed dosing regimen 100% of the time, which is unsupported by sufficient facts or a reliable methodology. (*Id.*).

i. Dr. Lynde's Convoyed Sales Opinion

Defendants argue that Dr. Lynde has improperly included certain non-infringing uses of Idelvion as part of his "convoyed sales" analysis. (*Id.* at 27). Defendants assert that Dr. Lynde has included as "convoyed sales": (1) any non-infringing on-demand Idelvion prescriptions for a

patient on an allegedly infringing prophylaxis treatment regimen; (2) sales of Idelvion to patients who are on a non-infringing prophylactic dosing regimen outside the ranges described in the asserted claims and the Idelvion label, but who, at some prior point in time, were prescribed an allegedly infringing regimen; and (3) sales of Idelvion for on-demand or non-infringing use before the patient begins an allegedly infringing prophylaxis regimen. (*Id.* at 27). Defendants argue that these sales to patients on a non-infringing regimen should be excluded from the damages analysis. (*Id.*). I agree with Defendants.

Patentees are allowed to recover for damages based on the profits a patentee would have received had the infringer not infringed. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 504 (1964), *citing* 35 U.S.C. § 284. Where it is reasonably foreseeable that the patentee would have benefited from a sale but for the infringement, the patentee is entitled to recover for that sale. *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1125 (Fed. Cir. 2003). In order to prevent a patentee from collecting damages that "constitute more than what is 'adequate to compensate for the infringement,'" the Federal Circuit has developed a "functional relationship" test. *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1550 (Fed. Cir. 1995). "A patentee may recover lost profits on . . . a convoyed sale[] if both the patented and unpatented products 'together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit,'" and the patent-related feature drives demand for the functional unit as a whole. *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008) (quoting *Rite-Hite*, 56 F.3d at 1549).

A convoyed sales analysis may apply to method patents and product patents. *See State Contracting & Eng'g Corp. v. Condotte Am. Inc.*, 346 F.3d 1057, 1074 (Fed. Cir. 2003). For a patentee to recover damages on convoyed sales, there must be a functional relationship between

the patented product and the sale of an unpatented product. *Am. Seating Co.*, 514 F.3d at 1268. The patented and unpatented items "must function together . . . so as to produce a desired end product or result." *Rite-Hite*, 56 F.3d at 1550. Products sold for use in a convoyed method do not need to be either sold or used at the same time as the product sold for use in the infringing method. *See DuPuy Spine Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1333 (Fed. Cir. 2009).

By asking whether non-infringing uses were "follow on" or "but for" uses of the accused product, Dr. Lynde failed to apply the correct "functional unit" test in making his damages determination. (D.I. 217 at 28). Courts have found a functional unit only where the unpatented item was largely rendered "useless" without the counterpart patented feature or product, which is not the case here where patients start with an on-label dosing regimen and are later prescribed a dosing regimen outside the ranges described in the claims, nor when patients are given a second prescription for Idelvion use in an emergency situation. *See Rite-Hite*, 56 F.3d at 1550 ("Lost profits cannot be recovered on unpatented items 'that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage.'").

When a doctor prescribes Idelvion for both on-demand use (non-infringing) and prophylaxis (allegedly infringing), the patient generally receives separate prescriptions, written for separate purposes. (*Id.* at 29). Unlike a razor and a razor blade, or a printer and printer ink cartridges, a non-infringing on-demand prescription for Idelvion does not require an allegedly infringing prophylactic prescription to be functional to protect a patient seeking on-demand use of the drug. At oral argument, Plaintiffs' counsel argued that the non-infringing on-demand prescriptions are driven by the prescriptions of the infringing sale as a matter of convenience for

the patient. (D.I. 262 at 76:8-11). Whether demand for the non-infringing prescription is driven by the patented infringing prescription is not the focus of the legal test, however. These prescriptions necessarily function separately from one another and as such, they are not a "functional unit" for the purposes of a convoyed sales analysis.

Plaintiffs suggest that they are due the lost profits on all non-infringing sales that occur after the prescription of an infringing regimen for the duration of the patient's life, theorizing that but for the initial prescription of Idelvion with an infringing regimen, the patient would be an Alprolix patient and Plaintiffs would have made the profits from those sales.[1] Unlike the example of a razor and razor blades, the drug itself is not patented here. Moreover, sales of non-infringing uses of Idelvion to patients who at some prior point in time were prescribed an allegedly infringing regimen are functionally separate from the prior prescriptions. The patented and unpatented methods do not "function together . . . so as to produce a desired end product or result," but rather operate independently to protect the patient at different points in time. *See Rite-Hite*, 56 F.3d at 1550.

Even more clearly, including sales of prior non-infringing uses of Idelvion to patients who are later prescribed an allegedly infringing regimen in a convoyed sales analysis would not satisfy the purpose of the functional relationship test, which was derived in order to prevent a patentee from collecting damages beyond that which is "adequate to compensate for the infringement." *See Rite-Hite*, 56 F.3d at 1550. While an infringing and non-infringing regimen, prescribed at different points in time, might work together to protect a patient with hemophilia B

[1] At oral argument, counsel was asked, if a doctor prescribes Idelvion on an infringing dosage regimen and subsequently increases the dosage such that the prescription no longer infringes, whether Plaintiffs should be awarded lost profits for the "rest of the patient's life." Counsel replied in the affirmative. (D.I. 262 at 71:16-25).

throughout their life, each is functionally distinct in its operation. Non-infringing and allegedly infringing uses of Idelvion at different points in time are therefore not a "functional unit."

The functional unit test is designed to preclude a patentee from collecting damages for non-infringing and unpatented features or products. *See Rite-Hite*, 56 F.3d at 1558. Dr. Lynde's damages opinion overstates the footprint of the patented method in the marketplace. It includes almost all Idelvion uses after the patent issued. It makes no distinction between infringing prophylaxis uses and non-infringing prophylaxis and on-demand uses, so long as the patient is at some time prescribed a dosing regimen described in the asserted claims. I will, therefore, exclude Dr. Lynde's convoyed sales opinions.

ii. Dr. Sidonio's Opinions about Idelvion use

Defendants argue that Dr. Lynde's damages analysis relies on Dr. Sidonio's opinion that all Idelvion patients are always fully adherent to their prescribed dosing regimens, which they contend is unsupported and therefore should be excluded. (D.I. 217 at 29-30). Defendants further assert that Dr. Sidonio has limited experience with respect to the prescription of Idelvion and treatment of hemophilia B patients. (*Id.* at 31).

Dr. Sidonio is Director of Clinical Research of the Hemostasis/Thrombosis Program at Emory University, which has 80 hemophilia B patients in its program. (D.I. 227 at 34). On the basis of his position, it appears that Dr. Sidonio is qualified within the meaning of Federal Rule of Evidence 702 to opine on adherence to prescribed dosing regimens of Idelvion. *See Schneider*, 320 F.3d at 404 ("We have interpreted [the qualification] requirement liberally. . . ."). If Defendants have specific contentions with regard to Dr. Sidonio's opinion of nearly 100% adherence to prescribed dosage amounts, they can offer competing testimony from their own experts or challenge the strength of Dr. Sidonio's opinion on cross-examination before the jury. I

will not exclude Dr. Sidonio's opinions regarding patient adherence to prescribed Idelvion dosage amounts at this stage.

b. Opinions of Dr. Camire and Dr. Ward

Defendants move to exclude certain opinions of Plaintiffs' experts Dr. Camire and Dr. Ward on the grounds that material essential to provide support under 35 U.S.C. § 112 cannot be incorporated by reference to non-patent publications. (D.I. 217 at 33; *see* 37 C.F.R. § 1.57(d)). "Essential material" is that which is necessary to satisfy the written description requirement on the "manner and process of making and using" the invention. 37 C.F.R. § 1.57(d)(1). Drs. Camire and Ward rely on two scientific papers, the Schulte reference and the Metzner reference, which are incorporated by reference into the specification of the patent. (*E.g.*, D.I. 219-1, Ex. 1 at 9:65-67).[2] The two publications provide examples and animal data for FIX-albumin fusion proteins relevant to the experts' written description and enablement analyses. (D.I. 227 at 38). Plaintiffs contend that the information contained in the publications incorporated by reference comprise part of the knowledge in the prior art and, therefore, should not be excluded. (*Id.*).

At oral argument, Plaintiffs appeared to concede that C.F.R. § 1.57 governs this issue. (D.I. 262 at 32:2-36:5).[3] Plaintiffs said, however, that the regulation does not matter. Information that is well-known in the art need not be described in detail in the specification. *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1359 (Fed. Cir. 2019) ("a patentee may rely on information that is well-known in the art for purposes of meeting the written description requirement because the specification is viewed from the perspective of [a skilled artisan].") (cleaned up). I am not

[2] The Metzner reference is not actually cited in the patent; only the Schulte reference is cited. The Schulte reference cites the Metzner reference. (D.I. 219-1, Ex. 35). Thus, it seems the Metzner reference is not actually incorporated by reference into the patent.

[3] I say "appeared to concede" because counsel danced and dodged in answering my questions on this point.

persuaded, at this point, that the description of five FIX-albumin fusion proteins in the Schulte and Metzner references, having been published as scientific papers, comprised what was "well-known" in the art at the time. But that is not the issue before me now. Plaintiffs cannot rely on the fact that these references appear in the specification to supplement the written description or to support enablement. Therefore, I will exclude the opinions of Drs. Camire and Ward to the extent that they rely on the Schulte and Metzner references based on their incorporation in the specification.

Defendants also take issue with the two experts' reliance on the phrase "representative subspecies" to refer to variations of the individual components of the claimed chimeric FIX polypeptides referenced in the Asserted Patents' specification, "but that are not themselves a chimeric FIX polypeptide." (D.I. 217 at 34). Defendants argue that Drs. Camire and Ward should not be allowed to opine that representative "subspecies" provide written description support under the "representative species" test. (*Id.*). Defendants contend that "subspecies" do not satisfy the Asserted Claims' structural or functional limitations and thus are not "species" of the claimed genus. (*Id.*).

Insofar as Defendants present this argument in a *Daubert* motion, the motion is denied. At oral argument, however, the issue was resolved when the parties agreed not to use the word "subspecies" so as to avoid the risk of confusing the jury, and to use the word "components" instead.

IV. CONCLUSION

For the foregoing reasons, **IT IS HEREBY ORDERED** that Defendants' Motion to Exclude Certain Opinions of Dr. Sidonio and Dr. Lynde (D.I. 213) is:

1. **GRANTED** as to Dr. Lynde's opinions regarding non-infringing on-demand prescription of Idelvion for a patient on an allegedly infringing prophylaxis treatment regimen;
2. **GRANTED** as to Dr. Lynde's inclusion in his convoyed sales analysis of sales of Idelvion to patients who are on a non-infringing prophylactic dosing regimen outside the ranges described in the asserted claims and the Idelvion label, but who, at some prior point in time, were prescribed an allegedly infringing regimen;
3. **GRANTED** as to Dr. Lynde's inclusion in his convoyed sales analysis of sales of Idelvion for on-demand or non-infringing use before the patient begins an allegedly infringing prophylaxis regimen; and
4. **DENIED** as to Dr. Sidonio's opinion regarding Idelvion use.

Defendants' Motion to Exclude Certain Opinions of Dr. Rodney Camire and Dr. E. Sally Ward (D.I. 215) is **GRANTED** to the extent that they rely on the Schulte and Metzner references, based on their incorporation in the specification, to support written description or enablement, but without prejudice as to demonstrating what was contained in the prior art.

Entered this 4 day of March, 2020.

Edmond G. Andrews

United States District Judge