IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC., AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC., Defendant.	Civil Action No. 15-839-RGA

MEMORANDUM ORDER

Presently before me is Defendant Hospira, Inc.'s Motion for Summary Judgment (D.I. 196); Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited's Motion to Exclude Testimony of Dr. Gregory K. Bell (D.I. 204); and Defendant Hospira, Inc.'s Motion to Exclude the Testimony of Randal Heeb, Ph.D. (D.I. 202). I have considered the parties' briefing. (D.I. 197; D.I. 227; D.I. 242; D.I. 206; D.I. 223; D.I. 244; D.I. 203; D.I. 225; D.I. 246). I held oral argument on June 28, 2017.

I. LEGAL STANDARD

A. Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury

to return a verdict for the non-moving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." FED. R. CIV. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247–49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

B. Federal Rule of Evidence 702

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony, stating that:

> 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 o[r] 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) (footnote and internal citations omitted).[1] The proponent of expert testimony must "demonstrate by a

[1] The Court of Appeals wrote under an earlier version of Rule 702, but subsequent amendments to the rule were not intended to make any substantive change.

preponderance of evidence that the [expert's] opinions are reliable." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994).

II. DISCUSSION

A. Summary Judgment

1. Safe Harbor

There are genuine disputes of material fact as to whether Hospira's manufacture of twenty one lots of EPO for commercial inventory in 2013 to 2015 was "solely for uses *reasonably* related to the development and submission of information" to the FDA. *See Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, 809 F.3d 610, 614 (Fed. Cir. 2015) (emphasis added). For example, there is evidence that Hospira manufactured a large quantity (tens of millions of doses) of EPO in its 2013, 2014 and 2015 manufacturing campaigns. (D.I. 228-1 at 21–27 ¶¶ 54–64, 151 n.31). The commercial value of this is in the hundreds of millions. (D.I. 228-1 at 151 n.31). Hospira's own documents and statements to the FDA indicate that the manufacture of some of the lots was for "commercial inventory." (*See, e.g.*, D.I. 228-1 at 184). Thus, although Hospira has evidence that its EPO was manufactured and used to gather information for FDA submission pursuant to FDA guidelines and information requests, that is insufficient to show that there is no genuine of dispute of material fact that the quantity of EPO produced was reasonably related to the development and submission of information to the FDA. (*See* D.I. 197 at 6–9).

I am therefore denying summary judgment because there is a genuine dispute of material fact as to the applicability of the Safe Harbor. *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1347 (Fed. Cir. 2007) ("The variety of experimental activity that may apply to any specific biologic or physiologic investigation reinforces the fact-dependency of the

inquiry."); *Chang v. Biosuccess Biotech Co.*, 76 F. Supp. 3d 1022, 1036 (C.D. Cal. 2014) ("Whether a 'use' falls within the Safe Harbor Exemption is a fact-based issue."); *Isis Pharm., Inc. v. Santaris Pharma A/S Corp.*, 2014 WL 794811, at *13 (S.D. Cal. Feb. 27, 2014) ("The Court finds this question is, as with most questions involving a determination of what is reasonable, best left to the trier of fact.").

2. Claims 24 and 27 of the '298 Patent

i. Claim 24

There is a genuine dispute of material fact as to whether Hospira's process selectively elutes the desired EPO isoforms. Amgen puts forward sufficient evidence that Hospira's "Downstream Manufacturing process" selectively elutes the EPO isoforms. (*See, e.g.*, D.I. 228-2, Exh. 19, HOS13296, Exh. 20 ¶¶ 48–49, 52–56, Exh. 21 ¶¶ 10, 24–26).

Hospira's argument that its method merely practices the "single-step" process of Lai is not persuasive. *See, e.g., Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1377 (Fed. Cir. 2002) ("[P]racticing the prior art is not a defense to literal infringement."). For example, there is evidence that Lai does not achieve the same degree of purity of isoforms having nine to fourteen sialic acids as Hospira's mixture. (D.I. 228-2, Exh. 20 ¶¶ 41–42; D.I. 1-1, Exh. A at 9:1–3, 10:39–41). Thus, there is a genuine dispute of material fact as to whether Hospira infringes the "selectively eluting" limitation of claim 24.

ii. Claim 27

Hospira argues that its process does not infringe because the process does not isolate individual isoforms. This is premised on an improper construction of claim 27. Claim 27 provides:

> A method for obtaining an erythropoietin composition having a predetermined in vivo specific activity comprising preparing a mixture of two or more erythropoietin isoforms of claim 1.

(D.I. 1-1, Exh. A, claim 27). Nothing in this language suggests that the individual isoforms of claim 1 have to be separately prepared prior to making the mixture. I have never held that this was the case. Rather the language "preparing a mixture of two or more" of the isoforms of claim 1 naturally allows for the simultaneous preparation of a mixture of the isoforms of claim 1. The specification supports this reading. (D.I. 1-1, Exh. A, 6:61–7:3). Hospira's reading is too limiting. *See also Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1378 (Fed. Cir. 2001) ("[I]t is [] well established that a claim construction that excludes a preferred embodiment is *rarely, if ever, correct.*"). Thus, summary judgment is improper with respect to claim 27.

B. Dr. Bell

Amgen seeks to exclude Dr. Bell's testimony on the following grounds: that (1) his non-infringing alternative theory is improper, (2) his hypothetical-negotiation analysis is improperly tied to what eventually happened, and (3) his "scoring system" is not a generally accepted methodology.

Amgen argues that Hospira's non-infringing alternative is that Hospira could discard the infringing batches before patent expiration and create new ones after patent expiration. (D.I. 206 at 6). Given that Hospira has made no commercial use of the allegedly infringing EPO, reliance on this non-infringing alternative is proper. *See Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (considering "[t]he extent to which the infringer has made use of the invention; and any evidence probative of the value of that use").

Amgen argues that Dr. Bell's analysis improperly replaces the hypothetical negotiation's inquiry into what the parties would have expected at the time of the negotiation with a

"backward-looking inquiry" into what actually happened later. (D.I. 206 at 7–8). This is not persuasive because consideration of "book of wisdom" evidence is permissible, at least in this context. *See, e.g.*, *Sinclair Ref. Co. v. Jenkins Petroleum Process Co.*, 289 U.S. 689, 698 (1933) ("But a different situation is presented if years have gone by before the evidence is offered. Experience is then available to correct uncertain prophecy. Here is a book of wisdom that courts may not neglect. We find no rule of law that sets a clasp upon its pages, and forbids us to look within.").

Amgen argues that Dr. Bell's three-point "scoring system" is unreliable and, in the alternative, would be unduly prejudicial and misleading to the jury. Addressing the Federal Rule of Evidence 403 issue first, I think his scoring system has minimal probative value and is substantially outweighed by the dangers of undue prejudice and juror confusion. While I do not have a problem with Dr. Bell's underlying analysis, I am concerned with the scoring system. The scoring system makes Dr. Bell's analysis sound like a scientifically-precise analysis, which it is not. *See Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1315 (Fed. Cir. 2014) ("This court has [] recognized that estimating a reasonable royalty is not an exact science."). Because Federal Rule of Evidence 403 decides the matter, it is not necessary to address the *Daubert* issue.

C. Dr. Heeb

Hospira argues for the exclusion of Dr. Heeb's testimony. (*See generally* D.I. 203). One argument that Hospira raises is for the exclusion of Dr. Heeb's MWP-MWA opinion. Hospira argues that Dr. Heeb performs a "Maximum Willingness to Pay" ("MWP") and "Minimum Willingness to Accept" ("MWA") analysis to determine that the reasonable royalty would be a lump-sum payment from $153.9 million (MWP) to $415.3 million (MWA). (D.I. 203 at 4). Hospira argues that the $415.3 million figure is unreliable because it assumes two counterfactual

premises: (1) Hospira would be able to take away Amgen's sales from DaVita, and (2) Amgen's Epogen sales would continue at a fixed rate with respect to Aranesp. I agree that the $415.3 million figure is unreliable because it assumes Hospira would be able to take away Amgen's sales from DaVita.

In determining the MWA, Dr. Heeb assumes that Hospira's EPO product would take Amgen's DaVita sales. The DaVita sales occur in the dialysis market, which is dominated by DaVita and a competing product made by Fresenius. (D.I. 205-3, 86:4–7). At the time of the hypothetical negotiation, Amgen and DaVita were in an exclusive supply contract requiring DaVita to purchase 90% of its EPO from Amgen through at least 2019. The DaVita contract has since been renegotiated. (*See* D.I. 205-5 at 11; D.I. 247-2, 94:12–95:8). Thus, at the time of the hypothetical negotiation, Hospira's EPO could not be freely purchased by DaVita. A damages calculation that assumes otherwise does not fit the facts of the case. Dr. Heeb admits, "If one were to credit a scenario in which Hospira targets primarily Fresenius, Amgen's MWA would have been $170.4 million." (D.I. 247-1 at 45, 81–82). Thus, for this reason alone, the maximum MWA Dr. Heeb can put before the jury would be $170.4 million.

The $415.3 million figure is also challenged on the basis that it assumes that Epogen sales would continue at a fixed proportion in relation to another Amgen product, Aranesp (Amgen's second-generation competitor to Epogen). While certain facts suggest that Amgen is transitioning sales away from Epogen to Aranesp (D.I. 205-3, 138:23–139:5; D.I. 205-5 at 12–13; D.I. 247-2, 144:18–145:4), this is insufficient to render the $415.3 million figure unreliable. To the extent the $170.4 million figure rests on the same assumption, Hospira is free to cross-examination Dr. Heeb on this point.

Thus, I am excluding evidence offered for the purpose of supporting the $415.3 million figure and argument related to the $415.3 million figure. This ruling does not exclude evidence offered for the purpose of supporting the $170.4 million figure and argument related to the $170.4 million figure. Hospira's arguments for excluding other aspects of Dr. Heeb's testimony are better suited for cross-examination and are denied.

III. CONCLUSION

For the foregoing reasons, Defendant's Motion for Summary Judgment (D.I. 196) is **DENIED**. Plaintiffs' Motion to Exclude Testimony of Dr. Gregory K. Bell (D.I. 204) is **GRANTED-IN-PART** and **DENIED-IN-PART**. Defendant's Motion to Exclude the Testimony of Randal Heeb, Ph.D (D.I. 202) is **GRANTED-IN-PART** and **DENIED-IN-PART**.

It is **SO ORDERED** this 7 day of September, 2017.

Richard G. Andrews
United States District Judge