IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC,

Plaintiff,

v.

BAXALTA INC., BAXALTA US INC., and NEKTAR THERAPEUTICS,

Defendants.

No. 16-cv-1122-RGA

MEMORANDUM ORDER

Presently before the Court are the parties' *Daubert* motions. (D.I. 243, 250). I have reviewed the parties' briefing. (D.I. 244, 251, 270, 271, 279, 283).

I. BACKGROUND

Plaintiff asserts claims 1–9 of U.S. Patent No. 9,364,520 ("the '520 patent"). (D.I. 1). The '520 patent is directed to forms of factor VIII, "a protein necessary for normal blood clotting in response to injury." (D.I. 99 at 1). The patent claims factor VIII conjugates not found in nature, made up of recombinant factor VIII and one or more biocompatible polymers chemically bonded to factor VIII at the protein region known as the "B-domain." (*Id.* at 1, 3). The claimed factor VIII conjugates are formed through a process called pegylation, which is the conjugation of recombinant factor VIII with polyethylene glycol ("PEG"), a biocompatible polymer. (*Id.* at 5). Claims 1 and 9 are independent claims. Claims 2–8 depend from claim 1.

The accused product is Adynovate, a pegylated factor VIII used to treat hemophilia A. (D.I. 28 ¶ 25; D.I. 247 at 1). Hemophilia A is a congenital bleeding disorder caused by deficient or defective factor VIII. '520 patent at 1:25–32.

The parties previously moved for summary judgment. I granted Plaintiff's motion with respect to Defendants' invalidity defense of lack of utility. (D.I. 319).

The parties now each move to exclude expert opinions on reasonable royalties for failure to meet *Daubert* standards. Plaintiff moves to exclude the testimony of Dr. Gordon Rausser (D.I. 243), and Defendants move to exclude the testimony of Dr. Sumanth Addanki (D.I. 250).

II. LEGAL STANDARD

Rule 702 provides that an expert witness may offer opinion testimony 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 Rules also "assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 594, 597 (1993). "The relevance prong [of *Daubert*] requires the proponent [of the expert testimony] to demonstrate that the expert's 'reasoning or methodology can be properly applied to the facts in issue.'" *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012) (quoting *Curtis v. M & S Petroleum, Inc.*, 174 F.3d 661, 668 (5th Cir. 1999)). "The reliability prong [of *Daubert*] mandates that expert opinion 'be grounded in the methods and procedures of science and . . . be more than unsupported speculation or subjective belief.'" *Johnson*, 685 F.3d at 459 (quoting *Curtis*, 174 F.3d at 668).

In assessing the "reliability" of an expert's opinion, the trial court may consider a list of factors including: "whether a theory or technique . . . can be (and has been) tested," "whether the theory or technique has been subjected to peer review and publication," "the known or potential rate of error," "the existence and maintenance of standards," and "general acceptance" of a theory in the "relevant scientific community." *Daubert*, 509 U.S. at 593–94; see also *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) ("*Daubert* makes clear that the factors it mentions do *not* constitute a 'definitive checklist or test.'"); *U.S. v. Valencia*, 600 F.3d 389, 424 (5th Cir. 2010). "The proponent need not prove to the judge that the expert's testimony is correct, but she must prove by a preponderance of the evidence that the testimony is reliable." *Johnson*, 685 F.3d at 459 (quoting *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (en banc)). At base, "the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court." *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015). Indeed, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

III. ANALYSIS

A. Dr. Rausser's Reasonable Royalty Testimony

Plaintiff argues that Dr. Rausser's reasonable royalty opinion should be excluded for three reasons.

First, Plaintiff argues that Dr. Rausser's analysis is inconsistent with the assumption that the '520 patent is valid and infringed. Plaintiff asserts that Dr. Rausser improperly relies on the anticipation, non-utility, and noninfringement analyses of Defendants' technical experts to

apportion minimal value to the '520 patent in the hypothetical negotiation. (D.I. 244 at 4–11). Plaintiff further argues that, in doing so, Dr. Rausser opines on technical issues beyond his expertise. (*Id.* at 11–12).

I do not find Dr. Rausser's testimony inconsistent with the assumption that the '520 patent is valid. Dr. Rausser opines that the '520 patent adds little to Adynovate's value because, among other reasons, Adynovate's extended half-life is largely derived from the prior art. (D.I. 245, Ex. B ¶ 104). Relying on Dr. Zalipsky's anticipation testimony, Dr. Rausser concludes that the patent "makes at most a small 'improvement' to the prior art," and thus the parties to the hypothetical negotiation "would have accorded little or no value to the '520 patent compared to the prior art." (*Id.*, Ex. B ¶¶ 126–28).[1] Plaintiff argues that Dr. Rausser wrongly imports a risk of anticipation into his hypothetical negotiation. (D.I. 244 at 5–7). I disagree. Validity does not define a patent's economic value—a patent can be valid yet offer little economic value over existing inventions. Thus, like anticipation, damages may require technical comparisons between the claimed invention and the prior art, albeit for different purposes. To make those comparisons, Dr. Rausser properly relies on Dr. Zalipksy's technical analyses of the claimed invention and the prior art. I do not think Dr. Rausser's testimony is tainted by Dr. Zalipsky's ultimate conclusion that the '520 patent is invalid.

Similarly, I find that Dr. Rausser properly relies on Dr. Thakker's invalidity testimony. (D.I. 244 at 7–9). Plaintiff argues that Dr. Rausser improperly relies on Dr. Thakker's finding

[1] Dr. Rausser applies the *Georgia-Pacific* factors to determine the reasonable royalty that would have resulted from a hypothetical negotiation. *Georgia-Pacific* factor nine considers "[t]he utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results." *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). Therefore, prior art is relevant to damages in that it provides a comparison point for the "utility and advantages" of the patented invention. *See Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prods. Group, LLC*, 879 F.3d 1332, 1351–52 (Fed. Cir. 2018).

that the '520 patent fails to demonstrate extended factor VIII half-life. (D.I. 245, Ex. B ¶ 127). As discussed in my summary judgment opinion, utility can be met without showing extended half-life. (D.I. 319 at 20). Therefore, although the parties to the hypothetical negotiation would assume that the '520 patent meets § 101 utility, they would not necessarily assume that the claimed invention extends half-life. Plaintiff's remaining arguments relate to whether Dr. Thakker is factually incorrect and should be addressed during cross-examination.[2]

In contrast, I do find portions of Dr. Rausser's testimony inconsistent with the assumption of infringement. (D.I. 244 at 9–11). Dr. Rausser opines that the parties to the hypothetical negotiation would assign little value to the '520 patent in part because the patent disparaged random pegylation, a characteristic of Adynovate. (D.I. 245, Ex. B ¶¶ 130–31). I construed the "isolated polypeptide conjugate" limitation in claim 1 of the '520 patent as "a polypeptide conjugate where conjugation was not random." Therefore, if Adynovate is assumed to have infringed claim 1, it cannot have been the product of random pegylation.[3, 4] Dr. Rausser's opinions based on the erroneous assumption that Adynovate is the product of random pegylation are excluded.

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[2] Plaintiff argues that because Adynovate was available and marketed for its extended half-life at the time of the hypothetical negotiation, the parties must have known that the claimed invention extends half-life. (D.I. 244 at 8–9). Plaintiff conflates the accused product and the claimed invention. Extended half-life is not a claim limitation. *See* '520 patent, claims 1–9. Thus, the assumption that Adynovate infringes the '520 patent does not automatically mean that the claimed invention extends half-life. Dr. Thakker's opinion is based on his analysis of a figure in the '520 patent. (D.I. 245, Ex. B ¶ 127, Ex. J ¶¶ 54–55). Whether that analysis is correct is a disputed issue of fact.

[3] The only claim in the '520 patent that does not have the "isolated polypeptide conjugate" limitation is claim 9. Dr. Rausser does not limit his opinion regarding random pegylation to damages arising under claim 9. (D.I. 245, Ex. B ¶¶ 130–31).

[4] Plaintiff also argues that Dr. Rausser relies on his own improper technical analyses. (D.I. 244 at 11–12). The precise basis for Dr. Rausser's opinions is not clear from his report. (D.I. 245, Ex. B ¶¶ 130–31). I believe this is an issue best addressed on cross-examination.

Second, Plaintiff argues that Dr. Rausser's apportionment calculation lacks economic foundation. (D.I. 244 at 12–14). Dr. Rausser initially finds that a maximum of 20% of Adynovate's value may be attributed to the '520 patent.[5] Plaintiff asserts that Dr. Rausser then arbitrarily reduces the apportionment from 20% to 2–4%. (*Id.*).

As discussed, Dr. Rausser relies on Dr. Zalipsky and Dr. Thakker's technical opinions to opine that much of Adynovate's value can be attributed to the prior art as opposed to the '520 patent. (D.I. 245, Ex. B ¶¶ 126–28, 133; D.I. 271 at 13–14). Dr. Rausser also finds, based on Dr. Zalipsky's testimony, that less than 10% of Adynovate factor VIII conjugates could infringe any of the '520 patent claims. (D.I. 245, Ex. B ¶ 132 (finding less than 10% of factor VIII in Adynovate meets the SEQ ID NO. 4 claim limitation)). Dr. Rausser explained during deposition that he reached the 2% apportionment floor by multiplying his 20% starting point by the 10% of Adynovate conjugates that infringe. (D.I. 271 at 14; D.I. 272-1, Ex. 2 at 289:21–290:12). Defendants assert that Dr. Rausser ultimately reached a conservative estimate of 2–4% based on the totality of the evidence. (D.I. 271 at 14).

Dr. Rausser provides an alternative apportionment rate for claim 9. Plaintiff argues that Dr. Rausser improperly relies on his claim 9 analysis to support the 2–4% range for claims 1–8. (D.I. 244 at 13). Claim 9 is the only '520 patent claim that requires the conjugates to be "monopegylated." Dr. Rausser opines that the reasonable royalty rate would be "very low" based on claim 9 alone, because only about 0.2% of Adynovate is monopegylated. (D.I. 245, Ex. B ¶¶ 132, 135). Defendants argue that, applying the same analysis as for claims 1–8, a 0.2% monopegylation frequency would result in an apportionment rate of 0.04% (20% starting point x

[5] Plaintiff does not challenge Dr. Rausser's use of the 20% starting point as part of its *Daubert* motion. (D.I. 244 at 12 n.11).

0.2% of Adynovate conjugates that infringe claim 9). (D.I. 271 at 14–15). It appears that Dr. Rausser made a calculation error during deposition to reach a result of 4% rather than 0.04%. (D.I. 272-1, Ex. 2 at 253:12–20). Plaintiff argues that the deposition testimony shows that Dr. Rausser inappropriately conflates the apportionment analyses for claims 1–8 and claim 9. (D.I. 244 at 13–14). Dr. Rausser has since corrected himself. (D.I. 272-1, Ex. 4 (Rausser deposition errata)).

I find that Dr. Rausser has provided sufficient evidence to show that he applies reliable methods to the facts of this case to support his apportionment opinion. Plaintiff's arguments go to the weight and credibility of Dr. Rausser's testimony, which should be addressed in cross-examination.

Third, Plaintiff argues that Dr. Rausser fails to show the licenses he relied on are technologically or economically comparable to the license resulting from the hypothetical negotiation.

"When relying on licenses to prove a reasonable royalty, alleging a loose or vague comparability between different technologies or licenses does not suffice." *LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 79 (Fed. Cir. 2012); *see also Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1327–32 (Fed. Cir. 2009) (finding reliance on license agreements "radically different" from a license resulting from the hypothetical negotiation weighed strongly against the jury's lump-sum damages award). However, the "degree of comparability of [the agreements] as well as any failure on the part of [the expert] to control for certain variables are factual issues best addressed by cross examination and not by exclusion." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012).

Regarding technical comparability, Dr. Rausser opines that comparable licenses "would be those that license one patent or a small increment of technology, to be used in manufacturing a Factor VIII product." (D.I. 245, Ex. B ¶ 57). He analyzes the four selected licenses to show that each includes one or two patents (or patent applications) and covers technology to manufacture factor VIII products. (*Id.* ¶¶ 58–61).

Plaintiff argues that Dr. Rausser's "expansive criteria" for comparability is insufficient to meet the *Daubert* standard. (D.I. 244 at 16). Plaintiff relies on *Lucent*, which found the lack of comparability between the prior licenses and the hypothetical negotiation weighed strongly against the jury's lump-sum damages award under *Georgia-Pacific* factor two. 590 F.3d at 1325–32.[6] The court primarily focused on the difference between lump-sum and running royalty licenses. *Id.* at 1326. The damages award relied on eight licenses, only four of which purported to be lump-sum licenses. The court found the fact that all four licenses covered "PC-related patents" was mere "personal computer kinship" insufficient to "impart[] enough comparability to support the damages award." *Id.* at 1328.

Plaintiff also analogizes Dr. Rausser's testimony to the excluded testimony in *M2M Solutions LLC v. Enfora, Inc.*, 167 F. Supp. 3d 665 (D. Del. 2016). (D.I. 244 at 17). In *Enfora*, I excluded reasonable royalty testimony because the expert failed to show "a basis in fact to associate the royalty rate used in [the] prior licenses to the particular hypothetical negotiation at issue in [that] case." *Id.* at 677. The damages expert's only rationale for comparability was undisclosed conversations with a technical expert. Further, neither expert referenced the specific

[6] Notably, *Lucent* addressed the sufficiency of the evidence supporting a jury's damages award, a different inquiry from the present issue of *Daubert* admissibility.

technology in the asserted patent or the allegedly comparable licenses, "aside from the hazy reasoning that they all relate to product features rather than core technology." *Id.* at 677–78.

I find *Lucent* and *Enfora* distinguishable. In both cases, the parties failed to even identify the relevant technology in the asserted patent and the prior licenses. *See Lucent*, 590 F.3d at 1328 (describing only the broad industry of personal computing); *Enfora*, 167 F. Supp. 3d at 677 (merely providing that the licenses addressed "particular user features, which would have greater value to users than the user feature addressed by the [asserted patent]"). Here, Dr. Rausser has identified the relevant field as manufacturing factor VIII products and described the specific manufacturing technology in each of the prior licenses. (*See* D.I. 245, Ex. B ¶¶ 57–61).[7] Plaintiff argues that Dr. Rausser needed to "specify the type of 'Factor VIII product' at issue in the four licenses," and specifically compare that type of product to the '520 patent, which covers pegylation of full-length factor VIII. (D.I. 244 at 16). Plaintiff essentially argues that Dr. Rausser fails to show a sufficient degree of technical comparability between the selected licenses and the license resulting from the hypothetical negotiation. I believe Dr. Rausser has provided enough evidence of technical comparability to meet the *Daubert* standard. Questions of degree should be addressed through cross-examination, not exclusion. *See ActiveVideo*, 694 F.3d 1312.

Plaintiff also argues that Dr. Rausser fails to show sufficient economic comparability. Plaintiff asserts that the license resulting from the hypothetical negotiation would be a non-exclusive, running royalty license between competitors, and of Dr. Rausser's four selected

[7] Plaintiff adds that Dr. Rausser does not rely on any technical experts, making his opinions *ipse dixit*. (D.I. 244 at 16–17). Dr. Rausser quotes from the licensed patents/patent applications but does not cite to support from technical experts. (D.I. 245, Ex. B ¶¶ 57–61). I do not think that alone warrants exclusion. Plaintiff has already deposed Dr. Rausser on the technical basis for his opinions and will have the opportunity to further explore the issue at trial. (*See, e.g.*, *id.*, Ex. C at 198:11–18).

licenses, only one is non-exclusive,[8] two are between competitors, and none use a running royalty. (D.I. 244 at 18).

Plaintiff's strongest argument relates to Dr. Rausser's use of lump-sum licenses to support a running royalty hypothetical license. "Significant differences exist between a running royalty license and a lump-sum license." *Lucent*, 590 F.3d at 1326. A lump-sum license can still be relevant to running royalty damages, but "some basis for comparison" must exist. *See id.* at 1330. Defendants argue that *Lucent* is inapposite because here, unlike in *Lucent*, the parties agree that damages should be in the form of a running royalty. (D.I. 271 at 18–19). Defendants further argue that, "while it may be difficult to determine a lump sum from a running royalty," as shown in *Lucent*, "the opposite is not true." (*Id.* at 19).

Defendants provide no support for their proposition that a lump-sum license may easily support a running royalty license, but not vice versa. The court in *Lucent* made clear that lump-sum and running royalty licenses rely on "different considerations" and have "fundamental differences." 590 F.3d at 1326, 1330. It follows that those differences would be relevant to any comparison between lump-sum and running royalty licenses, regardless of which type of license results from the hypothetical negotiation.

Dr. Rausser describes the four selected licenses as having (1) "an upfront payment of $4 million, a regulatory milestone payment of $2 million, and no running royalty" (the Bolder

[8] Defendants argue that exclusivity is not an issue because Dr. Rausser opines that the hypothetical negotiation would result in an exclusive, rather than non-exclusive, license. (D.I. 271 at 20). Plaintiff asserts the Dr. Rausser provides contradicting opinions. (D.I. 279 at 10). Dr. Rausser first states that he has "presumed the license to be exclusive." (D.I. 245, Ex. B ¶ 36). He then later states that "a pharmaceutical company might be willing to pay a premium to license—or especially to exclusively license—one or more patent families, which enable it to obtain exclusivity or primacy in the market for treatment of hemophilia A with recombinant Factor VIII." But he then goes on to conclude that "no such premium would be economically reasonable for this narrowly limited, non-exclusive hypothetical license." (D.I. 245, Ex. B ¶ 57). While I agree that Dr. Rausser's testimony is inconsistent, I do not think that alone warrants excluding the entirety of Dr. Rausser's comparable licenses opinion.

Biotechnology-Bayer license), (2) "an upfront lump sum of $50,000, patent cost reimbursement of $18,789.20, regulatory milestone payments totaling up to $3.4 million, a sales milestone payment of $5 million if sales of licensed products exceeded $100 million, and a running royalty of 1% of net sales" (the University of Rochester-Bayer license), (3) "an annual maintenance fee of $50,000 and a running royalty rate of 0.5%" (the Grifols Biologicals-Baxter license), and (4) "an upfront signing fee of $85,000, an annual maintenance fee of $45,000 . . . , and an annual royalty of $85,000 . . . [, where the] annual royalty was to be increased by 25% every two years" (the University of Connecticut-Baxter license). (D.I. 245, Ex. B ¶¶ 58–61). Three of the four licenses include a lump-sum (upfront) payment. The first license has no running royalty, and the remaining three combine a running royalty with lump-sum, milestone, and/or annual payments. Dr. Rausser makes no effort to reconcile these features with the hypothetical license. (*See* D.I. 245, Ex. B ¶¶ 57–61). Therefore, I find Dr. Rausser has failed to show "some basis for comparison" to rely on the selected licenses to support his running royalty opinion. *See Lucent*, 590 F.3d at 1330.

Dr. Rausser's opinions cannot be saved by the fact that his estimated damages are comparable to, or even "far less" than, the values in the selected agreements. (D.I. 271 at 19). Comparability is a preliminary issue. An expert cannot retroactively justify the use of certain agreements by asserting that his ultimate damages value is similar to the values in those agreements. (*See* D.I. 179 at 10). Therefore, Dr. Rausser's comparable license opinion is excluded.

B. Dr. Addanki's Reasonable Royalty Testimony

Defendants argue that Dr. Addanki's reasonable royalty opinion should be excluded for two reasons.

First, Defendants argue that Dr. Addanki relies on the Nash Bargaining Solution and fails to tie his analysis to the facts of this case.

In the patent context, the Nash theorem provides that where two parties are bargaining, under a certain set of premises, the Nash Bargaining Solution is a 50/50 split of the incremental profits earned by the infringer from the use of the asserted patents. *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1325, 1333–34 (Fed. Cir. 2014). "Anyone seeking to invoke the theorem as applicable to a particular situation must establish [a real world fit to that set of premises], because the 50/50 profit-split result is proven by the theorem only on those premises." *Id.* at 1332. Otherwise, use of the Nash Bargaining Solution is a "rule of thumb" inadmissible under *Daubert*. *Id.*; *see also Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1315 (Fed. Cir. 2011) (finding the 25% rule of thumb for a baseline royalty rate "fundamentally flawed" and inadmissible).

In *VirnetX*, the Federal Circuit held that the expert failed to tie the Nash premises to the facts of the case and thus the district court erred in admitting his reasonable royalty opinion. 767 F.3d at 1331–34. The expert first determined the incremental (*i.e.*, additional) profits associated with the use of the patented technology. Invoking the Nash Bargaining Solution, he assumed that the parties would split those profits 50/50. He then reduced the plaintiff's share by 10% to account for its weaker bargaining position, resulting in a 45/55 split. *Id.* at 1325, 1331. The court found the expert's use of a 50/50 starting point inadmissible, even with the 10% adjustment to account for certain individual circumstances. *Id.* at 1333–34.

In contrast, a handful of courts have found a 50/50 profit-split properly tied to the facts of a case. Plaintiff cites to *AstraZeneca AB v. Apotex Corp.*, in which the Federal Circuit affirmed the district court's bench trial damages award with a 50% royalty rate in the hypothetical license.

The Federal Circuit upheld the award based on the district court's factual findings that (1) Apotex had an unusually high expected gross margin on its generic sales, (2) Apotex lacked noninfringing alternatives, (3) AstraZeneca would be unwilling to license its technology due to the unique nature of the relevant generic market, and (4) similar rates in Apotex's other related licenses and settlements. 782 F.3d 1324, 1332–33 (Fed. Cir. 2015). Similarly, under *Daubert*, district courts have allowed expert testimony supporting a 50/50 split where the expert relied on the parties' prior negotiations and agreements. *DSM IP Assets, B.V. v. Lallemand Specialties, Inc.*, 2018 WL 1950413, at *5 (W.D. Wis. Apr. 25, 2018) (the expert presented evidence of other instances where the defendant agreed to a 50/50 split); *see also Robocast, Inc. v. Microsoft Corp.*, 2014 WL 350062, at *2–3 (D. Del. Jan. 29, 2014) (holding that a 50/50 profit-split may be sufficiently related to the facts of a case with "the sort of facts analogous to facts usually used in reasonable royalty analyses," such as the parties' licensing history).

Here, Dr. Addanki does substantial analyses to determine "end points of the bargaining range for the hypothetical negotiation." (D.I. 252, Ex. A ¶¶ 61–69). He derives a maximum royalty rate from the incremental profits Baxalta would expect to earn from Adynovate (*Id.* ¶ 61), and a minimum royalty rate from the profits Bayer would expect to lose by granting a license to Baxalta (*Id.* ¶¶ 62–68). He then assumes that Bayer and Baxalta, the parties to the hypothetical negotiation, had equal bargaining power, and thus a reasonable royalty rate is "the mid-point of the bargaining range." (*Id.* ¶ 70). Defendants argue that Dr. Addanki's second step is an impermissible use of the Nash Bargaining Solution. (D.I. 251 at 3–7).

The entirety of Dr. Addanki's analysis regarding the 50/50 split states:

> I am aware of no evidence that would provide either party more bargaining power than the other in the hypothetical negotiation. I have estimated each party's reservation price and it is reasonable as a matter of economics that the parties would have agreed to share the gains from granting Baxalta a license to the '520

> patent equally. Accordingly, a reasonable royalty rate for the '520 patent is the mid-point of the bargaining range, which is 23.75 percent. Indeed, in connection with Nektar's planning related to the Baxter / Nektar Development Agreement, it modeled an outcome of its negotiation with Baxter that it stated "assumes 50-50 split of incremental value between Baxter and Nektar." Even after paying a royalty assessed at this rate, Baxalta would still expect to make substantial positive gross profits from selling Adynovate.

(D.I. 252, Ex. A ¶ 70). Plaintiff argues that Dr. Addanki does not rely on the Nash Bargaining Solution but applies the *Georgia-Pacific* framework to account for the similar size and sophistication of the negotiating parties, which indicates equal bargaining power. Both Bayer and Baxalta are "publicly-traded companies in the pharmaceutical industry with longstanding expertise in hemophilia treatment." (D.I. 270 at 3–4, 9–10; *see also* D.I. 252, Ex. A ¶¶ 23–31).

Dr. Addanki cites to a document, which he claims is evidence of an agreement between Baxter and Nektar resulting in a 50/50 split of incremental profits ("the Nektar document"). (D.I. 252, Ex. A ¶ 70). The Nektar document appears to be a single slide from an email chain, titled, "Nektar's Share of Overall Value ~20%." A footnotes states, "Assumes 50-50 split of incremental value between Baxter and Nektar." (D.I. 252, Ex. D). Plaintiff asserts that the Nektar document relates to Nektar's efforts with Baxalta to develop and commercialize Adynovate.[9] (D.I. 270 at 11). Defendants argue that it lacks foundation and is not a comparable agreement supporting Dr. Addanki's reasonable royalty testimony. (D.I. 251 at 10–13; D.I. 283 at 5–7).

The Nektar document does not indicate if and how it relates to the Nektar-Baxalta agreement concerning Adynovate. (*See* D.I. 252, Ex. D). Dr. Addanki appears to have inferred that the "50-50 split" in the Nektar document refers to the Nektar-Baxalta agreement based on

[9] Dr. Addanki, consistent with this assertion, describes the Nektar document as "planning related to the . . . Development Agreement." Dr. Addanki's report offers no reason to believe that development agreements are generally comparable to patent license agreements.

"the timing," and the fact that the Nektar document pertains to hemophilia therapy and was produced during discovery. (D.I. 252, Ex. B at 127:18–130:16). Dr. Addanki's reliance on the Nektar document is clearly distinguishable from the use of related agreements upheld in *Apotex* and *DSM*. The present record fails to show that the Nektar document is an agreement, let alone an agreement that is sufficiently comparable to the hypothetical license.[10]

Aside from the Nektar document, Dr. Addanki merely states that a 50/50 split would be "reasonable as a matter of economics." (D.I. 252, Ex. A ¶ 70). That is little more than a "vague reference[] to experience and common sense" insufficient to tie the 50/50 split to the facts of this case. *See Numatics, Inc. v. Balluff, Inc.*, 66 F. Supp. 3d 934, 961 (E.D. Mich. 2014); *see also Good Tech. Corp. v. Mobileiron, Inc.*, 2015 WL 4090431, at *7 (N.D. Cal. July 5, 2015) (excluding expert testimony that "fails to tie the 50/50 split to the specifics of the case or to explain why such a split would be reasonable—other than to invoke a boilerplate assertion about the relative bargaining powers of the parties"); *Oracle Am., Inc. v. Google Inc.*, 798 F. Supp. 2d 1111, 1119 (N.D. Cal. 2011) (excluding expert testimony that purported to apply the Nash Bargaining Solution but "glossed over the axioms underlying the Nash solution without citing any evidence to show that those assumptions were warranted in the present case").

Dr. Addanki's 50/50 split analysis is materially identical to the excluded testimony in *VirnetX*. Dr. Addanki invokes the Nash Bargaining Solution without establishing the necessary Nash premises. Instead of applying the 50/50 split to the incremental profits directly, like the expert in *VirnetX*, Dr. Addanki applies the split to a range of royalty rates, with the upper bound based on the incremental profits. *See VirnetX*, 767 F.3d at 1331–34. I do not think that changes

[10] Dr. Addanki offers no explanation in his report for why he relies on the Nektar document rather than the actual Nektar-Baxalta agreement.

the admissibility analysis. Dr. Addanki's use of a range of royalty rates does not cure his failure to tie the Nash premises to the facts of this case.

Therefore, Dr. Addanki's opinion that a reasonable royalty rate is "the mid-point of the bargaining range" is excluded, including any subsequent opinions that rely on that mid-point rate. (*See* D.I. 252, Ex. A ¶¶ 70–73).

Second, Defendants argue that Dr. Addanki has failed to apportion damages.

Royalties must be apportioned between the infringing and noninfringing features of the accused product. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226–27 (Fed. Cir. 2014). The royalty base should not be larger than the smallest salable unit embodying the patented invention. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 904 F.3d 965, 977 (Fed. Cir. 2018). When the smallest salable unit itself has noninfringing features, the patentee must estimate what portion of that smallest salable unit is attributable to the patented technology. *Id.*

Dr. Addanki opines that Adynovate is the smallest salable unit practicing the '520 patent. (D.I. 252, Ex. A ¶ 37 n.42). Dr. Addanki accounts for apportionment by comparing Baxalta's profits from Adynovate to its profits from Advate, an older generation product. Dr. Addanki considers Adynovate and Advate materially identical aside from Adynovate's infringing features. He thus estimates the value of the '520 patent by calculating the incremental value of Adynovate over Advate.

> [T]he circumstances surrounding the sale of Adynovate are particularly suitable to the valuation of the '520 patent to Baxalta because we can observe how the addition of the patented feature affected Baxalta's profits. Specifically, we can observe actual market outcomes when Baxalta has sold a [recombinant Factor VIII] product *without the patented feature* (*i.e.*, Advate) and a second product that is essentially the same in every way except that it *incorporates the patented feature* (*i.e.*, Adynovate). To obtain any profit from selling Adynovate that could *not* be earned by selling only Advate, Baxalta would have to practice Bayer's

> patented invention. Consequently, the expected amount of any incremental profits from selling Adynovate (*i.e.*, the profits in excess of the profits from selling only Advate) is the most that Baxalta should be willing to pay to license the '520 patent [*i.e.*, the upper bound for a reasonable royalty rate].

(D.I. 252, Ex. A ¶ 37). Dr. Addanki conducts detailed economic analyses to determine Baxalta's incremental profits from Adynovate, including consideration of sales and patient data for Adynovate, Advate, and other factor VIII products. (*Id.* ¶¶ 38–61).

Defendants appear to dispute the factual basis of Dr. Addanki's apportionment opinion. Defendants assert that Dr. Addanki ignores two differences between Adynovate and Advate. Specifically, pegylation outside the B-domain (derived from the prior art U.S. Patent No. 7,199,223 ("the '223 patent"))[11] and the BAXJECT III administration device.[12] Defendants argue that both are noninfringing features of Adynovate that require further apportionment. (D.I. 251 at 15–20; D.I. 283 at 8–9).

The fact that Adynovate has some pegylation outside the B-domain is not a distinct feature in itself. The '520 patent claims pegylation "at the B-domain" of factor VIII. '520 patent, claims 1–9. I have made clear that infringement does not require complete homogeneity—that is, some PEGs may attach outside the B-domain. The B-domain limitation is met when there are more PEGs inside the B-domain than would have resulted from random pegylation. (D.I. 319 at 9; D.I. 195 at 6 & n.1). Adynovate, which is presumed to infringe, must

[11] Defendants also argue that Dr. Addanki fails to account for the value attributable to the prior art generally. (D.I. 251 at 15–16). But, beyond conclusory statements, Defendants' arguments all relate to pegylation outside the B-domain as described in the '223 patent. (*Id.* at 16–17, 19).

[12] Adynovate comes in powdered form and must be reconstituted in sterile water before use. The BAXJECT III is an allegedly improved reconstitution device that requires fewer steps than other devices on the market. (D.I. 251 at 19–20).

meet the B-domain limitation. Therefore, all pegylation in Adynovate, both inside and outside the B-domain, comprise a single infringing feature.[13]

The BAXJECT III device is irrelevant. Defendants do not dispute that at the time of the hypothetical negotiation, the BAXJECT III was only used with Advate and had not yet been approved for use with Adynovate. (D.I. 270 at 19; *see* D.I. 283 at 7–10). As such, the BAXJECT III could not have been a feature of Adynovate.

I find Dr. Addanki's apportionment analysis sufficiently reliable and related to the facts of this case. Therefore, Dr. Addanki's reasonable royalty opinion is admissible under *Daubert*.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's motion to exclude the testimony of Dr. Rausser (D.I. 243) is **GRANTED-IN-PART** and **DENIED-IN-PART**, and Defendants' motion to exclude the testimony of Dr. Addanki (D.I. 250) is **GRANTED-IN-PART** and **DENIED-IN-PART**.

IT IS SO ORDERED this 25 day of January 2019.

United States District Judge

[13] I understand Defendants may also be arguing that since the '223 patent described pegylation of Factor VIII generally, and Adynovate is a pegylated Factor VIII, the '223 patent contributes value to Adynovate. (*See* D.I. 251 at 15–17, 19). Although reasonable, I do not think Defendants' theory is necessarily correct. Both the '223 patent and the '520 patent provide methods for pegylating Factor VIII. There may or may not be overlap between those methods. I do not think the possibility of overlap is sufficient to warrant exclusion of Dr. Addanki's reasonable royalty opinion.