IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., Plaintiff, v. REVANCE THERAPEUTICS, INC. AND AJINOMOTO ALTHEA, INC. D/B/A AJINOMOTO BIO-PHARMA SERVICES, Defendants.	Civil Action No. 21-1411-RGA

MEMORANDUM OPINION

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ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is Revance's Motion for Summary Judgment and Exclusion of Expert Opinion and Testimony (D.I. 344) and Allergan's motion for the same. (D.I. 347). I have considered the parties' briefing. (D.I. 345, 348, 356, 358, 362, 364, 398, 400, 401, 496, 512, 517, 530, 536, 537). I heard oral argument. (D.I. 529 at 1). For the reasons set forth below, Revance's motion is GRANTED IN PART AND DENIED IN PART. Allergan's motion is DENIED. Both motions are partially DISMISSED AS MOOT.

I. BACKGROUND

Allergan asserts four patent claims relating to Revance's commercial manufacture, use, sale, or offer for sale of Daxxify, an animal protein-free ("APF") product similar to Botox intended for the treatment of glabellar lines and cervical dystonia. (D.I. 348 at 4; D.I. 449). Two of the four are "formulation" claims (when referring to the patents, "Formulation Patents"); the other two are "manufacturing" claims (when referring to the patents, "Manufacturing Patents"). On August 29, 2023, I issued a claim construction decision (D.I. 211) and subsequently denied Revance's motion for reconsideration. (D.I. 262). On May 30, 2025, I issued an order dismissing Allergan Pharmaceuticals Ireland Unlimited Company and Allergan USA, Inc. as parties. (D.I. 558, 559), which renders many of the parties' lost profits arguments moot. *See* Sections III.B–D, *infra*. Assuming the validity of the patents, Revance concedes infringement of all the asserted claims. (D.I. 352 at 4; D.I. 477 at 14:16–15:16). Both parties now move for summary judgment on multiple issues and seek to exclude opposing expert opinions.

II. LEGAL STANDARDS

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. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "[A] dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Id.* 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*, 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). The non-moving party's evidence "must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance." *Williams*, 891 F.2d at 460–61.

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). 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*, 477 U.S. at 322.

B. *Daubert*

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 the proponent demonstrates to the court that it is more likely than not: (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's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702 (amended Dec. 1, 2023). 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]

III. DISCUSSION

A. The Conception Date for Allergan's Asserted Formulation Claims

Revance argues that Allergan's asserted formulation claims are not entitled to a conception date before October 6, 2005. The relevance of this dispute is that Revance wants to assert two pieces of art—Frevert and Webb—that will not be prior art if the formulation claims are entitled to that conception date. (D.I. 456). Revance's motion is denied with respect to claim 6 of the '878 patent (the "Initial Potency Bufferless Claim") and granted with respect to claim 1 of the '216 patent (the "Three-Month Storage Buffered Claim"). For the first asserted claim, Allergan argues for the earlier conception date based on "actual reduction to practice." (D.I. 358 at 11–14). For the second asserted claim, Allergan argues for the earlier conception date based on conception and diligent reduction to practice. (*Id.* at 14–20).

1. The Initial Potency Bufferless Claim

The Initial Potency Bufferless Claim is directed to "animal-protein free formulations that comprise a surfactant (*e.g.*, poloxamer 188) and a disaccharide (*i.e.*, trehalose or sucrose) and have a specific pH. [This claim] further require[s] that the formulation 'retains an initial of potency of at least 50% of the theoretical maximum potency of the botulinum toxin after reconstitution.'"

[1] The Court of Appeals wrote under an earlier version of Rule 702. Subsequent amendments affect the substance of the rule, but I do not think they alter the applicability of the quoted discussion.

(D.I. 358 at 10) (citation omitted). I conclude that there is evidence that the inventor, Mr. Hunt, reduced claim 6 of the '878 patent to practice by no later than September of 2004.

To demonstrate actual reduction to practice, the inventor must have (1) "constructed an embodiment or performed a process that met all the [claimed] limitations of the [invention]; and (2) . . . determined that the invention would work for its intended purpose." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). A "rule of reason" analysis applies to determinations of whether there is sufficient evidence to corroborate the inventor's claim of an invention date earlier than the priority date obtained by virtue of the filing of the patent application to which priority is claimed. *Dionex Softron GmbH v. Agilent Techs., Inc.*, 56 F.4th 1353, 1360 (Fed. Cir. 2023) (citations omitted). Under the rule of reason, "each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is persuasive." *Id.* Corroborating evidence need not be entirely "independent" of the inventor. *Id.*

To satisfy this standard, Allergan points to Mr. Hunt's Experiment 14, conducted in August and September of 2004. (D.I. 358 at 13). Two formulations from that experiment, EXP14-033 and EXP14-058, both comprised a disaccharide, the surfactant P188, and an appropriate pH level, and retained an initial potency above 50%. (D.I. 345 at 8). The experimental formulations satisfy the limitations of the Initial Potency Bufferless Claim, and Revance does not challenge that conclusion. (D.I. 529 at 15:11–19).

Revance argues that Allergan has not satisfied the second requirement of reduction to practice: determining that the invention "would work for its intended purpose." *Cooper*, 154 F.3d at 1327. According to Revance, the "record shows no evidence that Mr. Hunt had an intended purpose for [the two formulations], or even determined that [the two formulations] would work for their intended purpose, given that he never established a target potency. . . ." (D.I. 362 at 4).

Drawing all reasonable inferences in favor of Allergan, *see Wishkin*, 476 F.3d at 184, I disagree, for two reasons: first, I define the Initial Potency Bufferless Claim's "intended purpose" more generally than Revance; second, I find sufficient evidence in the record to support a finding of genuine issues of material fact as to whether Mr. Hunt determined that the Initial Potency Bufferless claim would work for its intended purpose.

Start with the "intended purpose" of the Initial Potency Bufferless Claim. Determining the intended purpose of an invention is a question of law that draws from the language of the patent's claims and specification. *See Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1324–25 (Fed. Cir. 2019). Here, the intended purpose of the invention is clear from the preamble to claim 1 of the '878 patent (which applies to dependent claim 6): "[a]n animal protein free method to stabilize a serotype A Clostridial botulinum neurotoxin[.]" '878 patent, claim 1. *See, e.g., Z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007) (defining the intended purpose of an invention as the "*reduction*, rather than the elimination, of [] piracy" where the claims referred to "instructions to reduce use of [piracy]" and "[a] method for reducing [piracy]"). The purpose of the invention is therefore to "stabilize a serotype A Clostridial botulinum neurotoxin" via "[a]n animal protein free method. . . ." '878 patent, claim 1. Revance's brief, with its focus on target potency (D.I. 362 at 4), seems to suggest that achieving a certain potency must have been the purpose of the invention, but this definition is unduly narrow—achieving a target potency is a means, not an end, to stabilizing botulinum neurotoxin without using animal proteins, and the purpose of an experiment does not necessarily inform the purpose of the overall invention. To the extent that Revance argues that the purpose of an invention must perfectly mirror each of that invention's claim limitations, it is incorrect. Per *Barry*, 914 F.3d at 1325, "The 'intended purpose' need not be stated in claim limitations that define the claim scope." Indeed, requiring in every case that the "intended

purpose" requirement include a precise understanding of the claim limitations would render the reduction to practice inquiry redundant of conception.

The next step is to determine whether there exists a genuine issue of material fact regarding whether Mr. Hunt determined that the two formulations would work for their intended purpose, i.e., stabilizing botulinum neurotoxin.[2] Drawing all reasonable inferences in favor of Allergan, I find that there is. Neither party disputes that the overall goal of Mr. Hunt's project was to develop an APF means of stabilizing botulinum neurotoxin. Given that Mr. Hunt had himself "directed the manufacture of the [two] test formulations" (D.I. 346-1 at 162 of 209), and had noted the "good results" they yielded (D.I. 358 at 16), a trier of fact could reasonably find that he appreciated the results of those experiments for what they were. Under the rule of reason, this is sufficient. Revance's motion for summary judgment is denied in regard to the conception date for the Initial Potency Bufferless Claim.

2. The Three-Month Storage Buffered Claim

The Three-Month Storage Buffered Claim is directed to animal protein-free formulations comprising "a surfactant (*e.g.*, poloxamer 188), a disaccharide (*i.e.*, trehalose, sucrose, or lactose), and a buffer excipient that is 'sufficient to maintain a pH of from about 5.5 to about 6.5 upon reconstitution' with saline or water.'" (D.I. 358 at 11). "[This claim] further require[s] that the formulations retain . . . 50% potency after storage for three months in room temperature conditions (claim 1 of the '216 patent)." (*Id.*) Allergan argues that the asserted claim was conceived by

[2] Most cases discussing the "intended purpose" requirement focus on whether the inventor has adequately tested the invention to determine that it functions properly—not whether the inventor had an intended purpose in the first place. *See, e.g.*, *Barry*, 914 F.3d at 1322–26 (holding that a jury could have reasonably concluded that a follow-up was necessary to determine the effectiveness of a medical invention); *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1268 (Fed. Cir. 2002) (remanding on the issue of whether testing was necessary while determining the goal of the invention without analysis).

January 13, 2005, and that in any event, there exists a genuine issue of material fact regarding the date of conception. I disagree.

I agree generally with Revance's description of the relevant legal standard:

> Conception is a question of law based on underlying facts. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Conception is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Burroughs Wellcome Co. v. Barr Lab'ys, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994) (quotations omitted). "An idea is sufficiently definite for conception 'when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue.'" *Purdue Pharma LP v. Accord Healthcare Inc.*, 669 F. Supp. 3d 286, 311 (D. Del. 2023) (quoting *Creative Compounds, LLC v. Starmark Lab'ys*, 651 F.3d 1303, 1312 (Fed. Cir. 2011). That means, "conception must encompass all limitations of the claimed invention." *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed. Cir. 2003). Further, "[a] conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice." *Burroughs Wellcome*, 40 F.3d at 1229.

(D.I. 345 at 13). Like reduction to practice, conception is analyzed under the rule of reason. *Singh v. Brake*, 317 F.3d 1334, 1341 (Fed. Cir. 2003).

I am not convinced that Allergan's evidence of conception is sufficient under the rule of reason to raise a genuine dispute of a material fact. Unlike with the Initial Potency Bufferless Claim, Allergan cannot point to one document that proves the conception of the Three Month Storage Buffered Claim. (D.I. 358 at 14–19). The claim requires a surfactant, a disaccharide, a buffer excipient, and a specific potency. (*Id.* at 11). While Allergan points to Experiment 17 as evidence that Mr. Hunt conceived of the Three Month Storage Buffered Claim, no single formulation from that experiment includes each of the limitations of the claim. (*Id.* at 14–19). Two of the experiments, EXP17-078 and EXP17-080, contained a disaccharide and a surfactant, but no buffer excipient. (*Id.* at 16). Another experiment, EXP17-033, contained a disaccharide and buffer excipient, but no surfactant. (*Id.* at 15). With respect to potency, another claim

limitation, Revance offers deposition testimony indicating that the experiments were entirely empirical (D.I. 345 at 9), further suggesting that Mr. Hunt did not have a "definite and permanent idea of the complete and operative invention. . . ." *Burroughs Wellcome Co. v. Barr Lab'ys, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994) (quotations omitted).

Allergan protests that "the 'rule of reason test' is designed to be flexible and allows a patentee to prove conception across more than one document." (D.I. 358 at 18). Allergan correctly states the law, *see, e.g.*, *E.I. du Pont de Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1077 (Fed. Cir. 2019)), but misses the point. Allergan points to no testimony or documentation stitching together Allergan's disparate pieces of evidence and demonstrating that Mr. Hunt had a "definite and permanent idea" of the invention as it was ultimately claimed. Allergan's response to my October 31, 2024 Oral Order (D.I. 395) requesting direct evidence of conception solidifies my conclusion. (D.I. 398). On the potency limitation, for example, Allergan's response fails to identify any point at which Mr. Hunt settled on the 50% potency target for the asserted claim. I find that the Three Month Storage Buffered Claim is not entitled to a conception date before October 6, 2025. Revance's summary judgment motion is granted on the conception date of the Three-Month Storage Buffered Claim.

B. Non-Infringing Alternatives and "But-For" Causation Necessary for Lost Profits

Revance's second Motion for Summary Judgment asserts that the availability of acceptable, non-infringing alternatives negates the "but-for" causation necessary for lost profits damages. (D.I. 345 at 22). Similarly, Revance's first *Daubert* motion asserts that, for failing to account properly for acceptable non-infringing alternatives and for failing to show "but-for" causation, Dr. Meyer's lost profits opinions should be excluded.

On May 30, I issued an order dismissing Allergan Pharmaceuticals Ireland Unlimited Company and Allergan USA, Inc. as parties. (D.I. 558, 559). With that being the case, the issue of lost profits is moot, since Allergan, Inc. does not itself sell Botox products. Nevertheless, in the interests of judicial efficiency in the event of an appeal, and in light of Allergan's pending motion for reconsideration (D.I. 561), I include an explanation below as to why I disagree with Revance on its arguments concerning lost profits.

To recover lost profits, a patentee must show a "reasonable probability that, 'but for' infringement, it would have made the sales that were made by the infringer." *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1380 (Fed. Cir. 2017) (quoting *Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1353 (Fed. Cir. 2001)). A patentee can show 'but-for' causation using the factors set forth in *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978). Following *Panduit*, the patentee must prove four elements: "(1) demand for the patented product; (2) an absence of acceptable, non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of profit that would have been made." *Presidio Components*, 875 F.3d at 1380 (citing *Panduit*, 575 F.2d at 1156). The *Panduit* test is "useful, but non-exclusive." *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir. 2017). Once the patentee "establishes a reasonable probability of 'but for' causation, 'the burden shifts to the accused infringer to show that [the patent owner's 'but for' causation claim] is unreasonable for some or all of the lost sales.'" *Grain Processing Corp. v. Am. Maize-Prods Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999) (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc)).

Allergan concedes that under a traditional *Panduit* analysis, it loses. (D.I. 529 at 92:5–23). This is because, under *Panduit*'s second factor, "if there is a noninfringing alternative which any

given purchaser would have found acceptable and bought, then the patentee cannot obtain lost profits for that particular sale." *Mentor Graphics*, 851 F.3d at 1286; *see also Grain Processing*, 185 F.3d at 1351–52 ("[M]arket sales of an acceptable noninfringing substitute often suffice alone to defeat a case for lost profits."). Excluding Daxxify, there are three alternatives to Botox on the market: Ipsen's Dysport, Merz's Xeomin, and Evolus's Jeuveau. (D.I. 354 at 22). Plaintiffs do not attempt to contest that these are acceptable, non-infringing alternatives for the purposes of the *Panduit* test. (D.I. 358 at 20–23). Instead, Allergan "satisf[ies] the second Panduit element by substituting proof of its market share for proof of the absence of acceptable substitutes." *BIC Leisure Prod., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1219 (Fed. Cir. 1993) (citing *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989)). "This market share approach allows a patentee to recover lost profits, despite the presence of acceptable, noninfringing substitutes, because it nevertheless can prove with reasonable probability sales it would have made 'but for' the infringement." *Id.*

I agree with Allergan that the market share approach is appropriate in this case. "[C]ourts have given patentees significant latitude to prove and recover lost profits for a wide variety of foreseeable economic effects of the infringement." *Grain Processing*, 185 F.3d at 1350. In this case, the market share approach seems well-suited to demonstrating a "reasonable probability that, 'but for' infringement, [Allergan] would have made the sales that were made by the infringer." *Presidio Components*, 875 F.3d at 1380.

Revance's argument to the contrary focuses on the availability of non-infringing alternatives.[3] Revance argues, "[T]here is no dispute that customers could turn to acceptable, non-

[3] In arguing that the market share analysis is not always acceptable (D.I. 362 at 8), Revance cites *Slimfold Manufacturing Co., Inc. v. Kinkead Industries, Inc.*, 932 F.2d 1453, 1458 (Fed. Cir. 1991), in which the Federal Circuit held that failure to award lost profits based on the market share

infringing substitutes in the absence of DAXXIFY®, which precludes lost profits damages in this case." (D.I. 345 at 22). That misstates the law. As the Federal Circuit stated unambiguously, "This market share approach allows a patentee to recover lost profits, despite the presence of acceptable, noninfringing substitutes. . . ." *BIC Leisure,* 1 F.3d at 1219.

Revance's other arguments are equally unpersuasive. First, Revance suggests that *State Indus.*, 883 F.2d 1573, the first case to feature the market share approach to lost profits, is inapplicable on the facts of this case. Revance argues, "In [*State Industries*], the Federal Circuit permitted a lost profits analysis based on market share, but only because the record showed that 'all the competitors infringed or sold a far less preferable alternative' in the multi-competitor market." (D.I. 362 at 8) (quoting *State Indus.*, 883 F.2d at 1578). Cases since *State Industries*, however, have stressed the similarity of the competing products, rather than emphasizing *State Industries*' "far less preferable" language. In *BIC Leisure*, for example, the Federal Circuit declined to accept the market share approach on the grounds that the products at issue "differed significantly in terms of price, product characteristics, and marketing channels." 1 F.3d at 1219. In *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1356 (Fed. Cir. 2001), the Federal Circuit overturned a district court judge's denial of lost profits based on market share following a jury trial because, in part, the record had enabled "an analysis which excludes alternatives to the patented product with disparately different prices or significantly different characteristics." Revance's argument from *State Industries* ignores subsequent developments in caselaw, which suggest that similarity, rather than dissimilarity, between competing products enables a market share analysis of lost profits.

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approach did not constitute an abuse of discretion. *Slimfold*, however, concerned findings of fact. Revance's argument, that non-infringing alternatives negate the market share approach as a matter of law, takes *Slimfold* too far.

Second, Revance argues that Allergan has not demonstrated an "established" market share, a prerequisite to using the market share approach. (D.I. 362 at 10 (quoting *State Indus.*, 883 F.2d at 1578)). However, Allergan's damages expert provides enough evidence that Botox has a 50% market share, basing that on market reports and sales data (D.I. 358 at 22), for me to conclude that there exists a genuine dispute of material fact about market share. All that the market share approach requires is "credible evidence" of a given market share. *See Crystal Semiconductor Corp.*, 246 F.3d at 1355. Allergan's evidence is certainly "more than a scintilla. . . ." *Williams*, 891 F.2d at 460.

Third, Revance argues, "[T]here is no record evidence that Allergan would have made DAXXIFY® sales but for Revance's alleged infringement." (D.I. 362 at 10). But Allergan's damages expert "points to [an] investor presentation—from Revance itself—that expressly recognizes that the 'majority' of Daxxify's sales are [coming from Botox Cosmetic.]" (D.I. 358 at 22). That is enough to create a genuine dispute of material fact.

Revance's *Daubert* motion fails for all of the reasons outlined above. In addition, Revance's argument that Dr. Meyer's analysis fails because "she applied a market share analysis to *Panduit* Factor 4[,] [] *not* Factor 2" (D.I. 345 at 29) mistakenly puts form ahead of function. Damages experts are not legal experts—it is sufficient that Dr. Meyer's analysis be "factually reliable and economically sound. . . ." (D.I. 358 at 27).

In conclusion, I reject Revance's argument that the availability of non-infringing alternatives negates the "but-for" causation necessary for lost profits. Revance's second motion for summary judgment is dismissed as moot and, in the alternative, is denied. Revance's first *Daubert* motion is likewise dismissed as moot and, in the alternative, denied.

C. "Availability" of Revance's Design Around Options

Allergan contends that Revance's expert testimony regarding the availability of design around options is unreliable because it is speculative. (D.I. 348 at 27). Like the immediately preceding motions, *see supra* Section III.B, this motion is moot. Regardless, I explain below why I agree with Allergan's argument.

Per *Grain Processing*,

> When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time. The accused infringer then has the burden to overcome this inference by showing that the substitute was available during the accounting period. Mere speculation or conclusory assertions will not suffice to overcome the inference. After all, the infringer chose to produce the infringing, rather than noninfringing, product. Thus, the trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement. Acceptable substitutes that the infringer proves were available during the accounting period can preclude or limit lost profits; substitutes only theoretically possible will not.

185 F.3d at 1353 (citations omitted). In *Grain Processing*, the Federal Circuit upheld the lower court's finding that an alternative was "available" because "American Maize could readily obtain all of the materials needed for Process IV, ... the effects of the enzymes in starch hydrolysis were well known in the field at that time[, and] . . . Maize had all of the necessary equipment, know-how, and experience to [use an alternative.]" *Id.* at 1354.

Here, there is no evidence that Revance explored an alternative, non-infringing design, let alone implemented that design or sought regulatory approval. Instead, Revance asserts that "all Revance had to do was add animal proteins that were widely available, had already been widely used, and required no additional equipment, know-how, or experience." (D.I. 356 at 26). I am not convinced. Revance's expert testimony leaves to the imagination how one would add animal proteins, as well as navigate the regulatory process before the FDA. Absent any indication that

Revance at least considered the alternatives on which their experts have retroactively opined, I find that Revance's design-around alternatives are "[m]ere speculation" under *Grain Processing*. 185 F.3d at 1353.

As Allergan points out (D.I. 348 at 29), Federal Circuit precedent contains cases in which infringers' design-arounds were deemed unavailable despite having been actually designed. *See, e.g.*, *Micro Chem. Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1121, 1123 (Fed. Cir. 2003) (unavailable design-around was infringer's "Type 5" machine, to which the infringer actually switched after the lost profits period); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1331–32 (Fed. Cir. 2009) (holding that there was substantial evidence to support the jury's finding that the design-around to which the infringer actually switched after the lost profits period was unavailable). Revance's attempts to distinguish these cases are unconvincing. Revance points to the "984 hours to design and 330 hours to test the design-around" in *Micro Chemical* as evidence that the defendant in that case "did not have the necessary equipment, know-how, and experience" (D.I. 356 at 26–27) and the unsuccessful design attempts in *DePuy Spine* as evidence of lack of availability (*id.* at 27)—but having spent no time at all investigating their own workaround (D.I. 349-1 at 238–47 of 808) or seeking regulatory approval, Revance fares even worse on those scores. I find that Revance's imaginary homegrown alternatives were not "available."

Allergan's second *Daubert* motion is dismissed as moot, and, in the alternative, is granted.

D. Flow of Profits from Botox Sales to Allergan, Inc. and Allergan Ireland

Revance asserts in its third motion for summary judgment that because Allergan, Inc. and Allergan Ireland do not themselves sell Botox to end users, they cannot claim lost profits as a remedy. (D.I. 345 at 25). As with the preceding motions, *see supra* Sections III.B–C, this motion is moot. For the same reasons as above, however, I explain here why I disagree with Revance's

argument as to Allergan Ireland. There is now no dispute that Allergan, Inc. cannot claim lost profits. (D.I. 496 at 3 n.2 ("Allergan seeks Allergan Ireland's lost profits. . . .")).

When the parties initially briefed this question, the focus of the parties' dispute was Paik Exhibit 31, a "flowchart depicting the relationship between each of the plaintiffs with respect to the asserted patents and their economic interests in Botox. . . ." (D.I. 358 at 24). Revance argued that Paik Exhibit 31 was necessary to demonstrating that profits from sales of Botox "inexorably flow" to Allergan, Inc. (D.I. 345 at 25 (quoting *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008), *amended on other grounds*, 557 F.3d 1377 (Fed. Cir. 2009))). The "inexorable flow" theory, which remains untested at the Federal Circuit, suggests that "a parent company can recover on a lost profits theory when profits of a subsidiary [] flow inexorably up to the parent." *Mars*, 527 F.3d at 1367. Because Paik Exhibit 31 was inadmissible, Revance argued, Allergan, Inc. could not show that it was entitled to lost profits. (*Id.*). Allergan argued that Revance's motion was a premature motion *in limine*, and that in any event, Paik Exhibit 31 was admissible. (D.I. 358 at 24–25).

I agree with Allergan that Revance's motion, as initially presented, resembles a motion *in limine*. (D.I. 529 at 184:3–185:7). The parties have since submitted additional briefing, however, which presents the issue more squarely without the question of Paik Exhibit 31's admissibility. (D.I. 496, 512, 517). The additional briefing focuses on Allergan Ireland, rather than Allergan, Inc., and asserts that Plaintiffs' theory of lost profits is based on Allergan Ireland's "lost profits from sales of Botox® that it would have made to its cousin companies and U.S. distributors

Allergan USA [] and Abbvie US LLC [] but for Revance's infringing sales. . . ." (D.I. 496 at 2–3).[4]

"[A] plaintiff may establish lost profits for products sold through a distributor." *Abbott Diabetes Care Inc. v. Dexcom, Inc.*, 2024 WL 4875131, at *18 (D. Del. Nov. 13, 2024) (citing *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1372–73 (Fed. Cir. 2006)). As always, the fundamental inquiry of the lost profits analysis is, "[H]ad the Infringer not infringed, what would Patent Holder-Licensee have made?" *Id.* (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964)). Here, Allergan plausibly argues, "But for Revance's patent infringement, Allergan Ireland would have made additional profit from its sales of Botox® to its U.S. distributors." (D.I. 496 at 8). According to Allergan, Allergan Ireland sells Botox to Abbvie US at a price that "would result in [Abbvie US] earning a 5% return on its U.S. sales of Botox®. . . ." (*Id.* at 5). Therefore, "for each U.S. sale of Botox® lost due to Revance's infringement, Allergan Ireland would have made 95% of the consolidated incremental profit from that sale." (*Id.* at 6). This is a straightforward theory of lost profits that I see no reason to disallow.

Revance's main argument against permitting Allergan to proceed on its lost profits theory focuses on the sufficiency of Allergan's evidence rather than the merits of its legal argument. Revance argues, "Plaintiffs have not cited any evidence showing that Allergan Ireland itself makes a profit by making and selling Botox to its distributors." (D.I. 512 at 9). I disagree. Allergan cites testimony from Jill Carey, Senior Director, Head of Tax Controversy at Abbvie US, as well as Dr. Meyer's calculations of Allergan Ireland's lost profits. (D.I. 517 at 4–5: D.I. 451-1 at 28 of 96). That is enough to create a genuine dispute of material fact.

[4] According to Allergan, Abbvie US stepped into Allergan USA's role as the US distributor of Botox in March of 2023. (D.I. 496 at 5). Abbvie US's relationship with Allergan Ireland is subject to essentially the same terms as Allergan USA's relationship. (*Id.* at 5–6).

Revance's argument on the law is also unconvincing. Revance analogizes to *Intuitive Surgical, Inc. v. Auris Health, Inc.*, 2021 WL 3662842 (D. Del. Aug. 18, 2021). In that case, the patent owner sold the patented technology to a distributor, which then sold the technology to customers. *Id.* The patent owner and distributor then sued a purported infringer as co-plaintiffs, seeking the lost profits of the patent owner under the theory that after the distributor made sales to customers, "[t]he money [from the distributor's sales] then goes back to [the patent owner]." *Id.* at *3. The court in that case concluded,

> [The plaintiffs have] not shown how, under any theory or method, [the patent owner] would have made additional sales but for [the defendant's] alleged infringement. [The plaintiffs] ha[ve] only provided a theory of [the distributor's] lost profits and a conclusory statement that the profits of [the distributor] inexorably flow to its subsidiary [the patent owner].

Id. I disagree with Revance that *Intuitive* is on point. In this case, Allergan is not arguing that Abbvie US's profits "inexorably flow" to Allergan Ireland; instead, Allergan Ireland is seeking its own lost profits on the theory that it would have made more sales to Abbvie US but for the infringement.[5] Revance's cite to *Edgewell Pers. Care Brands, LLC v. Munchkin, Inc.*, 2022 WL 18932811, at *17 (C.D. Cal. July 6, 2022), is similarly unpersuasive as *Edgewell* too is addressing the inapposite "inexorable flow" theory.

I am also unconvinced by Revance's attempt to distinguish *In re Biogen '755 Patent Litigation*, 2018 WL 3586271, at *19–20 (D.N.J. July 26, 2018). In that case, the patentee sold the patented product to a distributor that sold the product to end consumers. *Id.* at *19. The district court determined as a matter of law at the summary judgment stage that the patentee's sales to the

[5] If the distributor agreement between Allergan Ireland and Allergan USA was for a set quantity of Botox product, regardless of how much Allergan USA ultimately sold to end consumers, Revance's argument would hold more weight. But under the terms of the agreement, Allergan Ireland's distributor submits orders to Allergan Ireland. (D.I. 439-11 ¶ 4.1). Those orders presumably vary in frequency and quantity based on demand.

distributor could not be excluded as a basis for lost profits. *Id.* In maintaining that *In re Biogen* is inapposite, Revance argues, "Unlike in *In re Biogen*, Plaintiffs here have never offered a damages opinion that calculates the lost profits for Allergan Ireland's sales to Allergan USA and instead rely on the collective lost profits of first three and now two Allergan entities without distinction." (D.I. 512 at 11). The *In re Biogen* court, however, never mentioned a damages report in its consideration of lost profits. Instead, it merely provided, "On the present record, and upon review of the cited cases, the Court finds that the intrafamily, intercompany sales from Biogen to U.S. Corp. can constitute 'sales' by Biogen for lost profits purposes." *In re Biogen*, 2018 WL 3586271, at *19.

With respect to *Abbott*, Revance writes, "Here, there is no evidence in the record of how any alleged lost sales of Allergan USA affect Allergan Ireland's sales to Allergan USA, thus Plaintiffs cannot show Allergan Ireland would have made any additional sales absent Revance's alleged infringement." (D.I. 512 at 12 (quoting *Abbott Diabetes Care*, 2024 WL 4875131, at *18 (cleaned up))). This strikes me as a repackaged attempt to attack Allergan as having failed to satisfy its evidentiary burden. For the reasons I explained above, that attack fails.

The rest of the parties' briefing concerns whether the "inexorable flow" theory is good law, and if so, whether Allergan can avail itself of that theory. Because Allergan Ireland seeks lost profits for its own sales to distributors, I decline to consider the "inexorable flow" theory, which I think Allergan has effectively abandoned. Revance's third motion for summary judgment is dismissed as moot, and, in the alternative, is granted as to Allergan, Inc., and is denied as to Allergan Ireland.

E. Dr. Meyer's Reasonable Royalty Opinions

Dr. Meyer uses different reasonable royalty analyses for the two different categories of asserted patents. I now describe them in a simplified fashion.

For the Manufacturing Patents, she determines that, without a license, Revance's entry into the market would have been delayed for some time. Based on estimates of the length of the delay and Revance's expected profits, she concludes that Revance would have received less revenue and gross profits because of that delay, and she estimates the "discounted" lost gross profits through 2025 to be between $281 and $377 million. (D.I. 346-2 at 97 of 269). Dr. Meyer chooses the 2025 cutoff because Revance expected to launch "a biosimilar to Botox [that year], which would have a significant impact on the neurotoxin product space." (*Id.* at 97 of 269 n.302). She says the hypothetical negotiation would result in the parties' agreeing that Allergan would get the $281 to $377 million, in the form of a running royalty, which, given the life of the patents until 2029 and Revance's expected profits until 2029, would work out to a 15 to 20 percent [royalty] through September 25, 2023 and 12.5 to 17.5 percent thereafter. . . ." (*Id.* at 37 of 269).

For the Formulation Patents, Dr. Meyer apportions the patented benefits (primarily duration) as being responsible for 24% of Daxxify's sales price. (*Id.* at 104 of 269). She concludes that in the hypothetical negotiation, Revance would agree that Allergan would get all of that. (*Id.*). Daxxify came on the market in 2022. (*Id.* at 46 of 269).

Pursuant to the above theories, Dr. Meyer adds the two royalties together and determines that a reasonable royalty would be 39% to 44% of net revenue on the sales of Daxxify from launch to September 25, 2023, 36.5% to 41.5% of net revenue until September 21, 2026 (when the Formulation Patents expire), and 12.5% to 17.5% of net revenue until July 13, 2029 (when the Manufacturing Patents expire). As of November 10, 2023, the damages were $29.7 to $33.5

million. (D.I. 346-2 at 38 of 269). The amounts presumably have increased substantially since then.

Revance argues in support of its second *Daubert* motion that Dr. Meyer's reasonable royalty opinions should be excluded in their entirety, on the grounds that she (a) fails to apportion for the patented features of the Manufacturing Patents, (b) in regard to the Manufacturing Patents, applies an inappropriate bargaining split between the two parties, (c) uses an incorrect hypothetical negotiation date, and (d) conflates her reasonable royalty and lost profit opinions. (D.I. 345 at 34, 537 at 3–4 of 4). I tentatively agree with Revance on the second issue. The third issue is moot. I disagree with Revance on the first and fourth issues.

1. Dr. Meyer's "Design Around" Hypothetical Negotiation Analysis: Apportionment and Bargaining Split

Proof of damages must be tied to the claimed invention. *See LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 67 (Fed. Cir. 2012). One acceptable method of such apportionment is based on the infringer's cost savings—specifically, the costs the infringing party "would have incurred if it had chosen not to infringe." *Prism Techologies LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360 (Fed. Cir. 2017). *Prism Technologies* provides:

> Although a patentee must carefully tie proof of damages to the claimed invention's footprint in the market place, that requirement for valuing the patented technology can be met if the patentee adequately shows that the defendant's infringement allowed it to avoid taking a different, more costly course of action. A price for a hypothetical license may appropriately be based on consideration of the costs and availability of non-infringing alternatives and the potential infringer's cost-savings.

Id. at 1376 (internal citations and quotation marks omitted); *see also Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1240 (Fed. Cir. 2011) ("Reliance upon estimated cost savings from use of the infringing product is a well settled method of determining a reasonable royalty.") (quoting *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1090–81 (Fed. Cir. 1983)).

Revance makes two arguments against Dr. Meyer's approach: first, that it categorically fails to apportion for the value of the Manufacturing Patents (D.I. 345 at 34–37; D.I. 537 at 2–3 of 4), and second, that even if it apportions for the value of the Manufacturing Patents, it improperly "applie[s] a 100-0 bargaining split to the 'apportioned' amount" (D.I. 537 at 3–4 of 4) in violation of *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308 (Fed. Cir. 2014).[6] Though I disagree with Revance's first argument—as well as its characterization of Dr. Meyer's bargaining split—I ultimately agree with Revance that Dr. Meyer's approach appears to violate *Virnetx* because it adopts an arbitrary negotiation starting point.

Start with Revance's first argument. Revance argues that even if an expert employs a cost-for-time approach, as Dr. Meyer does here, the expert must still conduct a separate, additional apportionment analysis in order to survive a *Daubert* motion. (D.I. 345 at 34–37; D.I. 537 at 2–3 of 4). *Prism Technologies*, however, suggests that a cost-for-time approach, on its own, can meet the "requirement for valuing the patented technology. . . if the patentee adequately shows that the defendant's infringement allowed it to avoid taking a different, more costly course of action." 849 F.3d at 1376. In view of the fact that "there may be more than one reliable method for estimating a reasonable royalty[,]" *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333, 1340 (Fed. Cir. 2025) (en banc) (citation omitted), I am not persuaded that a cost-for-time approach that does not include a separate, explicit apportionment analysis must always fail to survive a *Daubert* motion.

Revance's second argument—that Dr. Meyer improperly attributed 100% of Revance's design-around savings through 2025 to Allergan in her hypothetical negotiation (D.I. 537 at 3–4 of 4)—mischaracterizes Dr. Meyer's approach, because it assumes that Revance will sell Daxxify

[6] I asked for and received additional briefing on the issue of the bargaining split. (D.I. 530, 536, 537). I note that Revance has not argued that the bargaining split issue is relevant to the Formulation Patents.

throughout the life of the formulation and Manufacturing Patents. If that assumption fails, Revance still retains the remaining portion of the design-around savings that would have otherwise gone to Allergan. Allergan's briefing is replete with other examples of the direct costs to Revance that Dr. Meyer explicitly omitted from her analysis, such as "direct program costs" of a design-around (D.I. 536 at 4 of 5), so it is likely inaccurate to characterize Dr. Meyer's bargaining split as giving *all* of Revance's savings through 2025 to Allergan.

Nevertheless, Dr. Meyer's analysis appears to violate *Virnetx* because it adopts an arbitrary starting point. Regardless of whether Dr. Meyer's bargaining split can fairly be called 100-0 (or 77-23 or 83-17 through 2029, as Allergan would characterize it (D.I. 536 at 4 of 5)), Dr. Meyer's approach of "equat[ing]" (D.I. 346-2 at 97 of 269) the royalty rate to Revance's expected profit losses was arbitrary, rather than based on the specific facts of the case. In *Virnetx*, the Federal Circuit rejected a 50-50 starting point because it was not tied to the facts of the case. 767 F.3d at 1332–34. In *Uniloc*, it rejected a "25 percent rule of thumb [] offered [] as a starting point. . . ." 632 F.3d at 1317. Here, Dr. Meyer assumed, without any analysis or evidence, that Revance's expected losses in Daxxify sales through 2025—the point at which it would have launched its own Botox biosimilar—should serve as the basis for her royalty analysis. That is the starting point and ending point of Dr. Meyer's analysis, neither of which is based on the specific facts of the case. I am doubtful that this approach survives *Daubert*.

Allergan asserts in response that *AstraZeneca*, 782 F.3d at 1334–35, supports Dr. Meyer's approach. (D.I. 358 at 36). It is certainly the case, as the Federal Circuit noted in *AstraZeneca*, that costs to an infringer to avoid infringement are "relevant to the [calculation of the] reasonable royalty. . . ." *AstraZeneca*, 782 F.3d at 1334. But *AstraZeneca* never suggested that a reasonable royalty analysis could start and end with that consideration, and, in any event, also devoted

extensive consideration to the question of whether the damages calculations at issue in that case properly apportioned for the value of the patented features of the infringing product. *Id.* at 1337–40.[7] Thus, I do not think *AstraZeneca* offers any support for concluding that Dr. Meyer's analysis could stop where it does. For the foregoing reasons, Allergan has not to date met its burden to persuade me that Dr. Meyer's analysis complies with Federal Rule of Evidence 702. I will hold a *Daubert* hearing next week on the basis for the split to give Dr. Meyer an opportunity to explain that basis. Absent a persuasive justification for Dr. Meyer's approach at that hearing, Revance's motion will be granted as it relates to Dr. Meyer's reasonable royalty analysis for the Manufacturing Patents.

2. Dr. Meyer's Hypothetical Negotiation Date

Revance initially contended that Dr. Meyer's use of a June 2019 hypothetical negotiation date for the licensing of the Manufacturing Patents was legal error. (D.I. 345 at 38). The parties have since agreed upon certain hypothetical negotiation dates. (D.I. 477 at 23:21–24:16).[8] This issue is moot.

3. Dr. Meyer's Alleged Conflation of Her Reasonable Royalty and Lost Profit Opinions

Dr. Meyer's report provides, in a footnote, "[I]f the finder of fact were to find that lost profits are not the proper measure of damages, an upward effect on the royalty to the Asserted

[7] Allergan quotes from *AstraZeneca* in a way that suggests that the Federal Circuit held that "the amount of delay before the infringer would have been able to market its new, non-infringing product" was a relevant factor. (D.I. 358 at 36) (cleaned up). I note that *AstraZeneca* specifically side-stepped ruling on whether FDA regulatory delay (as opposed to, say, delay caused by the need to overcome technical difficulties in making a product) could be a relevant consideration. 782 F.3d at 1335.

[8] The parties stated at the pretrial conference that they would submit a stipulation as to the hypothetical negotiation dates. (D.I. 177 at 23:18–24:16). The parties should advise me whether they have done that.

Manufacturing Patents would be warranted." (D.I. 364-2 at 106 of 269 n.338). Revance argues that this statement improperly conflates Dr. Meyer's reasonably royalty and lost profits positions. I disagree. Allergan's first explanation—that "Dr. Meyer refers to the fact that the royalty *base* necessarily increases when lost profits are unavailable to a direct competitor, as all of the infringer's actual sales are then subject to reasonable royalty damages" (D.I. 358 at 39)—does not pass the straight face test. The second, and contradictory, explanation—that "[t]he royalty to the Asserted Manufacturing Patents absent a lost profits award does not account for the fact that Allergan and Revance are competitors, as discussed in [*Georgia-Pacific*] Factor 5"—is plausible. Allergan and Revance are competitors. Despite the observation, which seems reasonable, Dr. Meyer does not use it to upwardly adjust the reasonable royalty rate. There is no "conflation," and I am not going to strike the footnote. The *Daubert* motion is denied on the footnote.

F. Allergan's Motions for Summary Judgment

I deny Allergan's first motion for summary judgment. Allergan's remaining motions for summary judgment are moot.

1. Allergan's Motion for Summary Judgment on Stipulated Claims

Allergan's first motion requests, in light of Revance's stipulated infringement (subject to the claims' validity) (D.I. 352 at 4), that I enter summary judgment that Revance has infringed those claims. (D.I. 348 at 8–9). Revance argues that such a judgment would be inappropriate because the stipulation assumes the claims' validity, which is still a live issue in this case. (D.I. 354 at 4–6).

Typically, motions for summary judgment of infringement are helpful because they resolve an issue in a case. (D.I. 529 at 173:9–16). Here, however, where the parties have stipulated to infringement, granting a motion for summary judgment would have no effect on the merits of the

issue and would instead lead to arguments about how to present the conclusion to the jury. (D.I. 529 at 172:6–22). Because the presentation of issues to the jury is something that can better be handled outside the summary judgment context, and because granting a summary judgment motion like this one would disincentivize future stipulations, which "conserve judicial and party resources" (D.I. 352 at 2), I deny this motion.

2. Allergan's Motion for Summary Judgment on the Safe Harbor Defense

Allergan's second motion contends that the 35 U.S.C. § 271(e)(1) safe harbor defense does not apply to Revance's commercial sales activity. (D.I. 348 at 9). Because the parties have agreed to certain hypothetical negotiation dates (D.I. 477 at 23:21–24:18), and, in any event, commercial sales are not protected by the safe harbor (D.I. 529 at 176:2–183:24), this issue is moot.

3. Allergan's Motion for Summary Judgment on the Hypothetical Negotiation Date

Allergan's third motion contends that Revance's proposed hypothetical negotiation date cannot be September 2011. (D.I. 348 at 15). Because the parties have agreed to certain hypothetical negotiation dates (D.I. 477 at 23:21–24:18), this issue is moot.

G. Allergan's Remaining *Daubert* Motions

I have already denied Allergan's first *Daubert* motion as it relates to Dr. Patel and all but Paragraph 25 of Dr. Dover's expert report. (D.I. 477 at 27:9–30:2). I addressed Allergan's second *Daubert* motion above in my discussion of lost profits. I now address the remainder of Allergan's first *Daubert* motion and Allergan's third *Daubert* motion.

1. Paragraph 25 of Dr. Dover's Report

Allergan contends that Paragraph 25 of Dr. Dover's report, which is directed to the ratio of patients that may be treated per vial of a given BoNT product (Daxxify versus Botox), should be excluded as unreliable. (D.I. 348 at 21).

Allergan's argument is focused on two things: first, Dr. Dover's report runs contrary to FDA-approved labelling; second, it is based solely on his subjective experiences. (*Id.*). Neither of these is a convincing reason to exclude his testimony. On the first point: courts have long recognized that clinicians prescribe "off-label." "The FDA does not prohibit doctors from prescribing a drug for an unapproved or off-label use, and it does not prohibit patients from using a drug for an unapproved or off-label use." *Allergan, Inc. v. Alcon Lab'ys, Inc.*, 324 F.3d 1322, 1324 n.1 (Fed. Cir. 2003). Departure from label instructions is no basis on which to exclude an expert's report when that practice is observed in the industry and by the courts. On the second point: Dr. Dover's report is informed by over forty years of practicing cosmetic dermatology and his conversations with "hundreds of physicians across the country." (D.I. 356 at 16). He is well-qualified to provide an expert's perspective on customary prescribing practices. Thus, other than what I excluded in my recent order (D.I. 469), Allergan's motion is denied.

2. Ms. Trexler's Reasonable Royalty Analysis

Allergan's third *Daubert* motion asserts, "Ms. Trexler's reasonable royalty analysis [] relies on the purported 'price premium' of Daxxify over Botox Cosmetic to artificially undervalue the claimed technology." (D.I. 348 at 31). I find Ms. Trexler's approach to be reliable.

Ms. Trexler's method is as follows:

> (1) she uses DAXXIFY®'s price premium to account for the total value of features, patented and unpatented, which are unique to DAXXIFY® over competitors like Botox; and then (2) she uses survey data of what novel features patients value to isolate the value of the patented features from the other novel, unpatented features.

(D.I. 356 at 29) (citations omitted). I see no problems with this method. As I noted above in my discussion of Dr. Meyer's "design-around" reasonable royalty opinion for the Manufacturing Patents, proof of damages must be tied to the claimed invention. *See LaserDynamics,* 694 F.3d at 67. Here, Ms. Trexler has used survey data to identify the portion of Daxxify's price premium that is attributable to the patented features.

Allergan takes issue with the use of price premium, rather than entire price of the Daxxify product, as the royalty base (D.I. 348 at 32), but this argument makes little sense to me. It is the price premium that reflects the added value that Daxxify's novel features—both patented and unpatented—bring to the product. If none of these novel features existed, Daxxify would simply be a near-identical product to Botox, which could be sold for the same price (a "Botox baseline"), and which would derive no value from the patented inventions. Ms. Trexler's analysis takes the reasonable approach of starting from the Botox baseline, then adding the value of the patented features as a portion of the price premium *beyond* it. That works. Allergan further argues that "if Daxxify's price were the same as Botox Cosmetic's price, the patents would be found to have no value at all, and Revance would effectively set its royalty on a valid, infringed patent at 0%." (D.I. 348 at 36). Simply because a particular mode of analysis could be used to argue under a particular set of facts that a patent has no value does not mean that the mode of analysis is not a valid method or that it has been incorrectly performed. Nor does a zero valuation by one method mean that a positive value could not be established by another method. And, of course, some patents have little or no economic value.

Besides, as Revance points out, "Dr. Meyer assigns the entire price premium to the 'incremental value of duration,' a purported benefit of the Asserted Formulation Patents. If there were no price premium, Dr. Meyer's analysis would result in no value for this infringing feature.

Thus, Allergan's criticism applies equally to its own apportionment analysis." (D.I. 356 at 31–2) (citations omitted).

In conclusion, I find Ms. Trexler's analysis reliable. I do not preclude it. Allergan's motion as to Ms. Trexler is denied.

IV. CONCLUSION

For the reasons set forth above, Revance's motion is granted in part and denied in part. Allergan's motion is denied. Both motions are partially dismissed as moot.

An appropriate order will follow.