IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE VIROPHARMA INCORPORATED	:	
	:	**CIVIL ACTION**
Plaintiff,	:	
	:	
v.	:	
	:	**NO. 17-414**
CSL BEHRING LLC and CSL BEHRING GMBH	:	**CONSOLIDATED**
	:	
	:	
Defendants.	:	

Goldberg, J. **March 31, 2021**

MEMORANDUM OPINION

This patent infringement case involves drugs used for the treatment and prevention of a condition known as hereditary angioedema. Plaintiff Shire ViroPharma Incorporated ("Plaintiff") alleges that Defendants CSL Behring LLC and CSL Behring GMBH (collectively, "Defendants") have infringed upon four of Plaintiff's patents used in treating this condition. Defendants asserts counterclaims for both invalidity and for a declaration of noninfringement.

At issue before me are the parties' competing motions to exclude all or portions of opinions contained in both parties' expert reports under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579. For the following reasons, I will grant only a small portion of the many challenges raised, as most are quibbles over basic evidentiary disputes or differing theories, which have no applicability to the Daubert analysis.

I. FACTUAL BACKGROUND

A. Hereditary Angioedema

Hereditary angioedema ("HAE") is a rare genetic disorder causing insufficient natural production of functional or adequate amounts of a protein called C1 esterase inhibitor ("C1-INH"). This protein helps to regulate several complex processes involved in the immune system and fibrinolytic system functions. HAE exists in two forms. Type I occurs where the individual produces either no or low C1-INH. Type II is present where the individual has the normal amount of C1-INH, but that C1-INH does not properly function. Patients suffering from HAE experience symptoms including unpredictable, recurrent attacks of swelling commonly affecting the hands, feet, arms, legs, face, abdomen, tongue, genitals, and larynx. Currently, there are approximately 6,500 people in the United States who suffer from this condition.

HAE may be treated by administration of a drug containing a C1 esterase inhibitor in order to restore sufficient levels of C1-INH so as to prevent or reduce the frequency or severity of HAE attacks. HAE can be treated either acutely—meaning immediate treatment of an HAE attack in order to slow it down or stop it altogether, or prophylactically—meaning administration of a medication on a regular basis to prevent attacks.

B. The Infringement Lawsuits

On April 11, 2017, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 9,616,111 (the "'111 patent"), entitled "C1-INH Compositions and Methods for the Prevention and Treatment of Disorders Associated with C1 Esterase Inhibitor Deficiency." The claims of the '111 patent are directed generally to methods "for treating hereditary angioedema (HAE) . . . comprising subcutaneously administering . . . a composition comprising a C1 esterase inhibitor, a buffer selected from citrate or phosphate, and having a PH ranging from 6.5–8.0,

wherein the C1 esterase inhibitor is administered at a concentration of at least about 400 U/mL and a dose of at least about 1000 U. . . ." Plaintiff is the owner of all rights, title, and interest in the '111 patent.

On July 25, 2017, Defendants began U.S. sales of a prophylactic C1 esterase inhibitor treatment for subcutaneous administration. Defendants marketed the new C1 esterase inhibitor product as "Haegarda," which received FDA approval on June 22, 2017. The FDA also granted Haegarda orphan drug exclusivity. On July 25, 2017, Defendants issued a press release announcing the availability of Haegarda in the United States. The Haegarda product label instructs, in part, that the drug is a "plasma-derived concentrate of C1 Esterase Inhibitor (Human)" to be used for "routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients." The label further directs Haegarda's self-administration by subcutaneous injection.

Having obtained the '111 patent, Plaintiff began development of its own subcutaneous prophylactic C1-INH therapy, commonly referred to as either "Cinryze SC," "SHP616," or "TAK616 SC." Shortly after the release of Haegarda, Plaintiff ceased the development of this therapy.

Based on Defendants' intent to start selling Haegarda, Plaintiff initiated this action on April 11, 2017, the same day that the '111 patent issued. Plaintiff filed a first amended complaint on April 28, 2017, and a second amended complaint on August 24, 2017, setting forth allegations of direct infringement, inducement of infringement, contributory infringement, and willful infringement.

Thereafter, on September 25, 2018, the PTO issued a continuation patent—the '788 patent. Plaintiff filed a new Complaint in this matter on the same day—under Civil Action No.

18-1476—alleging that Defendants' Haegarda product also infringed at least claim 1 of the '788 Patent. The PTO then issued three more continuation patents—the '423 patent, the '690 patent, and the '595 patent. In response, Plaintiff amended its complaint twice to include those patents. On January 24, 2019, I consolidated both the original action, at Civ. A. No. 17-414, and the new action, at Civ. A. No. No. 18-1476.

Currently, only there are only three patents at issue—the '111 patent, the '788 patent, and the '423 patent (collectively, the "patents-in-suit"), with ten asserted claims. Following two claim construction hearings, the parties proceeded through and have completed both fact and expert discovery. Before me are competing motions to preclude expert testimony.

II. STANDARD OF REVIEW

Federal Rule of Evidence 702 provides:

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

Fed. R. Evid. 702. Rule 702 places district courts in the role of "gatekeeper," requiring courts to "'ensure that any and all [expert] testimony . . . is not only relevant, but reliable.'" Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999) (quoting Daubert, 509 U.S. at 589). The party offering an expert must demonstrate, by a preponderance of the evidence, that the expert's qualifications and opinions comply with Federal Rule of Evidence 702. See Daubert, 509 U.S. at 592–93 (citation omitted). Rule 702 has "a liberal policy of admissibility," Pineda v. Ford Motor

Co., 520 F.3d 237, 243 (3d Cir. 2008) (quotation omitted), and "the rejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702, Advisory Comm Notes (2000). As the Court in Daubert stated: "Vigorous 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." 509 U.S. at 595.

The Daubert inquiry "embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." Schneider ex re. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted).

A. Qualifications

In Waldorf v. Shuta, 142 F.3d 601 (3d Cir. 1998), the United States Court of Appeals for the Third Circuit articulated the "qualification" standard for an expert:

> Rule 702 requires the witness to have "specialized knowledge" regarding the area of testimony. The basis of this specialized knowledge "can be practical experience as well as academic training and credentials." . . . We have interpreted the specialized knowledge requirement liberally, and have stated that this policy of liberal admissibility of expert testimony "extends to the substantive as well as the formal qualification of experts." . . . However, "at a minimum, a proffered expert witness . . . must possess skill or knowledge greater than the average layman . . . ."

Id. at 625 (citations omitted).

Construing this standard, the Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994). In other words, "an expert's qualifications should be assessed 'liberally,' recognizing that 'a broad range of knowledge, skills, and training qualify an expert as such.'" Thomas v. CMI Terex Corp., No. 07-3597, 2009 WL 3068242, at *5 (D.N.J. Sept. 21, 2009) (quoting Paoli, 35 F.3d at 741). An expert will not

be excluded "simply because [the court] does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." Holbrook v. Lykes, Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996). The focus, instead, is on whether the qualifications that an expert does have provide a foundation for the witness to testify meaningfully on a given matter. See Buzzerd v. Flagship Carwash of Port St. Lucie, Inc., 669 F. Supp. 2d 514, 522 (M.D. Pa. 2009) (citing Rose v. Truck Ctrs, Inc., 611 F. Supp. 2d 745, 749 (N.D. Ohio 2009)) ("The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.") (quoting Berry v. City of Detroit, 25 F.3d 1342, 1351 (6th Cir. 1994)).

B. Reliability

The reliability restriction requires that the testimony be based upon "the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'" and that the expert have "'good grounds' for his or her belief." Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). In that respect, reliability mandates an examination into the expert's conclusions in order to determine "whether [the conclusions] could reliably flow from the facts known to the expert and [the] methodology used." In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prod. Liab. Litig., 706 F.3d 217, 225 n.7 (3d Cir. 2013) (quoting Oddi v. Ford Motor Co., 234 F.3d 136, 146 (3d Cir. 2000) (internal quotation marks omitted)).

The Third Circuit has identified the following non-exhaustive factors to be taken into consideration when evaluating the reliability of a particular methodology: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the

known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. Elcock v. Kmart Corp., 233 F.3d 734, 745–46 (3d Cir. 2000). Although this list of factors is lengthy, not each factor will be relevant to every reliability analysis. The "test of reliability is 'flexible.'" Kumho, 526 U.S. at 141. According to the Supreme Court, "Daubert's list of specific factors neither necessarily nor exclusively applies to all experts." Id. The relevance of the Daubert factors depends "on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Id. at 150 (internal quotation marks and citations omitted).

Importantly, the rule does not require the party proffering the expert to demonstrate the "correctness" of the expert's opinion. Paoli, 35 F.3d at 744 (concluding that the "evidentiary requirement of reliability" amounts to a lower burden "than the merits standard of correctness"). Rather, the party need only demonstrate "by a preponderance of the evidence" that the expert's opinion bears adequate indicia of reliability. Id. Indeed, "[a] judge will often think that an expert has good grounds to hold the opinion . . . even though the judge thinks the opinion otherwise incorrect." Id. Therefore, "[t]he focus . . . must be solely on principles and methodology, not on the conclusions that they generate." Daubert, 509 U.S. at 595. "When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010), aff'd, 564 U.S. 91 (2011).

C. Fit

The issue of fit "is one of relevance and expert evidence which does not relate to an issue in the case is not helpful." In re TMI Litig., 193 F.3d 613, 670 (3d Cir. 1999). The standard for fitness is "not that high" but is "higher than bare relevance." Paoli, 35 F.3d at 745. To determine whether an expert's testimony "fits" the proceedings, this Court asks whether it "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a); see also UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres, 949 F.3d 825, 835 (3d Cir. 2020). "'Fit' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." Id. (quoting Daubert, 509 U.S. at 591). "Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge *for purposes of the case*." Id. (quoting Paoli, 35 F.3d at 743 (emphasis in original)).

III. PLAINTIFF'S MOTION TO PRECLUDE EXPERTS

Plaintiff seeks to preclude portions of opinions offered by five of Defendant's experts: Mr. Scott Lassman, Dr. Timothy Craig, Dr. Lisbeth Illum, Mr. Nicholas Godici, and Dr. Christine Meyer. I will consider each individually.

A. Scott Lassman

Scott Lassman's expert testimony pertains to Plaintiff's development, and eventual discontinuation of SHP616, a subcutaneous C1-INH product. Plaintiff was developing SHP616 for prophylactic treatment of HAE before Defendants launched Haegarda. When Defendants launched Haegarda, the FDA granted it Orphan Drug Exclusivity,[1] which in turn foreclosed the

[1] "Orphan Drug Exclusivity" is "[g]ranted to drugs designated and approved to treat diseases or conditions affecting fewer than 200,000 in the U.S. (or more than 200,000 and no hope of recovering costs)" and "[b]ars FDA from approving any other application . . . for the

immediate launch of SHP616. Plaintiff's FDA expert, Suzanne Sensabaugh opined that, as of July 25, 2017—the date that accused product Haegarda launched—a company in Plaintiff's position "would have had a reasonable expectation of filing the [biologics license application][2] for SHP616 by June 27, 2018, and receiving FDA approval twelve months later without delay in June 2019." (Def.'s Resp., Ex. 1, Dep. of Suzanne Sensabaugh ("Sensabaugh Dep."), 23:14–24:5.) Thus, Ms. Sensabaugh's opinion is relevant to Plaintiff's claim that Defendants' infringement delayed Plaintiff's release of its own product.

Defendants offer Scott Lassman to rebut this opinion. Mr. Lassman counters that Ms. Sensabaugh's report "focuses solely on FDA regulatory procedures and does not acknowledge or address any of the commercial issues that affected [Plaintiff's] decision whether or not to seek approval of and/or launch [SHP616]." (Pl.'s Mot., Ex. A ("Lassman Rep.") ¶ 13.) Although Mr. Lassman agrees with Ms. Sensabaugh's description of the regulatory process, he contends that it is "only a small piece of the puzzle, and not close to the most significant piece for determining whether or not [Plaintiff] would continue developing [SHP616]." (Id.) He notes that even in the absence of Orphan Drug Exclusivity for Haegarda, "it is likely that [Plaintiff] would have discontinued development of [SHP616] anyway based on other factors limiting its commercial value to [Plaintiff]" including the decision to prioritize development of a different drug. (Id. ¶ 12.)

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same drug for the same orphan disease or condition for seven years." https://www.fda.gov/media/92548/download (last visited Nov. 11, 2020).

[2] A "biologics license application" or "BLA" is "a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce." https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber (last visited Nov. 11, 2020).

Plaintiff seeks preclusion of Mr. Lassman's opinion to the extent he speculates on Plaintiff's state of mind and why Plaintiff discontinued the development of SHP616. Defendants respond that Mr. Lassman's opinions are not based on inferences regarding Plaintiff's intent, but rather on both his thirty years of related experience and Plaintiff's own statements explaining why it terminated development of SHP616.

It is well settled that experts may not provide testimony concerning "the state of mind" or "culpability" of defendants, corporations, regulatory agencies, and others. Wolfe v. McNeil–PPC, Inc., 881 F. Supp. 2d 650, 661–62 (E.D. Pa. 2012); see also In re Tylenol (Acetaminophen) Mkting, Sales Practices, & Prods. Liab. Litig., 181 F. Supp. 3d 278, 295 n.27 (collecting cases holding that expert witnesses are not permitted to testify regarding intent, motive, or state of mind, or evidence by which such state of mind may be inferred). Indeed, the question of intent constitutes a "'classic jury question and not one for experts.'" Robinson v. Hartzell Propeller, Inc., 326 F. Supp. 2d 631, 648 (E.D. Pa. 2004) (citations omitted); see also In re Rosuvastatin Calcium Patent Litig., MDL No. 08-1949, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) ("Generally, expert witnesses are not permitted to testify regarding 'intent, motive, or state of mind, or evidence by which such state of mind may be inferred.'") (internal quotations omitted); Bracco Diagnostics, Inc. v. Amersham Health, Inc., 627 F. Supp. 2d 384, 440 (D.N.J. 2009) (precluding pharmaceutical expert from testifying as to what pharmaceutical company was "trying" to do with its marketing strategy and what it believed was right or wrong); Deutsch v. Novartis Pharms. Corp., 768 F. Supp. 2d 420, 433, 443 (E.D.N.Y. 2011) (stating that the expert "walks a fine line between testifying as to what information is reflected in certain documents, and testifying to what certain individuals at Novartis thought about the information and their motivations for characterizing the information in a particular way").

Mr. Lassman's opinion straddles the line between permissible and impermissible expert testimony. Certainly, Mr. Lassman may, based on his FDA experience, discuss how Plaintiff's internal company documents reflect other problems that arose in the testing and marketing of SHP616. (See, e.g., Lassman Rep. ¶ 41 ("enrollment of patients into the Phase 3 trial for CINRYZE SC began to run behind schedule due to, among other things, prioritization given to enrollment of HAE patients into the TAKHZYRO clinical trial); ¶ 48 ("[T]he commercial potential of CINRYZE SC was significantly eroded by the long delays that bedeviled the program."); ¶ 51 ("Shire faced major manufacturing issues and delays that affected its C1-INH products."). Mr. Lassman may also within the bounds of his expertise,[3] testify as to how such circumstances could have impacted any decision by Plaintiff to launch its product earlier, or what a reasonable pharmaceutical company may have done under such circumstances.

Mr. Lassman's report, however, crosses the line by repeatedly opining that "even in the absence of ODE [Orphan Drug Exclusivity], it is likely that Shire would have discontinued

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[3] In a one-sentence challenge to Mr. Lassman's qualifications, Plaintiff argues that Mr. Lassman is an attorney who never worked at the FDA or for a pharmaceutical company and has never assisted any company with the actual issue on which he opines: termination of a drug development program based on "prioritizing" another drug.

This argument provides little basis for me to question Mr. Lassman's qualifications. Mr. Lassman has been working as an attorney for thirty years in FDA law. He was Assistant General Counsel at the trade association Pharmaceutical Research and Manufacturers of America, which represents the research-based pharmaceutical and biotechnology industry in the United States. He handled FDA regulatory and legislative issues, including industry initiatives regarding the approval requirements for drugs and biological products. (Lassman Rep. ¶¶ 1–7.) He also routinely "provide[s] counseling to pharmaceutical and biotechnology companies seeking to obtain orphan drug designation and/or orphan drug exclusivity for drug and biological products under development or seeking to avoid being blocked by orphan drug exclusivity awarded to a competitor's product." (Id. ¶ 8.) As this experience directly relates to the issues here and qualifies him—under Daubert's liberal standards—to opine on FDA regulatory issues, I find no merit to Plaintiff's cursory challenge to his qualifications. See Kannankeril v Terminix Int'l, 128 F.3d 802, 809 (3d Cir. 1997) ("[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.").

development of CINRYZE SC anyway based on other factors limiting its commercial value to Shire." (Id. ¶ 39.) On multiple occasions throughout his report, Mr. Lassman delves into Plaintiff's subjective thought processes and motivations behind the decision not to launch this product. By way of example, his report states:

- Shire prioritized TAKHYZYRO over CINRYZE SC because it viewed TAKHZYRO as having the potential to be a superior subcutaneous treatment for long-term prophylaxis of HAE. (Id. ¶ 44.)

- Based upon the above perceived benefits, Shire sought to position TAKHZYRO as a "disease modification" treatment for HAE with the potential to become the new standard of care. . . . CINRYZE SC was considered to be an 'insurance policy' and thus its development needed to proceed until it was known whether TAKHYZYRO would be successful. (Id. ¶ 47.)

- CINRYZE SC was viewed as less profitable than CINRYZE IV due to its higher cost of goods sold (COGS). . . . Shire had no expectation it could recoup this higher COGS by doubling the price of CINRYZE SC. (Id. ¶ 53.)

- Shire did not believe that either CINRYZE SC or HAEGARDA would receive ODD or ODE because they were line extensions of previously approved C10INH products that were not expected to be clinically superior to the previously approved IV versions. (Id. ¶ 54.)

- When all of the information is considered as a whole . . . it is clear that Shire's decision to terminate the CINRYZE SC program was primarily due to factors independent of HAEGARDA's ODE. It does not appear, based on Shire's internal documents, that Shire would have launched CINRYZE SC but for HAEGARDA's ODE designation. (Id. ¶ 57.)

- [E]ven if approval of CINRYZE SC were delayed in the United States by HAEGARDA's ODE, I do not believe this played a major role in shire's decision to discontinue development of CINRYZE SC. (Id. ¶ 65.)

Defendants respond that these statements do not constitute opinions on Plaintiff's intentions in discontinuing the SHP616 program, but rather the "rationale" for Plaintiff's decision to discontinue the development of SHP616. (See Defs.' Opp'n 1.) Mere substitution of the word "rationale" for the word "intent," however, does not render Mr. Lassman's opinions admissible. Indeed, Defendants' argument confirms that Mr. Lassman's report involves an

impermissible attempt to infer from the contents of Plaintiff's internal documents what Plaintiff must have been thinking or intending with respect to its SHP616 program. Such opinions improperly usurp the role of the jury to draw reasonable inferences from the evidence.

While "every context in which an expert might discuss information about corporate state of mind may not overstep boundaries into the jury's role, it is clear that experts cannot render opinions on the defendants' corporate state of mind." In re Tylenol, 181 F. Supp. 3d 278, 295–96; see In re Seroquel Prods. Liab. Litig, No. 06-md-1769, 2009 WL 3806436, at *8 (M.D. Fl. July 20, 2009) ("[I]t is one thing for an expert to testify . . . to explain and compare information in Seroquel marketing materials to other evidence—and quite another matter for an expert witness to render an opinion concerning what a drug company intended or sought to achieve through the use of those marketing materials. The latter are proper subjects for closing argument, not expert testimony."). Accordingly, I will grant Defendant's motion to exclude any portion of Mr. Lassman's testimony that comments on subjective motivations.

B. Dr. Timothy Craig

Plaintiff next challenges the opinions of Defendant's physician expert, Dr. Timothy Craig. Because Dr. Craig's experience pertains to Plaintiff's challenge, a brief summary of his qualifications is warranted. Dr. Craig is a medical doctor, a Distinguished Educator at Pennsylvania State University, and the Chief of the Allergy/Immunology Section, the Director of Allergy and Respiratory Clinical Research, Clinic Director of the alpha-1-deficiency Clinical Research Center, and Program Director of the Allergy/Immunology Fellowship. He is currently a member of the Medical Advisory Board for the Hereditary Angioedema Association of America and has been providing clinical care and doing clinical research for HAE patients for over twenty years. (Pl.'s Mot., Ex. C. Opening Report of Timothy Craig ("Craig Opening Rep.")

¶¶ 3–5.) It should also be noted that Dr. Craig was a principal clinical investigator in the Phase II and Phase III clinical trials that demonstrated the safety and efficacy of Haegarda. (Id. ¶ 7.)

Dr. Craig has submitted four reports (Opening Report, Responsive Report, Reply Report, and Supplemental Report) regarding the "clinical aspects" of "treatment of HAE." Plaintiff presses multiple challenges to Dr. Craig's reports, arguing that: (1) Dr. Craig's infringement analysis is devoid of scientific validity; (2) Dr. Craig's invalidity for obviousness opinion is outside the scope of his expertise; (3) Dr. Craig is not qualified to opine on agency; and (4) Dr. Craig is not an economist and cannot offer opinions on market share. I address each challenge separately.

1. Dr. Craig's Infringement Analysis

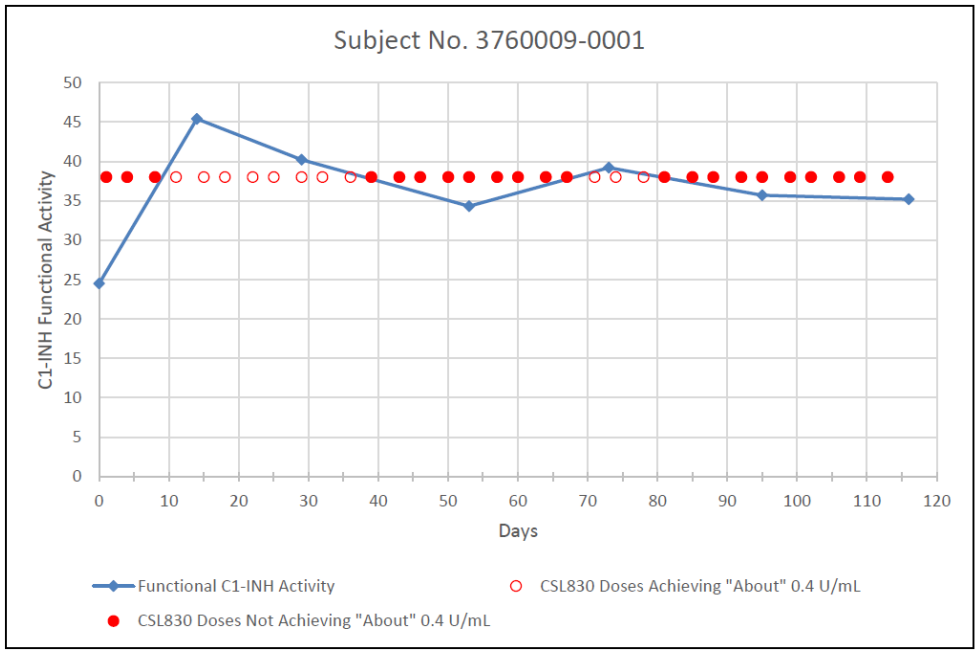
Dr. Craig's first challenged opinion relates to the requirement in the patents-in-suit, that administration of the composition result in an "increase[]" in the "level of C1 esterase inhibitor in the blood of the subject to at least about 0.4 U/mL." In an effort to establish that Defendants' product Haegarda does not infringe on this requirement, Dr. Craig opines that Plaintiff has "failed to establish that every sale of Haegarda results in achievement of the claimed blood levels, as required in the asserted claims of the '111, '788, and '595 patents." (Pl.'s Mot., Ex. B, Responsive Rep. of Timothy Craig ("Craig Resp. Rep.") ¶ 19.) Specifically, Dr. Craig notes that during Defendants' Phase II clinical study of Haegarda (the "3001 Study"), subjects received multiple doses of the drug and not all patients "achieved or maintained C1-INH blood levels of 0.4 U/mL for the duration of their treatment," with 14% of doses across all study subjects "fail[ing] to result in a C1-INH blood level of at least 0.38 U/mL." (Id. ¶ 21.) Thus, according to Dr. Craig, "not every dose of [Haegarda] achieved a result that would infringe the claims of the '111, '788, and '595 patents." (Id.)

Plaintiff now argues that Dr. Craig's opinion is unreliable, positing four separate challenges to his methodology: (a) improper use of a straight-line analysis; (b) inclusion of data from the baseline blood level measurement; (c) inconsistency with claim construction; and (d) Dr. Craig's lack of familiarity with his own analysis.

a. Use of Straight-Line Analysis

Much of the infringement analysis in this case relies on the pharmacokinetic[4] data generated from Defendants' own clinical trials to show that patients who take Haegarda achieve blood levels of "at least about 0.4 U/mL." According to Plaintiff, Defendants' counsel took that pharmacokinetic data from the 3001 Study and charted it on forty-graphs (one for each subject in the clinical trial). The charts reflect the C1-INH levels of each subject during each of the seven times when blood was drawn from the subjects over the course of the sixteen weeks when doses of Haegarda were being administered. These charts have a straight line to connect each blood measurement, as demonstrated in the following exemplar graph:

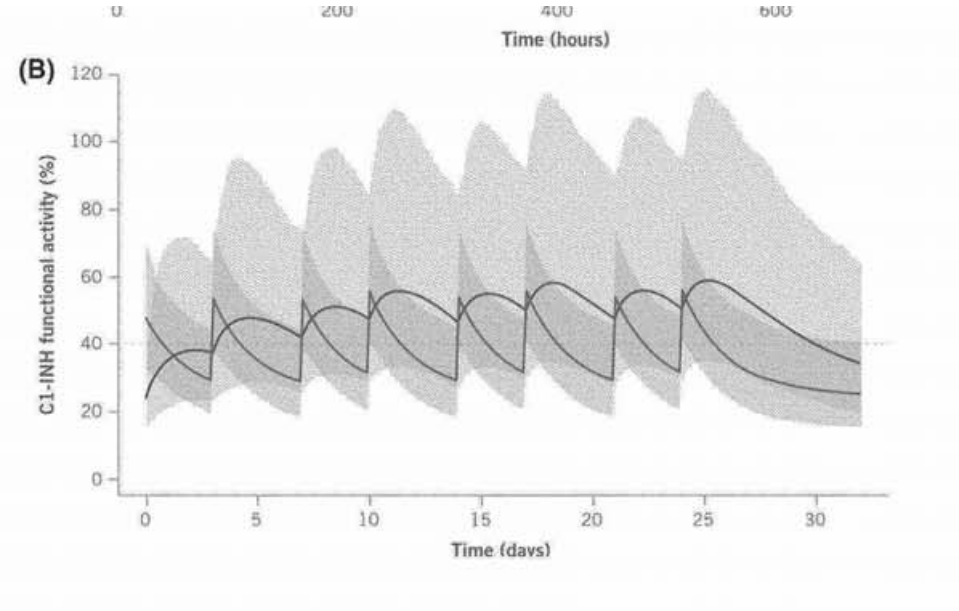
[4] "Pharmacokinetics, sometimes described as what the body does to a drug, refers to the movement of drug into, through, and out of the body—the time course of its absorption, bioavailability, distribution, metabolism, and excretion." https://www.merckmanuals.com/professional/clinical-pharmacology/pharmacokinetics/overview-of-pharmacokinetics (last visited March 23, 2021).



(Craig Resp. Rep., Attachment A.) Upon review of these charts, Dr. Craig assumed that the subjects' actual blood levels of C1-INH increased and decreased consistent with those lines. He concluded that patients do not *always* achieve the claimed blood levels for each and every administered dose of Haegarda, as reflected by the solid dots on the lines of the graph. Absent a consistent blood level of "about 0.4 U/mL," Dr. Craig suggests that Haegarda does not infringe upon the patents-in-suit.

Plaintiff contends that this analysis is inherently unreliable because it "ignores the well-understood dose response curve for C1-INH blood levels and the Court's claim construction." (Pl's Mot. 7.) Plaintiff asserts that, as shown in Haegarda promotional material, C1-INH levels do not move along the straight lines in the charts used by Dr. Craig, but rather gradually rise and fall between subcutaneous administrations of Haegarda, creating a "scalloped" dose response

pattern as shown below:



(Pl.'s Mot., Ex. N, Haegarda Website.)

Plaintiff points out that, when asked about this discrepancy at his deposition, Dr. Craig testified that, given this latter chart, he would have no idea whether the patient got above 0.4 U/mL after doses one, two, and three. (Pl.'s Mot., Ex. M, Dep. of Timothy Craig ("Craig Dep.") 163:1–165:12.) He further indicated that the blue line in the charts he relied upon was an "extrapolation" made by whoever drew those charts, and the charts did not depict an accurate dose response curve. (Id. at 165:21–166:18.) Plaintiff now asserts that Dr. Craig's "straight line" methodology differs significantly from Defendant's own published and peer-reviewed analysis of the same clinical data and constitutes an unreliable and unscientific method of evaluating patient blood levels.

Defendants respond that this criticism is unfounded because the "scalloped" response is a result of a simulation based on a pharmacokinetic model that aggregated data from multiple clinical trials involving multiple patients. Defendants explain that Dr. Craig's "straight line" charts reflect an analysis of individual patient data from the Haegarda Phase II clinical trial.

According to Defendants, the charts on which Dr. Craig relies are entirely consistent with blood level analysis of individual patients. Indeed, Dr. Craig testified that one may not always expect a "scalloped" response—where the blood level goes up and down—between doses. (Craig Dep. 162:22–25.) Defendants reason that these charts, and Dr. Craig's analysis of them, also show that it takes several doses before an individual patient achieves a C1-INH blood level of 0.4 U/mL, which is also reflected on shaded portion of the "scalloped" graph.

Considering these competing arguments, in the context of a Daubert analysis, I find that the conflicting opinions on the propriety of Dr. Craig's straight-line analysis bear not on the reliability of his analysis, but rather on the correctness of his opinion. Under Daubert, a court may not evaluate the credibility of opposing experts or the persuasiveness of their conclusions. Walker v. Gordon, 46 F. App'x 691, 695 (3d Cir. 2002); see also In re Chocolate Confectionary Antitrust Litig., 289 F.R.D. 200, 210 (M.D. Pa. 2012) ("Obviously, Defendants vigorously dispute [the expert's] conclusions, but the court finds that these disputes go to the weight, and not the admissibility, of [the] expert testimony."). Rather, it is enough to find that the methodology used by the expert is reliable. Walker, 46 F. App'x at 695.

Here, Dr. Craig is clearly qualified to opine on this subject area, given his decades of experience in treating HAE patients and participating in clinical trials of HAE drugs. His methodology rests on the same clinical data relied upon by Plaintiff's experts, except that Dr. Craig subjects that data to a different analysis, focusing on each individual subject and describing the trends in blood levels based on measurements at each dosage. To the extent the straight-line trends improperly disregard the fluctuations in blood levels, Plaintiff may explore these alleged flaws through cross examination. Plaintiff's own experts' disagreement with Dr. Craig's methodology in determining dose response patterns is a credibility and weight dispute

for the jury and not a basis for Daubert exclusion. Plaintiff has made an insufficient showing that Dr. Craig's methodology is inherently unscientific or unreliable. "As long as an expert's scientific testimony rests upon good grounds, based upon what is known, it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." Alco Indus., Inc. v. Wachovia Corp., 527 F. Supp. 2d 399 (E.D. Pa. 2007) (quoting Troche v. Pepsi Cola Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998)). Accordingly, I will deny Plaintiff's Motion on this ground.

b. Inclusion of Data from "Baseline" Blood Level Measurement

Plaintiff's second challenge to the reliability of Dr. Craig's infringement analysis contends that he improperly includes data from a "baseline" blood level measurement by measuring the C1-INH levels in a subject's blood before administration of Haegarda (reflected in the first blue diamond in the straight-line chart above). Plaintiff asserts that "information about C1-INH blood levels taken *prior to* administration of Haegarda does not and cannot inform on the 'pertinent inquiry'—whether *administering* Haegarda increases C1-INH levels as claimed by the Shire patents." (Pl.'s Mot. 10.)

Defendants respond that plaintiff's criticism is inaccurate. The first four circles (three filled, one open) on the first chart above reflect the first four doses of Haegarda. Dr. Craig explained that although he counted those doses, he recognized that "[t]he pharmacokinetics take[] a while for the build-up. (Craig Dep. 164:11–14.) He also noted that the first dose "does not relate to a person being treated as of yet." (Id. at 161:7–13.)

A dispute over interpretation of the data again goes to weight not admissibility. During cross-examination, Plaintiff can question Dr. Craig regarding whether the initial sampling point

is relevant to the question of whether administration of Haegarda increases the level of C1-INH in the blood. This criticism, however, does not warrant blanket exclusion of his entire opinion.

c. Inconsistency with Claim Construction

Plaintiff next contends that Dr. Craig's opinion is inconsistent with the Court's claim construction. Plaintiff argues that the claims of the patents-in-suit do not require that a subject reach the claimed blood levels of "at least about 0.4 U/mL" for any particular duration. Rather, according to Plaintiff, "[b]lood levels must simply reach 'at least about 0.4 U/mL' **any time** 'after administration of the composition.'" (Pl.'s Mot. 9–10 (emphasis added).) Thus, Plaintiff contends that Dr. Craig's analysis—that patients in the study did not "achieve[] or maintain[] C1-INH blood levels of 0.4 U/mL for the duration of their treatment"—conflicts with the claim construction and would mislead the jury.

Nothing in the claim construction, however, includes the words "any time." Rather, as set forth in my claim construction opinion, I construed the patent to require that "the administration of the composition increases the level of C1 esterase inhibitor in the blood of the subject to at least about 0.4 U/mL after administration of the composition." (D.I. 237 at 28.) Consistent with this construction, Dr. Craig evaluates blood levels after the administration of each dose of Haegarda and notes that, evaluating blood levels on a dose-by-dose base, the C1-INH levels did not consistently remain at "at least about 0.4 U/mL." Neither of the parties ever sought clarification of the term "administration" and whether it meant administration of one dose or many doses. Certainly, Plaintiff is free to argue that it is improper to analyze infringement dose-by-dose, and that infringement must be determined based on measurement of blood levels after several doses of Haegarda, thus allowing for the build-up of C1-INH in the blood to the claimed levels. Such argument, however, has no place in a Daubert motion.

d. Lack of Familiarity With Analysis

Plaintiff's last challenge asserts that Dr. Craig's infringement opinions should be excluded because Dr. Craig admitted that he did not personally perform the analysis of the data from 3001 Study himself. Plaintiff argues that Defendants' counsel made the graphs appended as Attachment A to his report, and that Dr. Craig blindly accepted those graphs as accurate. (Craig Dep. 147:12–149:2.) Plaintiff posits that because Dr. Craig made no effort to check the underlying data reflected in the graphs, determine whether the data reflected in those graphs was correct, or identify the counsel that prepared the graphs, his opinion is unreliable. (Id. at 143:18–144:25, 158:20–159:4.)

Federal Rule of Evidence 703 provides, in relevant part:

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.

Fed. R. Evid. 703. To determine whether "an expert's data is of a type reasonably relied on by experts in the field," the court must "assess whether there are good grounds to rely on this data to draw the conclusion reached by the expert." Montgomery Cnty. v. Microvote Corp., 320 F.3d 440, 448 (3d Cir. 2003) (quotation omitted). "If the data underlying the expert's opinion are so unreliable that no reasonable expert could base an opinion on them, the opinion resting on that data must be excluded." Id. (quotation omitted).

Here, while Plaintiff focuses on the possibility that Dr. Craig has not independently verified underlying facts on which he bases his opinion, it disregards that the facts themselves are indeed reliable. The underlying data comes directly from Defendants' own Phase III study of Haegarda and reflects the C1-INH levels of the subjects at various times after administration of

doses of Haegarda. Although Dr. Craig did not know who specifically prepared the charts in question, those charts simply plot the blood level data as measured during the course of the clinical study and connect that data using straight lines. Plaintiff does not claim that such numerical data from scientific studies is not the type reasonably relied upon by experts in the field. Indeed, Plaintiff admits that this Phase III clinical data is the basis for other published and peer-reviewed analysis, and Plaintiff's own experts rely on that same data, but simply apply a different method for analyzing it.[5]

Dr. Craig ultimately used his scientific and medical knowledge, together with his extensive period in the treatment of HAE, to opine on what this pharmacokinetic data established. Such an opinion is sufficiently reliable for purposes of Daubert. See Inline Connection Corp. v. AOL Time Warner Inc., 472 F. Supp. 2d 604, 613 (D. Del. 2007) (declining to exclude expert report based simply because expert failed to investigate or lacked adequate familiarity or knowledge about the underlying data on which his report was based; "[a]n expert is

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[5] Plaintiff relies on the case of Bruno v. Bozzuto's, Inc., 311 F.R.D. 124, 127–28 (M.D. Pa. 2015) for the proposition that "experts who use data in their reports without independently verifying the accuracy or reliability of those figures fail to satisfy this Circuit's reliability requirement." (Pl.'s Mot. 11.)

Bruno, however, was a breach of contract action wherein the plaintiff's damages experts decided to use internal financial projections purportedly created by the defendant to estimate the sales plaintiff's business would realize after 2007. Id. at 127–28. Resort to those internal projections was necessary because the plaintiff had previously destroyed their sales data. The experts had done no independent research to verify the validity of those profit projections or how those projections were created. Id. Here, however, the data upon which Dr. Craig relies is scientifically factual data published in a study and submitted to the FDA for use in approval of Haegarda.

permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation.").[6]

2. Obviousness Opinion

Plaintiff next challenges Dr. Craig's opinion on obviousness set forth in his opening expert report. (Craig Opening Rep. § X.) On this issue, Dr. Craig states:

> I have been informed that for a patent to be invalid as obvious, a person of ordinary skill in the art, in view of the prior art, must both be motivated to pursue the claimed invention and must have a reasonable expectation of successfully achieving the claimed invention. In my opinion, as of March 2013, a person of ordinary skill in the art would have been motivated to decrease the treatment burden for HAE patients by decreasing the total number of injections (for the multi-injections regimens) and decreasing the injection volumes (for the larger-volume injection regimen). To achieve these goals, a person of ordinary skill in the art would seek to obtain further concentrated C1-INH compositions, including further concentrated compositions compared to those disclosed in the Schranz Poster. A person of ordinary skill in the art would have reasonably expected these high concentration C1-INH pharmaceutical compositions to successfully prophylactically treat HAE.

(Craig Opening Rep. ¶ 168.) Upon further detailed analysis of two prior art references—the *Schranz* Poster and *Gatlin*[7]—Dr. Craig concludes that the method of treatment described in

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[6] Plaintiff alternatively argues that the charts on which Dr. Craig relies contain at least seventeen errors as to the precise blood level measurements and double counts some data, yet Dr. Craig was unaware of these errors. Defendants do not dispute that there are some data errors in the charts presented in Dr. Craig's responsive report but contend that these are merely typographical mistakes made when copying individual patient blood level measurements into a spreadsheet for generation of the graphs and do not alter Dr. Craig's ultimate conclusion that not all doses of Haegarda result in an increase in C1-INH blood levels to at least about 0.4 U/mL.

I decline to find that such data errors render the entirety of Dr. Craig's infringement opinions unreliable. Rather, Plaintiff will be able to expose the alleged incorrect data during cross-examination.

[7] The *Schranz* Poster is a scientific poster by Plaintiff's employees, including Jennifer Schranz, which details Plaintiff's subcutaneous administration of a high concentration C1-INH formulation to HAE patients, resulting in an increase of C1-INH blood levels to 0.4 U/mL. The

several claims of both the '788 patent and the '595 patent would have been obvious to a person of ordinary skill in the art. (Id. ¶ 217.)

Plaintiff now argues that although Dr. Craig refers to *Gatlin* throughout his reports, Dr. Craig lacked any knowledge of that prior art reference when preparing his report. Plaintiff points to Dr. Craig's deposition—which took place after the submission of his expert report—where he was repeatedly asked when he first reviewed *Gatlin* and consistently responded that he had never seen *Gatlin* before his deposition:

> Q. Okay. Now, turning to Exhibit 14, the Gatlin chapter, when was the first time you saw that?
> A. I just saw it now.
> Q. Okay. But before right now, when was the first time you saw it?
> A. I just saw it now.
> Q. You've never seen that before?
> A. No, I have not.
> Q. Okay. So I take it that to the extent you offer opinions about that chapter in your report, those opinions don't come from you.
> . . .
> A. The techniques do, but no, not the chapter.
> Q. Okay. And that chapter is not the type of thing that you, in the course of your work as a treating physician, look at.
> . . .
> A. That would be correct.

(Craig Dep. 183:3–17 (objections omitted); see also id. at 189:7–12.) Plaintiff contends that "Dr. Craig's complete unfamiliarity with a prior art reference that is the cornerstone of one of his principal obviousness opinions, coupled with his admission that he ordinarily would not read formulation papers like *Gatlin* as a treating physician, is a clear failure to satisfy the 'reliability' and 'qualifications' requirements of Rule 702." (Pl.'s Mot. 13.)

Gatlin reference is a chapter in a formulation textbook that generally describes techniques to reduce pain and irritation when formulating injectable drugs. (Pl.'s Mot., Ex. P.)

Citing to the references to the *Gatlin* references in Dr. Craig's Opening, Reply, Supplemental Expert Reports, and *Inter Partes Review* declarations filed in May 31, 2017 and December 18, 2018, Defendants reason that Dr. Craig must have seen *Gatlin* in order to include it in his reports.[8] Defendants argue, without citation to the record, that "Dr. Craig simply mis-recollected his prior review of the *Gatlin* reference." (Defs.' Opp'n 9.)

Such arguments are insufficient to counter Dr. Craig's explicit and unequivocal deposition admission that he had not seen *Gatlin* prior to the date of his deposition, that he had no independent knowledge of *Gatlin*, and that *Gatlin* was not the type of reference he would have consulted. Importantly, Defendants' counsel did not attempt to clarify the deposition record or refresh Dr. Craig's recollection. Nor was this testimony corrected through an errata sheet. Consequently, Dr. Craig's complete unfamiliarity with *Gatlin* precludes him from relying on it in his report to opine that the patents-in-suit were obvious. See Johns Hopkins Univ. Alcon Labs., Inc., No. 15-525, 2018 U.S. Dist. LEXIS 70403, at *18 (D. Del. Mar. 1, 2018) (finding that expert's admission during deposition that he did not review actual survey questions or answer choices in the survey forms on which he opined, but merely looked at summary slide presentations of the survey data, precluded expert from testifying that the surveys had methodological flaws), adopted by 2018 U.S. Dist. LEXIS 69403 (D. Del. Apr. 25, 2018).

Defendants also argue that Plaintiff overstates the significance of the *Gatlin* reference to Dr. Craig's obviousness opinions. They posit that the primary reference relied on by Dr. Craig is the *Schranz* Poster, and that his citation of *Gatlin* is simply representative of the general knowledge of persons of ordinary skill in the art that the target volume for subcutaneous

[8] Defendants also cite to Dr. Craig's deposition testimony wherein he was shown *Gatlin* and responded, "I remember that," seeming to remember only that his reports cited *Gatlin*. (Crag Dep. 180:2–181:3.) Immediately after that remark, Craig expressly clarified that he had not previously seen *Gatlin* before his deposition.

injections should be limited to 1–2 mLs. As Dr. Craig admitted, however, he is not a drug formulator and, as a treating physician, would not read formulation papers like *Gatlin*. Thus, he has no independent expertise on which to opine that a skilled formulator would seek to obtain further concentrated C1-INH compositions. (Craig Dep. 185:22–186:24.)

For the reasons stated above, I will exclude Dr. Craig's obviousness opinion to the extent it relies on *Gatlin* as a prior art. Dr. Craig may opine on obviousness by reference to the *Schranz* Poster.

3. Agency Opinion

Plaintiff also seeks to exclude a portion of Dr. Craig's Responsive Report that states "because I understand SPNN to not be an agent of [Defendant] CSL Behring, and none of [Plaintiff] Shire's experts have provided evidence that instructions and administration conducted by SPNN resulted in an infringing act, I disagree with Drs. MacGinnitie's and Bell's contention that CSL Behring has infringed the asserted claims through SPNN's actions." (Craig Resp. Rep. ¶ 25.)

By way of background, SPNN is a nursing service called Specialty Pharmacy Nursing Network, with whom Defendants have a Master Services Agreement requiring SPNN to perform nursing services for Defendants, including teaching patients to self-administer Haegarda in accordance with the Haegarda Prescribing Information. Based on his understanding that a person can infringe a claim indirectly by inducing other people to infringe, Plaintiff's expert, Dr. Andrew MacGinnitie, has opined that the administration of Haegarda indirectly infringes the patents-in-suit because Defendant, "through SPNN, sells, offers to sell, and uses HAEGARDA and "administers HAEGARDA to HAE patients according to the HAEGARDA Prescribing Information in an infringing manner." (Defs.' Opp'n, Ex. 10, ¶¶ 27, 152.) Dr. MacGinnitie

further remarks that the Agreement requires SPNN nurses to administer and teach patients to administer Haegarda according to the Haegarda prescribing information. (Id. ¶ 153.)

Dr. Craig disagrees and notes that "Dr. MacGinnitie has failed to establish that the actions of Specialty Pharmacy Nursing Network ('SPNN') bind CSL Behring. Namely, I intend to testify that the Master Services Agreement between SPNN and CSL Behring expressly denotes SPNN as an 'independent contractor' and removes CSL Behring from liability for any of SPNN's actions." (Craig Resp. Prep. ¶ 6.) Dr. Craig goes on to state that:

> The Master Services Agreement between CSL Behring and SPNN clearly indicates that SPNN's relation to CSL Behring is that of an independent contractor. . . . The agreement further specifies that SPNN "shall have no power to bind CSL Behring in any capacity." I have also reviewed the Affidavit of Cherylann Gregory, relied upon by Shire to claim CSL Behring has directly infringed the asserted patents through SPNN, and Ms. Gregory does not allege that SPNN constitutes CSL Behring's agent anywhere within the statement.

(Craig Resp. Rep. ¶ 24.)

Plaintiff now contends that this portion of Dr. Craig's report must be excluded for several reasons. First, according to Plaintiff, Dr. Craig admits he is a medical doctor with no legal training and no expertise in contract interpretation. (Craig Dep. 50:21–51:17.) Moreover, Plaintiff points out that Dr. Craig concedes that he had not seen the SPNN contract prior to this litigation and "was never intend[ing]" to offer any expertise in opinion on the contract. (Id. at 173:9–175:7.) Finally, even if he were qualified, Plaintiff argues that SPNN's agency relationship with Defendants is a question of law.

On these points, I agree with Plaintiff. Questions of agency, independent contractors, and whether the actions of one can bind another are legal questions. Dr. Craig does not profess to have any legal expertise and experience, let alone any legal understanding of what constitutes an

"agent" under the law. He also does not purport to have any specialized experience with the particular SPNN contract. Accordingly, I will exclude this portion of his opinion.[9]

4. Market Share Opinion

Plaintiff's final challenge to Dr. Craig concerns paragraph eleven of his Responsive Report:

> Close to the launch of Haegarda® in 2017, I believed that the introduction of Haegarda® and lanadelumab would significantly expand the HAE prophylactic market. In February of 2017, approximately 20% of my HAE patients were on prophylaxis therapy. I expected that number to increase to about 50% following the entry of Haegarda® and lanadelumab onto the market, with the movement of patients, currently on acute-only therapy, to these new prophylaxis therapies. I believed that Haegarda® and lanadelumab would split this new expansion in the prophy [sic] market assuming lanadelumab achieved the roughly 90% efficacy.

(Craig Resp. Rep. ¶ 11.) Plaintiffs assert that although Dr. Craig may have personal knowledge of the treatment landscape of his own patients, he is not an economist or an expert in the HAE market at large. Accordingly, his experience as an "expert consumer" does not allow him to offer this opinion.

As noted above, Dr. Craig has more than two decades treating HAE patients and working with pharmaceutical companies on new HAE treatments. Moreover, Dr. Craig was invited by

[9] Defendants respond that, to the same extent such opinions by Dr. Craig are excluded, Plaintiff's experts, Drs. MacGinnitie, Klibanov, and Derendorf, must be disqualified to opine on the relationship between SPNN and Defendants. Defendants, however, misunderstand the distinction between Dr. Craig's report and those of Plaintiff's experts. Dr. Craig opines on the legal concept of agency and whether the SPNN contract defines SPNN as an agent whose actions can legally be imputed to Defendants for purposes of *direct* infringement. Plaintiff's experts, on the other hand, simply note that under the plain terms of the contract, SPNN has been hired to teach patients how to administer Haegarda in accordance with the Prescribing Instructions. If a jury accepts such facts as true, that contract would constitute inducement of another to infringe, *i.e. indirect* infringement. Plaintiff's experts' testimony does not require any legal interpretation or analysis. As such, I will not exclude their testimony.

Deutsche Bank to speak on recent and upcoming developments in the treatment of HAE, wherein he offered the same views as expressed in his report. (Defs.' Opp'n, Exs. 15, 16.) Based on that experience Dr. Craig is qualified to opine that he "believed" or "expected" that HAE prophylactic market would expand within the introduction of Haegarda and that the percentage of *his* HAE patients on prophylaxis therapy would increase to about 50%. I therefore deny Plaintiff's motion to exclude this opinion.[10]

C. Dr. Lisbeth Illum

Plaintiff's next Daubert challenge focuses on Defendant's formulation expert Dr. Lisbeth Illum, who opines on protein drug formulation and development, specifically formulations suitable for subcutaneous administration, as of March 2013. (Pl.'s Mot., Ex. F, Report of Dr. Lisbeth Illum ("Illum Rep."), ¶ 6.) According to Plaintiff, Dr. Illum goes beyond her area of expertise in offering legal opinions regarding inventorship of the patents-in-suit, and opines that "individuals at Sanquin who worked on developing low volume, high concentration C1-INH compositions in collaboration with [Plaintiff], should have been named as inventors on the Asserted Patents." (Id. ¶ 15; see also ¶ 339.) Dr. Illum also avers that based on a contractual agreement between Plaintiff and Sanquin, Shire and Sanquin should be co-owners of the patents. (Id. ¶ 339.)

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[10] Plaintiff's reliance on Advanced Medical Optics, Inc. v. Alcon, Inc., No. 03-1095, 2005 WL 782809 D. Del. Apr. 7, 2005) is misplaced. There, the expert sought to testify about the competitive advantage that certain cataract surgical equipment having the invention of each of the two patents in suit would have in the market. Id. at *2. He rested his opinion on the fact that he was a "sophisticated consumer" because he had been performing cataract surgery for thirty years. Id. at *3. The court excluded the testimony, finding that he had no expertise in the analysis of sales and market trends for this equipment and simply being an "expert consumer" did not remedy this deficiency. Id.

By contrast here, Dr. Craig does not opine definitively that the introduction of Haegarda would expand the HAE prophylactic market. Rather, he intends to testify, based on his own experience with his patients, as to why he *believes*, from a medical perspective, that the share of *his own* patients on prophylactic therapy would increase following the entry of Haegarda.

District courts "must ensure that an expert does not testify as to the governing law of the case." Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). Expert witnesses are prohibited from rendering a legal opinion because "it would usurp the District Court's pivotal role in explaining the law to the jury." Id. (citing First Nat'l State Bank v. Reliance Elec. Co., 668 F.2d 725, 731 (3d Cir. 1981)); see also QVC, Inc. v. MJC Am., Ltd., No. 08-3830, 2012 WL 13565, at *2 (E.D. Pa. Jan. 4, 2012) (noting that experts may not apply the resulting law to the facts of a case to draw a legal conclusion). Nonetheless, "testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." Grill v. Aversa, No. 12-120, 2014 WL 4784150, at *2 (M.D. Pa. 2014) (quoting Fed. R. Evid. 704).

Inventorship is a question of law with underlying factual issues. Vanderbilt Univ. v. ICOS Corp., 601 F.3d 1297, 1303 (Fed. Cir. 2010); Checkpoint Sys., Inc. v. All-Tag Sec. S.A.. 412 F.3d 1331, 1338 (Fed. Cir. 2005). "A patent is invalid if more or less than the true inventors are named." Troyan, Ltd. v. Kokymat SA, Irori, 299 F.3d 1292, 1301 (Fed. Cir. 2002). Thus, the determination of whether a person is a joint inventor is fact specific[.]" Fina Oil & Chem. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). "[T]o be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention." Id.

Here, the majority of Dr. Illum's inventorship opinion stays within the confines of her expertise and avoids explaining the law. Section VII of Dr. Illum's report engages in an extensive discussion of how others—including both Defendants and Sanquin (the Stichting Bloevoorziening)—invented the claimed compositions before the inventors of the patents-in-suit. (Illum Rep. § VII.) With respect to Sanquin specifically, Dr. Illum discusses how it first made a

500 U/mL C1-INH composition in 2009. (Id. ¶¶ 216–224.) She then details how Plaintiff's inventors "each possessed personal knowledge" of both Defendants' and Sanquin's development of a C1-INH composition, and that Plaintiff used Sanquin's earlier work, as set forth in a 2009 Sanquin report and a July 2010 Sanquin presentation, to assist in formulation of the asserted patents. (Id. ¶¶ 329–333.) She concludes that:

> I understand that all properly named inventors must have been involved in some part of the conception of the claimed invention. As explained above in § VII.B, *supra*, it is my opinion that Sanquin first invented a 500 U/mL C1-INH formulation with sodium citrate and a pH of 7.0 in May 2009. Further, as explained in § XII.B, *supra*, Sanquin also invented a 1000 U/mL C1-INH formulation comprising sodium citrate and having a pH of 6.78–6.84 by at least July 2010.
>
> . . .
>
> The Asserted Patents' claimed C1-INH compositions each require: (1) sodium citrate, citrate, or phosphate ('111 patent); (2) an overall pH ranging from 6.5–8.0; (3) a C1-INH concentration of at least about 400 U/mL, at least about 500 U/mL, about 500 U/mL, or about 400-600 U/ML; and (4) C1-INH comprising the amino acid sequence of residues 23 to 500 of SEQ ID NO: 1 or an amino acid sequence of at least 95% identical to residues 23 to 500 of SEQ ID NO: 1. In my opinion, Judith Bloem and Anky Koenderman [of Sanquin] developed a formulation that met each of these four criteria by at least May 2009 and conveyed that information to the named inventors. Accordingly, it is my opinion that Judith Bloem and/or Anky Koenderman at the very least contributed to the permanent and definite idea of the claimed C1-INH compositions, and should, therefore, be listed as inventors of Shire's Asserted Patents.

(Id. ¶¶ 338–39.)

Given Dr. Illum's expertise in protein formulations, such testimony regarding the contribution of individuals at Sanquin to the conception of the asserted patents is permissible under Daubert. I will therefore deny Plaintiff's motion to exclude it.

Somewhat more problematic are Dr. Illum's opinions set forth in paragraphs 340 to 342 of her report. In paragraph 340, Dr. Illum reviews a Manufacturing and Distribution Agreement

entered into by Plaintiff and Sanquin, wherein they agree that they "shall jointly own all data, information, materials and inventions and intellectual property rights therein, created and/or invented jointly by an employee(s) of Sanquin and an employee(s) of [Shire]." (Id. ¶ 340.) Although Dr. Illum concedes that she is not an attorney, she opines that "this January 2010 agreement clearly indicates that any invention, such as the 500 U/mL or the 1000 U/mL Cinryze® formulations created by Judith Bloem and Anky Koenderman, would be, at the least, co-owned and not wholly assigned to [Plaintiff]." (Id.) Such an opinion—aside from exceeding the bounds of her expertise in protein drug formulations by discussing the import of a contract—attempts to offer an impermissible legal conclusion. See Comcast Cable Commc'ns, LLC v. Sprint Commc'ns Co., LP, 203 F. Supp. 3d 499, 546 (E.D. Pa. 2016) ("[A]n expert may testify based on a document that has legal effect so long as he does not opine on the legal effect of the document."); Dow Chem. Canada Inc. v. HRD Corp., 656 F. Supp. 2d 427, 435–36 (D. Del. 2009) (holding that the law "firmly prohibits expert testimony as to legal duties, standards or ramifications arising from a contract (quotations omitted)). Accordingly, I will exclude this testimony.

Likewise, in paragraphs 341 and 342 of her report, Dr. Illium opines that Plaintiff "purposefully excluded Judith Bloem and/or Anky Koenderman from the patents-in-suit" and that Plaintiff's individual inventors "knew of [Plaintiff's] desire to exclude Sanquin from exercising its rights to the claimed C1-INH formulation. (Illum Rep. ¶¶ 341–42.) As noted above, it is well settled that experts may not provide testimony concerning "the state of mind" or "culpability" of defendants, corporations, regulatory agencies, and others. Wolfe v. McNeil–PPC, Inc., 881 F. Supp. 2d 650, 661–62 (E.D. Pa. 2012); see also Deutsch v. Novartis Pharms. Corp., 768 F. Supp. 2d 420, 448 (S.D.N.Y. 2011) (precluding an expert witness from testifying

as to pharmaceutical company's bad faith); see also In re Rosuvastatin Calcium Patent Litig., MDL No. 08-1949, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) ("Generally, expert witnesses are not permitted to testify regarding 'intent, motive, or state of mind, or evidence by which state of mind may be inferred.'") (internal quotations omitted). Given this prohibition, I will exclude such opinions.

D. Nicholas Godici

Plaintiff further seeks to strike the Opening and Reply Reports of Defendants' expert, Nicholas Godici, and to preclude his testimony in its entirety. Mr. Godici, who is a former patent examiner and PTO Commissioner, purports to testify on the "rules, practices, and procedures governing the filing and examination of patent applications in the PTO and on the file history of the patents-in-suit, including the submissions made by the applications and the actions taken by the PTO." (Pl.'s Mot., Ex. G., Opening Rep. of Nicholas Godici ("Godici Opening Rep.") ¶ 15.) He ultimately intends to opine on whether certain of Plaintiff's conduct, if found to be true by a finder of fact, would support a finding of inequitable conduct. (Id. ¶ 158.)

Plaintiff urges that Mr. Godici's testimony must be excluded because: (1) the report's discussion of inequitable conduct is a legal framework disguised as expert opinion; (2) his opinions impermissibly undermine the presumption of validity; (3) his testimony regarding PTO procedures will not assist the Court as trier of fact; and (4) his summary of the file histories is not helpful. Defendants respond that none of these challenges go to the admissibility of his testimony.

1. Testimony Regarding Inequitable Conduct (Opening Report ¶¶ 48–55 & 108–158.)

Plaintiff first contends that Mr. Godici attempts to usurp the role of the Court and the factfinder by setting forth the standard for inequitable conduct and then applying that legal

framework to the facts of this case. Plaintiff asserts that although Mr. Godici attempts to characterize his opinions as "Patent Office practices and procedure," they are more akin to a legal brief and, therefore, warrant exclusion.

"[T]his Court has a strong and consistent view with respect to the admittance of the testimony of 'patent law experts.'" W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc., No. 11-515, 2015 WL 12815314, at *3 (D. Del. Nov. 20, 2015). It "has at times permitted testimony from such experts, including with regard to inequitable conduct allegations, so long as the testimony clearly related to the ins and outs of internal PTO practices and procedures." Id. (citing cases). Beyond that narrow topic, however, courts have generally excluded patent law expert testimony relating to inequitable conduct largely because such testimony frequently amounts to the proffering of impermissible legal opinions. Id. at *3–5 (excluding Mr. Godici's testimony where, in an effort to rebut allegations of inequitable conduct, he reviewed the prosecution history of the patent-in-suit and explained how those records objectively indicated that the defendants made attempts to meet their duties to the PTO); see also AstraZeneca UK Ltd., IPR v. Watson Labs., Inc. (NV), No. 10–915, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012) ("[T]he judges in this District have a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances.") (citing cases); Brigham & Women's Hosp. Inc., No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) ("The law of this district is clear that experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on 'substantive issues of patent law.'"); In re Rosuvastatin Calcium Patent Litig., MDL No. 08-1949, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) (excluding patent law expert's opinions and testimony regarding the intent prong of inequitable

conduct); Revlon Consumer Prods. Corp. v. L'Oréal S.A., No. 96–192, 1997 WL 158281, at *3 (D. Del. Mar. 26, 1997) (concluding that while the proffered patent law expert could testify with respect to "matters of PTO practice and procedure[,]" it would not allow him "to testify as an expert on inequitable conduct; to do otherwise would usurp the respective functions of the . . . Court")).

Here, Mr. Godici ventures precisely into this forbidden territory. Paragraphs forty-eight through fifty-five of his opening report are (a) a summary of the law regarding the duty of candor and good faith and duty of disclosure as set forth in the Code of Federal Regulations, and (b) the case law setting forth the parameters for a claim of inequitable conduct. Although Mr. Godici prefaces his opinion with the statement that, "I will not attempt to instruct the court on the law of inequitable conduct," that is precisely what he proceeds to do over the course of multiple pages. I will exclude any such testimony.

Thereafter, in paragraphs 108 to 158 of his opening report, Mr. Godici expressly provides opinions as to whether Plaintiff's conduct supports a finding of inequitable conduct and, in turn, the unenforceability of the entire patent-in-suit. Mr. Godici states that certain facts "would support a finding of inequitable conduct" if considered under Federal Circuit law. (Godici Opening Rep. ¶¶ 113, 119, 125, 131, 137, 148, 154.) Despite Defendants' suggestion that such testimony is simply about PTO practice and procedure, I find that this portion of his opening report improper legal analysis and legal opinion.

2. Opinion Regarding PTO's Limited Resources (Opening Report ¶¶ 20–22, 36, 155)

Plaintiff next challenges Mr. Godici's opinions regarding the PTO's limited resources and the real-life constraints on examiners' time. Specifically, Mr. Godici describes various limitations that could result in a patent examiner's mistake in approving a patent:

- "While PTO examiners strive to make the best possible decisions on patentability there are real life constraints on their time. On average the number of hours spent on any individual application is 'only about 20 hours.'" (Godici Opening Rep. ¶ 20.)

- "[T]he PTO budget relies only on the fees collected from patent and trademark applicants and others who use the services of the PTO. Therefore, to keep the fees for filing and prosecuting a patent application reasonable for the inventor the PTO must work with a resource constraint. Therefore, it is very important that applicants and their representatives comply with the duty of candor and duty of disclosure to ensure the PTO considers all of the material information necessary to make the best possible patentability decisions." (Id. ¶ 21.)

- "While the PTO strives to issue only valid patents, it is sometimes necessary to challenge the validity and/or enforceability of a patent when patent rights have been improperly granted. This may occur because information or evidence exists that was not before the examiner during the examination process or the examiner was misled by the applicant as to the scope and content of the prior art or some other requirement for patentability." (Id. ¶ 22.)

- "[T]he PTO examiner's ability to uncover certain types of non-patent prior art such as prior public uses, sales and offers for sale of the invention or prior products offered in the marketplace is limited. Therefore, PTO databases do not always contain all the pertinent prior art. Additionally, examiners have the discretion of which databases to search, if any. These databases are typically searched using what is known as 'keyword' or 'text' searching. Thus, if certain keywords are not used in the search query, relevant prior art may not be uncovered." (Id. ¶ 36.)

- "Based on my review of the file histories of those patents, it is my opinion that the Sanquin Report was misunderstood or misunderstood by the PTO examiner." (Id. ¶ 155.)

Plaintiff argues that such opinions undermine the bedrock principle that patents are entitled to a presumption of validity. 35 U.S.C. § 282. Defendant counters that such opinions simply provide context for the trier of fact with respect to PTO practices and procedures.

Under 35 U.S.C. § 282, "[a] patent shall be presumed valid" and the burden of establishing invalidity rests on the party asserting such invalidity. Id. The presumption of

validity is a "presumption that the PTO does its job properly." Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1367 n.1 (Fed. Cir. 2001). Thus, courts have repeatedly and consistently precluded expert testimony from Mr. Godici and similar experts who purport to offer opinions about imperfections, obstacles, problems, and mistakes at the PTO. See, e.g., Commowealth Sci. and Indus. Rsch. Org. v. Mediatek Inc., No. 12-578, 2015 WL 12806515, at *5 (E.D. Tx. June 29, 2015) (finding prejudicial Mr. Godici's testimony regarding quotas, mistakes at the PTO, average number of hours worked on applications, and limited resources, all offered to emphasize that the PTO has limited ability to grant valid patents); Icon-IP Pty Ltd. v. Specialized Bicycle Components, Inc., 87 F. Supp. 3d 928, 947 (N.D. Cal. 2015) (holding that an expert may not offer generalized testimony about quotas, time pressures, or the problems examiners generally face in completing their work at the PTO, as it would undermine the presumption of validity under 35 U.S.C. § 282); Wright Asphalt Prods. Co., LLC v. Pelican Refining Co., LLC, No. 09-1145, 2012 WL 1936416, at *7 (S.D. Tex. May 29, 2012) (precluding expert from testifying about problems at, and the propensity for error in, the Patent Office, and the effect on the validity of specific patents).

Mr. Godici's proposed testimony here is identical to that precluded in the foregoing cases. He does not opine about deficiencies in the examination process of the specific patents-in-suit. Rather, he seeks to talk only generally about practices that could undermine the presumption of validity set forth in 35 U.S.C. § 282. Such testimony is of limited probative value to Defendants and highly prejudicial to Plaintiff. While Defendants may present argument that the PTO is not perfect and may make a mistake—such as not reviewing certain prior art or

considering invalidity arguments—Defendants may not put the imprimatur of an expert on such testimony.[11] Accordingly, I will preclude Mr. Godici from offering these opinions.

3. Testimony Regarding PTO Procedures (Opening Report ¶¶ 17–47.)

Paragraphs seventeen to forty-seven of Mr. Godici's Opening Report discuss internal PTO processes and procedures. Although Plaintiff acknowledges that such testimony is permissible, it contends that Mr. Godici's explanation of PTO procedure will not be relevant or helpful—*i.e.*, will not "fit" the case—particularly where inequitable conduct will be before the Court and not a jury. As such, Plaintiff requests that this testimony be excluded.

PTO procedures are generally foreign to the average person and even to the average jurist. Certainly it may be helpful "to hear someone experienced in those procedures explain how they operate in terms that a layperson can understand." Bausch & Lomb, 79 F. Supp. 2d at 256. Repeatedly, courts in this district have admitted such testimony. See, e.g., W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc., No. 11-515, 2015 WL 12815314, at *4 (D. Del. Nov. 20, 2015) (permitting Mr. Godici's opinions and proposed testimony regarding general practices and procedures); Brigham & Women's Hosp. Inc. v. Teva Pharms. USA, Inc., No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) (permitting patent law expert to testify only as to PTO

[11] Defendants cite to two cases authored by the Honorable Leonard Stark, wherein he allowed "evidence and argument" consistent with what a jury would learn from a video presented by the Federal Judicial Center. That video discusses the patent process and notes that "[e]xaminers have a lot of work to do, and no process is perfect." Int'l Bus. Machs. Corp. v. Groupon, Inc., No. 16-122, 2018 WL 3007662, at *1 (D. Del. June 15, 2018). Based on that video, Judge Stark noted that the parties could present testimony that the PTO has a heavy workload and all institutes make mistakes. Id.; see also Intellectual Ventures I LLC v. Symantec Corp., No. 10-1067, 2015 WL 82052, at *1 (D. Del. Jan. 6, 2015).

Judge Stark's cases present a markedly different situation than the one before me in that a neutrally-presented FJC patent video about the patent process was presented. Here, Defendants seek to present their own expert for the purpose of criticizing the PTO and to suggest that its work is somehow flawed.

practices and procedures); Proctor & Gamble Co. v. Teva Pharm. USA, Inc., No. 04-940, 2006 WL 2241018, at *1 (D. Del. Aug. 4, 2006) (restricting testimony of patent law expert to PTO practice and procedures); but see AstraZeneca UK Ltd., IPR v. Watson Labs, Inc., No. 10-915, 2012 WL 6043266, at *2 (D. Del. Nov. 14, 2012) (excluding, without explanation, testimony as to PTO procedures); Corning Inc. v. SRU Biosys., No. 03-633, 2004 WL 5523178, at *1 (D. Del. Nov. 5, 2004) (excluding, without explanation, expert opinions on PTO procedures).

Here, Mr. Godici's testimony would provide useful background on the procedures at the PTO. Plaintiff identifies, and I find no potential prejudice from its admission. Absent a basis for exclusion at this time, I will admit testimony consistent with this portion of his report.[12]

4. Summary of File Histories (Opening Report ¶¶ 56–107)

Finally, Plaintiff objects to the admission of any portion of Mr. Godici's report that provides a selective recitation of the prosecution history of the patents-in-suit.

"[I]n [the District of Delaware] parties are generally not permitted to explain patent prosecution histories through expert testimony." Brigham and Women's Hosp., 2010 WL 3907490, at *2 (citation omitted). Nonetheless, "such testimony is sometimes admitted when needed." W.L. Gore, 2015 WL 12815314, at *4 (permitting Mr. Godici's summary of the prosecution history of the asserted patents); see also Novartis Pharm. Corp. v. Teva Pharm. USA, Inc., No. 05-1887, 2009 WL 3754170, at *8 (D.N.J. Nov. 5, 2009) (permitting patent law expert to testify regarding "the underlying facts regarding the prosecution of the [asserted patent] applications").

While it would be preferable to have fact witnesses narrate the file history, it appears that such testimony may not be available because the three named inventors had almost no

[12] As set forth above, testimony consistent with paragraphs 20–22 and 36 of his report remains excluded.

involvement in the patent prosecution process and left Plaintiff's employ before even the '111 patent had issued. In the absence of any fact witness who can present these file histories, Mr. Godici's narration of this background, prosecution history, and *inter partes* review proceedings will serve to advance the trial.

Plaintiff does not dispute that such expert testimony may be admissible, but contends that Mr. Godici's summary is incomplete because he failed to review many of Shire's submissions. (Pl.'s Reply Br. 7 (citing Mr. Godici's deposition testimony).) I note that Mr. Godici concedes this point and indicated that he "selected what [he] thought was important." (Pl.'s Mot., Ex. T, Dep. of Nicholas Godici ("Godici Dep.") 49:8–18.) To the extent that Mr. Godici's summary excludes portions of the history that Plaintiff believes are relevant, Plaintiff may raise those portions through cross-examination. For purposes of this Motion, however, I will not preclude this part of Mr. Godici's testimony.

E. Dr. Christine Meyer

Finally, Plaintiff's challenge Dr. Christine Meyer, who is Defendants' damages expert offered to rebut the damages testimony of Plaintiff's damages expert, Dr. Gregory Bell. Dr. Meyer opines that the total damages possibly payable by Defendants for infringement of the patents-in-suit between July 2017 and July 2019 is $101.7 million to $102.6 million. Plaintiff posits two bases for exclusion of Dr. Meyer's testimony: (1) her lost profit opinion is not sufficiently reliable, and (2) she should not be permitted to rely on data that Defendants failed to disclose during discovery.

1. Reliability of Lost Profits Opinion

In paragraphs 37–40, 54, 58, 104–05, 121(a), 130–51, Exhibits 3, 4(a)–(b), 7(b)–(d) & (f), 8(b)–(e) & (g), and Figures 1–3 and 5 of her Report, Dr. Meyer opines on what Plaintiff's

lost profits would be if it could prove infringement. In doing so, she relies heavily on data sourced from a company called Adivo Associates ("Adivo"). (Pl.'s Mot., Ex. J, Rep. of Christine Meyer ("Meyer Rep.") ¶ 37.) According to Dr. Meyer, Adivo is a company with a channel of data providers, including hospitals and specialty pharmacies, from which it collects data and projects this patient-level claims data across the entire market. (Id.) Dr. Meyer, in rendering her opinion, considered two Adivo-generated documents: (1) Adivo Sales Data (a one-sheet excel data providing sales information by product and type of use, such as prophylactic or on-demand), and (2) Adivo Switching Data (a single PowerPoint presentation showing data on switches to and from certain products) (collectively, "Adivo Data").

Plaintiff argues that Dr. Meyer did not rely on any actual data, collection reports, or other information underlying either the Adivo Sales Data or Switching Data. Rather, as Plaintiff presses, her understanding of the Adivo Data is based solely on two thirty-minute interviews her team conducted with Defendants' employee, Paul Jens. According to Plaintiff, Dr. Meyer did not speak with or question anyone from Adivo about the data or how it was collected, review the "procurement audits," or independently verify the data. Plaintiff urges that Dr. Meyer's lack of familiarity with the Adivo Data precludes a full assessment of the validity or applicability of that data.

As noted above, Federal Rule of Evidence 703 provides that an expert may base his or her opinion on previously-existing data as long as it is "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Fed. R. Evid. 703. To determine whether "an expert's data is of a type reasonably relied on by experts in the field," the court must "assess whether there are good grounds to rely on this data to draw the conclusion reached by the expert." Montgomery Cnty. v. Microvote Corp., 320 F.3d 440, 448

(3d Cir. 2003). In order to rely on secondary sources, the expert must demonstrate that (1) he or she has conducted some sort of independent investigation or verification to ensure the data is both accurate and helpful to the court, and (2) the investigation is sufficiently thorough such that the expert has gained a working familiarity with the borrowed data. Bruno v. Bozzuto's, Inc., 311 F.R.D. 124, 144 (M.D. Pa. 2015).

Plaintiff asserts that Dr. Meyer's reliance on the "unreliable and unverified Adivo Data is precisely the type of expert testimony Delaware courts routinely exclude under Rule 702." (Pl.'s Mot. 24.) However, the cases on which Plaintiff relies involved expert reliance on forward-looking subjective financial projections prepared by the proffering parties where the expert had no personal knowledge of the assumptions that were made or the qualifications of the persons in charge of making the assumptions. See, e.g., Mosaid Techs. Inc. v. LSI Corp., No. 10-192, 2014 WL 807877, at *2–3 (D. Del. Feb. 28, 2014) (excluding expert testimony as to lost profits where expert relied on a business plan prepared by the plaintiff which included several central assumptions that were not independently verified by the expert); Chemipal Ltd v. Slim-Fast Nutritional Foods Int'l, 350 F. Supp. 2d 582, 589–92 (D. Del 2004) (excluding expert damages testimony which relied on a presentation prepared by defendant setting forth a marketing estimate where expert did not conduct any independent analysis, did not use any expertise to evaluate secondary sources relied upon by the estimate, and did not know what the data represented, how it was compiled, or how it was evaluated or chosen); Legendary Art, LLC v. Godard, No. 11-0674, 2012 WL 3550040, at *4 (E.D. Pa. Aug. 17, 2012) (excluding expert damages testimony where expert relied on profit and loss projections supplied by plaintiff and where expert did nothing to verify these profit and loss projections and had no familiarity with the methods or reasoning used to arrive at these projections).

Here, by contrast, the data relied upon by Dr. Meyer is not based on forward-looking subjective projections requiring multiple assumptions, but rather rests on fact-based, historical sales and switching data. Specifically, as explained by Dr. Meyer, she was able to examine the sales as well as switches to and from several products used in the treatment of HAE by using data sourced from Adivo, which consisted of a representative sample of patient-level claims data that is projectable to address the entire market. (Meyer Rep. ¶ 37.) Dr. Meyer looked at Adivo Sales Data available from first quarter 2016 through 2019, which provided an *actual, not projected*, overview of sales of prophylactic treatments over time. (Id. ¶¶ 38–39.) The Adivo Switching Data showed, for 2018, where patients new to Haegarda came from, and suggested that Haegarda's sales were not all the result of switches from Cinryze. (Id. ¶ 39.) Based on that specific data, Dr. Meyer then calculated damages using three alternative methodologies and factoring in several specific adjustments (Id. ¶¶ 130–51.)

In doing so, Dr. Meyer did not blindly accept assumptions made by a third-party. Rather, during her staff's interviews with Defendants, Defendants indicated that the data compiled by Advio was the type of data and information that would have been used by Defendants in the ordinary course of business when making business decisions with regards to Haegarda. (Pl.'s Mot., Ex. V, Dep. of Christine Meyer ("Meyer Dep.") 115:11–18.) She explains that "[b]ased on [her] experience working on cases involving the economics of pharmaceuticals" she was aware and had a general understanding of Advio as a source of data, and she knew that data from Adivo was commonly used in the pharmaceutical industry. (Id. 121:5–122:9.) Although Dr. Meyer did not form opinions about individual employees of Advio, she reviewed the Advio data "in light of other information available to [her], and that certainly was consistent with both [Defendant]'s impression of Advio having experience and Advio indicating that they had experience in the

field." (Id. at 128:18–129:4.) She also learned the process by which Advio provided to Defendants a series of different reports and data over time, and what verification processes were in place at the data collection stage. (Id. at 149:12–20.) Moreover, she understood that Defendants did their own validation and concurred with the reliability of the data. (Id. at 150:2–4.) In addition, she did a comparison of the Advio Switching Data to the Advio Sales Data to understand the methodology and how the data was used in the ordinary course of business. (Id. at 153:22–154:7.) Finally, Dr. Meyer compared the Advio Sales Data against Haegarda sales data for a particular period in gauging the reliability and accuracy of Advio Sales Data. (Id. at 160:13–18.)

Based on this testimony, I find that the data on which Dr. Meyer based her opinion is of a type reasonably relied upon by experts in the field.[13] Dr. Meyer demonstrated that she conducted an independent verification to ensure the data was both accurate and helpful to the court and that the investigation was enough to provide her a working familiarity with the borrowed data. See Bruno, 311 F.R.D. at 144. Although Plaintiff identifies portions of Dr. Meyer's testimony where she was unable to explain what portions of the Advio data meant, such deficiencies may be explored through cross-examination and do not affect the admissibility of

[13] Plaintiff contends that the Advio Data, which is a compilation of sales information prepared by Advio and shared with CSL, constitutes double hearsay. Federal Rule of Evidence 703, however, "permits experts to rely on hearsay so long as that hearsay is of the kind normally employed by experts in the field." In re TMI Litig., 193 F.3d 613, 697 (3d Cir. 1999).

To the extent Plaintiff challenges Dr. Meyer's reliance on her associates to verify the data, it is well recognized that, "[a]n expert witness is permitted to use assistants in formulating his expert opinion." Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 612 (7th Cir. 2002). "Where the expert was directly involved with the research, analysis or drafting of the report, even with substantial assistance from a colleague or associate, his involvement in and knowledge of the report are matters of weight, not admissibility." Lee Valley Tools, Ltd. v. Indus. Blade Co., 288 F.R.D. 254, 266 (W.D.N.Y. 2013).

her testimony. See Daubert, 509 U.S. at 596 ("Vigorous 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.").

2. Failure to Produce Data in Discovery

In a footnote argument, Plaintiff also alleges that Dr. Meyer's opinions should be excluded insofar as they rely on data from Adivo Associates because Defendants failed to disclose the Adivo Data during fact discovery despite numerous, specific requests from Plaintiff. Plaintiff asserts that it requested Adivo Data in its document requests, during a July 31, 2019 deposition, and in an August 27, 2019 email. Yet, on August 29, 2019, Defendants allegedly refused to produce the Adivo Data and stated that it would "stand on [its] production to date." (Pl.'s Mot., Ex. Y.) Defendants subsequently produced the Adivo Data for the first time with the expert report of Dr. Meyer on December 10, 2019. Plaintiff now contends that Defendants' "refusal prejudiced [Plaintiff's] ability to conduct fulsome fact and expert discovery." (Pl.'s Mot. 23 n.13.) In turn, it presses that Defendants should not now be rewarded for intentionally withholding the Adivo Data during fact discovery.

Plaintiff's Daubert motion is not the proper time to litigate this discovery dispute. Plaintiff admits that the parties exchanged emails about the production of Adivo Data periodically from July 2019 to August 2019, with Plaintiff arguing that such data was responsive to several of its production requests. (Pl.'s Mot., Ex. X.) Defendants disputed Plaintiff's claims and believed that they had complied with document production. (Id.) Yet, at no point did Plaintiff seek to litigate that dispute via a motion to compel or otherwise bring the dispute to my attention. Thereafter, in December 2020, after production of Dr. Meyer's report, Plaintiff again requested that Defendants produce the Adivo Data, threatening to "seek appropriate relief from

the court and to depose additional fact witnesses." (Pl.s Mot., Ex. Y.) After additional productions of Adivo material, Defendant insisted that it produced "substantially more Adivo material than Dr. Meyer actually relied upon in her report," that it had nothing further, that the parties' joint request for extension of the expert discovery schedule had minimized any possible prejudice to Plaintiff, and that it considered the matter resolved. (Id.) After Defendants' January 17, 2020 email, this issue does not appear to have arisen further.

In the pending April 2020 Daubert motion, Plaintiff now seeks—through a footnote argument—the extraordinary remedy of precluding Dr. Meyer's testimony. This argument constitutes a belated attempt to litigate a motion to compel that could have been filed in the many months during which this discovery was at issue. Indeed, to wholly exclude Dr. Meyer's testimony now would reward Plaintiff for not attempting to cure any discovery problems earlier. Moreover, aside from suggesting that it has been denied the opportunity for "fulsome fact and expert discovery," Plaintiff has articulated no clear prejudice.[14] This is clearly not an appropriate argument to raise in a Daubert motion.

IV. DEFENDANTS' MOTION TO PRECLUDE EXPERTS

Defendants have filed a Daubert motion seeking to preclude portions of opinions offered by three of Plaintiff's experts: Dr. Gregory Bell, Mr. Robert Stoll, and Dr. Bernhardt Trout.

A. Dr. Gregory Bell

Dr. Gregory Bell is Plaintiff's damages expert who opines as to the amount of damages Plaintiff has suffered from both lost profits and loss of reasonable royalties. See AstraZeneca AB v. Apotex Corp., 782 F.3d 1324, 1330 (Fed. Cir. 2015) (holding that the two "alternative

[14] Defendants suggest that Adivo Data is publicly available and that, had Plaintiff truly wanted this data, it could have obtained it.

categories of infringement compensation" under section 284 are "the patentee's lost profits and the reasonable royalty he would have received through arms-length bargaining."). Defendants seek to exclude Dr. Bell's testimony on two grounds. First, they contend that Dr. Bell's lost profits and reasonable royalty opinions fail to properly apportion damages, as required in a patent infringement action. Second, they posit that his opinions improperly rely on the regulatory opinions or the knowledge of others.

1. Failure to Apportion Damages

A patentee is entitled to damages that are related to the patented features of a product, but not to unpatented features found in the same product. Sonos, Inc. v. D & M Holdings Inc., 297 F. Supp. 3d 501, 514 (D. Del. 2017). Thus, it is well established that the patentee must provide "evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features" or demonstrate that "the entire value of the whole machine, as a marketable article, is properly and legally attributable to the patented feature." Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1318 (Fed. Cir. 2011) (quoting Garretson v. Clark, 111 U.S. 120, 121 (1884)); see also Commonwealth Sci. & Indus. Research Organisation v. Cisco Sys., Inc., 809 F.3d 1295, 1301 (Fed. Cir. 2015) (noting that under the patent damages statute, 35 U.S.C. § 284, "damages awarded for patent infringement 'must reflect the value attributable to the infringing features of the product, and no more.'" (quoting Ericsson, Inc. v. D–Link Sys., Inc., 773 F.3d 1201, 1226 (Fed. Cir. 2014))). "[E]ven when the accused infringing product is 'the smallest salable unit,' the patentee 'must do more to estimate what portion of the value of that product is attributable to the patented technology' if the accused unit is 'a multi-component product containing several non-infringing features with no relation to the patented feature.'" AstraZeneca AB, 782 F.3d at 1338

(quotations omitted). The Federal Circuit does not require "absolute precision in [applying the principles of apportionment]; on the contrary, it is well-understood that this process may involve some degree of approximation and uncertainty." Bio-Rad Labs., Inc. v. 10X Genomics Inc., 967 F3d 1353, 1377 (Fed. Cir. 2020) (quoting VirnetX, Inc. v. Cisco Sys., Inc., 767 F.3d 1308, 1328 (Fed. Cir. 2014)).

The "entire market value" rule is an embodiment of the apportionment requirement. Under this rule, the patentee may rely on the entire market value of the accused product—and thus avoid the need for apportionment—if the patentee demonstrates that "the patented feature creates the 'basis for the customer demand' or 'substantially create[s] the value of the component parts.'" Uniloc USA, 632 F.3d at 1318 (alteration in original) (citations omitted); see also VirnetX, Inc. v. Cisco Sys., Inc., 767 F.3d 1308, 1329 (Fed. Cir. 2014) (holding that the entire market value rule applies if the patentee establishes that its "patented technology drove demand for the entire product."). The entire market value rule "is designed to account for the contribution of the patented feature to the entire product." AstraZeneca, 782 F.3d at 1338. A patentee may "assess damages based on the entire market value of the accused product *only where* the patented feature creates the basis for customer demand or substantially creates the value of the component parts." Id. at 1327 (emphasis in original) (quoting Versata Software, Inc. v. SAP Am., Inc., 717 F.3d 1255, 1268 (Fed. Cir. 2013)); see also Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1549 (Fed. Cir. 1995) (holding that the entire market value rule will permit[] recovery of damages based on the value of a patentee's entire apparatus containing several features when the patent related feature is the basis for customer demand" (internal quotations omitted)). Stated differently, "[a] patentee may recover lost profits on patented components sold with a patented item, a convoyed sale, if both the patented and unpatented products 'together

were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit'" and the patent-related feature drives demand for the functional unit as a whole. Am. Seating Co. v. USSC Group, Inc., 514 F.3d 1262, 1268 (Fed. Cir. 2008) (quoting Rite-Hite, 56 F.3d at 1550).

The Federal Circuit addressed the application of the entire market value rule to pharmaceutical products in AstraZeneca AB v. Apotex Corp., 782 F.3d 1324, 1338 (Fed. Cir. 2015). AstraZeneca involved a branded pharmaceutical patentee's suit against a generic competitor. The patent on the drug's active ingredient had expired, but the plaintiff still held "formulation patents claim[ing] three key elements—the drug core, the enteric coating, and the subcoating," which encompassed the "complete omeprazole product" accused of infringement. Id. at 1338. The generic manufacturer defendant contended that the entire market value rule was violated by any damages calculation that failed to exclude the active ingredient.

The Federal Circuit declined to require apportionment, reasoning that "the [asserted] patents cover the infringing product as a whole, not a single component of a multi-component product." Id. It further concluded that, because the "formulation . . . created a new, commercially viable omeprazole drug . . . previously unknown in the art and . . . novel in its own right," the district court did not err in declining to "exclude the value of the active ingredient when calculating damages." Id. at 1340; see also Idenix Pharms. LLC v. Gilead Sciences, Inc., No. 14-846, 2018 WL 922125, at *7 (D. Del. Feb. 16, 2018) (finding that entire market value rule does not apply where "there is substantial evidence to support the jury's implicit findings that the [patented product] covers the [accused infringing product] . . . and that 'there is not unpatented or non-infringing feature in the [accused] product[s],' as their active ingredient is the [patented product]."). Nonetheless, AstraZeneca explicitly refused to adopt a

rule making the entire market value rule "*per se* inapplicable in the pharmaceutical context." Id. at 1337–38; see also Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC, 879 F.3d 1332, 1348 (Fed. Cir. 2018) (noting that apportionment also functions on an "intra-patent" level, so that "when a patent covers the infringing product as a whole, and the claims recite both conventional elements and unconventional elements, the [finder of fact] must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone.") (citing AstraZeneca, 782 F.3d at 1338).

Here, Plaintiff asserts that apportionment is unnecessary because the claimed inventions cover the entirety of the accused product. It posits that the patents-in-suit cover methods for treating HAE, which involve subcutaneous administration of a certain composition. The accused product, Haegarda, allegedly infringes both: (1) the method for treating hereditary angioedema ("HAE") by administering a pharmaceutical composition, and (2) the pharmaceutical composition itself. According to Plaintiff, this case does not involve a "multi-component" product that necessitates a separate apportionment analysis because the accused product is the pharmaceutical product itself.

Defendants respond that apportionment remains necessary. They reason that Dr. Bell fails to separately account for profits and royalties generated by demand for the patented features of the accused infringing product, Haegarda, and those profits and royalties attributable to other, non-patented features of the product, including Haegarda's alleged benefits of (a) efficacy, safety, patient convenience, and access, (b) weight-based dosing, and (c) price. Defendants reason that, under Federal Circuit law, Dr. Bell must account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim,

standing alone. As Dr. Bell makes no attempt to parse the incremental value of any features or components of Haegarda, Defendants contend that Dr. Bell's analysis is unreliable and must be excluded under Daubert.

The evidence before me does not permit a determination of whether apportionment is required. On one hand, Plaintiff's expert opines that the patents-in-suit cover the infringing product as a whole. (Bell Rep. ¶ 42.) On the other hand, Defendants provide evidence that dosing advantages, price, safety, and patient access all drive demand for Haegarda, and that Dr. Bell has failed to account for these factors. Indeed, the conflicting arguments present a matter of competing expert opinion, which are not appropriate for determination during Daubert motion practice.

Nonetheless, I also find that for Daubert reliability purposes, Dr. Bell's opinion satisfies apportionment requirements by applying the accepted apportionment methodologies for both his lost profits and reasonable royalty analyses. I address each individually.

a. Lost Profits

In a patent infringement case, to recover lost profits as actual damages, the patentee must demonstrate that there was a reasonable probability that, "but for" the infringement, it would have made the infringer's sales. Rite–Hite, 56 F.3d at 1545. The Federal Circuit has adopted a four-factor test, first articulated in Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152 (6th Cir. 1978), as a standard, non-exclusive method for a patentee to establish entitlement to lost profits damages and satisfy the apportionment requirement. Rite-Hite, 56 F.3d at 1545; State Indus., Inc. v. Mor–Flo Indus., Inc., 883 F.2d 1573, 1577 (Fed. Cir. 1989). Under the Panduit test, the patentee must establish: (1) demand for the patented product; (2) absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the

demand; and (4) the amount of profit it would have made. Rite–Hite, 56 F.3d at 1545. To establish an entitlement to lost profits, a patentee need not negate every possibility that a purchaser might not have purchased a product other than its own. Rite–Hite, 56 F.3d at 1545. Rather, if the patentee establishes each of the Panduit factors, the court may reasonably infer that the claimed lost profits were in fact caused by the infringing sales. Id. Thus, by satisfying the Panduit test, the patentee can establish its *prima facie* case with respect to "but for" causation, and the burden shifts to the infringer to show that the inference is unreasonable for some or all of the lost sales. Id.

For purposes of this Motion, only the first Panduit factor is at issue. Dr. Bell's report opines, based on his review of the evidence and Plaintiff's experts Dr. Andrew MacGinnitie and Dr. Klibanov, that demand for Haegarda is driven only by (a) the desire for patient-administered subcutaneous delivery, in the context of (b) the need to provide prophylaxis for HAE patients, and (c) the desire to use a C1-INH to provide that prophylaxis. (Bell Rep. ¶ 42.) He posits that the patents-in-suit cover all three of these elements of demand. (Id.) In particular, he notes that the subcutaneous administration element of the demand for Haegarda is particularly important and was a "key advantage" of Haegarda over products that were currently on the market at the time of Haegarda's launch. (Id. ¶¶ 43–50.) Based upon several sources—including the expert report of Dr. Andrew MacGinnitie, Defendants' own market research which identified subcutaneous administration as the most desire area of improvement for HAE prophylaxis treatments, and Defendants' own marketing plans and internal analyses which indicated that Haegarda's subcutaneous treatment drove demand—Dr. Bell understood that subcutaneous administration was the "central attribute" that drove demand of both Haegarda and the patents-in-suit. (Defs.' Mot., Ex. 3, Dep. of Gregory Bell ("Bell Dep."), 221:23–224:6.)

Defendants challenge Dr. Bell's conclusion on three grounds, none of which I find have merit. First, they contend that Dr. Bell has no independent understanding of the claimed features that drove demand. They cite to Dr. Bell's testimony that he had never seen the patents before, and therefore, could not independently determine the claimed features of the patents. (Bell Dep. 89:25–90:9, 153:1–13.) Defendants note that Dr. Bell relies solely on other expert testimony to determine what the central attribute of the patents-in-suit was and what drove demand for Haegarda.

"While experts may not simply 'parrot' ideas of other experts," they "are permitted to rely on materials used by other experts in developing their own opinions." I.B.E.W. Local Union 380 Pension Fund v. Buck Consultants, No. 03-4932, 2008 WL 2265269, at *3 (E.D. Pa. June 3, 2008) (quotations omitted). Experts "may use a mix of objective data and subjective analysis from another expert to . . . create an admissible report," and the testifying expert's knowledge regarding the underlying facts "go[es] to the weight accorded to [that expert's] report and testimony, rather than its admissibility." Id. (quoting In re Wagner, No. 06-1026, 2007 WL 966010, at *4 (E.D. Pa. Mar. 29, 2007)). "[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert." Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 613 (7th Cir. 2002) (Posner, J.); see also Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd., 286 F.R.D. 266, 271 (W.D. Pa. 2012) ("[I]t is well-settled that one expert may rely upon another expert's opinion in formulating his own.").

Here, Dr. Bell is a damages expert and does not purport to have the expertise to opine on the scope of the asserted claims. Indeed, he admitted at this deposition that he did not independently review the patents to determine the attributes claimed by the patents-in-suit. (Bell

Dep. 89:25–90:9, 163:1–13.) Rather, he appropriately relied on testimony from Plaintiff's experts Dr. McGinnitie and Dr. Klibanov to determine what constituted the central attributes of both the patents-in-suit and Haegarda. Such reliance is entirely proper. To hold otherwise would mean that every economics expert must likewise be a technical expert on the patent at issue. As Defendants have identified no case law that so requires, I reject this argument.

Second, Defendants contend that although the "subcutaneous administration" element, common to Haegarda and the patents-in-suit, drove the demand for Haegarda, not all of the asserted claims of the patents-in-suit have "subcutaneous administration" or "prophylaxis of HAE" as one of their elements. Specifically, out of the ten claims that Plaintiff plans to assert at trial, four of them—claims 6, 18, 23, and 24 of the '423 patent—are pharmaceutical composition claims that do not require or claim "subcutaneous administration" or prophylaxis use. Thus, according to Defendants, "nearly half of the asserted claims have nothing to do with the features Dr. Bell claims drive demand—and profits—for Haegarda." (Defs.' Mot. 6.)

As noted by Plaintiff, however, an expert's failure to apportion damages on a claim-by-claim basis goes to the weight of the expert opinion and its admissibility. Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc., No. 15-819, 2018 WL 2551053, at *3 (D. Del. May 8, 2018) (finding that expert's failure to apportion damages on a claim-by-claim basis goes to the weight of the evidence, not to admissibility); Greatbatch Ltd. v. AVX Corp., No. 13-723, 2015 WL 9171042, at *7 (D. Del. Dec. 11, 2015) (declining to exclude patent damages expert's opinion for failure to apportion damages on a patent-by-patent basis). To the extent Dr. Bell bases his apportionment on the "subcutaneous administration" component and some of the asserted claims do not have that component as an element, Defendants may raise this point on cross-examination. I decline, however, to preclude Dr. Bell's testimony on this ground.

Finally, Defendants cite to both their own experts and other evidence to establish that factors other than those identified by Dr. Bell drove the demand for Haegarda, including weight-based dosing and pricing. Defendants note that Dr. Bell never conducted any surveys to establish what factors drove the demand for Haegarda, never reviewed surveys performed by anyone else, and never spoke to an HAE patient or HAE-treating physician, other that Dr. Andrew MacGinnitie. They conclude that because Dr. Bell assumed that each and every sale of Haegarda was driven solely by the features in the asserted claims rather than Haegarda's full collection of benefits, both patented and non-patented, Dr. Bell's lost profits analysis is unreliable under Daubert.

Defendants argument is nothing more than a dispute over facts and "reflects a fundamental confusion about the role of the court as a gatekeeper, under Daubert, to determine the admissibility of evidence, and the role of the jury, as a fact finder, to determine the weight to be accorded to admitted evidence." ID Security Canada, Inc. v. Checkpoint Systems, Inc., 249 F. Supp. 2d 622, 691 (E.D. Pa. 2003). "A party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination." Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414 (3d Cir. 2002); Voilas v. Gen. Motors Corp., 73 F. Supp. 2d 452, 461 (D.N.J. 1999) (declining to exclude expert opinion simply because expert failed to consider certain facts that bore on the validity of his conclusion).

Defendants are free to present their contrary position that other attributes of Haegarda drove demand. Moreover, they may cross-examine Dr. Bell about whether he considered those factors and discounted them or simply failed to consider them at all. The factfinder then may make a determination regarding whether to accept or reject Dr. Bell's analysis. Defendants'

challenge, however, does not affect the reliability of Dr. Bell's testimony for purposes of a Daubert analysis.

In short, I will deny Defendants' Motion to preclude Dr. Bell's lost profits opinion.

b. Reasonable Royalty

Defendants also move to exclude Dr. Bell's reasonable royalty opinion based on his alleged failure to account for patented versus unpatented features of Haegarda.

Damages in a patent infringement case shall be "no less than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. § 284. A reasonable royalty is defined as the amount that a willing licensor and licensee would bargain for at an arm's length hypothetical negotiation occurring on the date the infringement began. Unisplay, S.A. v. Am. Elec. Sign Co., Inc., 69 F.3d 512, 517 (Fed. Cir. 1995) (citing Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075, 1078 (Fed. Cir. 1983)).

A reasonable royalty analysis also requires apportionment. As the Federal Circuit has explained, "[w]here small elements of multi-component products are accused of infringement, calculating a royalty on the entire product carries a considerable risk that the patentee will be improperly compensated for non-infringing components of that product." Laser Dynamics, Inc. v. Quanta Comput., Inc., 694 F.3d 51, 67 (Fed. Cir. 2012). The general rule, therefore, is for "royalties [to] be based not on the entire product, but instead on the 'smallest salable patent-practicing unit.'" Id. (citation omitted). Establishing a reasonable royalty "is not an exact science," and "there may be more than one reliable method for estimating a reasonable royalty." Summit 6, LLC v. Samsung Elecs. Co., Ltd., 802 F.2d 1283, 1296 (Fed. Cir. 2015)).

One common way to determine a reasonable royalty is through the application of the so-called Georgia-Pacific factors. See Uniloc, 632 F.3d at 1317; Exmark Mfg. Co. Inc. v. Briggs &

Stratton Power Prods. Grp., LLC, 879 F.3d 1332, 1348–49 (Fed. Cir. 2018). In Georgia–Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116 (S.D.N.Y. 1970), modified and aff'd, 446 F.2d 295 (2d Cir. 1971), the District Court for the Southern District of New York described fifteen factors as a "comprehensive list of evidentiary facts relevant . . . to the determination of the amount of a reasonable royalty for a patent license."[15] Georgia–Pacific, 318 F. Supp. at 1120. "In performing a hypothetical negotiation analysis, it is important to recognize that some of the Georgia–Pacific factors may be of minimal or no relevance to a particular case and other factors may have to be molded by the Court to fit the facts of the case at hand." Procter & Gamble Co. v. Paragon Trade Brands, Inc., 989 F. Supp. 547, 607 (D. Del. 1997).

"Several of the Georgia-Pacific factors address apportionment, including (a) the utility and advantages of the patent property over the old modes or devices, if any, that had been working out similar results (factor no. 9); (b) the nature of the patented invention, the character of the commercial embodiment of it as owned and produced by the licensor, and the benefits to those who have used the invention (factor no. 10); and (c) the portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the

[15] The Georgia-Pacific factors include: (1) the royalties received by the patentee for the licensing of the patent, (2) the rates paid by the licensee for the use of other comparable patents, (3) the nature and scope of the license, (4) the licensor's established policy to not license others or condition the licensed use of the invention, (5) the commercial relationship between the licensor and licensee as competitors, (6) the effect of selling the patented invention in promoting sales of the parties' other patented or non-patented products, (7) the duration of the patent and term of the license, (8) the established profitability of the patented product, (9) the utility and advantages of the patented property over previous technology, (10) the nature of the patented invention, (11) the extent to which the infringer has made use of the invention, (12) the portion of the profit or selling price that is customary in the particular business to allow for the invention's use, (13) the portion of the realizable profit or selling price attributable to the patented invention as distinguished from non-patented elements, features added by the infringer, the manufacturing process, or business risks, (14) the opinion testimony of qualified experts, and (15) the amount that a licensor and licensee would have agreed upon at the time of the infringement in an arm's length negotiation. Georgia-Pacific, 318 F. Supp. at 1120.

manufacturing process, business risks, or significant features or improvements added by the infringer (factor no. 13)." Microchip Tech. Inc. v. Aptiv Servs. US LLC, No. 17-1194, 2020 WL 5203600, at *5 (D. Del. Sept. 1, 2020).

Defendants here contend that Dr. Bell does not conduct a standard Georgia-Pacific analysis with respect to patented versus non-patented features. Rather, they posit that although Dr. Bell purports to consider the thirteenth Georgia-Pacific factor, he gives no opinion regarding the "portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements." (Defs.' Mot. 11.) Defendants concede that Dr. Bell provides opinions regarding the manufacturing process, business risks, and significant features or improvements added by the infringer, but argue that he gives no opinion regarding the portion of the realizable profit that should be credited to certain features such as price and weight-based dosing.

Upon review of Dr. Bell's report, I disagree. Dr. Bell's report reveals that he works through each of the relevant Georgia-Pacific factors in order to opine on reasonable royalty.[16] (Bell Rep. ¶¶ 78–92.) In doing so, Dr. Bell draws comparisons from the Halozyme-ViroPharma Agreement, which was an exclusive license related to the development of subcutaneous administration of a C1-INH formulation for HAE prophylaxis. (Id. ¶ 81.) He concludes that four of the thirteen Georgia-Pacific factors have the potential for the hypothetical negotiation between Plaintiff in Defendants in July 2017 to yield a reasonable royalty rate that is higher than

[16] Plaintiff reiterates its argument that apportionment of a royalty is not required where, as here, the patents cover the pharmaceutical product itself, making the patented product the smallest saleable unit. It posits that the only purported "unpatented or non-infringing" features that Defendants identify are Haegarda's comparatively lower price, its weight-based dosing, efficacy, patient convenience, and/or safety. According to Plaintiff, these are not "non-patented features," but rather are inherent properties directly related to the purpose of the claimed compositions and methods. As I noted above, this argument rests on a disputed issue of fact which I cannot resolve here.

the ten percent royalty rate associated with the Halozyme-ViroPharma Agreement, while only one of the factors would yield a lower reasonable royalty rate. (Id. ¶ 93.)

To the extent Defendants contend that Dr. Bell fails to opine on the portion of the realizable profit that should be credited to certain features such as price and weight-based dosing, such an argument is not the proper subject of a Daubert motion, as it turns on the resolution of a factual dispute—specifically, whether the features identified by Defendants are non-patented components that drive demand for Haegarda. In other words, it is not the methodology that is being challenged, but rather the underlying assumptions. See, e.g., MiiCs & Partners, Inc. v. Funai Elec. Co., Ltd., No. 14-804, 2017 WL 6268072, at *5 (D. Del. Dec. 7, 2017) (holding that defendants' objection that expert did not sufficient explain to what extent each factor impacts the final royalty rate is not a Daubert issue); Helios Software, LLC v. SpectorSoft Corp., No. 12-81, 2015 WL 3622399, at *4 (D. Del. Dec. 7, 2017) ("[Defendant's] criticisms of the adequacy of [the expert's] new apportionment analysis—including the extent to which his Georgia-Pacific analysis fully accounts for non-patented features, including those which were previously accused of infringing the '571 and '237 patents, and any contradictions with his previous opinions—go to the weight rather than the admissibility of his analysis.").[17]

Certainly, Defendants will be free to cross-examine Dr. Bell on his factual assumptions underlying his reasonable royalty opinion. To the extent Defendants can establish at trial that Dr. Bell improperly applies the entire market value rule and fails to apportion between patented

[17] Defendants cite to Exmark Manufacturing Company Inc. v. Briggs & Stratton Power Products Group, LLC, 879 F.3d 1332 (Fed. Cir. 2018) for the proposition that an expert's superficial analysis of Georgia-Pacific factors is insufficient to support damages. Exmark, however, involved an appeal from a jury verdict awarding damages. The Federal Circuit found that the expert's testimony at trial failed to properly support the damages award as it did not analyze the portion of realized profits attributable to non-patented elements. That case was not decided on a Daubert motion.

and non-patented components of Haegarda, Dr. Bell's testimony may be deemed an insufficient basis on which to support a damages award. For purposes of this Daubert motion, I decline to exclude his testimony.

2. Opinions on Regulatory Matters

Defendants' second broad attack on Dr. Bell's testimony concerns his "opinions based on his own interpretation of FDA regulatory issues." (Defs.' Mot. 12.) Defendants first note that Dr. Bell expressly admitted that he is not a regulatory expert. (Bell. Dep. 18:1–11, 168:3–4.) Nonetheless, according to Defendants, Dr. Bell allegedly offers a number of independent opinions involving regulatory expertise. Defendants cite to several paragraphs of Dr. Bell's Report wherein he opines, based on review of records and other experts, that, the FDA relied on the subcutaneous administration attribute of Haegarda in order to grant it Orphan Drug Exclusivity ("ODE"). (Bell. Rep. ¶¶ 43, 74, 75, 77, 81, 85, 87.)

Defendants' objection is misplaced. Throughout his opening report, Dr. Bell does not attempt to offer any independent regulatory opinions beyond his area of expertise. Rather, he simply notes his "understanding" that the FDA's grant of ODE to Haegarda was based on its subcutaneous administration attribute. In his reply report, Dr. Bell clarifies that that understanding comes from Defendants' internal documents, the expert reports from Dr. MacGinnitie, and the expert reports from FDA regulatory expert Suzanne Sensabaugh. (Pl.'s Resp., Ex. F, Reply Rep. of Dr. Bell ("Bell Reply Rep.") ¶ 7(a) & n.13.) As discussed in detail above, "it is well settled that one expert may rely upon another expert's opinion in formulating his own." Carnegie Mellon, 286 F.R.D. at 271. Any challenge to Dr. Bell's independent

knowledge about these regulatory issues is proper for cross-examination, not a basis for exclusion.[18]

Alternatively, Defendants offer a vague challenge to Dr. Bell's opinions pertaining to a reasonable royalty to the extent he bases them on the "intent or knowledge of individuals he never spoke with." (Defs.' Mot. 13.) For example, Defendants note that when opining as to why Plaintiff never launched its SHP616 product, Dr. Bell relies on various assumptions as to the mental state of Plaintiff's employees in making that decision.

A review of Dr. Bell's report, however, reveals no such reliance on the intent or mental states of Plaintiff's employees in order to assess losses attributable to Haegarda's ODE. Neither party disputes that Haegarda's ODE legally precluded Plaintiff from launching its own subcutaneous C1-INH product, SHP616, for seven years. Relying on Plaintiff's other experts, Dr. Bell assumes that the sole reason Plaintiff did not launch SHP616 was because of Haegarda's ODE. On the basis of that assumption, he calculates lost revenue. To the extent Defendants can establish that his underlying assumptions are faulty or that he has no basis for those assumptions, they may cross examine him. Stecyk, 295 F.3d at 414. Dr. Bell's failure to address conflicting facts or statements, however, goes to weight not admissibility.

B. Mr. Robert Stoll

Mr. Robert Stoll is a former Commissioner of the PTO with significant experience dealing with the PTO and complying with its requirements of candor. He purports to (a) opine on matters related to PTO patent practice and procedures and their applications to the patents-in-suit, and (b) respond to opinions by Defendants' experts Lisbeth Illum and Nicholas Godici.

[18] Defendants cite to Dr. Bell's deposition transcript to argue that he contradicted his own statements that subcutaneous administration was the basis for Haegarda's ODE. Such evidence is for cross-examination.

(Defs.' Mot., Ex. 13, Stoll Report ("Stoll Rep.") ¶¶ 3, 11–12, 14, 18.) Defendants now seek to exclude his testimony to the extent he intends to opine either on technical issues in which he is not a person of ordinary skill in the art, or on intents, motives, states of mind, or legal conclusions.

1. Technical Issues

Defendants first contend that Mr. Stoll's education and practical experience are insufficient to qualify him as a person of ordinary skill in the art. Although Mr. Stoll does not hold himself out as a technical expert, Defendants assert that throughout his deposition, Mr. Stoll purported to speak from his own expertise when offering technical opinions that a prior art research report (the "Sanquin Report") was a failure and thus not a material reference. (Defs.' Mot. Ex. 14, Deposition of Robert Stoll ("Stoll Dep.") 128:3–24, 130:10–136:21, 272:20–273:14.) Defendants now seek to preclude Mr. Stoll's testimony to the extent he seeks to go beyond the bounds of his report and testify as a technical expert.

Upon full review of the cited portions of the deposition transcript, however, I find that Defendants significantly mischaracterize Mr. Stoll's testimony. His report expressly notes that "I do not profess to have special technical expertise in the patents-in-suit. I have been asked only to opine on matters related to USPTO patent practice and procedures and their application to the patents-in-suit. For technical matters in support of his opinions, I am relying on the analysis and opinions of Plaintiff's technical experts." (Stoll Rep. ¶ 15.) At his deposition, Mr. Stoll repeated those statements, noting that "I'm not a technical expert in this area, but I am a chemical engineer, so I do understand a lot of what's going on. And I can also read terms and I know what they are. So I have some skills in this particular area, but would not hold myself out as a technical expert in this particular subject matter." (Stoll Dep. 48:17–23.) He admitted that he is

not a person of ordinary skill in the art and, although he drew on his understanding of chemistry to comprehend the documents he read, he generally relied on Dr. Trout and Dr. Illum for the technical expertise. (Id. at 49:2–50:13.) Although Defendants criticize Mr. Stoll for relying on his understanding of chemistry, nothing in his testimony suggests that he based his opinions on solely his own technical knowledge rather than relying on the technical opinions of Plaintiff's experts.

Moreover, to the extent Mr. Stoll attempts to offer his own independent technical opinion regarding the materiality of the Sanquin Report, I find no error. Defendants cite Sundance Inc. v. Demonte Fabricating Ltd., 550 F.3d 1356, 1363 (Fed. Cir. 2008) for the proposition that witnesses unqualified in the pertinent art may not testify as an expert on underlying technical questions such as nature of the claimed invention, scope and content of the prior art, the differences between the claimed invention and the prior art, or the motivation of one of the ordinary skill in the art to combine them. Sundance, however, only held that it was "an abuse of discretion to permit a witness to testify as an expert on the issues of *noninfringement or invalidity* unless that witness is qualified as an expert in the pertinent art." Id. at 1363 (emphasis added). The Federal Circuit subsequently recognized that a witness not qualified in the pertinent art also may not testify on other technical questions such as obviousness or "the nature of the claimed invention, the scope and content of the prior art, the differences between the claimed invention and the prior art, or the motivation of one of ordinary skill in the art to combine these references to achieve the claimed invention." HVLPO2, LLC v. Oxygen Frog, LLC, 949 F.3d 685, 689 (Fed. Cir. 2020) (quotations omitted).

Nonetheless, numerous courts applying Sundance have permitted non-technical, patent-law experts to testify as to the materiality prong of the inequitable conduct inquiry—an inquiry

which is analyzed from the perspective of the PTO. See Network-1 Techs. v. Alcatel-Lucent USA, No. 11-492, 2017 WL 4173468, at *3 (E.D. Tex. Sept. 21, 2017) (distinguishing Sundance and permitting expert on PTO rules and practice to opine as to the materiality of the defendants' broadening contentions); Aevoe Corp. v. AE Tech Co., No. 12-0053, 2014 WL 4182343, at *2 (D. Nev. Aug. 20, 2014) (distinguishing Sundance and holding that an expert in PTO procedures could offer testimony regarding the materiality prong of the inequitable conduct inquiry); Eli Lilly & Co. v. Actavis Elizabeth LLC, No. 07-3770, 2010 WL 11570123, at *10 (D.N.J. May 13, 2010) (holding that expert with extensive experience working at PTO as an examiner was sufficiently qualified to offer his opinion as to materiality for purposes of an inequitable conduct analysis); The Holmes Grp., Inc. v. RPS Prods, Inc., No. 03-40146, 2010 WL 7867756, at *5 (D. Mass. June 25, 2010) (permitting PTO expert, who was a chemical engineer and patent attorney, to opine on whether an objectively reasonable patent examiner would have considered certain information material in deciding whether to allow the application to issue as a patent).

Here, Mr. Stoll does not purport to testify on issues of infringement and validity or on any other technical issues regarding the claimed invention. Rather, he seeks to opine, in part, that the Sanquin Report was not, from the perspective of the PTO, a material reference. In so opining, he relies on both Dr. Trout's expert report and his own reading of PTO documents. Nothing in that testimony constitutes an improper expert opinion beyond the scope of his expertise. To the extent he strays beyond such testimony into more technical areas, Defendants are free to object at trial. Based on the report and deposition before me, however, I find no basis on which to preclude Mr. Stoll's testimony.

2. Opinions on Intent, Motive, States of Mind, or Legal Conclusions

Defendants' second challenge to Mr. Stoll asserts that throughout his expert report and deposition testimony, Mr. Stoll "usurps the role of the judge and jury by opining on the intents, motives and states of mind of various witnesses." (Defs.' Mot. 20.) Specifically, Defendants cite to numerous portions of Mr. Stoll's report and deposition transcript in which he speaks to Plaintiff's and the inventors' intents, motives, and state of mind in order to conclude that Plaintiff did not engage in inequitable conduct during patent prosecution.

Plaintiff agrees that an expert cannot render a legal opinion and that the testimony of patent law experts is routinely excluded. Plaintiff further remarks that the challenged portions of Mr. Stoll's report are included solely to respond to the opinions of Defendants' expert, Mr. Godici. It concedes that "[i]f Mr. Godici's opinions are excluded, then the portions of Mr. Stoll's Report that respond to Mr. Godici on this point (paragraphs 133, 152, 148, 175, and 178) are not necessary." (Pl.'s Resp. 18.)

As set forth in detail above, I intend to exclude Mr. Godici's testimony (a) setting forth a summary of the law regarding the duty of candor and good faith, and setting forth the parameters for a claim of inequitable conduct (Godici Opening Rep. ¶¶ 48–55) and (b) offering an express opinion as to whether certain of Plaintiff's conduct support a finding of inequitable conduct (Godici Opening Rep. ¶¶ 108–58). In turn, the responsive testimony by Mr. Stoll (Stoll Rep. ¶¶ 133, 152, 148, 175, 178) is no longer necessary and will likewise be excluded.

C. Dr. Bernhardt Trout

The last challenged expert is Dr. Bernhardt Trout, who is an expert in chemical engineering, biochemistry, and biopharmaceutical formulations, particularly protein formulations. (Def.'s Mot., Ex. 15, Report of Bernhardt Trout ("Trout Rep.") ¶ 1.) Plaintiff

offers him to testify as to formulation issues such as stability, viscosity, and solubility, and the scope and content of the prior art, including challenges faced by those formulating proteins for subcutaneous administration. In addition, Dr. Trout opines that the administration of the inventions claimed in the patents-in-suit had "surprising and unexpected results."

Evidence of "unexpected results" allows a patent-holder to rebut a *prima facie* case of obviousness by showing that the "claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995). The reasoning behind this consideration is straightforward: "that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." In re Mayne, 104 F.3d 1339, 1343 (Fed. Cir. 1997) (quoting Soni, 54 F.3d at 750). To qualify as unexpected, the claimed properties or results must be different "in kind and not merely in degree" from the results of the prior art. In re Huang, 100 F.3d 135, 139 (Fed. Cir. 1996) (quotations omitted). "In order for a showing of unexpected results to be probative of nonobviousness, such evidence must at least establish that: (1) there actually is a difference between the results obtained and those of the closest prior art, and (2) the difference actually obtained would not have been expected by one skilled in the art at the time of the invention." Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 364 F. Supp. 2d 820, 908 (S.D. Ind. 2005) (citing In re Freeman, 474 F.2d 1318, 1324 (3d Cir. 1973)). "An examination for unexpected results is a factual, evidentiary inquiry." Mayne, 104 F.3d at 1343.

In an effort to establish that the patents-in-suit had surprising and unexpected results, Dr. Trout opines:

> 351. The inventions of the patents-in-suit surprisingly and unexpectedly provided a high concentration of C1-INH

formulation for subcutaneous administration with acceptable stability, viscosity, solubility, tolerability, and bioavailability. As I explained in more detail in Section II.A-B, literature from March 2013 and before explains that developing a high concentration protein formulation was challenging, if not impossible. These challenges include higher protein aggregation and increased viscosity, which complicates the ability to administer through injection. . . . As a result, POSITAs attempting to solve the need for a subcutaneous, prophylactic C1-INH treatment primarily focused on low concentration approaches. The prior art identified by CSL, including the *Schranz* Poster and *Gatlin*, confirms as much. The inventors of the patents-in-suit, however, overcame these challenges and developed a high concentration C1-INH formulation for subcutaneous administration that was sufficiently stable, soluble, and non-viscous.

352. Even if POSITAs at the time attempted to develop high concentration C1-INH formulations to overcome these challenges, they likely would have experimented with additional aggregation. . . . As explained in Section II.A-B, there were a wide range of potential buffers and excipients from which to choose, and approved subcutaneous formulations used different buffers and excipients than those used in intravenous formulations. . . . CSL itself began subcutaneous formulation experiments by testing various buffers not included in its BERINERT intravenous formulation. . . . CSL began pursuing a high-concentration formulation with the same excipients and the FDA responded by "rais[ing] a major concern with regard to aggregate formation due to the higher concentration which may result in potential safety events such as thrombosis."

353. In addition, a POSITA would have been surprised that a C1-INH product administered subcutaneously would not have significant problems achieving the necessary bioavailability without the aid of spreading agents such as hyaluronidase as products administered subcutaneously must move through the subcutaneous space before they are effective. . . . Indeed, as explained above in Section IV.1-4, the *Schranz* Poster taught away from the 333 U/mL approach of the Prior 200 Study and toward the lower concentration coformulation (i.e., with hyaluronidase) approach of the current 204 Study.

354. Additionally, it would have been surprising to a POSITA that a higher concentration formulation could be safely injected without pain. *Gatlin*, for example, taught away from higher concentrations to "hide" the drug from pain receptors. . . . The

> *Schranz* Poster similarly focused on low concentration formulations, as using solely C1-INH at a higher concentration failed due to pain and tolerability issues. . . . The patents-in-suit and the unexpected success of using a high concentration formulation made subcutaneous treatment possible.

(Trout Rep. ¶ ¶ 351–54 (internal citations omitted).)

Defendants now challenge Dr. Trout's "surprising and unexpected results" opinion on two grounds. First, they contend that such opinions are not scientifically supported or supportable. Second, they claim that these opinions are outside the scope of his technical expertise.

1. Scientific Supportability of the Unexpected Results Opinions

Defendants contend that Dr. Trout's presentation of "surprising and unexpected results" is "cursory, conclusory, and delves into the medical and clinical aspects of the claimed invention." (Defs.' Mot. 23.) Specifically, they assert that because the asserted patents contain no example or actual data where any subject received the CI-INH formulations by subcutaneous administration, there is nothing in the patents-in-suit that can be called upon as reflecting the tolerability, bioavailability, or lack of injection pain of the claimed inventions, and thus no frame of reference of how or why the identified results are in any way surprising or unexpected. Moreover, Defendants aver that Dr. Trout does not compare stability, viscosity, solubility, tolerability, bioavailability, or lack of injection pain to any prior art, as is required by Federal Circuit precedent, or to what a POSITA would have expected. Finally, Defendants stress that Dr. Trout's opinions run contrary to the scientific evidence.

Plaintiff counters each of Defendants' arguments. First, it notes that even though unexpected results need not appear in the specification, the shared patent specification here provides stability, viscosity, solubility, and purity data for claimed compositions, and discloses

that the subcutaneous formulation will provide sufficient bioavailability and that the citrate is tolerable as a buffer for pain. Second, Plaintiff posits that Dr. Trout does, in fact, compare the claimed compositions and methods to the subcutaneous formulations disclosed in the *Schranz* Poster and other prior art. Finally, Plaintiff contends that Dr. Trout spends forty-five pages in his report explaining the many known and potentially insurmountable challenges a formulator POSITA would expect would prevent the development of a high concentration subcutaneous C1-INH formulation. (See Trout Rep. ¶¶ 69, 74, 80, 113.)

Completely lacking from the parties' briefing is any discussion about how these factual disputes affect the analysis of the Daubert factors. Defendants' brief focuses on facts, or the lack thereof, and concludes that a skilled artisan with this record could not reasonably opine that the claimed inventions provide surprising or unexpected results. In a similar vein, Plaintiff's brief attempts to substantiate Dr. Trout's conclusion by reviewing statements in the specification, the closest prior art, and Dr. Trout's citations to scientific articles to substantiate his opinion that a POSITA would not have expected to successfully create a high concentration C1-INH formulation with acceptable stability, viscosity, solubility, tolerability, and bioavailability. Such arguments do not go to whether Dr. Trout's methodology in opining on surprising or unexpected results was reliable. Rather, they turn on the parties' varying interpretation of the facts and whether such facts are scientifically sufficient to support a finding of non-obviousness.

Daubert's reliability rule does not require the party proffering the expert to demonstrate the "correctness" of the expert's opinion. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3d Cir. 1994) (concluding that the "evidentiary requirement of reliability" amounts to a lower burden "than the merits standard of correctness"). Rather, the party need only demonstrate "by a preponderance of the evidence" that the expert's opinion is reliable. Id. Therefore, "[t]he focus .

. . must be solely on principles and methodology, not on the conclusions that they generate." Daubert, 509 U.S. at 595. "When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010), aff'd, 564 U.S. 91 (2011).

Here, I find that Dr. Trout's methodology is not excludable under Daubert. He considers the specification, the prior art, and what a POSITA would have expected. To the extent his conclusions are scientifically inaccurate, Defendants may explore those inaccuracies on cross-examination and present conflicting evidence in its case-in-chief.

2. Qualification

Alternatively, Defendants argue that Mr. Trout lacks the technical expertise to render this opinion. Specifically, Defendants identify several portions in Mr. Trout deposition wherein he stated that he lacked the technical expertise to answer questions on the purported unexpected results regarding "tolerability" and "bioavailability" set forth in his report, and suggest that such details were "really for the medical experts." (Defs.' Mot., Ex. 18, Dep. of Bernhardt Trout ("Trout Dep."), 240:18–249:18.) Because Dr. Trout lacks the relevant technical expertise to address tolerability, bioavailability, and injection site pain, Defendants posit that the Court should exclude his opinions on unexpected results.

Plaintiff responds that Dr. Trout is a Professor of Chemical Engineering at MIT with over twenty years of experience in protein formulation. It notes that Defendants do not dispute Dr. Trout's qualification to testify on issues of stability, viscosity, solubility, and the scope and content of the prior art, including challenges faced by those formulating proteins for subcutaneous administration. Rather, Defendants challenge only Dr. Trout's ability to opine on

bioavailability[19] and tolerability (including injection pain caused by a formulation) because he is not a physician. According to Plaintiff, however, formulator and physician areas of expertise overlap, and Dr. Trout is more than qualified to opine on bioavailability and tolerability from a formulator's perspective, which is highly relevant to a person of ordinary skill in the art of formulation of a high concentration subcutaneous protein formulation since these parameters contribute to its ultimate viability.

As set forth above, "[q]ualification requires 'that the witness possess specialized expertise.'" Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008) (quoting Schneider ex re. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003)). There is a liberal policy of admissibility and the Third Circuit has held that a "broad range of knowledge, skills, and training qualify an expert." Id. (quoting Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741–42 (3d Cir. 1994)). "If the expert meets liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility." Kannankeril v. Terminix Int'l, 128 F.3d 802, 809 (3d Cir. 1997) (citing Paoli, 35 F.3d at 741).

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[19] "Bioavailability" is defined as:

> [T]he extent and rate at which the active moiety (drug or metabolite) enters systemic circulation, thereby accessing the site of action. Bioavailability of a drug is largely determined by the properties of the dosage form, which depend partly on its design and manufacture. Differences in bioavailability among formulations of a given drug can have clinical significance; thus, knowing whether drug formulations are equivalent is essential.

https://www.merckmanuals.com/professional/clinical-pharmacology/pharmacokinetics/drug-bioavailability (last visited Nov. 4, 2020).

Defendants concede that a drug formulation expert, like Dr. Trout, may consider bioavailability and tolerability, but they highlight Dr. Trout's own deposition testimony that issues of bioavailability and tolerability require a medical expert to explain. A closer look at Dr. Trout's testimony, however, reveals that he is qualified to testify as to precisely the issue here—whether a formulator of ordinary skill in the art would have deemed the bioavailability and tolerability results surprising and unexpected, such that the formulation of the patents-in-suit would not have been obvious. Repeatedly, he emphasized that a "skilled formulator . . . would certainly be concerned about the effect of subcutaneous—going from IV to subcutaneous in terms of bioavailability." (Trout Dep. 241:16–23.) As to the clinical/medical aspects—once the formulations are administered to a patient—he explained that the bioavailability would have to be reserved for a medical expert. (Id. at 242:14–244:3.) Similarly, as to tolerability, Dr. Trout noted that pain/tolerability concerns from a formulation perspective are directly related to higher concentration, which the prior art teaches away from, and that the skilled person "would be concerned, particularly based on the teachings of *Gatlin* and *Schranz*, that going from a lower to a higher concentration would result in—in pain." (Id. at 245:12–21, 246:5–14; Trout Rep. ¶ 354.) Stated simply, Dr. Trout stayed well within the bounds of his expertise to opine on the "surprising and unexpected" nature of the results from the perspective of a person of ordinary skill in the art of pharmaceutical formulation.

Should Dr. Trout seek to go beyond his expertise at trial and opine on the results achieved by the claimed inventions from a medical perspective, Defendants will be free to object. Based on both his report and his deposition testimony, I find that Dr. Trout is adequately qualified to render his "surprising and expected" opinions.

V. CONCLUSION

For all of the reasons set forth above, I will grant the parties' Daubert Motions in part and deny them in part as set forth in this Opinion. An appropriate Order follows.