IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELA PHARMA SCIENCES, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-cv-365 (MN)
	)	
ETON PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

ORDER

At Wilmington this 8th day of February 2022:

Before the Court is Exela Pharma Sciences, LLC's ("Plaintiff") motion to exclude the expert testimony of Eton Pharmaceuticals, Inc.'s ("Defendant") expert Dr. Steven W. Baertschi ("Dr. Baertschi"). (D.I. 164). Plaintiff seeks to exclude Defendant's expert as unreliable and unhelpful pursuant to Rule 702 of the Federal Rules of Evidence and the standard set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). For the reasons set forth below, the Court grants Plaintiff's motion with respect to Dr. Baertschi's non-infringement opinions that are based on an erroneous legal theory.

1. Facts

Plaintiff owns several patents that cover its ELCYS® product. (D.I. 1; D.I. 70). ELCYS® is an L-cysteine hydrochloride injection that, per its labeling, "is indicated for use as an additive to amino acid solutions to meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN) and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN." (D.I. 70 ¶¶ 13, 19). Defendant filed abbreviated new drug application ("ANDA") No. 214082 to market a generic version of ELCYS®, prompting Plaintiff to file this suit alleging infringement of six patents.

Defendant's ANDA sought approval to market a product that appears to fall within the scope of several of the patents-in-suit. Defendant's expert, Dr. Baertschi, however, filed an expert report opining that what matters for infringement is not what the ANDA specification *allows* the applicant to market, but what product the Defendant *will* ultimately bring to market. Dr. Baertschi then relied on biobatch data from Defendant's ANDA to conclude that Defendant's product will not infringe the patents-in-suit. Plaintiff contends that Dr. Baertschi's expert report is unreliable because "if a product that an ANDA applicant is asking the FDA to approve falls within the scope of an issued patent, a judgment of infringement must necessarily ensue." (D.I. 167 at 1–2). Because Plaintiff believes Dr. Baertschi's non-infringement position is based on a legally incorrect theory, Plaintiff moved to exclude Dr. Baertschi's opinions as unreliable and unhelpful under Rule 702 and *Daubert*. (D.I. 164).

2. Legal Standard

Rule 702 of the Federal Rules of Evidence states:

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

FED. R. EVID. 702. The proponent of the expert testimony bears the burden of proving its admissibility by a preponderance of evidence. *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 92 (D. Del. 2016); *Daubert*, 509 U.S. at 592 n.10.

"Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). First, to be qualified, a witness must possess specialized expertise. *Id.* Second, to be reliable, the opinion must be "ground[ed] in the methods and procedures of science" and "more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Third, the expert's opinion "must be relevant for the purposes of the case and must assist the trier of fact." *Schneider*, 320 F.3d at 404.

3. Discussion

Dr. Baertschi explained the premise for several of his non-infringement positions as follows:

> I also understand that where claimed ranges overlap with ranges sought for the proposed ANDA product, from a legal standpoint this may constitute infringement. However, I have been told that this is only the case where the ANDA and supporting material do not provide evidence of what the actual results for the Proposed ANDA Product will be.

(D.I. 167, Ex. A ¶ 26). The first question presented by Plaintiff's motion is whether courts must find infringement as a matter of course when the ANDA specification is within the scope of a patent, or if they should base their infringement decision on the product the applicant is likely to bring to market. If the Court finds that Dr. Baertschi has offered a non-infringement opinion that is premised on misunderstanding of the law, the Court must next determine whether to exclude portions of his report on that basis.

A. Defendant's Expert Offered Non-Infringement Positions Premised on a Misunderstanding of the Law

The Court agrees with Plaintiff that Dr. Baertschi's non-infringement position is based on an incorrect legal theory. "What a generic applicant asks for and receives approval to market, if within the scope of a valid claim, is an infringement." *Sunovian Pharmaceuticals, Inc. v. Teva*

Pharmaceuticals USA, Inc., 731 F.3d 1271 (Fed. Cir. 2013). Defendant's contention that *Sunovian* only governs "specific situations where the information disproving infringement is not included in the ANDA" is not persuasive.

In *Sunovian*, the generic applicant sought approval to market a drug with a levorotatory isomer level of 0.0–0.6%. *Id.* at 1275. The district court construed the patent-at-issue in that case to cover drugs containing "less than 0.25% of levorotatory isomer," meaning that what the generic applicant sought approval to market was within the scope of the patents-at-issue. But after the generic applicant certified to the district court that it would not market a product with less than 0.3% levorotatory isomer and produced internal manufacturing guidelines requiring its product to contain at least 0.3% levorotatory isomer, the district court entered summary judgment of non-infringement. *Id.* at 1278.

The Federal Circuit reversed, holding that "if a product that an ANDA applicant is asking the FDA to approve for sale falls within the scope of an issued patent, a judgment of infringement must necessarily ensue." *Id.* The Court made clear that "[w]hat [the generic] has asked the FDA to approve as a regulatory matter is the subject matter that determines whether infringement will occur[.]" *Id* at 1279. The panel reasoned that if generics do not to intend to infringe, they should not request, or accept, approval to market a product within the scope of patented claims.

Defendant casts *Sunovian*'s holding as limited to cases where the generic supports its non-infringement position with evidence outside of the ANDA. It notes that in *Sunovian*, the evidence submitted to the district court and rejected by the Federal Circuit was not submitted to the FDA as part of the ANDA. Defendant insists that the infringement analysis "must focus on what the ANDA applicant will likely market if its application is approved," *Merck Sharp & Dohme Corp. v. Amneal Pharms. LLC,* 881 F.3d 1376, 1385 (Fed. Cir. 2018) (quoting *Glaxo, Inc. v. Novapharm,*

Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997)), and this analysis must be conducted by reference to "the ANDA itself, materials submitted by the ANDA applicant, and any other relevant evidence submitted by the applicant or patent holder," *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248–49 (Fed. Cir. 2000). (D.I. 169 at 3–4). In support of this position, Defendant points the Court to cases where the Federal Circuit has reviewed infringement judgments by reference to "all relevant evidence."

The Court, here, concludes that the ANDA specification controls the infringement analysis when it speaks to a claim limitation, and the Court should examine other materials to look at the product that the generic company is likely to sell when the ANDA specification is silent on that limitation. To be sure, in *Glaxo* and *Abbott*, two cases decided before *Sunovian*, the Federal Circuit examined ANDA materials other than the specification. 110 F.3d 1562 (Fed. Cir. 1997); 300 F.3d 1367 (Fed. Cir. 2002). But as the Federal Circuit explained in *Ferring B.V. v. Watson Labs., Inc.*, it only did so because the ANDA specifications in those cases did not speak to the claim limitation at issue. 764 F.3d 1401 (Fed. Cir. 2014). "In some cases, the ANDA specification directly resolves the infringement question because it defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such a claim . . . [but] in cases in which the ANDA specification does not resolve the infringement question in the first instance, we have endorsed the district court's reference to relevant evidence, including biobatch data and actual samples of the proposed generic composition that the ANDA filer had submitted to the FDA." *Id.* at 1408–09. Indeed, the *Ferring* panel reasoned that the case before it was more like *Glaxo* than *Sunovian* because the ANDA specification before it did not resolve the question of infringement. *Id.* at 1409. Consequently, the panel endorsed an infringement analysis based on all evidence relevant to what the generic applicant was likely to bring to market. But in *Par*

Pharmaceutical, Inc v. Hospira, Inc., the Federal Circuit looked no further than the ANDA specification because "the ANDA is not silent as to whether [the generic's] product could contain sufficient concentrations of elemental impurities such that" a claim limitation would be met. 835 F. App'x. 578, 586 (Fed. Cir. 2020). The case law, laid out above, makes clear that "if a product that an ANDA applicant is asking the FDA to approve for sale falls within the scope of an issued patent, a judgment of infringement must necessarily ensue." *Sunovian*, 731 F.3d at 1278.

Thus, Dr. Baertschi's non-infringement opinions are based on a legally erroneous premise. He focused on biobatch data even though the ANDA specification made clear that the product fell within the scope of Plaintiff's patent.

B. Defendant's Expert Should Be Excluded to the Extent His Opinions are Based on the Misunderstanding

Expert testimony must be relevant "to the task at hand." *Daubert*, 509 U.S. at 591. An expert's opinion that crucially depends on an incorrect legal theory is not likely to be relevant to the Court's fact-finding. Consequently, courts routinely preclude those portions of an expert's report that are premised on a misunderstanding of the law. *See Sprint Communications Co. L.P. v. Cox Communications Inc.*, 302 F. Supp. 3d. 597, 624 (D. Del. 2017) (excluding an expert's report because it "improperly applies legal principles" such that the Court had no confidence the expert "has reliably applied the principles and methods to the facts of the case," as required by Fed. R. Evid. 702(d)); *Major Tours, Inc. v. Colorel*, 799 F. Supp. 2d. 376, 409–10 (D.N.J. 2011) (precluding an expert's report after finding that the expert both relied on definitions that were incorrect as a matter of law and made technical errors); *Martinez v. Porta*, 601 F. Supp. 2d 865, 866 (N.D. Tex. 2009) ("While it is true that a qualified expert is not prohibited, ipso facto, from expressing an opinion on an ultimate issue of fact, such an opinion cannot be based on an erroneous

legal premise."). The Court sees no need to deviate from this general rule here. Dr. Baertschi's non-infringement positions are based on a contrary understanding of the law and are excluded.

THEREFORE, for the reasons set forth above, IT IS HEREBY ORDERED that, Exela Pharma Sciences, LLC's Motion to Exclude the Expert Testimony of Dr. Steven W. Baertschi (D.I. 164) is GRANTED. Dr. Baertschi is precluded from testifying regarding his non-infringement positions that are based on an incorrect understanding of the law.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge