United Therapeutics Corp. v. Liquidia Techs., Inc., 2025 NCBC Order 56.

STATE OF NORTH CAROLINA DURHAM COUNTY	IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION 21CVS004094-310
UNITED THERAPEUTICS CORPORATION and LUNG BIOTECHNOLOGY PBC, Plaintiffs, v. LIQUIDIA TECHNOLOGIES, INC. and ROBERT ROSCIGNO, Defendants.	**ORDER ON DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S MOTION TO EXCLUDE UTC'S EXPERT, DR. DAVID W. FEIGAL** **[PUBLIC][1]**

1. **THIS MATTER** is before the Court on Defendant Liquidia Technologies, Inc.'s Motion to Exclude UTC's Expert, Dr. David W. Feigal (the Motion), pursuant to Rules 702 and 403 of the North Carolina Rules of Evidence (the Rule(s)), (ECF No. 312).

2. The Court, having considered the Motion, the related briefing, relevant matters of record, and the arguments of counsel at a hearing on the Motion, concludes that the Motion should be **GRANTED in part** and **DENIED in part**, as provided below.

Brooks, Pierce, McLendon, Humphrey & Leonard, L.L.P., by Eric M. David, Jim W. Phillips, Jr., Kasi W. Robinson, and Sarah N. Schiavone; McDermott Will & Emery, LLP, by Douglas H. Carsten, Arthur P. Dykhuis, Katherine Pappas, Joshua Revilla, Courtney Seams, and Lillian J. Spetrino; and Goodwin Proctor, LLP, by William C. Jackson,

[1] Because certain materials referenced in this Order were filed under seal, the Court's ruling was provisionally filed under seal on 23 July 2025. The Court then permitted counsel for the parties to confer and advise the Court whether they contend any matters referenced herein should be sealed. Having afforded the parties this opportunity, the Court now files its Order on the public record.

for Plaintiffs United Therapeutics Corporation and Lung Biotechnology PBC.

Parker Poe Adams & Bernstein, LLP, by Stephen V. Carey, Corri A. Hopkins, and Andrew P. Tabeling; and Cooley, LLP, by Jonathan Davies, Sanya Sukduang, Lauren Strosnick, Adam Pivovar, Rachel L. Preston, Phillip Morton, Daniel Knauss, and Kyung Taech Minn, for Defendant Liquidia Technologies, Inc.

McGuire Woods, LLP, by David E. Finkelson, Miles O. Indest, Mark E. Anderson, Corinne S. Hockman, and Kyle S. Smith, for Defendant Robert Roscigno.

Earp, Judge.

I. FACTUAL BACKGROUND

3. Plaintiffs United Therapeutics Corporation and its subsidiary, Lung Biotechnology PBC (collectively UTC), and Defendant Liquidia Technologies, Inc. (Liquidia) are competitors in the business of developing treatments for pulmonary arterial hypertension (PAH). This dispute concerns the alleged misappropriation of trade secrets by Defendant Robert Roscigno (Roscigno), formerly a high-level UTC employee who subsequently worked for Liquidia.[2]

4. UTC has retained Dr. David W. Feigal (Feigal) as an expert witness in support of its claim for misappropriation of trade secrets. Feigal was tasked with reviewing documents that allegedly contain UTC's purported trade secrets, ascertaining the value of those trade secrets, and analyzing how they relate to the work done by UTC and Liquidia with respect to PAH treatments. (26 April 2024 Dep. of Dr. David W. Feigal [Feigal Dep.] 79:23–80:1, ECF No. 314.4 (under seal), ECF No.

[2] For a detailed factual background *see United Therapeutics Corp. v. Liquidia Techs., Inc.*, 2022 NCBC LEXIS 120 (N.C. Super. Ct. Oct. 13, 2022); *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 2024 NCBC LEXIS 100 (N.C. Super. Ct. July 31, 2024).

361 (public version) ("[T]he scope of what I was asked to do is to take a look at the value of these – of these documents, and how they related to UTC and Liquidia."); Feigal Dep. 274:3–7 ("So I approach the documents by saying these documents appear to be confidential documents, and they contain information . . . that's not readily ascertainable, and what's the value of that information? That was, sort of, the framework that I did my report.").)

5. Feigal is a physician, epidemiologist, and former employee of the U.S. Food and Drug Administration (FDA), who has held senior positions within the FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health. (Expert Report of David W. Feigal, Jr., M.D., M.P.H. [Feigal Report] ¶ 1, Appendix A, ECF No. 255.17 (under seal), ECF No. 335.17 (public version).)

6. While employed by the FDA, Feigal "advis[ed] and evaluat[ed] the development of hundreds of drugs[.]" (Feigal Report, Principal Opinions ¶ 4.) He "had direct responsibility for evaluating the adequacy of the preclinical and clinical studies that were the basis for New Drug Applications (NDAs) and had direct sign-off authority for their approval." (Feigal Report ¶ 10.)

7. In addition, Feigal has served as a consultant, assisting start-up companies with the development of research plans for medical products that meet the FDA's standards. (Feigal Report ¶ 14.)

8. Feigal has also held senior management positions in two pharmaceutical companies. From November 2006 through April 2008, Feigal served

as the Senior Vice President for Global Regulatory Affairs and Global Safety for Élan Pharmaceuticals where he "was responsible for the company's drugs and biologicals[.]" During Feigal's time there, "Élan successfully obtained FDA approval for a new treatment for Crohn's Disease and began large scale clinical trials for a treatment of Alzheimer's disease." (Feigal Report ¶ 15.) Feigal also served as the Vice President of Global Regulatory Affairs at Amgen, Inc. from May 2008 to July 2010, during which time "Amgen obtained approval of a new biological for osteoporosis in post-menopausal women." (Feigal Report ¶ 15.)

9. In his expert report (Report), Feigal groups the documents containing UTC's purported trade secrets (the UTC Documents) into six categories: (A) Financial Documents; (B) Regulatory Strategy and Product Development Planning Documents; (C) Marketing Documents; (D) Formulations and Pharmacokinetics Documents; (E) FDA Communications Documents; and (F) Clinical Trial Documents. (*See* Feigal Report §§ XI (A)–(F).) For each category, Feigal explains the importance and value of the documents within it and discusses the degree to which information in the documents is publicly available. Additionally, Feigal describes the FDA approval process in some detail, including the FDA's requirements and review practices. He also describes the costs and processes involved in drug development. (*See generally*, Feigal Report.)

10. Ultimately, Feigal opines that Liquidia's "learnings from the [UTC] [D]ocuments sped up the process [of developing its PAH treatment] by at least 1 to 3 years as compared to what Liquidia might have accomplished with Dr. Roscigno but

without his and Liquidia's misappropriation of trade secrets[.]" (Feigal Report, Principal Opinions ¶ 4.)

11. Alternatively, Feigal opines that by misappropriating the UTC Documents, Liquidia was able to avoid labor costs. Specifically, Feigal opines that without the UTC Documents, Liquidia "would have needed to hire an additional 2 to 4 full-time-equivalent employees or consultants[] with expertise in FDA requirements pertaining to pharmaceutical investigational drug product manufacturing, toxicology, clinical pharmacology of aerosolized drugs, clinical trials, and regulatory policies and requirements," in order to develop its PAH treatment. (Feigal Report, Principal Opinions ¶ 4.) Feigal further opines that the compensation needed for these additional employees or consultants would have been "50–75%" of Roscigno's salary. (Feigal Report, Principal Opinions ¶ 4 n. 274.)

12. In addition to the need for additional employees, Feigal opines that Liquidia was able to avoid other costs by using the UTC Documents. For example, Feigal opines that a particular market survey research document "generally costs companies about $1,000,000–$2,000,000." (Feigal Report ¶ 176.) He also opines as to the cost of reports commissioned by UTC and the cost of a pharmacokinetics (PK) study. (Feigal Report ¶¶ 182, 194.)

13. Feigal bases his opinions on his "experience working within pharmaceutical companies, successfully bringing products to market, at FDA advising and evaluating the development of hundreds of drugs, [and] as a consultant working with hundreds of small companies on their drug development plans and FDA

interactions[.]" (Feigal Report, Principal Opinions ¶ 4.) Feigal also reviewed the UTC Documents, interrogatory responses, and deposition transcripts, as well as the data cited by Liquidia's experts, FDA regulations and guidance, and clinical information available on clinicaltrials.gov, product labels, and other publicly available sources. (*See* Feigal Report, Appendix C; Responsive Expert Report of David W. Feigal, Jr., M.D., M.P.H. [Responsive Report] Appendix D, ECF No. 305.9 (under seal), ECF No. 367.50 (public version).)

II. PROCEDURAL BACKGROUND

14. On 3 July 2024, Liquidia moved for summary judgment, arguing that (a) UTC has not apportioned damages among identified individual trade secrets, (b) UTC did not maintain the UTC Documents as a compilation trade secret, (c) the FDA process for drug approval is not a unique process trade secret, and (d) UTC did not engage in reasonable efforts to maintain the secrecy of the alleged trade secrets. (Def. Liquidia Techs., Inc.'s Mot. Summ. J, ECF No. 284.) UTC submitted a brief in opposition to Liquidia's Motion for Summary Judgment on 19 August 2024, citing Feigal's Reports and testimony. (UTC's Summ. J. Opp'n Br., ECF No. 306 (under seal), ECF No. 365 (public version).) The Court addresses the summary judgment motion by separate order.

15. On 9 September 2024, Liquidia filed this Motion. Here, it argues that Feigal's opinions do not pass muster under Rule 702 and would mislead the jury in violation of Rule 403. After full briefing, the Court held a hearing on the Motion at which all parties were represented by counsel. (Not. of Hr'g, ECF No. 330.)

16. The Motion is now ripe for disposition.

III. LEGAL STANDARD

17. "The burden of satisfying Rule 702(a) rests on the proponent of the evidence[.]" *State v. Gray*, 259 N.C. App. 351, 355 (2018).

18. "Expert testimony is governed by North Carolina Rule of Evidence 702, which is now virtually identical to its federal counterpart and follows the *Daubert* standard for admitting expert testimony." *Crescent Univ. City Venture, LLC v. AP Atl., Inc.*, 2022 NCBC LEXIS 9, at **5–6 (N.C. Super. Ct. Feb. 8, 2022); *see Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). In applying the *Daubert* standard, North Carolina courts may seek guidance from federal case law. *State v. McGrady*, 368 N.C. 880, 888 (2016).

19. *Daubert* established a three-pronged test for admission of expert testimony: "(1) expert testimony must be based on specialized knowledge that will assist the trier of fact, (2) the expert must be qualified by knowledge, skill, experience, training, or education, and (3) the testimony must be reliable." *Insight Health Corp. v. Marquis Diagnostic Imaging of N.C., LLC*, 2017 NCBC LEXIS 14, at *39 (N.C. Super. Ct. Feb. 24, 2017) (citations and quotation marks omitted).

20. An expert's testimony is reliable if: (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case. N.C. R. Evid. 702(a)(1)–(3). The test of reliability is "flexible," and the court has "the same broad latitude when it decides how to determine reliability

as it enjoys in respect to its ultimate reliability determination." *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (citation omitted).

21. "The precise nature of the reliability inquiry will vary from case to case depending on the nature of the proposed testimony." *McGrady*, 368 N.C. at 890 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152–53 (1999)). In particular, "certain expert opinions may be more reliant on the experience of the expert and softer criteria." *Reed v MedStar Health, Inc.*, 2023 U.S. Dist. LEXIS 140788, at *39 (D. Md. Aug. 10, 2023) (cleaned up).

22. When evaluating the admissibility of an expert's testimony, the focus of the trial court's inquiry "must be solely on [the] principles and methodology" used by the expert, "not . . . the conclusions that they generate." *Daubert*, 509 U.S. at 595. "In addition . . . the trial court must assess 'whether [the] reasoning or methodology properly can be applied to the facts in issue.' " *State v. Babich*, 252 N.C. App. 165, 168 (2017) (quoting *Daubert*, 509 U.S. at 593). "The Supreme Court in *Daubert* referred to this as the 'fit' test." *Id.*

23. An expert does not testify on specialized knowledge "[w]hen the jury is in as good a position as the expert to determine an issue . . . because [the expert's testimony] is not helpful to the jury." *Braswell v. Braswell*, 330 N.C. 363, 377 (1991); *see also State v. Wilkerson*, 295 N.C. 559, 568–69 (1978) (framing expert admissibility as a question of "whether the witness because of his expertise is in a better position to have an opinion on the subject than is the trier of fact.").

24. Ultimately, the decision to exclude or admit expert testimony is within the sound discretion of the trial court. *United States v. Verduzco*, 373 F.3d 1022, 1035 (9th Cir. 2004) (Observing that the trial court has "broad discretion to admit or exclude expert testimony[.]"). The Court's role as gatekeeper is an important one, but it does not supplant the role of the adversarial system. "[R]ejection of expert testimony is the exception rather than the rule." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Production Liab. Litig. (No. II)*, 892 F.3d 624, 631 (4th Cir. 2018).

25. Additionally, pursuant to Rule 403, relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." N.C. R. Evid. 403.

IV. ANALYSIS

26. Liquidia requests that the Court exclude Feigal's opinions at summary judgment and at trial, arguing that: (1) all of the opinions advanced in Feigal's Report are the result of his speculation about the "state of mind" of both Defendants and the FDA; (2) Feigal's opinions regarding the "independent economic value" of a trade secret are unreliable because they lack supporting facts and a reliable methodology; and, relatedly, (3) Feigal's analysis of "independent economic value" does not address any value derived from secrecy. (*See* Br. Supp. Def. Liquidia Techs., Inc.'s Mot. Exclude UTC's Expert, Dr. David W. Feigal [Def.'s Br. Supp.], ECF No. 313 (under seal), ECF No. 358 (public version).)

A. State of Mind Testimony

27. Liquidia contends that Feigal's Report is rife with speculation regarding its state of mind, as well as that of FDA officials. (*See* Def.'s Br. Supp. 7–14.) UTC denies that Feigal's opinions involve anyone's motive, intent, or mental state and maintains that Feigel properly analyzed the value of UTC's trade secrets to a competitor. (Mem. Opp'n Liquidia Techs., Inc.'s Mot. Exclude UTC's Expert, Dr. David W. Feigal [Pls.' Br. Opp'n] 19–22, ECF No. 336 (under seal), ECF No. 368 (public version).)

28. "Expert testimony about an alleged infringer's intent, motive, or state of mind is inadmissible." *Fuma Int'l LLC v. R.J. Reynolds Vapor Co.*, 2021 U.S. Dist. LEXIS 198861, at *7 (M.D.N.C. Oct. 15, 2021). This is because "intent is a question for the trier of fact that does not require expert testimony." *Id.* at *7–8 (citing *BorgWarner, Inc. v. Honeywell Int'l, Inc.*, 750 F. Supp. 2d 596, 611 (W.D.N.C. 2010)). Furthermore, "expert testimony concerning state of mind, intent, or purpose is unreliable because it is not grounded in analytically sound principles or methods." *Id.* at *8 (citing *DePaepe v. GMC*, 141 F.3d 715, 720 (7th Cir. 1998)).

29. The same is true with respect to expert testimony concerning the "intent, motives, or states of mind" of regulatory agencies such as the FDA. *See In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("[T]he opinions of [expert] witnesses on the intent, motives or states of mind of . . . regulatory agencies . . . have no basis in any relevant body of knowledge or expertise.").

30. At various points in his Report, Feigal opines that UTC Documents were "valuable," "useful," "helpful," or "beneficial" to Liquidia. (*See, e.g.*, Feigal Report ¶ 135 ("Liquidia *would find this information useful* when planning out its own development program." (emphasis added)); Feigal Report ¶ 223 ("Obtaining confidential details about clinical trial data *is very beneficial* to Liquidia[.]" (emphasis added)). Liquidia contends that the only way Feigal could have reached specific conclusions about the value Liquidia actually placed on the information at issue "[would have been] to speculate about Liquidia's state of mind and subjective intent." (Reply Br. Supp. of Def.'s Mot. Exclude [Def.'s Reply] 2, ECF No. 339 (under seal), ECF No. 364 (public version).)

31. To the extent Feigel does not base his conclusions regarding what Liquidia actually valued on evidence in the record confirming his presumptions, the Court agrees with Liquidia. This is because "speculative or conjectural testimony is not permissible under the standards set forth for expert testimony in *Daubert* and Rule 702." *Reed*, 2023 U.S. Dist. LEXIS 140788, at *38.

32. On the other hand, given his qualifications and experience in the field, Feigel could well opine generally on the value this type of information would have to a competitor with limited FDA drug approval experience. (*See, e.g.*, Feigal Report ¶ 125 ("For a small company *like Liquidia* who was just entering into drug development, a financial roadmap like these would be extremely helpful." (emphasis added)); Feigal Report ¶ 132 ("[F]or a company *like Liquidia*, who has no history of successful drug development, a roadmap as to how to budget for the costs of

developing an inhaled treprostinil product is extremely valuable." (emphasis added)).)

33. Accordingly, while Feigal may opine that particular information would likely be valuable to a competitor in a similar position to Liquidia, he may not opine that Liquidia itself found the information to be valuable. *See Kruszka v. Novartis Pharms. Corp.*, 28 F. Supp. 3d 920, 931 (D. Minn. 2014) ("Feigal may not proffer an opinion relating to what individuals at Novartis or with the FDA thought with respect to certain documents or about their motivations."); *Scentsational Techs., LLC v. Pepsi, Inc.*, 2018 U.S. Dist. LEXIS 24375, at *37 (S.D.N.Y. Feb. 14, 2018) (Excluding an expert's opinion that the defendant "thought" a particular technology was a "valuable investment" as improper speculation as to the defendant's state of mind).

34. Similarly, Liquidia argues that Feigal's opinions regarding what "Liquidia would know" or "would not know", what Liquidia "learned", or what information Roscigno "wanted" or "relied upon", constitutes impermissible state of mind testimony. (*See, e.g.*, Feigal Report ¶ 121 ("Lacking this information Liquidia *would not likely have been able to* construct actionable development plans and appropriately plan for the allocation of resources necessary to overcome unavoidable development costs . . . . Without the [UTC] planning documents, Liquidia *may not have been able to* complete the studies necessary for an NDA." (emphasis added)); Feigal Report ¶ 127 (Roscigno *likely wanted* these budget categories as a reference when determining the development goals for LIQ861[.]" (emphasis added)); Feigal Report ¶ 138 ("In setting development goals for Liquidia's pivotal product, Roscigno

relied upon UTC's budgeting categories." (emphasis added)); Feigal Report, Principal Opinions ¶ 5(c) ("Liquidia *learned* from [UTC's] documents that a pharmacology-based 505(b)(2) strategy could be proposed to FDA[.]" (emphasis added)).)

35. Again, to the extent the record does not establish that Feigel's conclusions are supported by evidence that Liquidia actually knew or relied upon the information Feigel cites, the Court agrees with Liquidia that the testimony is impermissibly speculative. *Drake v. Allergan, Inc.*, 2014 U.S. Dist. LEXIS 151830, at *14–15 (D. Vt. Oct. 23, 2014) ("No expert shall be permitted to . . . speculate about other individual's or entity's motives, knowledge, or intent."). However, to the extent Feigal's opinions regarding Liquidia's acquired knowledge are based on facts gleaned from Liquidia's *own* documents, such testimony may be permissible. *See Knight v. Boehringer Ingelheim Pharms., Inc.*, 323 F. Supp. 3d 837, 852 (S.D. W. Va. 2018) (holding that plaintiffs' expert could testify as to what defendant "knew and communicated to the FDA" based on a review of defendant's "own documents.").

36. As for Feigal's opinions concerning the FDA, the Court observes that Feigal has knowledge of the FDA's regulation of prescription drugs and the process required for new drug approval. Testimony concerning the FDA approval process in general "would be helpful to the trier of fact from a regulatory perspective" and is permissible expert testimony. *Kruszka*, 28 F. Supp. 3d at 931. Furthermore, as is true of his testimony regarding Liquidia, Feigal "may testify as to what the FDA did, and what it said, based on the documents he reviewed." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 466 (S.D.N.Y. 2016).

37. Additionally, Feigal may testify, based on his FDA experience, regarding the FDA's general practices. (*See, e.g.*, Feigal Report, Principal Opinions ¶ 5(c) (opining that the FDA "would not have objected" to a particular study and that the FDA "also likely would not have volunteered" information regarding UTC's drug developments.).) Such testimony does not implicate the FDA's state of mind as to Liquidia's specific NDA and is subject to cross-examination.

38. Accordingly, with respect to "state of mind" testimony, the Motion is **GRANTED in part** and **DENIED in part** as provided above.[3]

B. Methodology

39. Liquidia argues that Feigal's opinions with respect to the value of the UTC Documents are inadmissible because they are inherently unreliable. Specifically, Liquidia argues that Feigal cannot opine about a "head start" period or about "labor costs avoided" because his analysis lacks an identifiable methodology. Liquidia further argues that Feigal's opinions regarding the value of the UTC Documents are unreliable because Feigal failed to assess the "independent economic value" of the trade secrets on a by-category or by-document basis. (Def.'s Br. Supp. 14–24.)

40. According to UTC, Feigal's opinions regarding this head-start advantage are informed by his subject-matter expertise with respect to the FDA's drug approval process, his twelve years as an FDA director evaluating drug development submissions, his work advising hundreds of companies on drug

[3] The Court's rulings apply equally to Feigal's Responsive Report, (ECF No. 305.9 (under seal), ECF No. 367.50 (public version)).

development plans and FDA interactions, and his experience conducting FDA-mandated, peer-reviewed scientific studies. UTC contends that Feigal also reviewed the UTC Documents, interrogatory responses, deposition transcripts, additional discovery material, data cited by Liquidia's putative experts, FDA regulations and guidance, clinical information available on clinicaltrials.gov, product labels, and other publicly-available sources. (Pls.' Br. Opp'n 9–15.) UTC further argues that Feigel is not required to apportion damages among the trade secrets at issue in order for his opinions to be admissible. (Pls.' Br. Opp'n 15–16.)

1. <u>Head Start Analysis</u>

41. In reaching his conclusion that Liquidia gained a 1-to-3-year head start in the FDA approval process from its alleged use of UTC's trade secrets, (*see* Feigal Report, Principal Opinions ¶ 4), Feigal relied on his professional experience. (Feigal Dep. 171:18–23 ("Q: How did you come up with this one to three years? A: It was based on my experience of having worked with many small companies, companies the size of Liquidia, that have never had an NDA approval, never filed an NDA, and what type of resources they have.").)

42. Liquidia argues that Feigal's opinion is subjective and should be excluded because it lacks a reliable methodology. (Def.'s Br. Supp. 16–17.) UTC responds that expert testimony based on experience – particularly the deep and significant experience that Feigel has had – is reliable and, in any event, Feigal relied on more than just his experience. (Pls.' Br. Opp'n 9–15.)

43. Expert testimony that is purely scientific, "is characterized by 'its falsifiability, or refutability, or testability.' " *Wilson*, 484 F.3d at 274 (quoting *Daubert*, 509 U.S. at 593). As such, scientific testimony is "objectively verifiable, and subject to the expectations of falsifiability, peer review, and publication." *Id.* (quoting Fed. R. Evid. 702 Advisory Committee Notes).

44. On the other hand, experiential expert testimony "'does not rely on anything like a scientific method' and thus its admissibility is not tied necessarily to its scientific testability." *SAS Inst., Inc. v. World Programming Ltd.*, 125 F. Supp. 3d 579, 589 (E.D.N.C. 2015) (quoting *Wilson*, 484 F.3d at 274). "[T]his does not lead to a conclusion that experience alone – or experience in conjunction with other knowledge, skill, training or education – may not provide a sufficient foundation for expert testimony." *Wilson*, 484 F.3d at 274 (citation and quotation marks omitted). Indeed, Rule 702 expressly provides that a witness may be qualified as an expert by experience. *See* N.C. R. Evid. 702(a) ("If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, *experience*, training, or education, may testify thereto in the form of an opinion[.]" (emphasis added)).

45. However, where a witness relies "solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Synopsys, Inc. v. Risk Based Sec., Inc.*, 2022 U.S. Dist. LEXIS 134694, at *12–13 (E.D. Va. July 28, 2022).

46. To that end, "[t]he Court must exclude an expert's testimony when it 'is connected to existing data only by the *ipse dixit* of the expert.' " *Silicon Knights, Inc. v. Epic Games, Inc.*, 2011 U.S. Dist. LEXIS 147633, at *24 (E.D.N.C. Dec. 22, 2011) (quoting *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997)). "In such cases, '[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.' " *Id.* (alteration in original).

47. A review of Feigal's Report shows that his opinions were guided by his deep understanding of the FDA's regulations, process, and procedures, particularly as applied to companies that have little experience with the NDA process. Feigal served in senior positions at FDA for 12 years. He held several director roles at FDA's Center for Drug Evaluation and Research, which is responsible for approving all new drugs. While at FDA, Feigal evaluated and advised on hundreds of drugs. He had direct authority to approve investigational studies and manufacturing methods of new drugs. He also assessed the adequacy of preclinical and clinical studies that were the basis for NDAs.

48. In addition to his direct FDA work experience, Feigal led the regulatory divisions of two major pharmaceutical companies that each obtained FDA approval for new products under his management. Further, Feigal has advised hundreds of companies on drug development plans and FDA interactions, including "start-ups" and small companies that have not previously had a product approved by FDA.

49. In his report, Feigal explains his understanding of the FDA in detail and then opines on the manner in which having the information that exists in the UTC

Documents would eliminate the need to engage in efforts and expend resources that would otherwise be necessary. Feigel's opinions are based on his knowledge of the FDA's practices, something he knows from his years of relevant work there. *See Reed*, 2023 U.S. Dist. LEXIS 140788, at *39–40 (admitting expert opinion regarding standard industry practice that was based on the experience of the expert and observing that "certain expert opinions may be more reliant on the experience of the expert and softer criteria." (citation and quotation marks omitted)). A calculation of the dollar value of the 1-3 year head start was left to another expert, Dr. Stec, and is not the subject of the Motion.

50. In addition, Feigal was not guided by his experience alone. In forming his opinions, Feigal reviewed interrogatory responses, deposition transcripts, the UTC Documents, and publicly available materials. (*See* Feigal Report Appendix C.) He also used his experience "work[ing] with many small companies, companies the size of Liquidia, that have never had an NDA approval, never filed an NDA, and what type of resources they have[,]" in forming his opinions. (Feigal Dep. 171:18–23.) *Compare In re Zetia (Ezetimibe) Antitrust Litig.*, 2021 U.S. Dist. LEXIS 251415, at *36 (E.D. Va. Aug. 16, 2021) (holding that the opinions of an experiential expert were reliable where the expert "reviewed litigation documents and publicly available information, including publications by the FDA; pharmaceutical websites; and articles[.]"); *with Reed*, 2023 U.S. Dist. LEXIS 140788, at *37 (holding that an experiential expert's calculation of losses amounted "to no more than conjecture or

speculation" where the expert explained that his assessment was "based on his experience" and "cite[d] to no data, scholarly publication, or other source[.]").

51. The Court concludes that Feigel's testimony is sufficiently reliable because it is "rooted in his long, relevant experience." *In re Zetia*, 2021 U.S. Dist. LEXIS 251415, at *20. Accordingly, Liquidia's Motion to exclude Feigel's testimony on this basis is **DENIED**.

2. <u>Avoided Labor Costs</u>

52. Feigal opines, as an alternative to his head start analysis, that Liquidia "would have needed to hire an additional 2 to 4 full-time-equivalent employees or consultants" at "50–75%" of Roscigno's salary in order to develop its PAH treatment. (Feigal Report, Principal Opinions ¶ 4 n. 274.) However, Feigal does not specify the skill set these additional employees would have had to have. Liquidia argues that Feigal is unable to do so because he does not know what skill set and experience the existing Liquidia employees had. According to Liquidia, this lack of knowledge makes Feigal's opinion unreliable. (Def.'s Br. Supp. 18.)

53. Liquidia also argues that because Feigal did not know Roscigno's salary prior to preparing his Report, his opinion that the additional employees would have been compensated at "50–75%" of Roscigno's salary is unreliable. (Def.'s Br. Supp. 18–19.)

54. These arguments go to the weight of Feigal's testimony rather than to its admissibility. *See Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195 (4th Cir. 2017) ("Questions regarding the factual underpinnings of the expert witness' opinion affect

the weight and credibility of the witness' assessment, not its admissibility." (cleaned up)); *Pope v. Bridge Broom, Inc.*, 240 N.C. App. 365, 374 (2015) ("[The] Court does not examine whether the facts obtained by the witness are themselves reliable" as this "is a question of the *weight* to be given the opinion by the factfinder, not the *admissibility* of the opinion." (emphasis in original) (quoting *United States v. Crabbe*, 556 F. Supp. 2d 1217, 1223 (D. Col. 2008))).

55. As with his head start analysis, Feigal relied on his experience in conjunction with litigation materials and other publicly available information to form his opinion. (*See* Feigal Report, Principal Opinions ¶ 4, Appendix C.) A fact-finder could conclude that it would be reasonable to assume that Liquidia was not overstaffed and that it would have required additional labor to develop the information it was able to glean from the UTC Documents. A fact-finder may accept or reject Feigal's explanation regarding how he reached the "50–75%" figure. (Feigal Dep. 233:25–234:2 ("[W]hat I was trying to say is that these people are not going to be as expensive as the most senior people in the company."); Feigal Dep. 235:1–2 ("[Because they would report to Roscigno] I was just saying that these are relatively less expensive hires than Dr. Roscigno[.]").)

56. "[T]he court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct." *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 690 (W.D.N.C. 2003) (citation omitted). Nevertheless, "[a]n expert must account for 'how and why' he or she reached the challenged

opinion." *Id.* at 691. The Court concludes that, in this case, Feigal has sufficiently done so for a fact-finder to evaluate his opinions.[4]

57. Liquidia's Motion to exclude Feigel's testimony on this basis is **DENIED**.

3. <u>Independent Economic Value</u>

58. While Feigal's Report sorts the UTC Documents into six categories, (*see* Feigal Report §§ XI (A)–(F)), Feigal analyzed the value of the trade secrets contained in them as a compilation, not individually or by category.

59. In its Motion for Summary Judgment, Liquidia argues that because UTC's experts did not apportion damages, UTC is unable to present evidence to support a claim for damages that does not involve misappropriation of all of the UTC Documents together, as a compilation. (Br. Supp. Def. Liquidia Techs., Inc. Mot. Summ. J. 23–25, ECF No. 286 (under seal), ECF No. 357 (public version).)

60. Likewise, Liquidia argues in this Motion that because Feigal bases his head start period, as well as the amount of avoided labor costs, on his assumption that *all* of the UTC Documents were misappropriated, any opinion he could offer at trial that might involve fewer than all of the UTC Documents would be unreliable speculation. (Def.'s Br. Supp. 22.)

61. It is true that Feigal's Report does not address damages in the event that some of the information contained in the UTC Documents allegedly

[4] Liquidia's expert also concluded that Liquidia would have needed at least one additional employee. (Dep. of Stephen Ogenstad 104:14–105:20, ECF No. 336.9 (under seal), ECF No. 369.8 (public version).)

misappropriated is not, in fact, trade secret information. (Feigal Dep. 242:2–4 ("For any of the categories, I didn't consider what the impact would be if you take that category out."); Feigal Dep. 248:10–19 ("Q: If more than one category drops out – your report doesn't – your principal opinions about the one to three years or two to four employees don't account for one or more categories being deemed not a trade secret by the Court? A: That's correct. I think the report implies that if some of these documents are not trade documents, it would be less than one to three, and less than two to four.").) In its brief in opposition to this Motion, UTC concedes that Feigal's analysis "accounts for the *cumulative impact* of all the trade secret information." (Pls.' Br. Opp'n 16 (emphasis added).)

62. It is also true that Feigal recognized that such a determination would impact his analyses. (Feigal Dep. 244:20–245:3 ("Q: If the court determined that clinical trial documents were not trade secret, would that impact your one to three years? A: Yes. Yes, it would. Q: But you didn't identify by how much? A: No.").) Feigal testified that he would be able to assess the extent to which the exclusion of a particular category of documents would impact his analysis, but he admitted that he did not offer any such opinions in his Report. (*See generally* Feigal Dep. 244:13–248:6; Feigal Dep. 247:14–248:1 ("So if you asked me to [assess the impact of a specific category of documents], I would take a look at the information that's in the documents and what they provided that would speed up the process. And if, in fact, they were allowed to speed up the process, then I would modify my one to three years,

two to four employees, based on the size of the advantage the court said was permissible . . . . The [R]eport does not do that right now.").)

63. UTC maintains that another of its experts, Dr. Stec (Stec), "opines on the present value of [the] 'head start,' and provides guidance for the jury to tailor its award based on the scope of misappropriation." (UTC's Summ. J. Opp'n Br. 18.) But Stec opines on the present value of Liquidia's alleged head start based only on its length—not on the scope of the misappropriation. For example, Stec values a one-year head start at $409,501,070 and a two-year head start at $734,838,395. (Expert Report of Jeffery A. Stec [Stec Report] 72, ECF No. 255.19 (under seal), ECF No. 335.19 (public version).) In addition, Stec provides a "range of potential additional monthly costs" based on Feigal's analysis regarding avoided labor costs. (Stec Report 73.)

64. Stec testified that he used Feigal's analysis in his calculations and that "you . . . would have to ask Dr. Feigal if he believes that the change – that the head start, length of the head start would change if you looked at a subset of the trade secrets. I don't know one way or the other." (Jeffery A. Stec Dep. Excerpts [Stec Dep.] 87:19–23, 94:7–14, ECF No. 303.10 (under seal), ECF No. 366.10 (public version).)

65. Like Feigal, Stec testified that he could "very easily . . . say what the damages impact would be of a change in the length of the head start" if provided with that information. (Stec Dep. 87:2–7.) However, his Report does not do so.

66. Without a stated reliable methodology for apportioning unjust enrichment damages in the event alleged trade secrets included in Feigel's

compilation are excluded, there does not appear to be a basis in the record provided for a jury to determine the extent of Liquidia's unjust enrichment. *See O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 399 F. Supp. 2d 1064, 1076–77 (N.D. Cal. 2005) (granting defendant's motion for judgment as a matter of law where plaintiff was unable to convince the jury that all trade secrets were misappropriated and plaintiff's expert provided the jury with a damages calculation based on an assumption that all trade secrets were misappropriated).[5] It remains to be seen whether this deficiency will present an impediment for UTC at trial.

C. Value Derived from Secrecy

67. Finally, Liquidia argues that Feigal's opinions regarding the independent economic value of UTC's alleged trade secrets are irrelevant because Feigal does not address their value "derived from secrecy." (Def.'s Br. Supp. 24–27.) UTC responds that Liquidia's assertion "is built on a faulty premise." It contends that Feigal did consider whether some of the information within the UTC Documents was publicly available when reaching his opinions. (*See* Pls.' Br. Opp'n 17–19.)

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[5] The same is not true to the extent Feigal has assigned a monetary value to specific costs that UTC argues Liquidia was able to avoid by using its trade secrets, such as the cost of a PK study. (*See* Feigal Report ¶ 194; *see also* Feigal Report ¶¶ 176, 182.) Nevertheless, Liquidia argues that Feigal's opinions regarding these avoided costs are unreliable because Feigal assumed that Liquidia avoided costs that it actually did not avoid. (Def.'s Br. Supp. 22–24.) For example, Feigal opined that Liquidia was able to avoid costs by performing a "bare" PK study as opposed to a traditional PK study. (Feigal Report ¶ 194.) However, Liquidia contends that it *did* perform a traditional PK study, so these costs were not actually avoided by Liquidia. (Def.'s Br. Supp. 23; Feigal Dep. 288:17–21.)

Liquidia's challenge, however, amounts to a disagreement "regarding the factual underpinnings" of Feigal's opinion which "affect[s] the weight and credibility" of Feigal's assessment, "not its admissibility." *Bresler*, 855 F.3d at 195. Liquidia is free to cross-examine Feigel on these points.

68. Pursuant to the North Carolina Trade Secrets Protection Act, N.C.G.S. § 66-152 *et seq.*, a "'[t]rade secret' means business or technical information . . . that [d]erives independent actual or potential commercial value *from not being generally known or readily ascertainable*[.]" N.C.G.S. § 66-152(3)(a) (emphasis added).

69. Feigal testified that he considered whether each UTC Document, in its entirety, was in the public domain, but he admitted that he did not consider whether each *piece* of information contained within each of the documents was public in some form. (*See, e.g.,* Feigal Dep. 343:15–22 ("Q: So you made no assessment as to whether the information that you say Dr. Roscigno copied was otherwise public in the public domain? A: I was aware of the confidentiality of the document from which it had come from, but I didn't look to see if that same information was in the public domain in some other form."); Feigal Dep. 346:10–17 ("Q: But you never went to go look to see – you only looked to see is this FDA document in the public, not whether [UTC] later made a decision to make that information public in a non-FDA document? A: That's correct. I did not look to see if there were bits and pieces of the FDA documents that were in the public documents.").)[6]

70. Nevertheless, in Feigal's view, Liquidia's "attempts to equate isolated disclosures in the public domain regarding UTC's clinical trials and development

[6] In fact, in some instances, Feigal concedes that pieces of information in the UTC Documents are publicly available. For example, in his Report, Feigal opines that Roscigno's notes from an FDA meeting are "valuable to UTC" because they provide "nonpublic information on UTC's path to regulatory approval," including "the maximum tolerated dose for TYVASO[.]" (Feigal Report ¶¶ 213–14.) However, during his deposition, Feigal agreed that the maximum tolerated dose for TYVASO has been publicly disclosed by UTC. (Feigal Dep. 353:17–24; 354:8–15.)

programs to the documents reflecting trade secrets misses the point." (Responsive Report ¶ 22.) According to Feigal, "[t]hese compilation documents reflecting trade secrets, which remain undisclosed, are commercially valuable because a putative competitor would need to invest significant time and resources to develop comparable material or a comparable body of knowledge on their own." (Responsive Report ¶ 22.) Therefore, UTC's position is that Roscigno purposefully curated and then misappropriated a group of documents that derive value from not being publicly available *as a collection*, regardless of whether some of the information contained within them is publicly available. Feigal bases his opinions on this position.

71. Six factors assist the Court to determine whether particular information is a trade secret:

> (1) the extent to which the information is known outside the business;
>
> (2) the extent to which it is known to employees and others involved in the business;
>
> (3) the extent of measures taken to guard the secrecy of the information;
>
> (4) the value of information to business and its competitors;
>
> (5) the amount of effort or money expended in developing the information; and
>
> (6) the ease or difficulty with which the information could properly be acquired or duplicated by others.

Combs & Assocs. v. Kennedy, 147 N.C. App. 362, 369–70 (2001); *accord Wilmington Star-News, Inc. v. New Hanover Reg'l Med. Ctr., Inc.*, 125 N.C. App. 174, 180–81 (1997). Factors 1, 5 and 6 are implicated here. *See Blusky Restoration Contrs., LLC v. Brown*, 2024 NCBC LEXIS 105, at **64 (N.C. Super. Ct. Aug. 7, 2024) (a

compilation trade secret may exist even where the information is publicly available if "the claimant encountered some difficulty in assembling each of the public components."); *RoundPoint Mortg. Co. v. Florez*, 2016 NCBC LEXIS 18, at **32 (N.C. Super. Ct. Feb. 18, 2016) ("Whether a compilation or manipulation of information deserves trade secret protection depends on several factors, including the difficulty with which the information could be gathered, compiled, or manipulated.").

72. After review, the Court concludes that there is sufficient record evidence to prove that, although some information in the UTC Documents is publicly available, much of it is not. With respect to the publicly available information, a fact-finder could conclude that UTC expended significant time and effort developing and including it in its drug development efforts and that Roscigno, recognizing the value of the documents that contain it, chose to include those documents in a larger compilation that he then shared with UTC's competitor.

73. Accordingly, on this basis, the Motion is **DENIED**.

D. <u>Rule 403</u>

74. With respect to Liquidia's argument that Feigal's opinions would mislead the jury, the Court has conducted the balancing test required by Rule 403 and concludes, at this stage, that the probative value of Feigal's opinions as provided above outweighs the dangers Rule 403 guards against. *See* N.C. R. Evid. 403; *Crescent Univ. City Venture, LLC*, 2022 NCBC LEXIS 9, at **34 ("In general, the exclusion of evidence under the balancing test of Rule 403 . . . is within the trial court's sound discretion." (citation omitted)). Nothing herein precludes the Court's

further consideration of Feigel's testimony pursuant to Rule 403 at a trial of this matter.

V. CONCLUSION

75. **WHEREFORE**, the Court, in its discretion, hereby **GRANTS in part** and **DENIES in part** the Motion as set forth herein.

SO ORDERED, this 29th day of July, 2025.

/s/ Julianna Theall Earp

Julianna Theall Earp
Special Superior Court Judge
for Complex Business Cases