UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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FERRING B.V. et al.,

Plaintiffs,

-against-

ALLERGAN, INC. et. al.,

Defendants.

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12-cv-2650 (PKC)

FINDINGS OF FACT AND CONCLUSIONS OF LAW

CASTEL, U.S.D.J.

Counter-claimant plaintiffs Serenity Pharmaceuticals Corporation ("Serenity") and Reprise Biopharmaceutics, LLC ("Reprise") bring two correction of inventorship claims against counter-claimant defendants Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc. (collectively, "Ferring"). Counterclaimants seek to correct assignee Ferring B.V.'s Patent Nos. 7,560,429 ("the '429 patent") and 7,947,654 ("the '654 patent) (collectively, the "patents in suit"), by adding Dr. Seymour Fein as a co-inventor. These are the Court's findings of fact and conclusions of law after a bench trial on the claims. Fed. R. Civ. P. 52(a)(1).[1]

[1] The citation to any evidence is intended to be illustrative and is not necessarily the sole evidentiary support for a finding. Any finding of fact improperly designated as a conclusion of law or vice versa should be considered under the proper designation.

FINDINGS OF FACT

I. The Patents-in-Suit

1. The patents in suit are assigned to Ferring and list Anders Nilsson, Hans Lindner, and Jørgen Wittendorff as inventors. (D.I. 400 ¶37; PTX-48 at FERALL0004336; PTX-49 at FERALL0004351.)

2. The patents are directed to pharmaceutical formulations of the drug desmopressin. (D.I. 401 ¶31.)

3. Desmopressin is a synthetic analog of vasopressin, which is a naturally occurring hormone that regulates the concentration of urine. (D.I. 400 ¶6; D.I. 401 ¶53.) It is used to treat conditions such as central diabetes insipidus (a type of diabetes where patients produce a lot of urine), primary nocturnal enuresis (bedwetting in children), and nocturia (frequent nighttime urination affecting sleep particularly in the elderly). (D.I. 399 ¶13; D.I. 400 ¶6.)

4. The ’429 patent, which issued on July 14, 2009, issued from U.S. Patent Application No. 10/513,437 (“the ’437 application”), which was filed on November 4, 2004. (D.I. 401 ¶32; PTX-48 at FERALL0004336.) The ’429 patent claims priority to Patent Cooperation Treaty (“PCT”) applications—PCT/IB02/04036 (“PCT ’036”; DTX-88) and PCT/IB03/02368 (“PCT ’368”; DTX-89)—and to Great Britain Application 0210397 (“GB ’397”; PTX-231). (D.I. 401 ¶32; PTX-48 at FERALL0004336.)

5. Independent claims 1, 6, and 10 of the ’429 patent, which Serenity and Reprise describe as exemplary, recite:

> Claim 1. An orodispersible solid pharmaceutical dosage form of desmopressin acetate, wherein said dosage form (A) disintegrates in the mouth within 10 seconds and (B) comprises an amount of

> desmopressin, measured as the free base, selected from the group consisting of 25 µg, 50 µg and 75 µg.[2]
>
> Claim 6. A process for preparing an orodispersible solid pharmaceutical dosage form of desmopressin acetate which disintegrates in the mouth within 10 seconds and which comprises an amount of desmopressin, measured as the free base, selected from the group consisting of 25 µg, 50 µg and 75 µg, said process comprising subliming solvent from a composition comprising desmopressin acetate and a solution of carrier material in the solvent, wherein the composition is in the solid state is a mold.
>
> Claim 10. A method of treating a disease or condition selected from the group consisting of incontinence, primary nocturnal enuresis (PNE), nocturia and central diabetes insipidus, comprising administering to a subject an effective and generally non-toxic amount of desmopressin acetate in an orodispersible solid pharmaceutical dosage form, wherein said dosage form (A) disintegrates in the mouth within 10 seconds and (B) comprises an amount of desmopressin, measured as the free base, selected from the group consisting of 25 µg, 50 µg and 75 µg.

(PTX-48 at claims 1, 6 and 10; D.I. 427 at 2.)

6. Serenity and Reprise contend that Fein's inventive contributions are illustrated by the claim to an "orodispersible solid pharmaceutical dosage form" which "comprises an amount of desmopressin, measured as the free base, selected from the group consisting of 25 µg, 50 µg and 75 µg." (D.I. 427 at 2; Trial Tr. at 23:17-26:13.) An orodispersible dosage form is one that is administered into the oral cavity and dissolves or "melts" and, thereby, disperses the drug in the mouth. (PTX-48 at 1:63-66, 2:18-23; PTX-49 at 1:66-2:2, 2:21-26.)

7. Fein admitted that he "did not claim to have come up with the specific doses claimed, 25, 50, and 75." (Trial Tr. at 26:9-13.) According to Fein, "[w]hile consulting for Ferring, it was

[2] The symbol "µg" stands for a microgram, or one millionth of a gram.

[his] idea to try administering low doses and/or establishing low plasma/serum levels of desmopressin."[3] (D.I. 430 ¶2.)

8. The '654 patent issued from U.S. Patent Application No. 12,116/487 ("the '487 application"), which was filed on June 18, 2009. (PTX-49 at FERALL0004351.) The '487 application is a continuation of the '437 application (the application which led to the '429 patent), and, as such, claims priority to PCT '036, PCT '368, and GB '397. (Id. at FERALL0004351.)

9. Exemplary claims of the '654 patent recite:

> Claim 1. A solid orodispersible pharmaceutical dosage form comprising from 10 to 600 µg desmopressin acetate, measured as the free base, which solid orodispersible dosage form disintegrates in the mouth within 10 seconds.
>
> Claim 2. The dosage form as claimed in claim 1, which is adapted for sublingual administration.
>
> Claim 9. A pack comprising an orodispersible solid pharmaceutical dosage form as defined in claim 1 together with instructions to place the dosage form in a patient's mouth beneath the tongue (for sublingual administration).

(PTX-49 at claims 1, 2 and 9; D.I. 427 at 2-3.)

10. Serenity and Reprise contend that Fein's alleged inventive contributions are illustrated by the claim to "10 . . . µg desmopressin" adapted for "sublingual administration." (D.I. 427 at 2;

[3] Low plasma/serum levels refer to the amount of an active ingredient in the bloodstream. To correlate a dose amount with a plasma/serum amount requires knowledge of a drug's bioavailability. (Trial Tr. at 27:8-16, 712:6-14.) Bioavailability refers to the amount of active ingredient that is absorbed in the bloodstream compared to the amount that is originally present in the administered dosage form. (D.I. 398 ¶20.) With improved bioavailability, patients experience the same clinical effect of a drug (measured by blood plasma/serum levels) with the use of a smaller amount of its active ingredient. (D.I. 400 ¶21; D.I. 399 ¶22; DTX-83 at FERALL004762.) Bioavailability is distinct from bioequivalence, which is defined as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 314.3 (2019). To compare bioequivalence of different formulations of drugs (i.e. oral tablet vs. orodispersible), one must know the bioavailability of each. (Trial Tr. at 712:6-14.)

Trial Tr. at 26:21-27:7.) Fein admits he did not invent the exact numerical range. (Trial Tr. at 26:24-27:7.)

11. Serenity and Reprise's claims to add Fein as sole inventor on the '429 and '654 patents were dismissed on summary judgment because Fein admitted that he did not contribute to the specific dose ranges patented. Ferring B.V. v. Allergan, Inc., 166 F. Supp. 3d 415, 423-24 (S.D.N.Y. 2016).

12. Though the '654 patent claims sublingual administration of the orodispersible tablet, neither patent-in-suit claims a particular route of absorption. The site of absorption of a chemical compound may affect both the time to achieve maximum blood plasma levels of the ingredient (T_{max}) and the amount of the active ingredient that enters the blood stream (C_{max}). (Trial Tr. at 176:2-177:7.) The common specification of the patents-in-suit states that "[t]he active [ingredient] may be absorbed across the sublingual mucosa, and/or otherwise from the oral cavity (e.g. across the buccal and/or gingival mucosa) and/or from the gastrointestinal tract for systemic distribution." (DTX-89 at FERALL0132138.)

13. Sublingual absorption of desmopressin requires sublingual administration, but sublingual administration does not necessarily result in sublingual absorption. (D.I. 401 ¶93; Trial Tr. at 31:21-31:5.)

II. Events Prior to Fein's Work on Desmopressin

14. Since the 1950s, Ferring has developed pharmaceutical products based on naturally occurring peptides produced by the pituitary gland. (D.I. 400 ¶2.) One of their products is desmopressin, which is a synthetic version of the peptides. (Id.)

15. Ferring sells desmopressin products under the name Minirin®. (D.I. 400 ¶8.)

16. In the 1990s, Ferring sold a patented swallowable oral tablet form of desmopressin under the name DDAVP® in the United States and Minirin® in Europe. (D.I. 399 ¶17; Trial Tr. at 251:5-252:22, 253:5-254:9; DTX-469; DTX-67.)

17. Through the 1990s, Ferring conducted research projects on desmopressin to improve the oral tablet. These are summarized in its "Minirin Development Catalogue 1984-1998," dated April 30, 1998. (D.I. 400 ¶18.)

18. As detailed in the Minirin Development Catalogue, between 1990-1994, Ferring tested sublingual administration of desmopressin with a water-based solution. (DTX-18 at FERALL0038551.) Ferring "conclude[d] that the uptake of dDAVP [desmopressin] from a sublingual administered water solution was very inferior to administration in the nasal cavity." (Id. at FERALL0038551.) The Catalogue describes no further work on sublingual dosage forms in the period from 1984-1998. (Trial Tr. at 373:21-374:21, 377:18-379:2.)

19. Ferring also examined the possibility of administering desmopressin with an orodispersible tablet. The company R.P. Scherer had developed an orodispersible drug delivery system known as the Zydis technology that dissolves in the mouth in a matter of seconds, even without water. (D.I. 400 ¶21; D.I. 401 ¶65; Trial Tr. at 383:6-9.) This formulation was referred to as the "snowflake" technology because the tablet was designed to dissolve quickly in the mouth, like a snowflake. (Trial Tr. at 341:17-342:14.)

20. In 1995, Ferring put forward a plan for an extended feasibility study of administering desmopressin with Zydis, but "[d]ue to the high cost and low patent protection, no development was started." (DTX-18 at FERALL0038550.)

III. With Patent Expiration Approaching, Ferring Accelerates Search for New Products and Chooses the Orodispersible Tablet

21. Ferring's patents on its oral tablet form of desmopressin were set to expire in November 2004 in Europe and November 2008 in the United States. (DTX-98 at FERALL0120040; PTX-405 at Non-AGN00164205; Trial Tr. at 248:17-249:14.)

22. In the late 1990s or early 2000s, Ferring began to explore new formulations of desmopressin to replace the soon-to-be expired patents. (D.I. 389 ¶10; D.I. 398 ¶21; DTX-83 at FERALL0004761; DTX-98 at FERALL0120039; DTX-105 at FERALL0111208.)

23. The Zydis orodispersible tablet was again considered. In March 1998, the general manager of Ferring U.K. suggested an "initial feasibility study" on desmopressin using the Zydis technology. The same Ferring employee noted that the Zydis form of an active ingredient which dissolved in the mouth exhibited improved bioavailability compared to oral tablets; for example, the bioequivalent dosage amount for the drug Eldepryl decreased from 10 mg in oral form to 1.5 mg in Zydis form. (D.I. 401 ¶65; DTX-83 at FERALL0004762.)

24. In June 1999, Wittendorff, the project director for all desmopressin projects at Ferring, reported to colleagues that his team held talks on the use of "a sublinqual [sic] tablet easily dissolvable" and the possibility of doing a feasibility study. (D.I. 400 ¶26; D.I. 401 ¶66; DTX-69 at FERALL0005510; Trial Tr. at 256:2-4.)

25. In August 1999, Dr. Jens Peter Nørgaard, the person at Ferring responsible for designing clinical development programs for desmopressin, gave a presentation in which he listed a "sublingual" formulation as a possible new product. (D.I. 399 ¶25; D.I. 400 ¶27; DTX-68 at FERALL0099123.)

26. In early 2000, Ferring set up a meeting with R.P. Scherer to discuss using Zydis with desmopressin, stating that "Zydis is the first choice" for a new formulation. (DTX-101 at FERALL0135476.)

27. Ferring referred to its work creating an orodispersible tablet as the "NewMin" program, for a new version of Minirin. (D.I. 401 ¶68; Trial Tr. at 650:8-11; PTX-183 at FERALL0119259.)

28. Ferring sought bioequivalence in its NewMin product because bioequivalence would allow Ferring to commercialize its product more quickly. (DTX-102 at FERALL0111416; Trial Tr. at 307:3-15.) Nørgaard's slides for a "Minirin Rollover" presentation dated January 2000 state that bioavailability, which would enable the team to determine more accurate and lower doses, was deemed "of less importance." (PTX-255 at FERALL0139894; D.I. ¶69.)

29. Ferring commissioned a feasibility study of the Zydis formulation between April and June 2000. (DTX-102 at FERALL0111416; D.I. 398 ¶39.) The feasibility study tested three formulations of orodispersible desmopressin, all three of which produced good chemical stability. (DTX-104 at FERALL0111122; D.I. 401 ¶69.)

30. In October 2000 Nørgaard and Thomas Senderovitz, a pharmacokinetics expert responsible for the early clinical development work on the orodispersible formulation, met with EMF Consulting to begin a modeling project on the clinical effect of the Minirin tablet in patients with nocturia. (DTX-21; D.I. 399 ¶56; D.I. 400 ¶27; Trial Tr. at 256:17-24.) The goal was to establish a pharmacokinetic/pharmacodynamic ("PK/PD") model for desmopressin to help the justification of dose selection for later studies. (DTX-22 at FERALL0139908; D.I. 399 ¶57; Trial Tr. at 682:21-24.) Specifically, the study would generate an estimate of the EC50 value for desmopressin, which is a value noting the blood concentration at 50 percent of an

active ingredient's maximum effect. (Trial Tr. at 121:9-16.) EMF Consulting presented on its findings in February 2002 and published a final report in May 2002. (DTX-23; DTX-24.) The report showed that bioavailability of Minirin at low doses produced a measurable antidiuretic effect. (DTX-23; DTX-27 at FERALL0008552-53; see D.I. 399 ¶¶82, 88.)

31. Ferring set a "Commercial GO/NO GO" deadline of July 2001 to decide whether to proceed with the orodispersible formulation. (DTX-108 at FERALL0111220.)

32. At the end of August 2001, Ferring decided to proceed with the orodispersible formulation of desmopressin using Zydis. (D.I. 398 ¶53; DTX-110.) In an August 31, 2001 email, Wittendorff wrote that Ferring "ha[d] now been given a go to plan in details for a new Minirin formulation," giving "this project very high priority." He discussed the need for "a pilot bio-study" "a.s.a.p." and stated that if there is "the slightest chance that Zydis is more bio-available than the current formulation we will board on doing clinical trials (Could potentially be already when we start the bio-equivalence study)." (DTX-100 at FERALL0119952.) Fein was not listed as a recipient of the email invitation and was not invited to the meeting scheduled for September 7, 2001 to discuss the "NEWMIN – New Minirin formulation." (Id.)

33. An August 30, 2001 draft protocol to evaluate the bioavailability of the new Minirin formulation later became the CS004 Study. The protocol anticipated testing the orodispersible tablet in 100, 200, and 400 µg amounts. (PTX-82.)

IV. Members of the Newmin Team Study the Effect of Low Doses of Desmopressin in the Non-Orodispersible Tablet Form

34. Separate from the work on the orodispersible form of desmopressin, members of the Newmin team sought to determine the optimal doses of desmopressin in non-orodispersible forms.

35. Nørgaard testified that he believed that, although desmopressin exhibited "very low bioavailability" when administered via oral tablet, lower doses than the conventional tablet would still achieve desired blood concentration levels to be effective based on the drug's potency. (D.I. 399 ¶¶26-28; Trial Tr. at 680:16-681:10.) He testified that he encouraged Ferring to adopt these ideas with respect to its Phase 2 and 3 trials for tablets designed to treat nocturia in the elderly, which were ongoing in the late 1990s. (Trial Tr. at 680:1-681:22.)

36. In 1996 Nørgaard published an article discounting higher doses because "[h]igher doses of DDAVP prolong the duration of pharmacologic action and might increase the risk of water intoxication," or hyponatremia. (Trial Tr. at 55:1-56:7; DTX-10 at FERALL0038560.)

37. In 1999 Nørgaard published an article on the PK/PD effects of the oral tablet form of desmopressin in which he noted that "even poor absorption of desmopressin may be sufficient to obtain the required level of plasma desmopressin" because it was a "very potent drug." (DTX-11 at FERALL0133253.) The article did not posit increased bioavailability at lower doses, but rather stated "I do not think increasing the availability of desmopressin is necessary" and that "it is good that there is a rather bad bioavailability of desmopressin" because increasing the amount in the blood would increase the duration of antidiuretic effect, which was not a desired outcome. (Id. at FERALL0133254.)

38. That same year Nørgaard presented at the International Children's Continence Society ("ICCS") conference in Denver. At the conference, he presented a slide from an intravenous administration trial that demonstrated desmopressin has a maximal effect at as low as 2-3 micrograms, or far lower plasma concentrations than were previously thought to be clinically

effective. (DTX-12 at FERALL0099758; D.I. 399 ¶36.) The slide does not account for duration of drug effectiveness. (Id.)

39. Based on these data, Nørgaard concluded in his slides that "[t]he need for high plasma levels of desmopressin is overestimated." (DTX-12 at FERALL0099767.)

40. In Nørgaard's Minirin Rollover presentation dated January 2000, he summarized his discussion at the ICCS Conference and concluded that "[t]he need for high plasma levels is overestimated," and that "[a]ntidiuresis can be obtained by low plasma levels." (PTX-255 at FERALL0139899.)

41. This hypothesis was stated differently in two presentations in October 2000: (1) a PK/PD expert report titled "Pharmacokinetics and pharmacodynamics of orally administered desmopressin (dDAVP)" dated October 10, 2000 and signed by Senderovitz that stated "[i]ncreased doses of dDAVP (and hence increased plasma concentrations) result in prolonged duration of pharmacological action – not necessarily more pronounced antidiuretic effects" (DTX-19 at FERALL0004788); and (2) a presentation by Senderovitz to Ferring's marketing partner Aventis summarizing findings of a study on the oral tablet form of desmopressin which stated that desmopressin is "effective even at *very* low plasma concentrations" (DTX-20 at FERALL0137396, 98.)

V. Prior Art Literature on Low Doses

42. Ferring also presented evidence that two studies from the 1980s concluded that low doses of desmopressin administered in oral tablet form exhibited antidiuretic effects at low plasma concentration levels. (DTX-398 (1986 study by T.D.M. Williams et al.); Trial Tr. at 146:10-18,

217:20-24 (discussing DTX-397 1985 study by Hammer)). At trial, Fein did not contest the findings of these studies. (Trial Tr. at 144:21-146:2; 149:15-24.)

VI. Fein's Work on NewMin

43. In the summer of 2001, Ronald V. Nardi was promoted to Corporate Vice President responsible for Ferring International's research and development. (D.I. 429 ¶8.)

44. Fein testified that he had conversations with Nardi about desmopressin in July 2001. Fein did not describe his invention to Nardi during those conversations. (Trial Tr. at 57:16-58:1; 59:15-19.)

45. Nardi testified that sometime in August 2001 he had an informal conversation with Fein about the problems of obtaining approval for a new form of desmopressin in Europe based on documented side effects including hyponatremia, or an abnormally low concentration of sodium in the blood. (D.I. 429 ¶¶13, 17-18; D.I. 420 ¶¶41, 48-49; PTX-390.)

46. Nardi testified that Fein commented on possible causes of the side effect based on Fein's previous research with desmopressin and that he believed hyponatremia was likely caused because the dosage levels were too high. (D.I. 429 ¶¶13, 17.) Nardi testified that Fein told him of Fein's belief that desmopressin would maintain its effectiveness to treat nocturia at much lower blood concentration levels than were used in current clinical practice, allowing for lower dosages and reduced side effects. (D.I. 429 ¶17; see D.I. 430 ¶40.)

47. Fein also told Nardi that a sublingual route of administration for the new formulation of desmopressin "had the potential to produce a higher bioavailability" and to "achieve the low doses and reduce variability." (D.I. 429 ¶18; D.I. 430 ¶¶40-41.)

48. Nardi testified that he invited Fein to Copenhagen to discuss his ideas with other Ferring employees working on the Newmin project. (D.I. 429 ¶20; D.I. 430 ¶43.) Fein traveled to Copenhagen between August 27-29, 2001 (D.I. 430 ¶44.)

49. At the time Fein served as an independent consultant to Ferring. (PTX-222; D.I. 430 ¶¶22–23.) He submitted monthly timesheets that were reviewed by Nardi to receive payment for his services. (PTX-400.)

50. Fein's timesheets from August 2001 state that of his 214.5 hours consulting in August, he consulted for 1.5 hours (1.0 hours on August 28, 0.5 hours on August 29) on the "Desmopressin Nocturia Program." (PTX-400 at Non-AGN00160722-23.) By contrast, over his three days in Copenhagen, Fein recorded 22.0 hours of work on a different project known as "Degarelix." (Id. at Non-AGN00160723; Trial Tr. at 84:8-20.)

51. While in Copenhagen, Fein had meetings scheduled with eight individuals, two of whom, Senderovitz and Nørgaard, were working on both Degarelix and the Desmopressin Nocturia programs. (PTX-152; Trial Tr. at 87:22-88:21, 270:15-271:6, 274:15-275:2, 276:20-277:4.) The other six were not working on the Desmopressin Nocturia program. Fein recalled meeting with Senderovitz but not Nørgaard. (D.I. 430 ¶¶47-48.) Fein also testified that he met with Wittendorff and that he told unidentified Newmin team members about his theories related to low dose and sublingual administration in "presentations" and "discussions." (D.I. 430 ¶¶49-50.)

52. Fein did not attend the scheduled Newmin team project meeting on August 30, 2001. Nardi testified that he presented Fein's ideas to the team. (D.I. 429 ¶¶20-21; PTX-149.)

53. Fein's timesheets from September 2001 state that of his 191.5 hours of consulting in September, he consulted for 20.0 hours over the course of several days on Desmopressin Nocturia. (PTX-400 at Non-AGN00160724-25.)

54. In a September 10, 2001 memorandum from Fein to a member of the Ferring team in Europe, Fein wrote that he had "only recently and in a cursory fashion begun to review the Desmopressin Nocturia FDA briefing document and summary of EU regulatory questions." (DTX-39 at FERALL0133620.) In the memo, Fein noted as issues affecting the approval of the drug in Europe "[t]he choice of the oral tablet as the formulation for this program, (the new, rapidly dissolving sublingual tablet may be preferable depending on its pharmacokinetics.)" (Id.)

55. That same day, Senderovitz emailed Nardi and Fein to discuss sample sizes offered "from the biometrics department" for the Zydis bioavailability study, suggesting a large range of dosages to test. (PTX-149.)

56. Nardi testified that he reported Fein's ideas to Ferring's Board of Directors at an October 11, 2001 meeting. (D.I. 429 ¶23; *see* PTX-404 at Non-AGN00163404 (stating on a slide for "Desmopressin" and "RP Scherer:" "sublingual administration" and "change dosage form").)

VII. Ferring Continues to Develop NewMin

57. In December 2001, the draft protocol for the Zydis bioavailability study was finalized (CS004.) (DTX-25; *see* DTX-86 (draft October 2001 version).) Unlike the draft protocol from August, the final version called for testing the formulation sublingually, but the dose amounts increased to 200, 400, and 800 µg. (DTX-25 at FERALL0005831, 32, 58; DTX-86.) The final

protocol noted that "the sublingual administration of the new oral formulation is not expected to show a dramatically increased bioavailability." (Id. at FERALL0005847.)

58. In response to the question whether Fein communicated any specific contributions for the CS004 protocol to others, he testified that he had an undated conversation with someone, "most likely" Senderovitz, though Fein "d[id]n't recall specifically." (Trial Tr. at 96:14-22; 104:11-23.) He has no documents to substantiate the substance or date of this conversation. (Id. at 104:11-105:1.)

59. Fein stated that he "attended none of the project team meetings planning [CS004]." (Trial Tr. at 120:14-16; see, e.g., DTX-85 (CS004 Clinical Team Meetings minutes listing attendees)). He stated he was not aware of any "written record to suggest that CS004 was created to test [his] ideas or concepts." (Trial Tr. at 120:21-23.)

60. The CS004 study was conducted between January 30 and March 8, 2002. (PTX-57 at FERALL0004881-85.) Its results confirmed a bioavailability for the Zydis form of desmopressin administered sublingually that was two to two-and-a-half times higher than the conventional existing tablet. (Id. at FERALL0004885.)

61. In March 2002 Ferring's Research Development Marketing Committee reviewed the results of the CS004 study and agreed that "a new dose range for nocturia could be generated with a lower starting dose." (PTX-183 at FERALL0119259.) Fein did not attend the meeting. (Id. at FERALL0119258.)

62. In April 2002 Nardi presented at another Ferring Board Meeting. (PTX-405; *see* D.I. 429 ¶33.) In that presentation he included an identical slide on R.P. Scherer's technology as that presented in the October 2001 Board Meeting. (Compare PTX-404 at Non-AGN163404, with PTX-405 at Non-AGN164159.) Another slide stated that Newmin presented "significantly

increased bio-availability" and listed "investigational tablets and dose range" lower than the doses of Ferring's oral tablets. (PTX-405 at Non-AGN164163.) Fein was not mentioned in the slides. (Id.)

VIII. Ferring Files Its Great Britain Patent Application

63. On April 15-16, 2002, Ferring convened a research and development meeting in Chilworth, England during which Fein spoke with Ferring's patent counsel regarding a provisional patent application on the new form of desmopressin. (PTX-97.)

64. On May 7, 2002, Ferring filed a patent application with the Great Britain Patent Office. (PTX-231 at FERALL0135031.) The application was entitled "Pharmaceutical Formulations" and included claims directed to "a pharmaceutical dosage form of desmopressin adapted for sublingual absorption" in "orodispersible" form. (Id. at FERALL0135062.) The application did not name any inventors, which is conventional in Great Britain. It claimed a tablet "adapted for sublingual administration" and the specification states that "[d]osage forms in accordance with the invention have improved bioavailability" and that "[r]elative low doses are also specifically contemplated, for example from 0.5 µg to 75 µg." (Id. at FERALL0135034, 36, 53.)

65. Ferring's patent counsel asked Wittendorff to "invite [anyone who was involved with the making of the invention to] (a) to prepare a narrative of their contribution . . . ." (PTX-392 at Non-AGN00151559.)

66. On May 14, 2002, Fein provided his two-page inventorship memo to Ferring. (PTX-390; PTX-401 at Non-AGN00160740-41; D.I. 430 ¶92.) It stated that he and Nardi jointly contributed to the invention and that his work on desmopressin began in November 2001 in preparation for a meeting in Copenhagen scheduled for the week of November 12, 2001. (PTX-390 at Non-AGN00151119.) (As will be seen, Fein, through his counsel, backed off this claim

and asserted that he alone had invented the improvement in desmopressin technology and he did so in August 2001. (PTX-218 at FERALL0132477).) The inventorship memo stated that he and Nardi came up with the idea of developing Zydis as "a sublingual, transmucosal dosage form" where a "lower administered dose might avoid some of the safety issues observed in elderly patients with the oral tablet" and shared these thoughts with senior managers of Ferring and Zydis in Copenhagen on November 12 or 13, 2001. (PTX-390 at Non-AGN00151120.)

67. At trial, Fein testified that the advantages that result from his alleged invention "depend upon there being sublingual absorption." (Trial Tr. at 19:17-20:3.)

68. Each of the other named inventors (Lindner, Nilsson, and Wittendorff) testified that they did not conceive of sublingual administration of lower doses. (See, e.g., Trial Tr. 26:10-13; 63:6-17, 67:17-20, 76:11-22, 79:9-16; 220:12-14, 220:18-221:2, 221:6-8, 231:11-13, 325:15-327:12.)

69. Nardi testified that at some point in the early 2000s he disclaimed co-inventorship of the sublingual absorption and low dose features and "advised Ferring that all information and hypotheses I knew concerning sublingual absorption of low dose desmopressin had come from Dr. Fein." (D.I. 429 ¶49.)

IX. Additional Developments on NewMin Between May 2002 and Fein's Termination

70. In June 2002 Senderovitz prepared a draft for another clinical study of desmopressin in Zydis form that would become the CS009 Study. (PTX-394; Trial Tr. at 123:3-8.) Senderovitz calculated clinical doses based on the bioavailability results of the earlier EMF Consulting study. (Trial Tr. at 735:5-736:1.)

71. Fein marked up the CS009 draft with several calculations that did not change the specific level of doses but converted their unit measurements. (Trial Tr. at 129:9-23; PTX-394 at Non-

AGN00151762.) He also proposed eliminating the top two doses. (Trial Tr. at 129:24-130:12.) He admitted that "going from five doses to three doses does not generate any data that would not have been available from the original five-dose study." (Id. at 130:14-17.)

72. The CS009 study was completed in September 2002 and confirmed the measurable effect of desmopressin at low doses when administered intravenously. (DTX-282; PTX-401.) Fein traveled to Copenhagen to present the results to the head of Ferring's clinical research department. (D.I. 430 ¶83; PTX-401 at Non-AGN00160748-52.)

73. On September 25, 2002, the final protocol for another study, the CS007A study, was finalized. CS007A was "designed to test the 10 microgram, 20 microgram and 40 microgram doses of the orodispersible tablet given sublingually." (D.I. 430 ¶85; DTX-57 at FERALL0027710).

74. Doses for the CS007A study came from Senderovitz's earlier CS007 protocol from April 2001 (Trial Tr. at 135:2-4, 136:5-16.) Fein admitted that the protocol refers to the "recently performed" EMF Consulting study as the source for data that lead to the selection of the doses for CS007A. (Id. at 132:10-133:3.)

X. Ferring Files Its Second Patent Application and Fein Is Terminated

75. On September 19, Ferring's patent counsel emailed Wittendorff relaying his "provisional determination of inventorship." (PTX-393.) He determined that "Ron Nardi and Seymour Fein jointly decided that sublingual/transmucosal absorption was the route of choice." (Id. at Non-AGN00151562.) He also determined that: "Thomas Senderovitz analysed existing Ferring data and showed that lower doses than had previously been administered orally should be feasible. Such low doses are contemplated in this invention." (Id.)

76. On September 20, 2002, Ferring filed PCT '036, entitled "Sublingual Pharmaceutical Formulation of Desmopressin," which named Fein as an inventor along with Nardi, Nilsson, Senderovitz, Lindner, and Wittendorff. (DTX-88.) PCT '036 claimed an orodisperible solid pharmaceutical dosage form adapted for sublingual absorption and administration. The specification discusses improved bioavailability of the invention and that "relative low doses are . . . contemplated." (Id. at FERALL0111504, FERALL0111523, FERALL0111532-34.)

77. Fein was terminated on November 7, 2002. (D.I. 430 ¶86; Trial Tr. at 39:6-9.)

78. Fein formed Reprise to hold and license his intellectual property. Reprise holds an ownership stake in Serenity. (Trial Tr. at 188:8-10, 191:21-23, 446:2-4, 446:25-447:2.)

XI. Ferring Amends Its Applications and the Patents-in-Suit Are Granted

79. Fein hired a patent attorney who communicated with Ferring's in-house attorney over Fein's alleged contributions to GB '397 and PCT '036. (Trial Tr. at 39:14-21; DTX-35.)

80. As part of this communication, Fein's attorney wrote to Ferring on December 16, 2002 and stated that "further investigation has revealed that the improvement to the desmopressin technology appears to have been invented by Dr. Fein in August, 2001, rather than November, 2001, as had initially been stated." (PTX-218 at FERALL0132477.) The inventorship memo written by Fein in May 2002 had claimed that Fein and Nardi had developed the inventive concept in November 2001. (PTX-390 at Non-AGN00151119-20.)

81. Following this correspondence, Ferring filed a new PCT application, PCT '368. (DTX-89 at FERALL0132135.) Compared to PCT '036, PCT '368 removed language on sublingual absorption from its claims and replaced it with the term "orodispersible." PCT '368 enlarged the scope of the specification to discuss absorption across the sublingual mucosa and other mucosa in the mouth such as the cheek (buccal) or gums (gingival), or anywhere along the

gastrointestinal tract. (Compare PTX-231 at FERALL0135033, 34, 53, with DTX-89 at FERALL0132137, 38, 58; see Trial Tr. at 42:11-14.)

82. Ferring added to PCT '368's specification three references explaining the use of sublingual administration in the prior art. The prior art references generally discuss the field's understanding as to the lack of effectiveness of sublingual administration. One of the prior art references, a study by Fjellstad-Paulsen et al., reported sublingual administration led to "no detectable desmopressin . . . in the blood," and another reported the sublingual route of administration was "objectionable" based on "a relatively long dissolving time." (DTX-89 at FERALL0132136-37.)

83. Unlike for PCT '036, Fein, Nardi, and Senderovitz were no longer listed as inventors on PCT '368 or any subsequent filings. (DTX-89 at FERALL0132136-37.)

84. During the prosecution of the '429 patent, Ferring amended its patent application several times in response to rejections from the Patent Examiner. (See PTX-42 at FERALL0000258; PTX-42C at FERALL0000401; PTX-42E at FERALL0000439; PTX-48 at FERALL0004346.) The amendments added that disintegration of the tablet would occur within 10 seconds and added specific dosage amounts of desmopressin. (Id.)

85. In remarks in response to the Examiner when adding the specific dosage amounts to the claim language, Ferring stated that its invention "achieves the unexpected result of increased bioavailability. That increased bioavailability means that the recited dosages, which are several times lower than that of standard oral dosage forms [in the prior art], are therapeutically useful." (PTX-42E at FERALL0000446-47.) The Examiner credited these findings in his reasons for allowance, stating that the invention was novel and non-obvious "for the reasons set forth during

prosecution," and noting that the claims are drawn to "relatively low doses" of desmopressin. (PTX-42H at FERALL0001065-66.)

86. The Examiner, in his Additional Remarks following allowance of the '429 patent, noted that the claimed invention was novel and non-obvious because, among other reasons, "one would not be motivated to formulate into [the claimed invention based on the prior art] because Fjellestad-Paulsen et al. teaches no antidiuretic effect or detectable plasma-dDAVP was found in pharmacokinetic study in healthy volunteers after 2 x 10 μg sublingual administration." (PTX-42F at FERALL0001071-72.)

87. The '654 patent is a continuation of the '429 patent. In its prosecution, Ferring amended the claims to recite specific dose ranges and added that the form would be adapted for sublingual administration. Ferring accompanied those amendments with the declaration of one of its employees, Rikard Sandstrom, in which he attested that the claimed invention was novel based on its "dramatic improvement in bioavailability" which gave an "ability to use a reduced dose to achieve the same therapeutic effect [that] also was surprising and unexpected." (PTX-46B at FERALL0001392.)

88. The Examiner in his Reasons for Allowance stated: "The instant application demonstrates that the solid orodispersible composition of desmopressin exhibited an approximately 60% greater bioavailability than the oral tablet. Thus, the claimed products exhibit an unexpected result and are both novel and unobvious over the prior act of record." (PTX-46C at FERALL0001619.) The Reasons for Allowance do not mention sublingual administration. (Id.)

XII. Findings on Fein and Nardi's Credibility

89. The Court finds that Nardi's testimony was not credible insofar as it related to the claim that Fein was a co-inventor. Nardi has a material interest in the outcome of this suit. He owns

an 18% stake in Reprise, which in turn has a 10% ownership interest in Serenity. (D.I. 429 ¶1; Trial Tr. at 191:21-23; 445:24-446:4.) He admits he "stand[s] to benefit from any of the benefits that accrue through the intellectual property held by Dr. Fein" in this case. (Trial Tr. at 447:3-10.) He was named as inventor and then was removed as an inventor along with Fein (D.I. 429 ¶49.) He knowingly embraced his status as an inventor but later switched postures and claimed that Fein was the sole inventor.

90. Evidence cited to by Nardi in his direct testimony does not support his statements. For example, as evidence that he discussed with the Newmin project team Fein's ideas at an August 30, 2001 meeting in Copenhagen he offers document PTX-149. (D.I. 429 ¶21.) But PTX-149 is dated October 9, 2001, and makes no reference to the August 30 meeting, Fein, or the sublingual route of administration. Nardi later admitted this. (Trial Tr. at 281:1-10.)

91. The Court also finds that Fein's testimony was not credible insofar as it related to his claim of co-inventorship. Notably, after he was terminated and hired a lawyer, he changed the date of his invention from November 2001 to August 2001 and claimed that he alone without input from Nardi conceived of the invention. (Compare PTX-390 at Non-AGN00151119, with PTX-218 at FERALL0132477.) In his inventorship memo, he identified November 2001 as the date he began working on Newmin. Fein then changed his story to a date that coincided with Ferring's initial work on the bioavailability study prior to adding in the sublingual route of administration.

92. On October 21, 2002, prior to leaving his position at Ferring, Fein established his own consultancy "CNF Pharma." (Trial Tr. at 185:17-186:2; DTX-141.) Fein claimed at trial that "CNF" stands for "Cheng and Fein" and "Nardi was never part of CNF Pharma." (Trial Tr. at 186:8-18.) Linda and Maria Cheng were co-founders of CNF Pharma. (Trial Tr. at 777:7-11

(citing Cheng Dep. at 53:7-12).) Linda Cheng was a consultant at Ferring with Fein and both Linda and Maria Cheng are partners in Reprise. (D.I. 82 ¶78; Trial Tr. at 777:7-11 (citing at Cheng Dep. at 171:25-172:5, 217:6-17.) Nardi testified that he "ha[s]n't seen the paperwork, but [he] think[s] [CNF] stands for Cheng and Fein," and that he has "never heard anyone assert that" it stood for Cheng Nardi and Fein. (Id. at 467:8-468:5; see id. at 446:17-22.) Nardi also testified that he "do[es]n't know anything at all about the workings of CNF. Never did." (Id. at 467:24-25.)

93. The Court discredits the testimony of Fein and Nardi and concludes that CNF stood for Cheng Nardi and Fein. CNF was created in October 2002 while Cheng, Nardi, and Fein continued to work for Ferring. (Trial Tr. at 185:17-186:2; DTX-141.) Cheng and Fein were consultants but Nardi was a senior employee who owed a fiduciary duty to Ferring.

XIII. Evidence Related to Sublingual Absorption

89. Both parties submitted evidence related to sublingual absorption that is briefly summarized below.

a. Serenity and Reprise's Evidence

90. Ferring received approval of the orodispersible formulation of desmopressin as claimed in the patents in suit in 2005 in Europe. It was sold under the name Minirin® Melt. (D.I. 400 ¶8.) Ferring received approval for its orodispersible formulation in the United States in 2018, which is sold under the name Nocdurna®. (Id. ¶9.)

88. Ferring met with the U.S. Food and Drug Administration ("FDA") in March 2007 to secure regulatory approval for its orodispersible tablet. The FDA asked Ferring to "clarify whether the absorption of Minirin Sublingual Melt is via the sublingual absorption route or via the combination of oral and gastrointestinal absorption route." (PTX-1010 at FERSER0000722).

In response, Ferring stated that "absorption by oral mucosa does take place . . . Absorption occurs via a combination of both the [gastrointestinal] and oral mucosa." (Id. at FERSER0000723.)

94. Ferring also presented studies and evidence to non-U.S. regulators (Australian, English, and Canadian) that suggested that the orodispersible tablet was absorbed via the oral mucosa, among others, following sublingual administration. (Trial Tr. at 593:6-16; PTX-402 at Non-AGN00161078 (English regulatory document stating "[T]he MELT is absorbed from the orobuccal mucosa"[4])); PTX-1002 at 18 (Australian regulatory document stating that "A new pharmacokinetic study in pigs showed absorption of desmopressin across the oral mucosa following sublingual administration"); PTX-1001 at ASR_FER0000000089 (Canadian regulatory document stating "Due to the rapid disintegration of DDAVP MELT, desmopressin is immediately available for absorption via the membranes of the mouth, followed by the pharynx, the oesophagus and the stomach").)

b. Ferring's Evidence

95. Ferring submitted evidence challenging whether sublingual administration leads to sublingual absorption and whether sublingual absorption leads to benefits over the oral tablet.

96. After GB '397 was filed, Ferring conducted a pilot study, CS020, to investigate the bioavailability of an orodsipersible tablet administered sublingually compared to the oral tablet. (See PTX-402 at Non-AGN00161073-74.) The study showed maximum plasma concentration of desmopressin in the bloodstream (absorption time, or T_{max}), occurred at 1.5 hours for a 240 µg

[4] Defendants' expert Richard Byrn testified that "[he's] not even a hundred percent sure what they're referring to by the oral buccal [sic] mucosa" but that he does not believe it is the same thing as the sublingual mucosa. (Trial Tr. at 594:13-17.) Fein testified that "orobuccal includes sublingual and the cheeks." (Id. at 199:5-17.)

dose of the orodispersible tablet, and at 1.0 hours for two 200 µgs of the oral tablet. (Id. at Non-AGN00161076.)

97. In 2004 Ferring conducted a bioequivalence study, CS019, that showed administering Ferring's orodispersible formulation sublingually achieved maximum plasma concentration of desmopressin in the bloodstream at approximately the same time as via the oral tablet route. (D.I. 399 ¶¶11, 110; DTX-71 at FERALL0051240.) The study was not designed to test whether sublingual absorption occurred. (D.I. 399 ¶110.)

98. Ferring introduced the FE-31 study, conducted in 2012-2013, that it alleged demonstrates "administering Ferring's orodispersible formulation of desmopressin sublingually does not have any discernible effect on absorption of desmopressin into the bloodstream." (D.I. 399 ¶11; D.I. 400 ¶42; DTX-72 at FERALL0138272.) The FE-31 study compared absorption of an orodispersible "investigational medicinal product" administered above and below the tongue. (DTX-72 at FERALL0138272.) The product was not desmopressin, and the disintegration time sublingually was two minutes, much longer than the melt time for desmopressin's orodispersible form. (Id.) The study showed near identical T_{max} values for sub- and supra-lingual administration. (Id. at FERALL0138274; D.I. 400 ¶¶42-46.)

XIV. CONCLUSIONS OF LAW

I. Correction of Inventorship

a. Legal Framework

99. 35 U.S.C. § 256 "provides a cause of action to interested parties to have the inventorship of a patent changed to reflect the true inventors of the subject matter claimed in the patent." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The standard for joint

inventorship "is one of the muddiest concepts in the muddy metaphysics of patent law." In re Verhoef, 888 F.3d 1362, 1365 (Fed. Cir. 2018) (internal quotation marks and citation omitted).

100. "[T]he issuance of a patent creates a presumption that the named inventors are the true and only inventors." Bd. of Educ. ex rel. Bd. of Trustees of Fla. State Univ. v. Am. Biosci., Inc., 333 F.3d 1330, 1337 (Fed. Cir. 2003). As such, parties wishing to be added as inventors must prove their case by "clear and convincing evidence." Id.

101. "[A]n inventorship analysis, like an infringement or invalidity analysis, begins as a first step with a construction of each asserted claim to determine the subject matter encompassed thereby. The second step is then to compare the alleged contributions of each asserted co-inventor with the subject matter of the properly construed claim to then determine whether the correct inventors were named." Trovan, Ltd. v. Sokymat SA, Irori, 299 F.3d 1292, 1302 (Fed. Cir. 2002).

i. Conception

102. To be added as a joint inventor, Fein must have "made 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." Fina Oil, 123 F.3d at 1473. Conception exists when "a definite and permanent idea of an operative invention . . . is known." Sewall v. Walters, 21 F.3d 411, 415 (Fed. Cir. 1994).

103. A contribution that is already in the prior art "cannot give rise to joint inventorship because it is not a contribution to conception." Nartron Corp. v. Schukra U.S.A Inc., 558 F.3d 1352, 1357 (Fed. Cir. 2009) (quoting Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1362 (Fed. Cir. 2004)). But a joint inventor need not contribute to the conception of "all of the limitations in any one claim of the patent," for the law only requires contribution "to the

conception of the subject matter of the claim." Duncan Parking Techs., Inc. v. IPS Grp., Inc., 914 F.3d 1347, 1358 (Fed. Cir. 2019) (quotations omitted).

ii. Collaboration

104. Joint inventorship also requires clear and convincing proof of collaboration. "[T]here must be some element of joint behavior, such as collaboration or working under common direction." Kimberly-Clark Corp. v. Proctor & Gamble Distrib Co., 973 F.2d 911, 917 (Fed. Cir. 1992).

iii. Corroboration

105. The law also requires "corroborating evidence of a contemporaneous disclosure that would enable one of ordinary skill in the art to make the invention." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1461 (Fed. Cir. 1994). Corroboration is determined under a "rule of reason" analysis, evaluating "all pertinent evidence." Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1461 (Fed. Cir. 1998).

106. An individual's testimony regarding their own inventorship "cannot, standing alone, rise to the level of clear and convincing proof." Symantec Corp. v. Comp. Assocs. Int'l, Inc., 522 F.3d 1279, 1295 (Fed. Cir. 2008). Testimony "that is supported only by testimonial evidence of other interested persons" is viewed "skeptical[ly]." TransWeb, LLC v. 3M Innovative Props. Co., 812 F.3d 1295, 1302 (Fed. Cir. 2016). There is "a clear requirement that [cross-corroboration] by interested parties must be corroborated by documentary testimony." Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc., 322 F.3d 1335, 1350 (Fed. Cir. 2003). "Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof" of corroboration. Trovan, 299 F.3d at 1302. The significance of a co-inventor's contribution is assessed "at the time it was completed." CardiAQ

Valve Techs., Inc. v. Neovasc Inc., 708 F. App'x 654, 660 (Fed. Cir. 2017). "The determination of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case." Fina Oil, 123 F.3d at 1473.

b. The Subject Matter Encompassed by the Claims

107. The parties have not asked for claim construction on the '654 or '429 patents. As such, they concede that the meanings of the terms in the exemplary claims are "clear and not in need of construction." Eli Lilly, 376 F.3d at 1360.

108. The scope of the claims encompasses specific dose ranges that the parties agree are relatively low dose amounts.

109. The dependent exemplary claims of the '654 patent (claims 2 and 9) recite sublingual administration of the low dosage orodispersible tablet.

110. While the common specification recites that absorption of desmopressin may be through the orobuccal mucosa, amongst other mucosa, the method of absorption is not claimed.

c. Serenity and Reprise Have Not Shown Proof of Corroboration by Clear and Convincing Evidence

111. As a threshold matter, Serenity and Reprise's claims to co-inventorship depend on the subject matter communicated by Fein to members of Ferring in and around the meeting in Copenhagen in August 2001. They cannot demonstrate by clear and convincing evidence that Fein communicated the inventive concepts of a sublingual route of administration or effective lower doses.

112. Evaluating "all pertinent evidence," Transweb, 812 F.3d at 1302, there is no corroborating evidence for Fein's alleged disclosures in August 2001.

113. Serenity and Reprise's primary evidence is Fein and Nardi's testimony related to the events in the summer of 2001. The Court finds the testimony of Fein and Nardi to be lacking in credibility insofar as it relates to Fein's inventorship claim. It is also lacking in documentary corroboration. (See supra Findings of Fact Section XII; Lacks Indus., 322 F.3d at 1350.)

114. Fein admitted that there is no written documentation for his discussions with Nardi or his discussions with NewMin team members in Copenhagen and that the purpose of the Copenhagen meetings was to "introduce myself and get to know you. That was the nature of those meetings." (Trial Tr. at 69:2-4, 81:8-15, 89:7-9, 89:21-90:13.) He admitted he did not attend any of the meetings in Copenhagen in August 2001 specifically focused on the Newmin project. (Id. at 159:19-160:5, 269:14-270:8.)

115. The only written documentation of Fein's work on desmopressin while in Copenhagen in August 2001 is a meeting agenda and handwritten time logs that do not confirm meetings were held, the substance of those meetings, or whether only non-desmopressin projects like Degarelix were discussed. (PTX-152 at FERALL0116115; PTX-400 at Non-AGN00160722-23; Trial Tr. at 89:21-90:13.)

116. Nardi's proof of corroboration that he conveyed Fein's concepts to the NewMin team on August 30, 2001 does not show that Nardi attended this meeting or what was discussed. (DTX-161; Trial Tr. at 269:17-270:8.) No other testimony is offered to corroborate Nardi's attendance or contribution to the August 30, 2001 meeting. None of Nardi's presentations after August 2001 to the Ferring board mention Fein.

117. Additional documentary evidence like Senderovitz's September 10 email does not mention Nardi or Fein suggesting lower doses and does not discuss sublingual administration. (PTX-149.) It does not show any contributions Nardi or Fein made from the August 30, 2001

Copenhagen meeting. Fein's September 10, 2001 memo does not discuss lower doses and does not attribute sublingual administration to Fein (DTX-39.) If anything, the mention of "the new, rapidly dissolving sublingual tablet" indicates the idea was already formulated by the Newmin team by this time. (Id.)

118. No other witnesses recall Fein describing the low dose or sublingual features to them. See Acromed Corp. v. Sofamor Danek Grp., Inc., 253 F.3d 1371, 1380 (Fed. Cir. 2001); TransWeb, 812 F.3d at 1302.

119. Circumstantial evidence of the CS004 and CS009 Clinical Study Protocols adding sublingual testing or removing higher dose sample sizes is insufficient to rise to the level of clear and convincing evidence of contribution. See Eli Lilly, 376 F.3d at 1364.

120. The fact that Fein was originally named on the PCT '368 and GB '397 does not rise to clear and convincing evidence that Fein "actually invented" that subject matter without additional proof of Fein's individual contribution. Sewall, 21 F.3d at 417. Nor do Fein's arguments that the other named inventors could not recall who conceived of the ideas of low dose or sublingual administration, because "that fact alone does not prove that [Fein] did conceive of the" invention. Tavory v. NTP, Inc., 297 F. App'x 976, 981 (Fed. Cir. 2008).

121. Serenity and Reprise have not presented sufficient corroborating evidence to satisfy the rule of reason analysis. Ethicon, 135 F.3d at 1461.

d. Serenity and Reprise Have Not Shown that Fein Contributed to the Conception of the Claimed Invention by Clear and Convincing Evidence

122. Beyond the threshold default described above, Serenity and Reprise have not presented clear and convincing evidence that Fein conceived of the concepts of lower doses or the sublingual route of administration. Fina Oil, 123 F.3d at 1473.

i. A Contribution Not Insignificant in Quality When Measured Against the Full Invention

123. Ferring argues neither low dose nor sublingual administration are significant contributions to the inventive concept.

124. The concept of using low doses of desmopressin in orodispersible form is not insignificant in quality when measured against the scope of the invention. Fina Oil, 123 F.3d at 1473.

125. Where a patentee argues during prosecution that a claim limitation "distinguished the claimed invention over the prior art," that demonstrates that the limitation "is an essential feature of the invention not insignificant in quality or well-known in the art." VerHoef, 888 F.3d at 1366–67.

126. In response to two rejections of the application that led to the '429 patent, (PTX-42B at FERALL0000382; PTX-42D at FERALL0000429-30), Ferring amended its application to add the requirement that the claimed dosage form include the specific low doses of 25 µ*g*, 50 µ*g*, and 75 µ*g*. (PTX-42E at FERALL0000439). It then added in its remarks to the Patent Office that its proposed invention achieves the "unexpected result of increased bioavailability" meaning that "the recited dosages, which are several times lower than that of standard oral dosage forms . . . are therapeutically useful." (PTX-42E at FERALL0000446-47.) The Patent Office then allowed the claims to issue. This demonstrates the significant quality of the claimed low dose feature. VerHoef, 888 F.3d at 1366–67.

127. Ferring's remarks on its continuation application that became the '654 patent are similar. Ferring touted the unexpected increased bioavailability of desmopressin in orodispersible form. (PTX-46B at FERALL0001392.) The Patent Office accepted this argument in its Reasons for

Allowance, discussing the novel and unobvious features of Ferring's product based on improved bioavailability. (PTX-46C at FERALL0001619.)

128. The sublingual administration element of the claims is a closer call, but it is also a contribution not insignificant in quality. Sublingual administration is only found in dependent claims of the '654 patent. "[A] dependent claim adding one claim limitation to a parent claim is still a claim to the invention of the parent claim, albeit with the added feature." Nartron, 558 F.3d at 1358. The Court considers the additional limitations in the context of the independent claim from which it depends. See id.; Yeda Research and Dev. Co. v. Imclone Sys. Inc., 443 F. Supp. 2d 570, 618 (S.D.N.Y. 2006).

129. The Patent Office, in allowing the claims of the '429 patent to issue, remarked that a person of ordinary skill in the art would not have been motivated to formulate Ferring's orodispersible tablet based on the poor results seen in Fjellstad-Paulsen's sublingual administration of the oral tablet. (PTX-42F at FERALL0001071-72.) While the '429 patent did not claim sublingual administration, the Examiner's statement applies to the inventiveness of the '654 patent claims because it reviewed the prior art common to both patents and noted the non-obviousness of the claimed route of administration.

130. Ferring repeatedly highlighted to the Examiner the invention's unexpectedly improved bioavailability. (PTX-46B at FERALL0001392 ¶6; see PTX-46A; PTX-46B/PTX-47.) The data used to support Ferring's expert's statement on improved bioavailability is discussed in the '654 patent's specification under Example 7, which uses sublingual administration. (See PTX-46 at FERALL0001160.)

131. Ferring's own development of the orodispersible tablet confirms the significance of the administration route. It wrote in the CS004 study (the basis for Example 7) that increased

bioavailability was unlikely with sublingual administration. When improved bioavailability was realized, the sublingual feature continued to be part of the development of the NewMin project. See Duncan Parking, 914 F.3d at 1359 (evaluating construction of invention to determine significance of co-inventor's contribution).

147. The parties' arguments challenging (1) whether sublingual administration leads to sublingual absorption; (2) whether sublingual absorption leads to improved bioavailability; and (3) evidence related to these arguments do not affect the determination that sublingual administration is a significant feature of the invention.

ii. Serenity and Reprise Have Not Offered Clear and Convincing Evidence of Conception

132. To conceive of an invention, an inventor must provide clear and convincing evidence that she has "do[ne] more than merely explain to the real inventors well-known concepts and/or the current state of the art," and must present evidence of contribution of "some significant manner." Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998). "[M]erely assisting the actual inventor after conception of the claimed invention" does not make one a co-inventor. Ethicon, 135 F.3d at 1460.

133. Fein has admitted his invention requires sublingual absorption, but the patents-in-suit do not claim sublingual absorption. (Trial Tr. at 19:17-20:3.) Without claiming conception of sublingual absorption Fein is left with the concepts of lower dose and sublingual administration. But there is evidence on the record that these ideas were being considered by Ferring employees for use in tests with the orodispersible tablet form.

134. Sublingual administration is applicable to the exemplary claims of the '654 patent. Ferring's earlier tests of sublingual administration and earlier studies including the Fjellstad-Paulsen study concluded sublingual administration did not produce favorable results and would

not have led a person of ordinary skill in the art to consider sublingual administration. (DTX-18 at FERALL0038551; DTX-89 at FERALL0132136-37.)

135. However, as part of the renewed interest in patenting a new desmopressin product, employees at Ferring in June and August 1999 offered as ideas "sublingual" orodispersible tablets. (DTX-68 at FERALL0099123; DTX-69 at FERALL0005510.) Given these considerations as part of the NewMin project, Serenity and Reprise have not proven that Fein contributed sublingual administration. Pannu, 155 F.3d at 1351.

136. To the extent Serenity and Reprise argue Fein conceived of lower doses as claimed in the '654 patent because he believed sublingual administration would lead to improved bioavailability, Serenity and Reprise have not proven conception by clear and convincing evidence. Again, Fein's actual testimony is that improved bioavailability would result from "the drug [] dissolving and being directly absorbed into the bloodstream through the capillary bed under the tongue." (D.I. 430 ¶40.) He later admitted sublingual administration does not necessarily result in sublingual absorption. (Trial Tr. at 32:3-5.)

137. By summer 2001, employees at Ferring knew that Zydis's orodispersible technology translated to improved bioavailability of other compounds (e.g., D.I. 401 ¶65; DTX-83 at FERALL0004762) and knew that there was a chance that using Zydis with desmopressin would result in improved bioavailability (DTX-100 at FERALL0119952.) Ferring was already planning the CS004 bioavailability study for the orodispersible tablet. (Trial Tr. at 160:22-161:2.) Thus, other members of the NewMin team were considering sublingual administration and improved bioavailability of the orodispersible form of desmopressin by the time Fein was alleged to have conceived of the idea to pair the two concepts. While Fein could have conceived of the idea that improved bioavailability would be greater with the addition of sublingual administration, for the

reasons explained above, see supra Conclusions of Law Section I.C, Serenity and Reprise have not corroborated this idea.

138. Serenity and Reprise have not proven by clear and convincing evidence that Fein conceived of the general use of lower doses of desmopressin. The idea of low doses based on potency of desmopressin was known in the prior art through the Hammer and Williams references and Nørgaard's articles and presentations prior to 2001. Nartron Corp., 558 F.3d at 1357; Ethicon, 135 F.3d at 1460.

139. Ferring had already by August 2001 hired EMF Consulting to establish dosing amounts for NewMin, and the results of the EMF Consulting tests along with the results of CS004 led to the lower doses in subsequent clinical studies. (Trial Tr. at 735:5-736:1; see id. at 132:10-133:3.)

140. Ferring's outside patent counsel, in filing GB '397, determined that Senderovitz had proposed the low dose portion of the invention. (PTX-393 at Non-AGN00151562.) There is no evidence that this was contested by anyone on the team at the time, including Nardi and Fein, who were still working on the NewMin team.

141. Low doses without sublingual administration are claimed in the '429 patent and claim 1 of the '654 patent and were allowed based in part on the unexpected success of improved bioavailability. Serenity and Reprise have not argued that Fein proposed the concept of improved bioavailability without sublingual administration or absorption.

142. Serenity and Reprise have not proven by clear and convincing evidence that Fein contributed "to the conception of the subject matter" of claims of the patents-in-suit in any manner that was not insignificant in quality. Duncan Parking, 914 F.3d at 1358.

II. Motions to Strike

143. Serenity and Reprise move to strike certain portions of Ferring expert Dr. Byrn's trial testimony disclosing opinions related to the FE-31 study because the testimony exceeds the scope of his opinions set forth in his expert report and direct testimony. The Court has not relied on the limited testimony proposed to be stricken in connection with determining correction of inventorship. The motion to strike will be denied as moot. Cf. Kowalski v. YellowPages.com, LLC, 10 cv 7318, 2012 WL 1097350, at *9, 11 (Mar. 31, 2012).

144. Ferring moves to strike paragraphs 49-54 of Serenity and Reprise's expert David O. Sussman's expert report discussing DTX-12 and DTX-13 on the grounds that the opinions expressed in those paragraphs exceed the scope of Dr. Sussman's expertise. The cited paragraphs relate to the PK/PD presentation given by Nørgaard to the ICCS in 1999. (Trial Tr. at 707:15-22; see D.I. 399 ¶¶35-39.) Dr. Sussman admitted he "do[es]n't consider [him]self an expert in pharmacokinetics," and Dr. Sussman does not have any specific training in pharmacokinetics. (Trial Tr. at 706:6-707:8.) He could not identify the type of graph displayed in Nørgaard's report that he criticized. (Id. at 708:16-21.)

145. The Court finds that Dr. Sussman has no meaningful expertise in pharmacokinetics and excludes his testimony in paragraphs 49-54 of his expert report. See Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 266 (2d Cir. 2002).

CONCLUSION

The Court concludes that counterclaim-plaintiffs have not proven by clear and convincing evidence that Fein contributed a conception to the claimed inventions of the '429 or

'654 patents that was not insignificant in quality. The Court finds in favor of counter-claim defendants Ferring on all claims. The Clerk of Court is directed to enter judgment for Ferring.

SO ORDERED.

P. Kevin Castel
United States District Judge

Dated: New York, New York
September 27, 2019