UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No.: 0:22-cv-61192-WPD

SCILEX PHARMACEUTICALS INC., ITOCHU CHEMICAL FRONTIER CORPORATION, AND OISHI KOSEIDO CO., LTD.,

Plaintiffs,

v.

AVEVA DRUG DELIVERY SYSTEMS, INC.,

Defendant.

COURT'S FINDINGS OF FACT AND CONCLUSIONS OF LAW

THIS CAUSE came before the Court during a four-day bench trial, which took place July 8-11, 2024. The Court has carefully considered the evidence presented, the testimony and credibility of the witnesses, including testimony of retained expert witnesses Dr. John Koleng, Dr. Charles Argoff, and Dr. Mark Prausnitz and fact witnesses Kip Vought (by video), Christopher Adams, Shane Haines, Suresh Khemani and the deposition transcripts of Tatsuya Mori, and Naoyuki Saida, and the arguments of counsel. The Court has considered the credibility of the witness and is otherwise fully advised in the premises.

According to Federal Rule of Civil Procedure 52(a), the Court makes the following Findings of Facts and Conclusions of Law.[1]

[1] To the extent Findings of Fact may be deemed Conclusions of Law, they shall be considered Conclusions of Law. Similarly, to the extent Conclusions of Law may be deemed Findings of Fact, they shall be considered Findings of Fact.

Procedural Posture

1. This action arises under the patent laws, Title 35, United States Code; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. 271(e)(5).

2. This action arose from Defendant Aveva Drug Delivery Systems, Inc. ("Defendant" or "Aveva")'s notification to Plaintiffs Scilex Pharmaceuticals Inc. ("Scilex"), Itochu Chemical Frontier Corporation ("Itochu"), and Oishi Koseido Co., Ltd. ("Oishi") (collectively, "Plaintiffs") by Notice Letter dated May 10, 2022, that it had filed an Abbreviated New Drug Application ("ANDA") No. 217221, seeking approval of a generic version of Scilex's topical lidocaine patch, ZTlido®, before expiration of U.S. Patent Nos. 9,283,174 ("the '174 patent"), 9,925,264 ("the 264 patent"), and 9,931,403 ("the 403 patent") (collectively "Asserted Patents").

3. Scilex is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and place of business at 960 San Antonio Road, Palo Alto, CA 94303.

4. Itochu is a company organized and existing under the laws of Japan, with its principal place of business located at 16th Floor, Itochu Bldg., 5-1, Kita-Aoyama 2-chome, Minato-ku, Tokyo 107-0061, Japan.

5. Oishi is a company organized and existing under the laws of Japan, with its principal place of business located at 1-933, Hon-Machi 1-Chome, Tosu, Saga 841-0037, Japan.

6. Aveva is a corporation organized and existing under the laws of the State of Florida, having offices at 3250 Commerce Parkway, Miramar, FL 33025 and 3200 Commerce Parkway,

Miramar, FL 33025, with packaging operations at 3280 Executive Way, Miramar, FL 33025, and an additional manufacturing site at 10200 NW 67th Street, Tamarac, FL 33321.

7. Plaintiffs filed this action on June, 22, 2022, and filed an Amended Complaint, the operative pleading, on December 27, 2022. *See* [DE's 1, 76 (redacted)/78 (sealed)].

8. Based on a covenant not to sue, in August 2022, the Court dismissed Aveva's counterclaims for non-infringement and invalidity of Plaintiffs' 623, 640 and 749 patents. *See* [DE 32].

9. The Amended Complaint asserted three (3) separate counts: Count I, for Infringement of the 174 Patent Under 35 U.S.C. § 271(e)(2); Count II, for Infringement of the 264 Patent Under 35 U.S.C. § 271(e)(2); and Count III, for Infringement of the 403 Patent Under 35 U.S.C. § 271(e)(2)). *See* [DE's 1, 76 (redacted)/78 (sealed)].

10. Aveva filed an Answer, Separate Defenses, and Counterclaims to Amended Complaint. *See* [DE 84].

11. Plaintiffs filed an Answer to the Counterclaim. *See* [DE 86 (redacted)/89 (sealed)].

12. Defendants Apotex Corp. and Apotex Inc. were dismissed as Defendants pursuant to a Stipulation. *See* [DE 105].

Background

13. Scilex markets a lidocaine topical system product called ZTLido 1.8%.

14. Oishi manufactures ZTlido® in Japan, and Scilex markets and sells ZTlido® in the United States.

15. The FDA approved ZTlido® on February 28, 2018.

16. ZTlido® is indicated for relief of pain associated with post-herpetic neuralgia ("PHN" in adults.

17. All three of the Asserted Patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication (the "Orange Book") Book for Plaintiffs' product ZTLido.

18. According to the Orange Book, the Asserted Patents are set to expire on May 10, 2031.

19. Aveva is seeking FDA approval of a generic lidocaine topical system called Lidocaine Topical System 1.8%.

20. Dermal patches are drug-containing patch products that are applied to the skin to treat a condition by delivering active pharmaceutical ingredients to the desired location.

21. The dermal patches at issue in this case are known as non-aqueous "matrix-type" patches, which contain the drug and adhesive in a single layer.

22. The "plaster" contains all the formulation components, including the drug substance (lidocaine), and may also be referred to as "drug-in-adhesive matrix."

23. Matrix type topical delivery systems can contain an active ingredient dissolved in a mixture of various components and excipients, including solvents, adhesives, permeation enhancers, softeners, solubilizers, plasticizers, tackifiers, and preservatives, and are typically manufactured using solvent, hydrogel or hot-melt based processes.

24. Generally, a solvent is "a substance capable of dissolving another substance (solute) to form a uniformly dispersed mixture (solution) at the molecular or ionic size level."

25. Generally, the term "solubilizer" is a relatively broad term that may refer to at least three types of chemicals. Depending on context, "solubilizer" may refer to a surface-active compound (also called a surfactant), a co-solvent, or a complexation agent.

26. A "co-solvent" can be a substance added to a primary solvent to increase the solubility of a compound.

27. A "surfactant" can be considered a substance that tends to reduce the surface tension of a liquid.

28. Typically, a "complexation agent" alters the solute by binding to it so that the solute-complexation agent complex is more compatible with the solvent.

29. The nature and primary function of a component or excipient in a manufacturing process or topical system may depend on the physical and chemical properties of the component or excipient; its relative amount in the formulation ingredients and finished composition; and the precise context in which it is used.

30. Aveva's "oleyl alcohol" raw material is a mixture of mono-alcohols, including oleyl alcohol, cetyl alcohol, stearyl alcohol, and linoleyl alcohol.

31. Oleyl alcohol is an unsaturated fatty alcohol, a non-ionic surfactant, and a mono-alcohol.

32. Oleyl alcohol is neither an organic acid nor a polyalcohol.

33. N-heptane is a straight-chain alkane.

34. N-heptane is neither an organic acid nor a polyalcohol.

35. Mineral oil is a mixture of higher alkanes.

36. Dipropylene glycol[2] is a polyalcohol.

37. Isostearic acid is an isomeric mixture of saturated, aliphatic branched-chain C18-fatty acids.

38. ZTLido is manufactured using a hot-melt method by completely dissolving lidocaine drug substance in a mixture of an organic acid (isostearic acid) and a polyalcohol (dipropylene glycol) before mixing in a plaster.

39. Aveva's patch is produced by an evaporative solvent method.

[2] Dipropylene glycol (DPG) may be referred to as 2-hydroxy-propyl ether. It is a mixture of three possible structural isomers.

40. In a typical solvent method, ingredients are dissolved and solubilized in a solvent, such as n-heptane or toluene, then the solvent is evaporated to form an adhesive layer.

41. Aveva uses an evaporative solvent method that requires dissolving solid lidocaine drug substance in n-heptane.

42. Aveva's patch uses only n-heptane, as a single solvent, to dissolve solid lidocaine and solubilize the components and plaster.

43. Essentially, Aveva uses four steps to prepare a lidocaine coating liquid solution for its evaporative solvent process. First, Aveva uses n-heptane to solubilize and blend polyisobutylene ("PIB") elastomers ("Blend #1"). Second, in a separate tank, Aveva uses n-heptane (and only n-heptane) to dissolve lidocaine ("Blend #2"). Third, Aveva mixes Blend #1 and Blend #2, along with mineral oil, isostearic acid, BHT, and colloidal silicon dioxide, until uniform. Fourth, Aveva adds terpene and oleyl alcohol, and mixes until uniform.

44. The process used to make Aveva's patch is substantially different than the process used to make ZTLido.

45. Aveva describes n-heptane as a formulation ingredient and solvent in its evaporative process.

46. During evaporation of n-heptane, there is also loss of other materials, including loss of volatile ingredients such as lidocaine.

47. In the "wet blend," there are "overages" added of lidocaine and BHT to compensate for defined process loss.

48. In the "dry state," Aveva's description of the composition of the finished patch product identifies n-heptane as a "Process Solvent" that is "removed during processing."

49. Aveva's finished product specifications, and corresponding analytical test results, show that a small amount of n-heptane remains in Aveva's patch as residual solvent.

50. Aveva's current product specifications require analytical measurement of the amounts of n-heptane, oleyl alcohol and isostearic acid that remain in Aveva's patch.

51. The specification for n-heptane is not more than ("NMT") 6000 ppm.

52. The actual amount of n-heptane in the representative samples of Aveva's patch submitted to FDA ranges from about 3300 to 3500 ppm, which is about 0.3% of the product.

53. Aveva's prescribing information and instructions include "n-heptane 99%" as an inactive ingredient.

Standing

54. Standing is a constitutional requirement pursuant to Article III and a threshold jurisdictional issue. *Havana Docks Corp. v. MSC Cruises SA Co.*, 484 F. Supp. 3d 1177, 1188 (S.D. Fla. 2020); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)).

55. "[P]laintiffs bear the burden of demonstrating that they have standing." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 430-31 (2021).

56. Itochu and Oishi have standing as the lawful owners of the Asserted Patents by assignment of all right, title, and interest in and to the Asserted Patents, including the right to bring infringement suits thereon.

57. "To have co-plaintiff standing in an infringement suit, a licensee must hold some of the proprietary sticks from the bundle of patent rights, albeit a lesser share of rights in the patent than for an assignment and standing to sue alone." *Ortho Pharm. Corp. v. Genetics Institute, Inc.*, 52 F.3d 1026, 1031 (Fed. Cir. 1995).

58. Exclusive licensees, parties who "hold exclusionary rights and interests created by the patent statutes, but not all substantial rights to the patent[,]" may sue as long as the patent owner is joined. *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 (Fed. Cir. 2007)

59. Scilex is the exclusive licensee to the Asserted Patents and has the exclusive right to commercialize ZTlido® within the United States.

60. Scilex is an exclusive licensee, and is co-plaintiff with the lawful assignees, Oishi and Itochu.

61. Plaintiffs met their burden to prove that Scilex has standing.

Claim Construction of "Dissolving Agent"

62. "Claim construction is to be determined by the court." *Trebor Indus., Inc. v. JL Gory, LLC*, No. 09-60214-CIV, 2010 WL 11549686, at *3 (S.D. Fla. Dec. 30, 2010) (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572-73 (Fed. Cir. 1997)).

63. "We consider the claim language, specification, prosecution history, and relevant extrinsic evidence in ascertaining the scope and meaning of the claims." *Reckitt Benckiser Inc. v. Watson Lab'ys, Inc.*, 430 F. App'x 871, 875 (Fed. Cir. 2011) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-17 (Fed. Cir. 2005) (en banc)).

64. Plaintiffs assert Claim 4 of the 174, 264 and 403 patents.

65. Essentially, the asserted claims cover a topical patch where lidocaine is dissolved in a combination of an organic acid (isostearic acid) and a polyalcohol (dipropylene glycol) before mixing that lidocaine solution in a "plaster."

66. The asserted patents describe six examples of the claimed patch, and two comparative examples.

67. Each patent Example provides a list of materials and components, followed by the "production method" to make the example patch, and lastly, the "resultant" final patch.

68. All six examples of the claimed patch describe the use of a combination of an organic acid (*e.g.*, isostearic acid) and a polyalcohol (*e.g.*, dipropylene glycol) to dissolve solid lidocaine drug substance before mixing with adhesives to obtain a "plaster solution."

69. A comparative example describes something that contrasts with and is different from the invention. In patent prosecution, comparative examples are intended to illustrate, by way of contrast, the claimed invention.

70. As such, Comparative Examples 1 and 2 are not covered by the asserted claims.

71. Comparative Example 1 describes the use of Polysorbate 80, as a single solvent, to dissolve lidocaine before mixing with adhesives to obtain a plaster solution. Polysorbate 80 was used to dissolve lidocaine and remain in the plaster solution.

72. Comparative Example 2 describes mixing lidocaine directly with adhesive base components, including 51.3% mineral oil, to obtain a plaster solution. No dissolving agent was used; the entire adhesive mixture was used to dissolve lidocaine.

73. The amount ("mass %") of each component in the Examples and Comparative Examples is summarized in Fig. 3 of the patents.

74. The patents state: "[I]n the present invention, a dissolving agent composed of an organic acid and a polyalcohol was used, and 0.5 to 7 mass % of lidocaine and/or its reactant was mixed in a plaster, thereby producing a non-aqueous patch in which the lidocaine is completely dissolved . . . ."

75. The patents also state that "a small amount of lidocaine is efficiently dissolved, and thereby the lidocaine can be released stably and reliably over a long period of time."

76. The patents further state that the "present invention is focused on a dissolving agent that can efficiently dissolve lidocaine over a long period of time, revealing that a dissolving agent composed of a mixture of an organic acid and a polyalcohol allows continuous and reliable dissolution of lidocaine."

77. Finally, the patents conclude that, where "lidocaine is not sufficiently dissolved and is crystallized; the crystallized lidocaine cannot be efficiently transferred to the skin."

78. The asserted patent claims were prosecuted in the following sequence: the 174 patent (filed February 3, 2014); the 264 patent (filed March 9, 2016); and the 403 patent (filed July 11, 2017).

79. Prosecution of the 174 Patent

a. Oishi's original patent application claims were broad, including because they covered "a dissolving agent composed of an organic acid and a polyalcohol, which are contained in a base."

b. The phrase "composed of" can be interpreted broadly to mean "comprising."

c. The Examiner rejected the original claims as obvious based on two prior art publications, *Hanma* and *Takada*.

d. The Examiner found that *Hanma* disclosed a patch containing both organic acids (such as isostearic acid) and alcohol solvents (including polyalcohols).

e. The Examiner also found that *Takada* disclosed use of polyalcohols, including dipropylene glycol, as "solubilizers."

f. In response to the November 2014 rejection, Oishi both narrowed and confirmed the scope of its claims.

g. In explaining its amendments, Oishi repeatedly distinguished *Hanma*, emphasizing that, in its claimed invention, lidocaine is dissolved in an organic acid and a polyalcohol.

h. In June 2015, the Examiner rejected the March 2015 amended claims as obvious based on an additional prior art publication, *Terahara*.

i. The Examiner found that *Terahara* "teaches a patch comprising . . . lidocaine" and an "adhesive layer . . . including isostearic acid (organic acid and dissolving agent)" and "dipropylene glycol (polyalcohol and dissolving agent)."

j. In response to the Examiner's June 2015 rejection based on *Terahara*, Oishi maintained its March 2015 claims, and argued that *Terahara* "provides no motivation, nor any reasonable expectation of success, to one skilled in the art to combine the particular compounds in the particular concentrations and ratios as instantly claimed."

k. Oishi did not dispute the Examiner's description of isostearic acid and dipropylene glycol in *Terahara*.

l. The Examiner rejected Oishi's July 2015 arguments.

m. In response to the August 2015 rejection, Oishi's lawyer at the time, Mr. Smith, requested an interview with the Examiner, which occurred on October 23, 2015.

n. The Examiner summarized that interview as follows:

Mr. Smith discusses the teachings of Terahara. It was noted that Terahara requires the use of certain components in order to dissolve the lidocaine, which are not required in the instant claims. Terahara additionally requires certain polymeric materials, which are not included in the instant

claims. It was noted by the Examiner that applicant is employing the use of comprising language, and it was suggested that Applicant amend to recite consisting of language or possible exclusionary language in an after final amendment.

o. In response to the August 2015 rejection, and based on the results of the October 2015 interview, Oishi amended and confirmed the scope of its claims, and further distinguished *Terahara*.

p. Oishi's amendments included narrowing the "dissolving agent" phrase from "composed of" to "consisting of" and "consists of."

q. The phrase "consisting of" signifies restriction and exclusion of unrecited steps or components.

r. Oishi also added a dependent claim, as suggested by the Examiner, to confirm that its claimed invention does not contain the "a basic nitrogen-including polymer nor does the plaster contain 2-ethylhexyl acrylate-vinyl acetate copolymer" described in *Terahara*, as supported by the absence of those two types of polymers from Examples 1-6.

s. In explaining the amendments and distinguishing *Terahara*, Oishi directed the Examiner to Example 3, including the use of only isostearic acid and dipropylene glycol to dissolve lidocaine to "separately" prepare a lidocaine "solution," and Examples 1-6 to confirm the absence of two types of *Terahara* polymers.

t. Oishi also confirmed the substance of the October 23, 2015 interview, including that Oishi distinguished *Terahara* from its claimed invention by stating "Terahara uses a solvent to solubilize the components."

u. In explaining the amendments and distinguishing *Terahara*, Oishi stated: "Claim 1 has been amended to provide that the dissolving agent consists only of an organic acid and a polyalcohol. This is not taught in *Terahara*. In fact *Terahara* uses toluene…to solubilize the plaster."

v. Oishi again relied on its patent Examples to confirm the scope of "[t]he present invention," which did not include use of the two types of *Terahara* polymers, "as evidenced in the Examples."

w. In the context of Oishi's October 29, 2015 arguments to the Examiner, and the Examiner's descriptions of *Terahara*, it is clear that the "additional dissolving agents" in *Terahara* include toluene, which Oishi argued is used to "solubilize the plaster."

x. Based on Oishi's October 29, 2015 amendments and arguments, the Examiner allowed the 174 patent claims, as distinguished from *Hanma*, *Takada* and *Terahara*.

80. Prosecution of the 264 Patent

a. Oishi filed the application leading to the 264 patent in March 2016.

b. Oishi began prosecution of the 264 patent by amending its claims, consistent with its amendments and arguments during prosecution of the 174 patent.

c. The Examiner originally rejected the claims for "double patenting," in view of the 174 patent.

d. Oishi overcame the double patenting rejection by filing a "terminal disclaimer."

e. Oishi's terminal disclaimer means that, to obviate the double patenting rejection, Oishi conceded the 264 patent claims are "not patentably distinct," and agreed that they would expire at the same time as the 174 patent.

f. Oishi also amended then-pending claim 1 to include the phrase "consisting essentially of" instead of "consisting of," but Oishi emphasized: "*No new matter is added*." (italics in original).

g. The phrase "consisting essentially of" permits inclusion of components not listed in the claim, provided they do not materially affect the basic and novel properties of the invention.

81. Prosecution of the 403 Patent

a. Oishi filed the application leading to the 403 patent in July 2017, as a continuation of the application leading to the 174 patent.

b. The claims were substantially the same as those of the 174 patent.

c. The Examiner requested a terminal disclaimer based on the 174 patent and the then-pending 264 patent application.

d. After Oishi filed a terminal disclaimer, the Examiner allowed the 403 patent claims, repeating the substance of the previous allowance.

82. In summary of the patent prosecution, the U.S. Patent Office rejected the original application claims based on prior art patches merely containing various organic acids and polyalcohols.

83. To overcome those rejections and obtain the asserted claims, Plaintiffs added claims 6 and 9 to confirm the function of the claimed "dissolving agent," and repeatedly represented the

following to the U.S. Patent Office, and to the public, that "In the present invention lidocaine is dissolved in an organic acid and a polyalcohol."

84. "In construing the meaning of claim terms, courts must first examine the patent's intrinsic evidence." *Trebor*, 2010 WL 11549686, at *3 (citing *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

85. "Intrinsic evidence includes the claim language, the specification, and the prosecution history." *Id.* (citing *Vitronics*, 90 F.3d at 1582; *Housey Pharms., Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1352 (Fed. Cir. 2004)). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Id.* (citing *Vitronics*, 90 F.3d at 1582).

86. "It is well settled that a patentee may define a claim term either in the written description of the patent or . . . in the prosecution history." *Honeywell Inc. v. Victor Co. of Japan*, 298 F.3d 1317, 1323 (Fed. Cir. 2002).

87. "The starting point for any claim construction must be the claims themselves." *Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999).

88. All asserted claims require a "dissolving agent . . . contained in a plaster." In addition, each of the asserted patents includes dependent claims requiring that lidocaine is "completely dissolved in the dissolving agent" and, separately, that lidocaine is "completely dissolved in the plaster."

89. A person of ordinary skill in the art ("POSA") "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313.

90. With respect to the Asserted Patents, a POSA would hold an educational degree like a Ph.D. or an equivalent in an area such as pharmaceutics or related disciplines, like chemistry or medicinal chemistry, plus two or more years of experience in pharmaceutical formulations including topical and/or transdermal drug delivery formulations. In addition, a POSA may have a less formal education but have more years of experience. For instance, they may have a master's or an equivalent in combination with, say, three to five or more years in pharmaceutical formulations. Because drug development is multidisciplinary, a POSA would have access to consult other members of a development team such as a physician with additional expertise.

91. A POSA would read and understand claims 1, 6 and 9 together to mean that claim 1 requires that the claimed "dissolving agent" dissolves lidocaine, and that claim 1 allows less than complete dissolving of lidocaine in the "dissolving agent," as well as the possibility of less than complete dissolving of lidocaine in the "plaster," even after the "dissolving agent" is "contained" in the "plaster."

92. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Thus, the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582.

93. "[I]n case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and meaning of the language employed in the claims." *Phillips*, 415 F.3d at 1315 (quoting *Bates v. Coe*, 98 U.S. 31, 38 (1878)).

94. The patents describe a problem with prior art non-aqueous patches: "These non-aqueous patches have poor permeability to the skin because the lidocaine is not dissolved and is present in a crystalline state."

95. The patents state a "Solution to Problem":

a. "Accordingly, in the present invention, a dissolving agent composed of an organic acid and a polyalcohol was used, and 0.5 to 7 mass% of lidocaine and/or its reactant was mixed in a plaster, thereby producing a non-aqueous patch in which the lidocaine is completely dissolved…"

b. "According to the present invention, a small amount of lidocaine is efficiently dissolved, and thereby the lidocaine can be released stably and reliably over a long period of time."

c. "Particularly, the present invention is focused on a dissolving agent that can efficiently dissolve lidocaine over a long period of time, …"

96. All six examples of the claimed invention, Examples 1-6, describe dissolving the lidocaine using the claimed "dissolving agent" combination of an organic acid and a polyalcohol.

97. All six examples of the claimed invention, Examples 1-6, describe the amount of the claimed "dissolving agent" used to dissolve lidocaine, including by a ratio of lidocaine to dissolving agent.

98. In contrast, Comparative Example 1 uses a single solvent to dissolve lidocaine, and Comparative Example 2 uses the entire adhesive mixture to dissolve lidocaine.

99. Figure 3 is a "chart of formulations" showing the percentage of each "component" used to make Examples 1-6, as well as Comparative Examples 1 and 2.

100. A POSA would understand the amounts in Figure 3 are not measurements of the amount of each ingredient remaining in each patent Example; instead, they are the "formulation" amounts that were "mixed" and "dissolved" to prepare each Example.

101. "[I]n addition to the specification, the prosecution history must be considered in construing claims." *Pall Corp. v. PTI Techs., Inc*., 259 F.3d 1383, 1391 (Fed. Cir. 2001) (citing cases), *vacated and remanded on other grounds*, 535 U.S. 1109 (2002).

102. The prosecution history "consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Phillips,* 415 F.3d at 1317.

103. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips,* 415 F.3d at 1317.

104. A court "must also examine the prosecution history to determine whether the patentee has relinquished a potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference." *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001).

105. The "case law does not require explicit redefinition or disavowal." *Trustees of Columbia Univ. in City of New York v. Symantec Corp*., 811 F.3d 1359, 1363 (Fed. Cir. 2016);

106. "The prosecution history is considered to determine whether or not there were any express representations made in obtaining the patent regarding the scope and meaning of the claims." *Bell*, 262 F.3d at 1268 (citing *Vitronics*, 90 F.3d at 1582).

107. "[A]ny explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to 'capture the scope of the actual invention' that is disclosed, described, and patented." *Aptalis Pharmatech, Inc. v. Apotex Inc.*, 718 F. App'x 965, 971 (Fed. Cir. 2018) (quoting *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1323 (Fed. Cir. 2015).

108. The prosecution history of any parent or grandparent application applies with equal force to subsequently issued patents, unless expressly rescinded. *See Biovail Corp. Int'l v. Andrx Pharms., Inc*., 239 F.3d 1297, 1301 (Fed. Cir. 2001).

109. In the prosecution history, to overcome the August 2015 rejection, and based on the results of the October 2015 interview, and to further distinguish the prior art *Terahara,* Oishi's amendments included narrowing the "dissolving agent" phrase from "composed of" to "consisting of" and "consists of," making the reason for this amendment not "tangential" to the accused equivalent.

110. In the prosecution history, the Examiner and Oishi correctly described the prior art publications *Hanma*, *Takada* and *Terahara*, and Oishi clearly and unmistakably distinguished those references based on its claimed "dissolving agent" actually dissolving lidocaine, as confirmed and illustrated by Oishi's patent Examples and Comparative Examples.

111. *Hanma* and *Takada*, read together, describe patches containing lidocaine, an organic acid, and a polyalcohol. And *Terahara*, standing alone, describes patches containing lidocaine, an organic acid, and a polyalcohol. Faced with that prior art, Oishi clearly and unmistakably confirmed that its "dissolving agent" (and only its "dissolving agent") dissolves lidocaine to distinguish *Hanma*, *Takada* and *Terahara*, and to overcome the Examiner's obviousness rejections.

112. During prosecution of the asserted patents, Oishi made clear that the claimed "dissolving agent" dissolves the lidocaine to distinguish prior art and obtain allowance of the asserted claims.

113. Thus, the Court finds that the prosecution record confirms that a POSA would understand the claimed "dissolving agent" both dissolves the lidocaine and prevents crystallization of lidocaine.

114. Based on the intrinsic evidence set forth above, the Court finds that the claims, written description and prosecution history make clear that a POSA would understand the claimed "dissolving agent" dissolves the lidocaine and prevents crystallization of lidocaine, including because Oishi distinguished its claimed invention from *Hanma*, *Takada* and *Terahara* and overcame prior art rejections based on the dissolving function of the claimed "dissolving agent."

115. "Only when the intrinsic evidence is insufficient to establish the clear meaning of the asserted claim, does the court turn to extrinsic evidence." *Trebor*, 2010 WL 11549686, at *3 (citing *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408, 1414 (Fed. Cir. 2000)).

116. "Extrinsic evidence includes expert testimony, inventor testimony, dictionaries, treatises, and prior art not cited in the prosecution history." *Id.* (citing *Zodiac*, 206 F.3d at 1414).

117. "Extrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

118. Here, although the Court need not consider the extrinsic evidence to evaluate a POSA's understanding of the claimed "dissolving agent," the Court finds that extrinsic evidence

provides further support that the claimed "dissolving agent" both dissolves the lidocaine and prevents crystallization of lidocaine. This extrinsic evidence includes but is not limited to:

a. Plaintiffs' descriptions of ZTLido to the FDA in various documents confirming that the "dissolving agent" dissolves lidocaine—*i.e.*, the claimed organic acid (such as isostearic acid) and polyalcohol (such as dipropylene glycol) function together as co-solvents to dissolve lidocaine, and then are mixed and contained in the plaster.

b. Oishi's February 2010 solvent study (which preceded filing of the asserted patents) using a "dissolving test," in which Oishi identified both dipropylene glycol and isostearic acid as a "solvent" and evaluated the "results of the dissolving test" as to whether it obtained "complete dissolution and no crystal."

c. During prosecution of the 640 patent (a closely related patent for which Plaintiffs filed a terminal disclaimer to obviate a double-patenting rejection of the 640 patent based on the asserted patents), to overcome prior art, counsel for Plaintiffs represented to the U.S. Patent Office that Oishi's "dissolving agent" is "used to dissolve the lidocaine and prevent crystallization of lidocaine."

Infringement

119. Plaintiffs have the burden of proving infringement by a preponderance of the evidence, *i.e.*, that it is "more likely than not" that the accused infringing product meets the limitations of the claims. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

120. In Hatch-Waxman cases, the question of infringement is a hypothetical one; "[t]he relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the

alleged infringer will likely market an infringing product." *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997). "What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists." *Id.*

121. Infringement is a question of fact. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.,* 418 F.3d 1326, 1340 (Fed. Cir. 2005); *see also Trebor*, 2010 WL 11549686, at *3 ("Application of the properly construed claim to the accused [product] is a question of fact.").

Literal Infringement

122. "Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device, *i.e.*, when the properly construed claim reads on the accused device exactly." *Cole v. Kimberly-Clark Corp*., 102 F.3d 524, 532 (Fed. Cir. 1996).

123. A dependent claim "shall be construed to incorporate by reference all the limitations of the claim to which it refers." 35 U.S.C. § 112(d).

124. "One who does not infringe an independent claim cannot infringe a claim dependent on . . . that claim." *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 798 (Fed. Cir. 1990) (quotation omitted).

125. At trial, Plaintiffs conceded that Aveva's patch does not literally infringe the asserted claims.

126. At trial, the Court granted Aveva's Motion pursuant to Fed. R. Civ. P. 52(c) for judgment as a matter of law as to no literal infringement in favor of Aveva.[3]

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[3] THE COURT: What's plaintiffs' position on the literal infringement?

MR. SUKDUANG: Your Honor -- with respect to literal infringement, Your Honor, as we indicated during the opening and through witnesses, we do not present a literal infringement position. It's doctrine of equivalence.

THE COURT: All right. So I'm going to grant the Rule 52 on literal infringement. We'll go forward on the doctrine of equivalence.

Tr. at 316:24—317:7.

127. Aveva's patch does not literally infringe the asserted claims because it does not contain any polyalcohol.

128. Aveva's patch does not literally infringe because it does not contain the claimed "dissolving agent."

129. The claimed "dissolving agent" must dissolve the lidocaine. Because Aveva uses only a single solvent, n-heptane, to dissolve the lidocaine, Aveva's patch does not infringe.

130. The Court finds and concludes that Aveva's patch does not literally infringe any of the asserted claims.

Infringement under the Doctrine of Equivalents

131. The Doctrine of Equivalents, an alternate method for proving infringement of a patent claim, is well-described as follows:

> A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents "if every element in the claim is literally or equivalently present in the accused device." *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997). This doctrine prevents an accused infringer from making only minor, insubstantial changes from the claimed invention to avoid infringement, while attaining the same functionality. Id. Equivalency under 35 U.S.C. § 112, supra, differs from, and should not be confused with, the doctrine of equivalents. *Valmont Industries, Inc. v. Reinke Mfg. Co., Inc.*, 983 F.2d 1039, 1042-43 (Fed. Cir. 1993).
>
> The essential inquiry under the doctrine of equivalents is whether "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). "An element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." *Eagle Comtronics, Inc. v. Arrow Commc'n Labs., Inc.*, 305 F.3d 1303, 1315 (Fed. Cir. 2002) (citing *Warner-Jenkinson*, 520 U.S. at 40); *see also Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950) ("*Graver II*"). As with literal infringement, infringement by equivalents is a question of fact. *Warner-Jenkinson*, 520 U.S. at 38.

Trebor Indus., Inc. v. JL Gory, LLC, No. 09-60214-CIV, 2010 WL 11549686, at *7 (S.D. Fla. Dec. 30, 2010).

132. Under the all elements rule, "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co*., 520 U.S. 17, 29 (1997).

133. Like the use of toluene in *Terahara*, Aveva uses n-heptane for dissolving solid lidocaine and solubilizing the components and plaster.

134. Like the use of Polysorbate 80 in Comparative Example 1, Aveva uses n-heptane, as a single solvent, to dissolve lidocaine.

135. Aveva's use of n-heptane for dissolving lidocaine is not equivalent to use of the claimed "dissolving agent" for dissolving lidocaine, including because n-heptane is a single solvent, like the single solvent described in *Terahara* and Comparative Example 1.

136. Aveva's patch is produced by an evaporative solvent method, like that in *Terahara,* a prior art cited by the Examiner.

137. Aveva's patch uses only n-heptane, as a single solvent, to dissolve solid lidocaine and solubilize the components and plaster, like Oishi Comparative Example 1 and like the use of toluene as a single solvent in *Terahara*.

138. While the patent examples and ZTLido use a hot melt method that requires dissolving lidocaine in, for example, isostearic acid and dipropylene glycol, Aveva uses an evaporative solvent method that requires dissolving solid lidocaine drug substance in n-heptane.

139. N-heptane is neither an organic acid nor a polyalcohol.

140. N-heptane, either alone or in combination with any other component, is not equivalent to any claimed "dissolving agent."

141. N-heptane is not equivalent to either an organic acid or a polyalcohol.

142. Therefore, finds and concludes that Aveva's patch cannot infringe because it does not contain any equivalent to the claimed "dissolving agent."

143. The process used to make Aveva's patch is substantially different than the process described in the patents, and the process used to make ZTLido.

144. The composition of Aveva's patch is substantially different than the compositions described in the patents, and the composition of ZTLido.

145. Prosecution history estoppel stands "as a legal limitation on the doctrine of equivalents." *Warner-Jenkinson*, 520 U.S. at 30.

146. "Once prosecution history estoppel limits the scope of a patent, the patentee may not recover for infringement where infringement would require an equivalence between a claim element and an aspect of the accused item that falls within the estoppel." *Wang Lab'ys Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1578 (Fed. Cir. 1997) (citing *Southwall*, 54 F.3d at 1579).

147. "The logic of prosecution history estoppel is that the patentee, during prosecution, has created a record that fairly notifies the public that the patentee has surrendered the right to claim particular matter as within the reach of the patent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 564-65 (Fed. Cir. 2000) ("*Festo VI*"), *vacated on other grounds*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) ("*Festo VIII*").

148. "Whether prosecution history estoppel applies to limit the doctrine of equivalents is a question of law . . . ." *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc*., 170 F.3d 1373, 1376 (Fed. Cir. 1999).

149. "Prosecution history estoppel can occur in two ways: 'either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel').'" *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1159 (Fed. Cir. 2019) (quoting *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006).

150. "Arguments and amendments made to secure allowance of a claim, especially those distinguishing prior art, presumably give rise to prosecution history estoppel." *Wang Lab'ys*, 103 F.3d at 1578 (citing *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211 (Fed. Cir. 1995)).

151. "Arguments made during the prosecution of a patent application are given the same weight as claim amendments." *Elkay Mfg. Co. v. Ebco Mfg. Co*., 192 F.3d 973, 979 (Fed. Cir. 1999).

152. To invoke argument-based estoppel, the prosecution history must evince a "clear and unmistakable surrender of subject matter." *Pharmacia*, 170 F.3d at 1376-77. "[C]lear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may also create an estoppel . . . because [t]he relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Pharma Tech Sols., Inc. v. LifeScan, Inc.*, 942 F.3d 1372, 1380-81 (Fed. Cir. 2019) (quoting *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed. Cir. 2007)).

153. "A patentee of course may not recapture during litigation subject matter that was ultimately rejected as unpatentable during prosecution, nor may the patentee adopt a position contradictory to that adopted before the PTO and expect to be believed." *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1329 (Fed. Cir. 2003).

154. A POSA would understand the patent prosecution record shows that Oishi clearly and unmistakably disclaimed use of anything other than a "dissolving agent consisting of an organic acid and polyalcohol" to dissolve lidocaine.

155. Oishi did not claim a single solvent to dissolve lidocaine. Instead, Oishi distinguished use of a single solvent in Comparative Example 1, and, to obtain allowance of the asserted claims, clearly and unmistakably (and repeatedly) disclaimed use of anything other than the claimed "dissolving agent" combination of an organic acid and polyalcohol to dissolve lidocaine.

156. The Court finds and concludes that Oishi clearly and unmistakably disclaimed use of anything other than a dissolving agent consisting essentially of an organic acid and a polyalcohol.

157. Because Aveva's patch does not contain a polyalcohol, Aveva's patch does not infringe.

158. In the context of Oishi's prosecution record, Aveva's use of n-heptane as a single solvent to dissolve lidocaine and solubilize components is comparable to the use of toluene in *Terahara*, and to the use of Polysorbate 80 in Comparative Example 1.

159. Because Oishi distinguished the use of toluene in *Terahara* from its claimed invention, and the Examiner accepted Oishi's distinction and relied on what the Examiner described as "additional dissolving agents" in *Terahara* to allow the asserted claims, the Court

finds that Aveva's use of n-heptane does not infringe, and cannot be considered equivalent to the claimed "dissolving agent."

160. The Court finds and concludes that Aveva's patch does not infringe any asserted claim because Aveva does not use either an organic acid or a polyalcohol to dissolve lidocaine, and n-heptane is not equivalent to the claimed "dissolving agent."

161. The "all elements rule" provides that the doctrine of equivalents does not apply if applying the doctrine would vitiate an entire claim limitation. *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) *see also Warner-Jenkinson*, 520 U.S. at 39 n.8) ("[I]f a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court . . . .").

162. "Claim vitiation applies when there is a 'clear, substantial difference or a difference in kind' between the claim limitation and the accused product." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1355 (Fed. Cir. 2010); *see also Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1339 (Fed. Cir. 2011) ("[F]inding a signal from one source to be equivalent to 'signals from a plurality of sources' would vitiate that claim limitation by rendering it meaningless. Such a theory of equivalence is legally insufficient."); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1347 (Fed. Cir. 2001) ("[I]f a patent states that the claimed device must be 'non-metallic,' the patentee cannot assert the patent against a metallic device on the ground that a metallic device is equivalent to a non-metallic device. The unavailability of the doctrine of equivalents could be explained either as the product of an impermissible vitiation of the 'non-metallic' claim limitation, or as the product of a clear and binding statement to the public that metallic structures are excluded from the protection of the patent.").

163. An equivalent of a missing claim element or limitation is found only if "'insubstantial differences' distinguish the missing claim element from the corresponding aspects of the accused device." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997)).

164. Aveva's oleyl alcohol component, a mono-alcohol, is substantially different than the claimed polyalcohol, dipropylene glycol.

165. Aveva's oleyl alcohol component does not provide substantially the same function, in substantially the same way, with substantially the same result as the claimed polyalcohol, dipropylene glycol.

166. At a basic level, the molecular structures and physicochemical properties of oleyl alcohol and the claimed polyalcohol are substantially different.

167. The claimed polyalcohols (including dipropylene glycol) are hydrophilic but oleyl alcohol is hydrophobic.

168. Plaintiffs' original United States application claims were expressly limited to "polyalcohol."

169. Mono-alcohols, including oleyl alcohol, were in the prior art at the time of Plaintiffs' original United States patent application claims, and at the time of their amendments of those claims.

170. The prior art cited by the Examiner described the use of mono-alcohol solvents in a patch formulation, including specifically use of an "oleyl alcohol" component,

171. Oishi did not disclose, describe or attempt to claim any set, or subset, of mono-alcohols in its patent applications or during prosecution of the asserted patents, despite studying several mono-alcohols.

172. A POSA would consider the use of mono-alcohols, including oleyl alcohol, in a non-aqueous patch to be foreseeable at the time of the original patent application claims and amendments.

173. The words "solubilize," "solubilizer," and "co-solubilizer" do not appear in the asserted patents. The words "solubilizer" and "solubilize" appear in the prosecution record, but only by reference to the content of the prior art.

174. The original application claims allowed other "dissolving agent" components, including other types of lidocaine solvents, but the narrowed "dissolving agent," in response to the Examiner's rejections, excluded any such additional components.

175. Based on the evidence that Oishi studied several mono-alcohols before limiting its patent application and claims to polyalcohols, the Court concludes that the accused mono-alcohol, oleyl alcohol, is not "tangential" to Oishi's narrowing of the "dissolving agent" to polyalcohols.

176. In light of the facts found by the Court in this case, finding a mono-alcohol to be equivalent to the specifically claimed polyalcohol (dipropylene glycol) would vitiate the polyalcohol limitation and render it meaningless.

177. The unavailability of the doctrine of equivalents to expand the "polyalcohol" and "dipropylene glycol" limitations to cover a mono-alcohol is based on impermissible vitiation, as well as the Examiner's acceptance of Oishi's clear and binding arguments limiting the claims to "polyalcohol."

178. The Court finds and concludes that Plaintiffs' doctrine of equivalents theory that a mono-alcohol (oleyl alcohol) could be equivalent to the claimed polyalcohol, dipropylene glycol, would vitiate the "polyalcohol" and "dipropylene glycol" claim limitations.

179. Plaintiffs are therefore precluded from expanding the asserted claims to cover the accused mono-alcohol, oleyl alcohol.

180. The Court finds and concludes that Aveva's oleyl alcohol (a mono-alcohol) is not equivalent to a specifically claimed "polyalcohol," "dipropylene glycol," under the doctrine of equivalents.

181. The Court finds, therefore, as a matter of law, that Aveva's use of a mono-alcohol component (oleyl alcohol) is not equivalent to, and does not infringe, the "polyalcohol" and "dipropylene glycol" limitations of the asserted patent claims.

182. Plaintiffs' "solubilizer" and "co-solubilizer" theories of equivalent infringement, that the isostearic acid and oleyl alcohol are co-solubilizers in Aveva's patch, and therefore function in the same way with the same result as the claimed "dissolving agent," is not adopted but rather is rejected by the Court as (a) foreclosed by the doctrine of equivalents based on impermissible claim vitiation as described above; (b) foreclosed by prosecution history estoppel because, *inter alia,* the Examiner accepted Oishi's clear and unmistakable disclaimer of "additional dissolving agents," and at least n-heptane and mineral oil would be additional "dissolving agents" in Aveva's patch[4]; and (c) equating the claimed "dissolving agent" with what Plaintiffs' contend is a "solubilizer" or "co-solubilizer" was not proven by a preponderance of the evidence at trial.

183. Because Oishi repeatedly distinguished prior art by making clear that its "dissolving agent" dissolves lidocaine, and the Examiner accepted and acknowledged those distinctions in allowing the patents, the Court finds and concludes that Plaintiffs cannot broaden the claims by re-defining the claimed "dissolving agent" to mean "solubilizer" or "co-

[4] The Court finds and concludes that, according to Plaintiffs' "solubilizer" theory, Aveva's patch would contain at least three to four "solubilizers": (1) isostearic acid; (2) oleyl alcohol; (3) n-heptane; and (4) mineral oil.

solubilizer" for the purpose of Plaintiffs' equivalent infringement claims in this case. If the Court were to accept Plaintiffs' arguments, then the claimed patch would merely contain an organic acid and a polyalcohol, like prior art patches identified by the Examiner.

184. Even if Plaintiffs' "co-solubilizer" theory of equivalents were not precluded by argument-based estoppel and vitiation, the Court would conclude that Plaintiffs did not meet their burden to prove that the accused oleyl alcohol component in Aveva's patch is equivalent to the specifically claimed polyalcohol, dipropylene glycol.

185. The claimed "dissolving agent" functions to dissolve lidocaine, but Aveva does not use olelyl alcohol or isostearic acid to dissolve the lidocaine.

186. In Aveva's patch, neither olelyl alcohol or isostearic acid function, either separately or together, as the claimed "dissolving agent."

187. Plaintiffs did not meet their burden to show that Aveva's patch contains the claimed "dissolving agent," or an equivalent to the claimed "dissolving agent."

188. Based on the foregoing, Aveva's patch does not infringe claim 4 of the 174 patent, claim 4 of the 264 patent, or claim 4 of the 403 patent.

Induced Infringement and Contributory Infringement

189. For the reasons set forth above, the Court finds and concludes that Aveva's lidocaine topical system 1.8% does not infringe the asserted patent claims, under literal infringement or equivalent infringement.

190. Liability for either induced infringement or contributory infringement requires, as a prerequisite, direct infringement by another. *See, e.g.*, *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 920-22 (2014) ("[A]s both the Federal Circuit and respondents admit,

where there has been no direct infringement, there can be no inducement of infringement under § 271(b).").

191. Because Plaintiffs did not meet their burden to prove that Aveva's patch infringes the asserted claims, there is no direct infringement, and thus no indirect infringement.

192. To prove induced infringement, a plaintiff must establish, by a preponderance of the evidence, that "the defendant possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc* in relevant part) (quoting *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990)).

193. The Court concludes that Plaintiffs did not meet their burden to prove specific intent to encourage another's infringement.

194. To the contrary, the evidence at trial proved that Aveva specifically intended to design around the asserted patents and succeeded in doing so. *See State Indus., Inc. v. A.O. Smith Corp*., 751 F.2d 1226, 1235–36 (Fed. Cir. 1985) ("keeping track of a competitor's products and designing new and possibly better or *cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent system is its so-called "negative incentive" to "design around" a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace."

195. To prove contributory infringement, Plaintiffs must establish, by a preponderance of the evidence, that "1) there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) that the component has no substantial noninfringing uses, and 4) that the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010) (citing 35 U.S.C. § 271(c)).

196. Because Plaintiffs did not meet their burden to prove direct infringement, there is no contributory infringement.

Conclusion

197. Based on the foregoing Findings of Fact and Conclusions of Law, Defendant Aveva is entitled to judgment in its favor on Plaintiffs' claims for infringement.

198. Pursuant to Federal Rule of Civil Procedure 58(a), the Court shall enter a separate final judgment.

DONE AND ORDERED in Chambers, in Fort Lauderdale, Broward County, Florida, this 26th day of August, 2024.

WILLIAM P. DIMITROULEAS
United States District Judge

Copies provided to:

Counsel of Record