

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

HOPE MEDICAL ENTERPRISES, INC.	:	CIVIL ACTION
	:	
v.	:	NO. 22-978
	:	
ACCORD HEALTHCARE, INC.	:	

MEMORANDUM

MURPHY, J.*

October 13, 2026

This is a patent-infringement case brought under the Hatch-Waxman Act. Hope Medical Enterprises, Inc. sued Accord Healthcare, Inc. for patent infringement under 35 U.S.C. § 271(e)(2). At trial, Accord offered defenses of noninfringement, obviousness, lack of written description, and prosecution laches. This memorandum summarizes the disputes and sets out our findings of fact and conclusions of law. We find for Hope in all respects and enter judgment accordingly.

I. PROCEDURAL HISTORY AND CLAIM CONSTRUCTION

Hope filed a complaint for patent infringement arising out of Accord’s submission of an abbreviated new drug application (ANDA) to the FDA seeking approval to launch its generic version of Hope’s sodium thiosulfate injection. DI 1. Hope asserted U.S. patent nos. 8,496,973 (the 973 patent); 9,345,724 (the 724 patent); 9,585,912 (the 912 patent); and 10,479,686 (the 686 patent). *Id.* ¶ 1. Hope later added U.S. patent no. 11,753,301 (the 301 patent), DI 62 ¶ 1, and at some point dropped the 686 and 912 patents, DI 154 at 1; DI 156 at ¶¶ I-II; DI 157 (July 31, 2024). As trial approached, the parties entered into a stipulation that the asserted claims 7 and 9

* Judge John Frank Murphy, of the United States District Court for the Eastern District of Pennsylvania.

of the 724 patent would rise and fall with asserted claims 7 and 9 of the 973 patent, respectively. DI 170 at ¶¶ 1-4; DI 172. The case went to trial on infringement and invalidity of claims 5-13 and 16-17 of the 301 patent and claims 7 and 9 of the 973 patent, with certain other claims swept in by stipulation:

Claims to be Tried	Corresponding Claims
5-13 of the '301 patent	22 of the '301 patent
5-13, 16 of the '301 patent	23 of the '301 patent
12 of the '301 patent	14 of the '301 patent
13 of the '301 patent	15 of the '301 patent
17 of the '301 patent	18 of the '301 patent
6, 16, 17 of the '301 patent	19 of the '301 patent
7 of the '973 patent	7 of the '724 patent
9 of the '973 patent	9 of the '724 patent

DI 170 at ¶¶ 1-4. Unless otherwise specified, the term “asserted claims” in this opinion means all the claims at stake: claims 5-19, 22, and 23 of the 301 patent; claims 7 and 9 of the 973 patent; and claims 7 and 9 of the 724 patent. *Id.* This decision, therefore, will discuss the following claims:

301 patent:

5. A pharmaceutical composition comprising pharmaceutical grade sodium thiosulfate in an aqueous pharmaceutically acceptable carrier, wherein the sodium thiosulfate used to prepare the pharmaceutical composition
 - contains no greater than about 10 ppm of non-purgeable organic carbon,
 - contains no greater than about 0.05 ppm of mercury,
 - contains no greater than about 2 ppm of aluminum,
 - contains no greater than about 0.003% by weight of selenium,
 - contains no less than about 98% by weight and no greater than about 102% by weight of sodium thiosulfate on an anhydrous basis measured by ion chromatography,
 - has a heavy metal content of no greater than about 10 ppm,
 - contains no greater than about 200 ppm of chloride,
 - contains no greater than about 0.001% by weight of sulfide,
 - contains no greater than about 0.002% by weight of iron,
 - contains no greater than about 0.01% by weight of calcium,
 - contains no greater than about 0.005% by weight of potassium,
 - contains no greater than about 0.1% by weight of sulfite,
 - contains no greater than about 0.5% by weight of sulfate,
 - contains no greater than about 3 ppm of arsenic,

contains no greater than about 0.001% by weight of lead,
has total aerobic count of microbial load of no greater than about 100 CFU/g,
has total yeast and mold count of no greater than about 20 CFU/g,
contains no greater than about 0.02 EU/mg of bacterial endotoxins,
contains no greater than about 0.002% by weight of nitrogen compounds,
contains no greater than about 0.005% by weight of insoluble matter,
contains no greater than 0.01% by weight of residual anti-caking agent,
and
contains no greater than ICH Q3C (R3) limits of organic volatile impurities.

6. The pharmaceutical composition of claim 5, wherein the aqueous pharmaceutically acceptable carrier is sterile water for injection.
7. The pharmaceutical composition of claim 6, wherein the pharmaceutical grade sodium thiosulfate contains no greater than about 8 ppm of non-purgeable organic carbon.
8. The pharmaceutical composition of claim 6, wherein the composition is formulated for oral, parenteral, inhalation, nasal, intravesical, vaginal, rectal, sublingual, ophthalmic, or topical administration.
9. The pharmaceutical composition of claim 8, wherein the composition is formulated for parenteral administration.
10. The pharmaceutical composition of claim 9, wherein the composition is formulated as a single dosage form.
11. The pharmaceutical composition of claim 6, further comprising an isotonic agent and one or more pH adjusting agents.
12. The pharmaceutical composition of claim 11, which is sterile and suitable for intravenous administration, wherein the isotonic agent is potassium chloride, present at about 4.40 mg/mL and the pH adjusting agents are boric acid, present at about 2.80 mg/mL, and sodium hydroxide.
13. The pharmaceutical composition of claim 12, wherein the pharmaceutical grade sodium thiosulfate is present at a concentration of about 250.0 mg/mL of sodium thiosulfate pentahydrate as measured on an anhydrous basis.
16. The pharmaceutical composition of claim 6, wherein the pharmaceutical grade sodium thiosulfate used to make the composition is anhydrous.
17. A method for treating platinum-induced ototoxicity, platinum-induced nephrotoxicity, cyanide poisoning, calciphylaxis, vascular calcification associated

with atherosclerosis or a fungal infection of the skin, nailbeds, or nails, comprising administering to a subject having or at risk of having platinum-induced ototoxicity, platinum-induced nephrotoxicity, cyanide poisoning, calciphylaxis, vascular calcification associated with atherosclerosis or a fungal infection of the skin, nailbeds, or nails a therapeutically effective amount of the pharmaceutical composition of claim 6.

973 patent:

7.¹ [A pharmaceutical composition comprising sodium thiosulfate pentahydrate and one or more pharmaceutically acceptable carriers or excipients, wherein the sodium thiosulfate pentahydrate

- contains no greater than about 10 ppm of non-purgeable organic carbon,
- contains no greater than about 0.01% by weight of carbonate,
- contains no greater than about 0.05 ppm of mercury,
- contains no greater than about 2 ppm of aluminum,
- contains no greater than about 0.003% by weight of selenium,
- contains no less than about 98% by weight and no greater than about

102% by weight of sodium thiosulfate on an anhydrous basis measured by ion chromatography,

- has a water content between 32% and 37% by weight,
- has a heavy metal content of no greater than about 10 ppm,
- contains no greater than about 200 ppm of chloride,
- contains no greater than about 0.001% by weight of sulfide,
- contains no greater than about 0.002% by weight of iron,
- contains no greater than about 0.01% by weight of calcium,
- contains no greater than about 0.005% by weight of potassium,
- contains no greater than about 0.1% of sulfite,
- contains no greater than about 0.5% of sulfate,
- contains no greater than about 3 ppm of arsenic,
- contains no greater than about 0.001% by weight of lead,
- has total aerobic count of microbial load of no greater than about 100

CFU/g,

- has total yeast and mold count of no greater than about 20 CFU/g,
- contains no greater than about 0.02 EU/mg of bacterial endotoxins,
- contains no greater than about 0.002% by weight of nitrogen compounds,
- contains no greater than about 0.005% by weight of insoluble matter,
- contains no greater than 0.01% by weight of residual anti-caking agent,

and

contains no greater than ICH Q3C (R3) limits of organic volatile impurities],

wherein the pharmaceutically acceptable excipient is water.

¹ The text of claim 4, from which claim 7 depends, is shown in brackets.

9.² [A pharmaceutical composition comprising sodium thiosulfate pentahydrate and one or more pharmaceutically acceptable carriers or excipients, wherein the sodium thiosulfate pentahydrate

contains no greater than about 10 ppm of non-purgeable organic carbon,
contains no greater than about 0.01% by weight of carbonate,
contains no greater than about 0.05 ppm of mercury,
contains no greater than about 2 ppm of aluminum,
contains no greater than about 0.003% by weight of selenium,
contains no less than about 98% by weight and no greater than about 102% by weight of sodium thiosulfate on an anhydrous basis measured by ion chromatography,

has a water content between 32% and 37% by weight,
has a heavy metal content of no greater than about 10 ppm,
contains no greater than about 200 ppm of chloride,
contains no greater than about 0.001% by weight of sulfide,
contains no greater than about 0.002% by weight of iron,
contains no greater than about 0.01% by weight of calcium,
contains no greater than about 0.005% by weight of potassium,
contains no greater than about 0.1% of sulfite,
contains no greater than about 0.5% of sulfate,
contains no greater than about 3 ppm of arsenic,
contains no greater than about 0.001% by weight of lead,
has total aerobic count of microbial load of no greater than about 100

CFU/g,

has total yeast and mold count of no greater than about 20 CFU/g,
contains no greater than about 0.02 EU/mg of bacterial endotoxins,
contains no greater than about 0.002% by weight of nitrogen compounds,
contains no greater than about 0.005% by weight of insoluble matter,
contains no greater than 0.01% by weight of residual anti-caking agent,

and

contains no greater than ICH Q3C (R3) limits of organic volatile impurities,

further comprising an isotonic agent and one or more pH adjusting agents,] which is sterile and suitable for intravenous administration,

wherein the isotonic agent is potassium chloride, present at about 4.40 mg/mL and the pH adjusting agents are boric acid, present at about 2.80 mg/mL and sodium hydroxide,

wherein the sodium thiosulfate pentahydrate is present at about 250.0 mg/mL.

Where useful, we adopt the parties' limitation-labeling scheme, reproduced below:

² The text of claims 4 and 8, from which claim 9 depends, is shown in brackets.

Table 1

'973	'301	Limitation
4pre		A pharmaceutical composition comprising sodium thiosulfate pentahydrate
	5pre	A pharmaceutical composition comprising <i>pharmaceutical grade</i> sodium thiosulfate
4a		and one or more pharmaceutically acceptable carriers or excipients,
	5a	in an aqueous pharmaceutically acceptable carrier,
4b	5b	wherein the sodium thiosulfate [4b - pentahydrate] [5b - used to prepare the pharmaceutical composition] contains no greater than about 10 ppm of <i>non-purgeable organic carbon</i> ,
4c		contains no greater than about 0.01% by weight of <i>carbonate</i> ,
4d	5c	contains no greater than about 0.05 ppm of <i>mercury</i> ,
4e	5d	contains no greater than about 2 ppm of <i>aluminum</i> ,
4f	5e	contains no greater than about 0.003% by weight of <i>selenium</i> ,
4g	5f	contains no less than about 98% by weight and no greater than about 102% by weight of <i>sodium thiosulfate on an anhydrous basis</i> measured by ion chromatography,
4h		has a <i>water content between 32% and 37%</i> by weight,
4i	5g	has a <i>heavy metal</i> content of no greater than about 10 ppm ,
4j	5h	contains no greater than about 200 ppm of <i>chloride</i> ,
4k	5i	contains no greater than about 0.001% by weight of <i>sulfide</i> ,
4l	5j	contains no greater than about 0.002% by weight of <i>iron</i>
4m	5k	contains no greater than about 0.01% by weight of <i>calcium</i> ,
4n	5l	contains no greater than about 0.005% by weight of <i>potassium</i> ,
4o	5m	contains no greater than about 0.1% by weight of <i>sulfite</i> ,
4p	5n	contains no greater than about 0.5% by weight of <i>sulfate</i> ,
4q	5o	contains no greater than about 3 ppm of <i>arsenic</i> ,
4r	5p	contains no greater than about 0.001 % by weight of <i>lead</i> ,
4s	5q	has total aerobic count of <i>microbial load</i> of no greater than about 100 CFU/g ,
4t	5r	has total <i>yeast and mold count</i> of no greater than about 20 CFU/g ,
4u	5s	contains no greater than about 0.02 EU/mg of <i>bacterial endotoxins</i> ,
4v	5t	contains no greater than about 0.002% by weight of <i>nitrogen compounds</i> ,
4w	5u	contains no greater than about 0.005% by weight of <i>insoluble matter</i> ,
4x	5v	contains no greater than 0.01% by weight of residual <i>anti-caking agent</i> ,
4y	5w	and contains no greater than ICH Q3C (R3) limits of <i>organic volatile impurities</i> .

DI 210 at 3.

Claim construction in the case yielded mostly agreed constructions, with the constructions and disputes listed below:

- The parties stipulated that “any of claim 4” (claim 7 in both the 973 and 724 patents) means “claim 4.” DI 53 at 14; DI 171-1 at ¶ 31; DI 204 at 10.
- The parties stipulated that “pharmaceutical grade” (claims 5-19 and 22-23 of the 301 patent) means “manufactured according to Good Manufacturing Practices (GMP) as detailed in the United States Code of Federal Regulations 21 C.F.R. 211 and meets one or more of the

purity levels recited herein.” DI 174 at ¶¶ 4-5; DI 204 at 10; *see also, e.g.*, 301 patent at 6:21-26. The parties further agreed that all expert opinions would be treated as applying that corrected construction. DI 174 at ¶ 5.

- The parties stipulated that “pharmaceutical composition” (claims 4, 7, and 9 of the 973 and 724 patents and claims 5-17 and 22-23 of the 301 patent) means “a composition suitable for administration to a subject for treating, preventing, or ameliorating one or more symptoms of a condition, disorder, or disease.” DI 53 at 14; DI 171-1 at ¶ 31; DI 204 at 10.
- The parties stipulated that “therapeutically effective amount” (claim 17 of the 301 patent) means “the amount of a compound that, when administered, is sufficient to treat or prevent development of, or alleviate to some extent, one or more of the symptoms of the disorder, disease, or condition being treated and sufficient to elicit the biological or medical response of a cell, tissue, system, animal, or human, which is being sought by a researcher, veterinarian, medical doctor, or clinician.” DI 53 at 14; DI 171-1 at ¶ 31; DI 204 at 10.
- The parties *disputed* the term “sodium thiosulfate pentahydrate” present in claims 7 and 9 of the 973 and 724 patents. DI 53 at 15-34; DI 204 at 11-24; DI 209 at 5-19. Accord sought a construction requiring that the sodium thiosulfate pentahydrate be present as a solid because it is specified to be in pentahydrate form. DI 53 at 15; DI 209 at 11-12. Judge Andrews held a *Markman* hearing but then reserved for trial the question of whether it should be limited to a solid form, stating that expert testimony would be helpful. DI 58. The parties presented that expert testimony at trial.

We conducted a 3-day bench trial from October 8-10, 2024. DI 179, 180, 181. The parties then submitted post-trial briefing. DI 203, 204, 209, 210, 211, 212. Upon request, the parties also submitted comprehensive proposed findings of fact. DI 218, 219. Under Rule

52(a)(1), we now state findings of fact and conclusions of law to resolve the following disputes: (1) whether Accord infringes the asserted claims with respect to its ANDA product; (2) whether the asserted claims are invalid as obvious; (3) whether the asserted claims are invalid as lacking written description; and (4) whether Hope is barred from asserting the 301 patent under the doctrine of prosecution laches.

II. FINDINGS OF FACT³

We will first state the undisputed facts, then our resolution of disputed facts related to various topics.

***Undisputed facts and other stipulations (adapted from DI 171-1)*⁴**

1. Plaintiff Hope Medical Enterprises, Inc., doing business as Hope Pharmaceuticals (“Hope”), is a corporation organized and existing under the laws of the State of Arizona, having a principal place of business at 16416 N. 92nd Street #125, Scottsdale, AZ 85260.

2. Hope owns the 973, 724, and 301 patents (the “asserted patents” or “patents-in-suit”). No party contests Hope’s standing for purposes of this action, and the parties agree that no proof of standing needed to be adduced at trial.

3. Defendant Accord Healthcare Inc. (“Accord”) is a company organized and existing under the laws of the State of North Carolina, having a principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617. Accord is a wholly-owned subsidiary of Intas Pharmaceuticals Limited.

³ The citations in this section are merely exemplary. We considered the entire record when rendering each finding of fact, and we weighed the credibility of the witnesses as well.

⁴ Some of the below are statements of law rather than fact, or mixtures, which should be understood to be the agreed position of the parties that we see no reason to contest. Also, not all of the undisputed facts turned out to be material to this decision. But they are included for completeness.

4. Intas Pharmaceuticals Limited (“Intas”) is a corporation organized and existing under the laws of India and has a principal place of business at Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad 380054, Gujarat, India. Intas was originally a named defendant in this action but was dismissed by stipulation of the parties and Order of the Court. DI 27. As part of that dismissal, Intas agreed “to abide by any judgment or order rendered in this Action (including appeals) as to Accord as if Intas were a named defendant, including with regard to the infringement and/or validity of any asserted patents.” *Id.*

5. Accord markets and distributes generic pharmaceutical products in the United States.

6. Hope is the holder of New Drug Application (“NDA”) No. 203923 for Sodium Thiosulfate Injection, 250 mg/mL (“Hope’s NDA Product” or the “NDA Product”), which received FDA approval on February 14, 2012. Hope’s NDA Product is indicated for sequential use with sodium nitrite for the treatment of acute cyanide poisoning that is judged to be serious or life-threatening. Hope commenced commercial sales of its NDA Product in 2012 after FDA approval.

7. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit have been listed in connection with NDA No. 203923 in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”).

8. Following the passage of the 1938 Food Drug and Cosmetic Act and the issuance of Good Manufacturing Practice (“GMP”) regulations in 1963, the FDA required that any new pharmaceuticals and their corresponding active ingredients be manufactured consistent with “pharmaceutical grade” standards set forth in 21 C.F.R. §§ 210, 211.

9. The United States Pharmacopeia (“USP”) published monographs for sodium

thiosulfate injection and sodium thiosulfate (the active ingredient in sodium thiosulfate injection).

The USP monograph in effect at the time of Hope's invention is USP XXXII (2009).

10. USP XXXII (2009) describes the formula for "Sodium Thiosulfate" as $\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$. This is the formula for sodium thiosulfate pentahydrate. Sodium thiosulfate pentahydrate has a water content between 32% and 37% by weight. *See also* 973 patent at 6:9-10; JTX-12; Day 1 (135:1-8, 138:8-16); Day 2 (16:9-13).

11. On or about April 29, 2022, Accord filed ANDA No. 217214 ("Accord's ANDA") with the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of a sodium thiosulfate injection USP, 12.5 grams/50 mL (250 mg/mL) single-dose vial ("Accord's ANDA Product") based on the Reference Listed Drug (RLD) Sodium Thiosulfate Injection, USP 250 mg/mL of Hope Pharmaceuticals (NDA # 203923).

12. Sodium thiosulfate as described in Drug Master File ("DMF") No. 36782 is used to make Accord's ANDA Product, if approved.

13. By filing the ANDA with the FDA, Accord has represented to the FDA that Accord's ANDA Product is bioequivalent to Hope's NDA Product.

14. Accord's ANDA includes a Paragraph IV certification alleging, *inter alia*, that the 301, 973, and 724 patents listed in the Orange Book as covering Hope's NDA Product are invalid, unenforceable, and/or not infringed by the drug products described in Accord's ANDA.

15. In two letters dated June 13, 2022 and October 13, 2023, which are described as being a "Notice of Paragraph IV Certification" (a "Paragraph IV notice letter"), Accord advised Hope of Accord's ANDA and Paragraph IV certifications alleging, *inter alia*, that the 301 patent (described in the October 13, 2023 letter), and the 973 and 724 patents (described in the June 13,

2022 letter) listed in the Orange Book were invalid, unenforceable, and/or not infringed.

16. On July 26, 2022, Hope filed its original complaint in the instant action against Accord for infringement of, *inter alia*, the 973 and 724 patents. DI 1. Hope commenced this action within the 45-day period after receiving the June 13, 2022 Paragraph IV notice letter, as described in 21 U.S.C. § 355(j)(5)(B)(iii).

17. On September 14, 2023, Hope filed an amended complaint in the instant action against Accord for infringement of, *inter alia*, the 301 patent. DI 62.

18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

19. This Court has personal jurisdiction because, among other things, Accord, through its counsel, has consented to personal jurisdiction in Delaware for purposes of this action, prior to the filing of the First Amended Complaint. DI 62.

20. Accord does not contest personal jurisdiction for purposes of this action.

21. Venue is proper in this Court because, among other things, Accord, through its counsel, has consented to venue in Delaware for purposes of this action, prior to the filing of the First Amended Complaint. DI 62.

22. Accord does not contest venue for purposes of this action.

23. The 301 patent is titled “Sodium Thiosulfate-Containing Pharmaceutical Compositions,” and issued on September 12, 2023, from U.S. Patent Application No. 18/108,803, filed on February 13, 2023.

24. For the purposes of trial, Hope asserts claims 5-19, 22 and 23 of the 301 patent.

25. The 973 patent is titled “Sodium Thiosulfate-Containing Pharmaceutical Compositions,” and issued on July 30, 2013, from U.S. Patent Application No. 12/831,331, filed

on July 7, 2010.

26. For the purposes of trial, Hope asserts claims 7 and 9 of the 973 patent.

27. The 724 patent is titled “Sodium Thiosulfate-Containing Pharmaceutical Compositions,” and issued on May 24, 2016, from U.S. Patent Application No. 14/310,133, filed on June 20, 2014.

28. For the purposes of trial, Hope asserts claims 7 and 9 of the 724 patent.

29. The patents-in-suit share a common specification and claim priority to the nonprovisional application No. 12/831,331, filed on July 7, 2010 (which eventually issued as the 973 patent). Craig Sherman, Catherine Marie Smith, Kevin Robert Wirtz, and Erich Schulze are identified on the cover pages of the patents-in-suit as inventors.

30. For the purposes of this litigation only, the asserted claims of the 301 patent, the 973 patent, and the 724 patent have a priority date of July 7, 2010.

31. Accord prepared four exhibit batches of its Active Pharmaceutical Ingredient (“API”) pursuant to DMF No. 36782. Those four batches are: C2100281 (Ar. No. 7521755009) (17.090 kg), C2100289 (Ar. No. 7521755011) (18.990 kg), and C2100297 (Ar. No. 7521755015) (12.490 kg), all three of which were manufactured in August 2021; and C2100301 (Ar. No. 7521755142) (14.840 kg), which was manufactured in September 2021.

32. Accord prepared three exhibit batches of its ANDA Product. Those three exhibit batches are: R2101148, R2101155, and R2101156.

33. Accord produced samples of API from batch numbers C2100281, C2100289, C2100297, and C2100301 to Hope in connection with this action. The API samples produced to Hope are representative of the quality of the API of the batches from which the samples were taken.

34. Accord produced samples of ANDA Product exhibit batch numbers R2101148, R2101155, and R2101156 to Hope in connection with this action. The ANDA Product samples produced to Hope are representative of the quality of the ANDA Product of the batches from which the samples were taken.

35. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 2 ppm of aluminum.

36. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.003% by weight of selenium.

37. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 10 ppm of cadmium, cobalt, vanadium, nickel, selenium, antimony, arsenic, mercury, aluminum, and lead.

38. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 200 ppm of chloride.

39. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.001% by weight of sulfide.

40. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.002% by weight of iron.

41. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.01% by weight of calcium.

42. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.005% by weight of potassium.

43. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.1% of sulfite.

44. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.5% of sulfate.

45. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 3 ppm of arsenic.

46. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.001% of lead.

47. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.02 EU/mg of bacterial endotoxins.

48. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.002% by weight of nitrogen compounds.

49. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.005% by weight of insoluble matter.

50. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than 0.01% by weight of residual anti-caking agent.

51. Accord does not add any anti-caking agents in the process of manufacturing API according to DMF No. 36782.

52. Accord is not aware of any testing of API manufactured according to DMF No. 36782 that indicated the presence of greater than 0.01% by weight of residual anti-caking agent.

53. Accord is not aware of any API manufactured according to DMF No. 36782 that contained greater than 0.01% by weight of residual anti-caking agent.

54. The API used in Accord's ANDA Product, manufactured according to DMF No. 36782, contains no greater than ICH Q3C (R3) limits of organic volatile impurities.

55. The starting materials used in manufacturing the API pursuant to DMF No. 36782

comply with ICH Q11 guidelines.

56. Accord's ANDA Product is a pharmaceutical composition wherein the aqueous pharmaceutically acceptable carrier is sterile water for injection.

57. Accord's ANDA Product is a pharmaceutical composition formulated for parenteral administration.

58. Accord's ANDA Product is a pharmaceutical composition formulated as a single dosage form.

59. Accord's ANDA Product is a pharmaceutical composition comprising an isotonic agent and one or more pH adjusting agents.

60. Accord's ANDA Product is a pharmaceutical composition which is sterile and suitable for intravenous administration, wherein the isotonic agent is potassium chloride, present at about 4.40 mg/mL and the pH adjusting agents are boric acid, present at about 2.80 mg/mL, and sodium hydroxide.

61. Accord's ANDA Product is a pharmaceutical composition comprising about 140 mg boric acid and about 220 mg potassium chloride.

62. Accord's ANDA Product is a pharmaceutical composition wherein the pharmaceutical grade sodium thiosulfate used to make the composition is anhydrous.

63. Accord's ANDA Product is a pharmaceutical composition that is a sterile, aqueous solution suitable for intravenous injection.

64. The potassium chloride used in Accord's ANDA Product is an isotonic agent.

65. The boric acid used in Accord's ANDA Product is a pH adjusting agent.

66. The sodium hydroxide used in Accord's ANDA Product is a pH adjusting agent.

67. Accord's ANDA Product, if approved, will contain API manufactured according to

Good Manufacturing Practices (GMP) as detailed in the United States Code of Federal Regulations 21 C.F.R. 210 and 21 C.F.R. 211.

68. U.S. Patent No. 1,219,819 (“Hutchins”) issued in 1917. (DTX-013)
69. U.S. Patent No. 1,854,762 (“Prunier”) issued in 1932. (DTX-014)
70. U.S. Patent No. 2,763,531 (“Levenson”) issued in 1956. (DTX-015)
71. Richardson, J.F., et al., Chemical Engineering, Particle Technology and Separation Processes, Vol. 2, 5th Edition (2002) (“Richardson”) published in 2002. (DTX-018)
72. Louis F. Fieser and Kenneth L Williamson, Organic Experiments, Seventh Edition, D.C. Heath. 1992 (“Fieser”) published in 1992. (DTX-057)
73. Bansal, R.P., et al., Activated Carbon Adsorption, 2005, pp. 355-358 (“Bansal”) published in 2005. (DTX-019)
74. Srinivasan, P.T., et al., Aluminum in drinking water: An overview, Water SA Vol. 25 No. 1 (1999) (“Srinivasan”) published in 1999. (DTX-020)
75. Koshima, H., et al., Adsorption of Metal Ions on Activated Carbon from Aqueous Solutions at pH 1-13, *Talanta*, Vol. 33, No. 5, pp. 391-395, 1986 (“Koshima”) published in 1986. (DTX-021)
76. Peters, R.W., et al., Removal of Sulfides from Waters and Wastewaters by Activated Carbon, *Reactive Polymers*, 5 (1987) 93-104 (“Peters”) published in 1987. (DTX-022)
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(DTX-027)

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(DTX-028)

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Findings of fact – Infringement-related

105. Accord’s ANDA Product is described in its ANDA. DI 171-1 at ¶ 11; *see also* PTX-31 at 2; Day 1 (142:24-143:13).

106. Accord certified to the FDA that “[t]he data and information” relating to its ANDA submission “have been reviewed and, to the best of [Accord’s] knowledge, are certified to be true and accurate,” and were submitted under the “warning” that “[a] willfully false statement is a criminal offense.” PTX-717 at 4.

107. Sodium thiosulfate as described in DMF No. 36782 will be used to make Accord’s ANDA Product, if approved. DI 171-1 at ¶ 12.

108. By filing its ANDA with the FDA, Accord has represented to the FDA that Accord's ANDA Product is bioequivalent to Hope's Product. DI 171-1 at ¶ 13; see also Day 2 (20:1-7).

109. Hope's expert, Robin D. Rogers, Ph.D., testified as "an expert in the field of chemistry, including the synthesis and analysis of inorganic salts and pharmaceutical compositions." Day 1 (132:10-132:15). He was compellingly qualified to testify on the topics he covered. *Id.* at 126:13-132:15.

110. Dr. Rogers analyzed Accord's ANDA and its ANDA Product. Day 1 (132:10-15); *see generally id.* (141:7-231:5).

111. In doing so, Dr. Rogers applied the parties' agreed-upon constructions or, for all other terms, applied the plain and ordinary meaning of the term, in his infringement analysis. Day 1 (161:3-162:18), (195:6-196:13).

112. Accord's ANDA Product will be labeled "Sodium Thiosulfate Injection, USP," meaning it "contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$ [sodium thiosulfate pentahydrate]" as required by the USP. Day 1 (146:22-147:4); PTX-31 at 2; JTX-12 at 1 (Official Monograph).

113. Accord's ANDA Product will be labeled "250 mg/mL," wherein the listed "masses are for sodium thiosulfate pentahydrate." PTX-261 at 1, 7; PTX-850; Day 1 (143:5-8), (146:7-12), (147:9-23).

114. Accord reported to the FDA that its "proposed product contains the same concentration of the active ingredient as the reference listed drug," "has the same dosage form as that of the Sodium Thiosulfate Injection 12.5 gm/50 mL (250 mg/mL) of Hope Pharmaceuticals (NDA # 203923), and is intended for the same indications, dosage regimen and route of

administration.” PTX-31 at 2, 4, 5, 12 (Table 11); see also Day 1 (147:9-148:17), (150:7-23), (151:7-16).

115. Accord developed and validated an assay for “Identification of Sodium Thiosulfate Pentahydrate in Sodium Thiosulfate Injection USP,” which used a sodium thiosulfate pentahydrate reference standard. JTX-25 at 22, 27; PTX-42 at 3 (same); PTX-38 at 2-4; DI 191, Exhibit C at 17-22.

116. The acceptance criterion for Accord’s assay was the “[r]ecovery of Sodium Thiosulfate pentahydrate,” and Accord reported that “[r]ecovery of Sodium Thiosulfate pentahydrate is between 99.8% and 100.5%.” JTX-25 at 16; PTX-41 at 11 (same); JTX-25 at 44; PTX-42 at 25 (same); DI 191, Exhibit C at 20-21 (92:11-93:06).

117. Accord said that its “assay of Sodium Thiosulfate pentahydrate in Sodium Thiosulfate Injection 12.5 grams/50 mL (250 mg/mL) is capable to produce specific, accurate and precise results.” JTX-25 at 22, 47; PTX-42 at 3, 28 (same).

118. Accord used this assay on batches of its ANDA Products and reported the results to the FDA. PTX-31 at 38-39; Day 1 (213:4-214:6).

119. During this lawsuit, the FDA asked Accord to “revise the assay test in the drug product release and stability specifications to indicate that the assay test results are reported as the amount of Sodium thiosulfate pentahydrate,” which Accord did and reported the concentration of “sodium thiosulfate pentahydrate” in its ANDA Product. PTX-839 at 3; PTX-840 at 5; PTX-841 at 3.

120. Accord’s ANDA Product will contain no less than about 98% by weight and no greater than about 102% by weight of sodium thiosulfate on an anhydrous basis measured by ion chromatography. DI 178 at 1 n.1; Day 1 (174:2-178:5), (178:3-180:4), (182:13-20); PTX-455 at

8; PTX-460 at 3; PTX-456 at 3; *see also* Day 1 (202:1-5).

121. Accord's ANDA Product will have a water content between 32% and 37% by weight. Day 1 (227:11-25), (228:2-8); JTX-12; *see also* DI 171-1 at ¶ 10.

122. A skilled artisan⁵ in 2010 would understand that the 973 patent's references to a pharmaceutical composition containing sodium thiosulfate pentahydrate and water referred to sodium thiosulfate in the aqueous solution on a pentahydrate basis, which a skilled artisan would have no difficulty measuring and reporting. JTX-1 at 22 (42:37-67); Day 1 (140:18-141:6); JTX-12 at 1 (referring to a solution of sodium thiosulfate in water as "contain[ing] . . . Na₂S₂O₃•5H₂O [sodium thiosulfate pentahydrate]").

123. An aqueous solution is a solution in which water is the solvent, which dissolves a solute. Day 2 (17:13-18).

124. Accord's ANDA Product will literally meet all limitations of claims 7 and 9 of the 973 patent. *See* FF 31-67, 109-123 *supra*; Day 1 (141:7-231:5). It therefore will infringe those claims.

125. Dr. Rogers's infringement analysis with respect to the 973 patent was complete, credible, and persuasive. Day 1 (141:7-231:5). We found no reason to disagree with it.

126. Except with respect to "sodium thiosulfate pentahydrate" and its water content, Accord presented no evidence that its ANDA Product will not practice all limitations of claims 7 and 9 of the 973 patent. DI 209 (addressing only those issues); Day 2 (16:5-19 specifically, 11:15-110:9 generally) (Dr. Rabinow addressing only those issues); DI 218 at 36-37 (addressing only those issues from infringement of claims 7 and 9 of the 973 patent).

⁵ Skilled artisan is our preferred short form of "person having ordinary skill in the art." POSA, POSITA, and PHOSITA are interchangeable as well.

127. Accord's ANDA Product will literally meet all limitations of claims 5-13, 16, and 17 of the 301 patent. *See* FF 31-67, 109-123 *supra*; Day 1 (141:7-231:5). It therefore will infringe those claims.

128. Dr. Rogers's infringement analysis with respect to the 301 patent was complete, credible, and persuasive. Day 1 (141:7-231:5). We found no reason to disagree with it.

129. Accord presented no evidence that its ANDA Product will not practice all limitations of claims 5-13, 16, and 17 of the 301 patent. DI 209 at 1-2 (not discussing the 301 patent); Day 2 (133:11-13) (Dr. Rabinow confirming that he offered no opinions regarding infringement of the 301 patent); DI 178 at 1 n.1 ("There is no dispute that the claims of the '301 patent are infringed[.]"); DI 218 at 36-37 (offering no proposed findings as to infringement of the 301 patent).

130. Accord's ANDA Product therefore also infringes claims 14-15, 18-19, and 22-23 of the 301 patent under the parties' stipulation. DI 170 at ¶ 4; DI 172.

Findings of fact – Obviousness-related

131. A person of ordinary skill in the art as of July 7, 2010, would have a B.S. in any of the pharmaceutical sciences plus five years of experience in the synthesis and analysis of inorganic salts in pharmaceutical compositions, including aqueous pharmaceutical compositions, or an M.S. in any of the pharmaceutical sciences plus three years of experience in the synthesis and analysis of inorganic salts in pharmaceutical compositions, including aqueous pharmaceutical compositions, or a Ph.D. plus one year of experience in the synthesis and analysis of inorganic salts in pharmaceutical compositions, including aqueous pharmaceutical compositions. Day 1 (159:13-25).

132. In material part, Dr. Rogers's opinions and Dr. Rabinow's opinions are not

affected by any competing definitions of a skilled artisan.

133. Dr. Rogers's obviousness analysis was complete, credible, and persuasive. Day 2 (154:6-158:18), (162:15-178:8), (225:1-229:10). We found no reason to disagree with it.

134. A skilled artisan would have been aware of general chemistry techniques, such as crystallization, adsorption, filtration, evaporation, and prevention of yeast, mold, bacterial endotoxins, and microbial load, but not as applied to the specific chemistry of ultrapure sodium thiosulfate for pharmaceutical use. Day 2 (155:7-11), (155:22-24), (194:7-17), (223:14-224:3), (227:3-15).

135. Chemistry is an unpredictable art generally and chemical purification techniques exhibit some degree of variability in performance based on conditions. Day 2 (155:12); (112:25-113:15); DTX-101 (Wieckhausen) at 2, 7.

136. Crystallization is an unpredictable art. Day 2 (156:12); (155:17-21).

137. There is no prior art disclosure of crystallization as a purification technique on the application specifically to sodium thiosulfate pentahydrate. Day 2 (223:14-18).

138. Applying even known chemistry techniques to achieve the claimed ultrapure sodium thiosulfate was unpredictable because of the various interconnected and unpredictable variables, such as pH, temperature, and choice of solvent, all of which interact with each other and the purity of the resulting product. Day 1 (58:3-59:2), (104:20-107:16); Day 2 (110:24-111:13), (136:11-16), (154:22-158:18), (164:16-165:6), (178:1-8).

139. The prior art does not disclose sodium thiosulfate meeting the limitations of the Asserted Claims. Day 2 (70:5-11).

140. There had been no attempt to ever try to get sodium thiosulfate purified to the extent claimed by Hope previously. Day 2 (70:5-9).

141. Hutchins (DTX-13) is a 1917 patent describing the industrial-scale synthesis of sodium thiosulfate by the action of sulfur upon sodium sulfite. Day 2 (34:3-11).

142. During prosecution of the 301 patent, the patent examiner allowed the application over “the closest prior art,” Levenson, which like Hutchins also discloses “sodium sulfite reacting with sulfur.” JTX-9 at 2794; DTX-15 (Levenson); Day 2 (34:19-20).

143. Hutchins does not teach the manufacture of sodium thiosulfate for pharmaceutical purposes. Day 2 (119:12-22); see also *id.* (120:3-5).

144. Hutchins does not teach the purity of the sodium thiosulfate composition synthesized according to its methods. Day 2 (122:11-15); (35:21-36:5), (123:22-25).

145. Before the asserted patents, the prior art offered little insight on purification of sodium thiosulfate. Day 2 (109:10-110:2).

146. Hutchins’ strategies to increase yield result in increased impurities and would be inappropriate to achieve ultrapure sodium thiosulfate for pharmaceutical use. Day 2 (162:15-19), (163:5-24), (166:1-14). Hutchins would have been entirely unhelpful to a skilled artisan attempting to achieve that goal.

147. Much higher impurities (e.g., 50,000 ppm) are tolerated for industrial processes like that in Hutchins, unlike pharmaceutical processes. Day 2 (185:11-13).

148. Hutchins does not disclose use of activated carbon. DI 206 at 7; DTX-13 at 2-4.

149. In 2007, Dr. Sherman began working to achieve sodium thiosulfate drug substance and drug product that met USP purity standards and were manufactured according to the GMP required by the FDA. Day 1 (51:14-24); see also PTX-626.

150. During pre-NDA discussions with the FDA, Hope proposed 10 specifications for the sodium thiosulfate drug substance based on then existing, USP quality specifications. Day 1

(54:7-13); PTX-637 at 20.

151. The FDA, however, rejected Hope's proposal, advising Hope that it would need to meet 18 additional "aspirational quality specifications" that exceeded then-existing USP specifications both in number and in levels. Day 1 (55:12-14), (56:8-57:1); JTX-41 ("FDA Letter").

152. The existing USP and other quality compendiums together failed to provide any requirements at all for more than a dozen impurities in the FDA Letter and likewise did not require sodium thiosulfate to be manufactured according to GMP. USP 23 (DTX-26); USP 32 (JTX-12); American Chemical Society Specifications (DTX-30); Japanese Pharmacopoeia (DTX-28); and European Union Pharmacopoeia (DTX-27).

153. The communications between Hope and the FDA were confidential. Day 1 (55:17-21); Day 2 (135:1-11).

154. The FDA Letter did not describe or suggest to a skilled artisan how to make pharmaceutical grade sodium thiosulfate that would simultaneously achieve all of the purity specifications of the asserted claims, such as the synthesis process to use, the purification methods, the order to perform the steps, or the conditions required to do so. Day 1 (57:2-4); Day 2 (174:8-175:2); Day 3 (14:6-14).

155. Nothing in the record persuasively explains how prior art or knowledge of skilled artisans would have assisted a skilled artisan in modifying Hutchins to manufacture according to GMP.

156. The combination of Hutchins (DTX-13) in view of the general knowledge of a skilled artisan does not disclose or provide a reasonable expectation of success in achieving each element of the asserted claims.

157. Nothing in the record persuasively demonstrates how a skilled artisan would use specific techniques, in what order, and under what conditions, to have a reasonable expectation of success in achieving the claimed ultrapure sodium thiosulfate simultaneously meeting each claimed impurity requirement. Nor is there sufficient evidence on the presence of a reasonable expectation of success specifically with respect to, e.g., insoluble matter, mercury, and sulfide.

158. Dr. Rabinow's analysis of how a skilled artisan would have and could have modified Hutchins lacked credibility because it was overly general, oversimplified, and conclusory, and because it typically addressed what might be possible without coupling with a reasonable expectation of success. Day 2 (54:5-11), (56:4-14), (91:11-14), (62:23-63:5), (67:6-10), (77:3-16), (78:20-79:11), (87:24-88:5), (65:18-66:4) (mercury), (66:10-67:5) (sulfide), (71:12-21) (yeast, mold), Day 2 (72:20-23) (microbial control).

159. Dr. Rabinow's cited "background" references do not relate to sodium thiosulfate and were not shown to provide a reasonable expectation of success. Day 2 (160:15-161:6), (169:19-170:5), (170:22-171:20).

160. Wastewater references do not apply to producing ultrapure sodium thiosulfate because they are a different art not immediately applicable to a pharmaceutical sodium thiosulfate solution. Day 2 (159:13-161:1), (166:18-167:2).

161. Wastewater or water treatment references would not work with ionic sodium thiosulfate solutions because applying that removal of ions from a solution in which ions are the product would be very difficult. Day 2 (160:2-8).

162. A skilled artisan would not have considered Dr. Rabinow's activated carbon references as background knowledge that would be applicable to manufacturing pharmaceutical grade sodium thiosulfate. Day 2 (171:21-172:5) (referring to DTX-19, DTX-20, DTX-21, DTX-

22, DTX-23, and DTX-24).

163. Dr. Rabinow's testimony about the Merck Documents, and the documents themselves, lack credibility because of the lack of foundation and hearsay nature of the documents, which gap Dr. Rabinow did not fill.

164. Hope sells an FDA-approved, individually packaged Sodium Thiosulfate Injection, USP. Day 1 (43:14-44:6).

165. Hope's Sodium Thiosulfate Injection, USP is coextensive with the asserted claims. Day 2 (183:3-5), Day 2 (179:25-180:25), (181:1-3).

166. Hope's Product comprises sodium thiosulfate pentahydrate, two excipients, and a minimal amount of two buffers, and is indicated for sequential use with sodium nitrite for treatment of acute cyanide poisoning that is judged to be life-threatening. PTX-735 at 2, 4-5; Day 2 (179:8-10), (181:25-182:24).

167. Each of the limitations of claims 5 and 7 of the 301 patent and claim 4 of the 973 patent meets all the requirements identified in the FDA February 8, 2008, letter to Hope, including those that were revised. Day 2 (179:19-181:3).

168. Hope also sells Nithiodote, a co-packaged product that includes its Sodium Thiosulfate Injection, USP and a sodium nitrite injection. Day 1 (43:14-21).

169. Hope's FDA-approved Sodium Thiosulfate Injection, USP, is a critical component of Hope's Nithiodote product because treatment of cyanide poisoning requires sodium thiosulfate injection and sequential use with sodium nitrite creates an exponential effect. Day 1 (91:4-12); Day 3 (26:17-19); JTX-45 at 3.

170. Accord applied only for approval of an individually packaged sodium thiosulfate injection, not the co-packaged sodium nitrite injection plus sodium thiosulfate injection. PTX-36

at 1.

171. As of July 7, 2010, there was a long-felt need for an FDA-approved sodium thiosulfate injection because there was no FDA-approved sodium thiosulfate injection for treatment of acute cyanide poisoning before Hope's product. Day 1 (45:24-46:25); JTX-10 at 4-5; JTX-45 at 3.

172. In 2006, the FDA announced that it was exercising enforcement discretion with respect to non-approved, grandfathered drugs. JTX-10 at 5-8; Day 1 (45:22-46:7); Day 3 (28:16-29:3).

173. The FDA recognized the long-felt need for Hope's Product when it sought a new drug application for a co-packaged Sodium Nitrite Drug Product and Sodium Thiosulfate Drug Product, which would require an FDA-approved sodium thiosulfate product. Day 1 (46:17-25); JTX-45 at 3; see also Day 3 (27:19-29:3).

174. The FDA recognized a long-felt need for Hope's product when it designated Hope's application for priority review. Day 3 (30:24-32:4) (Dr. Savello discussing PTX-700**), (32:22-33:5) (Dr. Savello discussing PTX-704** at 20-22, 42), Day 3 (31:7-32:4) (Dr. Savello testifying that the FDA's language was particularly meaningful).

175. Cyanokit, an alternative FDA-approved treatment for cyanide poisoning that contains hydroxocobalamin hydrochloride, did not meet the long-felt need because it must be reconstituted before it can be administered, forms a pigment that turns patients' urine and skin red for weeks, and is five times the cost of Nithiodote. Day 3 (34:20-35:10); Day 1 (89:12-14, 23-25).

176. Nithiodote does not need to be reconstituted, and sodium thiosulfate and sodium nitrite do not cause the reddening side effects. Day 3 (34:20-35:10).

177. The FDA gave Hope's application priority review despite the fact that Cyanokit was already on the market for years. Day 3 (35:13-22).

178. At least two other pharmaceutical companies, Keystone Pharmaceuticals and American Regent, previously marketed non-FDA approved sodium thiosulfate injections and the FDA removed those products from the market for quality and manufacturing failures in 2010 and 2011. Day 3 (36:11-16) (Dr. Savello discussing PTX-551**, PTX-528**), (36:11-37:16) (Dr. Savello discussing PTX-26**), (32:5-32:13) (Dr. Savello discussing PTX-704** at 22), (37:17-38:6) (Dr. Savello discussing PTX-683** at 1).

179. As of the trial, Hope was still the only supplier of pharmaceutical grade sodium thiosulfate for treatment of cyanide poisoning. Day 3 (27:11-13).

180. The United States Department of Homeland Security awarded Safety Act Designation to Hope's Product in 2013, 2018, and 2023. Day 1 (70:6-72:1), (71:14-72:1) (2023); Day 3 (39:2-20) (discussing PTX-127** (2013), PTX-129 at 1 (2018)).

181. The Safety Act Designation recognizes that Hope's Product is important to enhancing public safety, and confers upon the recipient liability and risk management protections due to the critical need for the anti-terrorism technology. Day 1 (71:14-72:19); PTX-129 at 3.

182. Neither Dr. Rabinow nor the Merck documents credibly evidenced simultaneous invention.

183. There is sufficient nexus between the claimed invention and the above-discussed long-felt need, failure of others, and praise because Hope's product is the invention claimed and the evidence relates to Hope's product.

Findings of fact – Written-description-related

184. The Asserted Claims require that the pharmaceutical grade sodium thiosulfate

contain “no greater than” a specific amount of various impurities, such as “no greater than about 2 ppm of aluminum,” “no greater than about 0.1% by weight of sulfite,” and “no greater than about 0.5% by weight of sulfate,” among others. JTX-5 at 27 (43:38-67).

185. Dr. Rabinow did not offer testimony regarding whether a skilled artisan would understand that the specification provides written description support for the Asserted Claims.

186. Dr. Rabinow did not offer testimony about whether a skilled artisan would understand that “no greater than” the claimed impurities was (or was not) described in the specification.

187. Accord advanced no evidence of its own germane to written description.

188. Hope requested that the FDA separate the original, combined requirement for sulfate and sulfite into two separate requirements, which Hope met. JTX-41 at 3 (setting limit for “Sulfate and Sulfite (as SO₄)” as not more than 0.1%); Day 1 (66:10-19); JTX-1 at 22 (41:64-65) (“contains no greater than about 0.1% of sulfite”), (41:65-66) (“contains no greater than about 0.5% of sulfate”).

189. Hope requested that the FDA change the aluminum limit from not more than 0.2 ppm to not more than 2 ppm, which Hope met. JTX-41 at 3; Day 1 (67:4-68:3); JTX-1 at 22 (41:53-54).

190. Dr. Rogers’s and Dr. Sherman’s testimony reflects that sulfate and sulfite presented a simultaneous “measurement” challenge, which Hope solved by “develop[ing] analytical methods to test each of those independently.” Day 1 (66:13-19); Day 2 (187:17-188:4).

191. Dr. Sherman testified that aluminum presented “technical challenges” due to the potential for “phosphate impurity” and “impact[ing] pH of the reaction.” Day 1 (67:4-25).

192. The FDA's agreement to raise the limits of sulfite, sulfate, and aluminum for approval of Hope's Product does not demonstrate that the Inventors failed to possess sodium thiosulfate with "no greater than" the claimed impurity limits.

193. A POSA would understand that the term "no greater than" in the Asserted Claims refers to the "level of detection up to" the claimed amount. Day 2 (187:8-13), (190:11-15), (227:20-229:10).

194. The claimed impurity ranges ("no greater than" a certain amount) are very narrow, or ultrapure, ranges. Day 2 (228:10-229:10).

195. The specification states that "where the sodium thiosulfate is described as 'containing no greater than' a certain amount of a particular material, the sodium thiosulfate does not contain a detectable amount of the material." JTX-1 at 7 (11:47-50); Day 2 (227:20-228:4).

196. The inventors prepared sodium thiosulfate with "no greater than" the impurities of the Asserted Claims, as reflected in Example 1 ("Preparation of Pharmaceutical Grade Sodium Thiosulfate Pentahydrate") and Table 1 (results of Example 1). JTX-1 at 17-18; Day 2 (154:6-20), (229:6-10).

197. For example, Table 1 describes sodium thiosulfate with 0.58 ppm aluminum, 0.01% sulfite, and 0.08% sulfate, which are "no greater than about 2 ppm of aluminum," "no greater than about 0.1% by weight of sulfite," and "no greater than about 0.5% by weight of sulfate," respectively. JTX-1 at 17-18 (Table 1), 22 (42:43-44, 55-57).

198. The specification also describes methods for determining the amount of aluminum, sulfate, sulfite, and other claimed impurities. JTX-1 at 5 (8:4-19), 6 (9:5-14); Day 2 (191:25-192:3).

199. A POSA reading the specification, especially in view of Example 1 and Table 1,

would understand that the Inventors possessed and enabled how to make sodium thiosulfate with “no greater than” each of the impurities of the Asserted Claims. Day 2 (154:6-20), (227:20-229:10).

200. Dr. Rogers’s testimony and Dr. Sherman’s testimony were entirely credible on the topic of written description.

Findings of fact – Other

201. Hope began prosecuting its sodium thiosulfate patents in 2009, and the 301 patent ultimately issued in 2023 through a series of eleven continuation applications, ten of which issued as United States patents. E.g., JTX-5 at 2-3, (63), (60).

202. Though the common specification of each states that the active ingredient “may be the anhydrous, the monohydrate, dihydrate, trihydrate, quatrahydrate, pentahydrate, or other hydrated forms of sodium thiosulfate” (301 patent at 6:8-17), all of Hope’s patents prior to the 301 patent claimed “a sodium thiosulfate pentahydrate.” Tr. Day 2 at 15:6-13.

203. Accord filed its ANDA, reciting the use of anhydrous sodium thiosulfate to form a sodium thiosulfate solution, on or about April 29, 2022, containing extensive testing results performed on its anhydrous drug substance, including its water content. DI 171-1 at ¶ 11; PTX-0030 and 31; PTX-0035; PTX-0038; PTX-0040 through 42.

204. Accord provided its required Notice Letter to Hope on June 13, 2022, outlining its noninfringement position that “[a]ll of the independent claims of the 973, 724, and 912 patents require ‘sodium thiosulfate pentahydrate’ having a ‘water content between 32% and 37% by weight’” while “[i]n contrast, Accord’s ANDA product includes anhydrous sodium thiosulfate that has a water content of 0.6% to 0.9%.” PTX-0036 at 6 (emphasis in original).

205. Hope subsequently filed the 301 patent application on February 13, 2023, nearly

fourteen years after the first provisional application, just months after receiving Accord's notice letter. DI 171-1 at ¶ 23; JTX-0005-0002.

206. The '301 patent issued on September 12, 2023, from U.S. Patent Application No. 18/108,803, filed on February 13, 2023. JTX-5 at 2; Day 1 (72:21-73:3).

207. Hope filed the 301 patent to more clearly cover non-pentahydrate forms because it learned that competitors were trying to circumvent Hope's patents by using anhydrous sodium thiosulfate as the active pharmaceutical ingredient. Day 1 73:4-9; PTX-36; PTX-825.

208. Hope is a small company that has never had more than two full-time employees and has no legal department. Day 1 (39:20-25, 72:14-20).

209. Hope's delay in filing for the 301 patent was not unreasonable.

210. Accord was not prejudiced in any way by Hope's decision to pursue and obtain the 301 patent.

III. ANALYSIS AND CONCLUSIONS OF LAW

a. Hope proved that the asserted claims are infringed.

We granted Hope's oral Rule 52(c) motion and held that Accord's ANDA Product infringes the asserted claims of the 301 patent as a matter of law.⁶ DI 178; *see also* FF 129. Thus, all that remains to be discussed are claims 7 and 9 of the 973 patent. We find that Accord's ANDA Product infringes claims 7 and 9 of the 973 patent. FF 124-26. For those claims, Hope indisputably established infringement except for Accord's argument that its ANDA product does not contain the claimed "sodium thiosulfate pentahydrate." FF 126; DI 218 at

⁶ As we explained: "There is no dispute that the claims of the 301 patent are infringed except that certain ranges in the ANDA only overlap those in the asserted claims. But this argument is foreclosed by *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278-79 (Fed. Cir. 2013). Accord did not dispute the dispositive nature of this authority." DI 178 at 1 n.1.

¶¶ 240-47 (advancing proposed findings of fact only on that issue); DI 209 (arguing noninfringement for only that reason). So we will next explain why we disagree with Accord’s position.

As a preliminary matter, the parties left it unclear whether the dispute ought to be viewed as a matter of claim construction, claim application, or a mix. Each, of course, argued that it wins either way. When the case was assigned to Judge Andrews, he held a claim construction hearing on the question, but deferred resolution until after trial. DI 58. Now we will resolve the dispute with the benefit of the factual record. Analytically, we view this principally as a claim construction decision with underlying fact findings. But it would not be unreasonable to view this as an entirely factual question, and we would reach the same result on the basis of the same findings.

Claims 7 and 9 of the 973 patent recite aqueous solutions, but depend from claim 4, which specifies the key ingredient — sodium thiosulfate — in pentahydrate form, seemingly as though it were still a solid. Did Hope draft claims that cannot be infringed? That happens sometimes, and it can be quite difficult to address. *See Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557-58 (Fed. Cir. 1995); *see also Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 77 F.3d 450, 451-57 (Fed. Cir. 1996) (Judge Newman’s dissent from denial of rehearing en banc). Accord could have simply argued that the claim is to a solution, and a hydrate does not exist in solution. Instead, Accord slightly obscures its core premise, arguing that the sodium thiosulfate pentahydrate should be construed to be a solid; or that the sodium thiosulfate in solution does not have a water content between 32% and 37%; or even that Accord’s product is not *made with* the pentahydrate form. In our view, these arguments are

facile and require studied indifference to largely undisputed facts about how skilled artisans understand and talk about these solutions.

To back up a bit, there is no dispute that sodium thiosulfate pentahydrate may be represented by the formula $\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$ and that sodium thiosulfate pentahydrate has a water content between 32% and 37% by weight. FF 10. And there is no dispute that Accord's ANDA product is an aqueous sodium thiosulfate solution made by dissolving anhydrous sodium thiosulfate in water.⁷ FF 62. But the claim does not specify what the solution was made with; just what it includes. So what does it mean for a solution to include a hydrate? As our fact-findings spell out in detail, in this specific context, we agree with Hope and Dr. Rogers that a skilled artisan would apply the claim language as-is by assessing the sodium-thiosulfate limitations on a pentahydrate basis. FF 111-123. That could be characterized as a claim construction with the same underlying findings of fact, but the result is the same.⁸

To address Accord's various sub-arguments, first Accord argues that Hope cannot prove that Accord infringes the "has a water content between 32% and 37% by weight" limitation. DI 209 at 5-10. This argument adds nothing to Accord's position because it is undisputed that sodium thiosulfate pentahydrate has a water content between 32% and 37% by weight. FF 10. Hence, when a skilled artisan assesses infringement on a pentahydrate basis, this claim limitation

⁷ If the claim had recited anhydrous sodium thiosulfate, presumably Accord would be making most of the same arguments, because anhydrous sodium thiosulfate does not exist in solution either.

⁸ If this had been a jury trial, we likely would have formally made these findings of fact underlying a claim construction along the lines of "sodium thiosulfate pentahydrate means sodium thiosulfate measured on a pentahydrate basis." This is hardly mangling the claim as Accord argues. Rather, the evidence indicates that it is a widely understood meaning in this context.

risers and falls with the rest of the requirements pertinent to sodium thiosulfate.⁹ Second, we disagree that the claims are either “inoperable” or “require sodium thiosulfate *made from* pentahydrate and water.” DI 209 at 10. Neither is the correct reading of the claim, as we found and explained above. Third, whether sodium thiosulfate pentahydrate is construed as a solid is irrelevant, and is yet another repackaged version of the same argument Accord makes. *Id.* at 11-12. Fourth, there is no problem with an untimely claim construction, *id.* at 12-13, because, as we explained, we could reach this result with no construction. Even if claim construction were essential, the parties postponed claim construction to trial, and it is a court’s obligation to construe the claims correctly. *See, e.g., O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1359-60 (Fed. Cir. 2008). Fifth, we disagree that Hope is reading pentahydrate out of the claims. *Id.* at 13-18. As Hope proved and we found, the pentahydrate limitation was satisfied. And to the contrary, Accord is the party proposing to rewrite the claims by introducing product-by-process limitations or ignoring evidence in favor of superficial arguments divorced from reality. Finally, we fail to see the relevance of Accord’s argument about the 301 patent. *Id.* at 18-19. A thoughtful strategy of clarifying claim language in continuing applications does not limit or abrogate claims in parent patents as a general matter.

For these reasons, we find that Accord’s ANDA Product infringes all asserted claims. FF 124-30.

b. Accord did not prove that the asserted claims are invalid as obvious.

Accord’s obviousness theory is somewhat unusual. Accord argues that the asserted claims would have been obvious in view of a 1917 patent to Hutchins combined with the

⁹ Consider the claim as a whole — Accord could make the same implausible arguments about any of the sodium-thiosulfate-related limitations.

knowledge of a skilled artisan. Hutchins offers a method for synthesizing sodium thiosulfate and general suggestions about purification, but no specific purification protocols and no discussion of purity levels akin to the claims at issue here. FF 141, 143-145, 148. Hutchins is not uniquely important to the analysis because the asserted patents are premised on long-known prior art synthetic methods like that of Hutchins. Hence, Accord rests the full weight of its obviousness defense on Dr. Rabinow's testimony that skilled artisans would have found it obvious to take a long-known substance and purify it to the specific degree that Hope claims in the patents. Largely because we found Dr. Rogers more credible than Dr. Rabinow on the relevant underlying facts relating to reasonable likelihood of success, we conclude that Accord did not prove obviousness here.

Obviousness under 35 U.S.C. § 103 is a question of law based on underlying findings of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The underlying factual considerations “include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations” bearing on obviousness. *Galderma Lab'ys, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 736 (Fed. Cir. 2013) (citing *Graham*, 383 U.S. at 17-18, and *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007)). Within the constraints of *Graham* and *KSR*, the obviousness analysis is flexible. Often, an obviousness determination “requires finding that a person of ordinary skill in the art would have been motivated to combine or modify the teachings in the prior art and would have had a reasonable expectation of success in doing so.” *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1347 (Fed. Cir. 2024) (quoting *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382 (Fed. Cir. 2019) and *Regents of Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018)). Accord bears the burden of proving that the asserted claims would have been

obvious and must do so by clear and convincing evidence. *See Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 973 (Fed. Cir. 2014). Typically, a challenger argues that the claims would have been obvious in view of some combination of identifiable items of prior art. “Though less common, in appropriate circumstances, a patent can be obvious in light of a single prior art reference if it would have been obvious to modify that reference to arrive at the patented invention.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016).

The central question at issue is whether Accord was able to demonstrate, by clear and convincing evidence, that a skilled artisan would have had good reason to modify Hutchins to achieve all of the purity levels claimed in Hope’s patents coupled with a reasonable likelihood of success of doing so. We find that Accord did not. To begin, Hope argues that Hutchins would be an unsuitable starting place, but we agree with Accord that as a matter of fact and law, there is nothing wrong with positing that a skilled artisan would have started with a reference that all agree discloses the key compound at issue. *See Infineum USA L.P. v. Chevron Oronite Co. LLC*, No. 2020-1333, 2022 WL 3147683, at *6 (Fed. Cir. Aug. 8, 2022) (nonprecedential); *Novartis Pharms. Corp. v. W.-Ward Pharms. Int’l Ltd.*, 923 F.3d 1051, 1059-60 (Fed. Cir. 2019). That is not to say that Hutchins is without drawbacks; those certainly factor into the likelihood of success arguments.

Turning to motivation, Accord relies on the FDA Letter, arguing that it may be considered even though it was confidential and citing *Endo Pharms., Inc. v. Actavis LLC*, 922 F.3d 1365, 1373 n.9 (Fed. Cir. 2019). DI 203 at 34. In *Endo*, there was a similar letter that had been sent to at least three companies. *Endo Pharms. Inc. v. Actavis Inc.*, 2017 WL 3731001, at *6 (D. Del. Aug. 30, 2017). The district court held that the letters were not generally available for § 102(b) purposes even though they had been sent to “three interested parties.” *Id.* But the

district court nonetheless considered the letters at least to show knowledge of a problem and motivation to solve it. *Id.* at *12 (also finding that the FDA letters did not establish reasonable likelihood of success). The Federal Circuit agreed but seemed to go further, suggesting that the letters *were* prior art, but under § 102(f). *Endo*, 922 F.3d at 1373 n.9 (citing *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401-02 (Fed. Cir. 1997)). Here, Accord did not argue that the FDA Letter was prior art per se, so we need not consider that potentially thorny issue. Rather, Accord just asks us to accept that the letter identifies the relevant problem and provides a reason to try to solve it. We agree. But, as in *Endo*, that leaves open the question of whether a skilled artisan would have had a reasonable expectation of success. Just because someone asks for something does not mean it would have been obvious to deliver.

That brings us to reasonable expectation of success, which is where Accord's evidence falls short. Dr. Rogers explained, credibly and entirely persuasively, many reasons why skilled artisans would not have considered achieving the claimed purity levels a predictable or routine task. FF 134-38, 159-62. Rather, the task carried considerable uncertainty, both for individual impurities recited in the claims and for the claimed combination. FF 134-38, 154-57. Dr. Rabinow, on the other hand, resorted to generalizations and oversimplifications that we did not find credible. FF 158-59. Accord embraces this approach, arguing that "Dr. Rabinow explained how the prior art *as a whole* would have guided a POSA to the techniques that would be suitable for synthesizing and purifying sodium thiosulfate meeting the claimed purity limitations with a reasonable expectation of success." DI 211 at 3. That approach is not wrong as a matter of law, but it opens the door to the risk of pervasive use of hindsight-driven conclusory testimony, which is exactly what Accord advanced at trial. FF 158. As Dr. Rogers's testimony credibly

demonstrates, this is not a case about mere routine optimization; the inventions required solving multiple difficult and interlocking problems simultaneously. FF 138, 154-57.

Although we found the lack of evidence on reasonable expectation of success dispositive, we also find that the objective evidence of nonobviousness further underscores Accord's failure of proof on obviousness. Hope demonstrated long-felt need, failure of others, and praise, and rebutted any suggestion from Accord of simultaneous invention. FF 164-82. And we agree with Hope that it is entitled to a presumption of nexus because we found that Hope's product is the claimed invention, demonstrated through Dr. Rogers's credible testimony. FF 165, 183.

c. Accord did not prove that the asserted claims are invalid as lacking written description.

Accord's written description defense focuses on the claims' use of language like "contains no greater than about" certain impurities, a range that Accord argues encompasses zero. DI 203 at 43-44 (highlighting aluminum, sulfate, and sulfite). Accord argues that "[t]here is certainly no evidence in the patent that the inventors were in possession of compositions containing down to zero" levels of impurities. *Id.* at 44. Further, Accord suggests that even if the lower end of the ranges were the limit of detection, the patent similarly lacks evidence of possession of "down to undetectable" levels of impurities. Accord implies, but does not cite any authority to support, that it is fatal to written description for a claimed range to include values not specifically disclosed in the patent, or values thought to be unachievable. *Id.*; DI 211 at 14-15 (Accord in reply distinguishing Hope's cases but presenting none of its own). Accord's expert, Dr. Rabinow, did not opine on written description. That leaves Accord to rely on the Asserted

Patents¹⁰ and its own interpretation of Hope’s witnesses’ testimony. Nonetheless, Hope provided Accord with a response that we find persuasive.

Written description is a fact question, and Accord carries the burden by clear and convincing evidence. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1354-55 (Fed. Cir. 2010) (en banc). Accord must prove that the patent specification does not reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter. *Id.* at 1351. Among other things, we are free to consider “the nature and scope of the claims[,] the complexity and predictability of the relevant technology.” *Id.* (also discussing “the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue,” quoting *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)). Adequate description for a claimed range is a fact-intensive inquiry, and there is no obvious reason why Accord’s argument should get automatic traction simply because the ranges could be understood to include zero, undetectable, or unachievable values.

First, we entirely agree with Hope that a skilled artisan would understand that the term “no greater than” in the Asserted Claims refers to the “level of detection up to” the claimed amount. FF 193-95. It is improper for Accord to advance a written description argument without resolving a material and underlying claim construction dispute. *Intellectual Ventures I LLC v. Motorola Mobility LLC*, 870 F.3d 1320, 1325-26 (Fed. Cir. 2017). But in any event, Accord does not dispute Hope’s view about detection, focusing on what can be achieved rather than measured. DI 211 at 14-15. Turning to achievability, we find no basis in written

¹⁰ In some situations, the patents alone are sufficient evidence. *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 927 (Fed. Cir. 2004).

description law to find — absent some meaningful factual record — that a skilled artisan would have concluded that patents fail to reflect that the inventors lacked possession of the claimed invention simply because the ranges include values that were difficult or impossible to achieve. Rather, “open-ended claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art.” *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1376-77 (Fed. Cir. 2007) (quoting *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1572 (Fed. Cir. 1991)). Indeed, “[a]s [the Federal Circuit] ha[s] recognized, [b]roadly articulated rules are particularly inappropriate in this area.” *RAI Strategic Holdings, Inc. v. Philip Morris Prods. S.A.*, 92 F.4th 1085, 1091 (Fed. Cir. 2024) (quoting *Indivior UK Ltd. v. Dr. Reddy’s Labs. S.A.*, 18 F.4th 1323, 1329-30 (Fed. Cir. 2021)). Hence, this is simply not a situation where the patents alone can prevail against the presumption of validity, and certainly not against Hope’s record, which we credit. We therefore find that Accord did not demonstrate that the Asserted Claims are invalid for lack of written description. FF 184-200.

d. The asserted claims are not unenforceable due to prosecution laches.

Finally, Accord argues that Hope should be barred from enforcing the 301 patent under the doctrine of prosecution laches. Accord’s theory, briefly, is that Hope lost its rights to enforce the 301 patent because it waited too long to pursue the 301 patent, the claims of which do not include the “pentahydrate” limitation like its ancestors in the same patent family. “Prosecution laches may render a patent unenforceable where a patentee’s conduct ‘constitutes an egregious misuse of the statutory patent system.’ Prosecution laches requires proving two elements: (1) the patentee’s delay in prosecution must be unreasonable and inexcusable under the totality of circumstances and (2) the accused infringer must have suffered prejudice attributable to the

delay.” *Personalized Media Commc’ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023) (quoting *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1360-61 (Fed. Cir. 2021)).

Accord’s laches defense is unpersuasive in every way. First, the defense is premised on Accord being successful with its noninfringement defense for the patents other than the 301 patent. It was not, as explained above. Because we found that Accord infringed the claims that recited the “pentahydrate” limitation, Accord was no worse off when the 301 patent issued. Second, even if we had found noninfringement of the other patents, we find that Hope’s delay in seeking the 301 patent was not unreasonable. FF 201-209. Accord presented not a shred of evidence that would allow us to conclude that 13 years was “too long,” or that a small company like Hope should not be entitled to pursue in good faith clearer claims to confront new competitors.¹¹ FF 209. Third, and again on the assumption that we had found noninfringement of the other patents, Accord was not prejudiced; it did not even attempt to introduce evidence of prejudice. FF 210. With no supporting authority, Accord asks us to *assume* prejudice as a matter of law in an ANDA case; that would be entirely inappropriate. DI 203 at 45-46. There is nothing “egregious” about Hope’s conduct, which on this record, was both prudent and harmless. For any and all of these reasons, we conclude that Accord is not entitled to a defense of prosecution laches.

IV. CONCLUSION

For the above reasons, we grant judgment in favor of Hope in all respects. A final order accompanies this memorandum.

¹¹ To be clear, there is nothing improper about drafting claims with an eye on competitor conduct. *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1247 (Fed. Cir. 2002) (“[I]t is legitimate to amend claims or add claims to a patent application purposefully to encompass devices or processes of others.”)