

NOTE: This disposition is nonprecedential.

**United States Court of Appeals  
for the Federal Circuit**

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**BRACCO DIAGNOSTICS INC.,**  
*Plaintiff-Appellee*

v.

**MAIA PHARMACEUTICALS, INC.,**  
*Defendant-Appellant*

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2020-1387

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Appeal from the United States District Court for the District of New Jersey in No. 3:17-cv-13151-PGS-TJB, Senior Judge Peter G. Sheridan.

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Decided: December 17, 2020

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WILLIAM R. ZIMMERMAN, Knobbe, Martens, Olson & Bear, LLP, Washington, DC, argued for defendant-appellant. Also represented by THOMAS P. KRZEMINSKI, KAREN MARIE CASSIDY, Irvine, CA.

DONALD RHOADS, Rhoads Legal Group PC, New York, NY, argued for plaintiff-appellee. Also represented by H. DANNY KAO, Kao & Associates, Pc, Flushing, NY.

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Before LOURIE, CLEVINGER, and CHEN, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Maia Pharmaceuticals, Inc. (“Maia”) appeals from a judgment of the United States District Court for the District of New Jersey that Maia’s sincalide product infringes U.S. Patent 6,803,046 (“the ’046 patent”), owned by Bracco Diagnostics, Inc. (“Bracco”). J.A. 1–8. The court entered the judgment pursuant to a stipulation of infringement by the parties in view of the court’s claim construction of the terms buffer, surfactant/solubilizer, and surfactant. *Bracco Diagnostics, Inc. v. Maia Pharms., Inc.*, No. 3:17-cv-13151, 2019 WL 4885888 (D.N.J. Oct. 3, 2019) (“*Claim Construction Order*”). Because Maia stipulated to infringement under a claim construction that is essentially correct, we *affirm*.

#### BACKGROUND

This appeal concerns a patent infringement action brought by Bracco under the Hatch-Waxman Act. Bracco owns the ’046 patent, listed in the Food and Drug Administration’s (FDA) Orange Book as covering Kinevac®, the active ingredient of which is sincalide. The ’046 patent has claims directed to sincalide formulations, methods for making and using sincalide formulations, and sincalide powder kits. ’046 patent col. 37 l. 40–col. 44 l. 30. Sincalide, a synthetic peptide hormone, is typically administered to stimulate gallbladder contraction, stimulate pancreatic secretion, and accelerate the transit of a barium meal through the small bowel. J.A. 79–80, 191; ’046 patent col. 13 ll. 40–58. Although sincalide was originally introduced in 1976, the ’046 patent purports to teach sincalide formulations that are “purer than prior art formulations, and have fewer degradants and more consistent potency” in

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part through addition of excipients<sup>1</sup> such as buffers, surfactants/solubilizers, and surfactants. '046 patent col. 1 ll. 9–26, 46–49. All 36 claims at issue in this litigation require sincalide, a buffer, and, depending on the claim, either a surfactant/solubilizer or a surfactant. *Id.* col. 37 l. 40–col. 40 l. 44.

In 2017, Maia filed a New Drug Application (“NDA”) for its own sincalide product pursuant to FDCA § 505(b)(2). It is undisputed that Maia’s sincalide product contains amino acid excipients. Maia certified pursuant to § 505(b)(2)(A)(iv) that its sincalide product would not infringe the '046 patent claims. Bracco filed suit in December 2017, alleging that Maia’s product does infringe the claims. Maia denied infringement, asserting that the amino acid excipients in its sincalide product do not act as buffers, surfactants/solubilizers, or surfactants, as required by the claims. Maia also counterclaimed that the claims are invalid. The parties requested that the district court construe the terms buffer, surfactant/solubilizer, and surfactant. Central to the claim construction dispute was whether the three terms encompass amino acids.

Claim 1 reads as follows:

1. A stabilized, physiologically acceptable formulation of sincalide comprising:
  - (a) an effective amount of sincalide,
  - (b) at least one stabilizer,

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<sup>1</sup> Although both parties reference “excipients” throughout their briefs, neither party defines the term. We accept the construction proposed by the district court: “An inactive substance that serves as the vehicle or medium for a drug or other active substance.” *Claim Construction Order*, 2019 WL 4885888, at \*2 n.1 (citing Oxford English Dictionary).

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- (c) a *surfactant/solubilizer*
- (d) a chelator,
- (e) a bulking agent/tonicity adjuster, and
- (f) a *buffer*.

'046 patent col. 37 ll. 41–49 (emphases added).

Several dependent claims contain “Markush” groups that further recite that buffers or surfactants/solubilizers can be selected from a list of excipients that includes amino acids. A Markush group “lists alternative species or elements that can be selected as part of the claimed invention.” *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1357 (Fed. Cir. 2016) (citing *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003)).

Claim 3 depends from claim 1, and recites that an amino acid can be selected as a buffer:

- 3. The formulation of claim 1, wherein said *buffer* is selected from the group consisting of . . . *one or more amino acids* . . . and biological buffers.

'046 patent col. 37 ll. 51–60 (emphases added).

Claim 6 depends from claim 1 and recites that an amino acid can be selected as a surfactant/solubilizer:

- 6. The formulation of claim 1, wherein said *surfactant/solubilizer* is selected from the group consisting of . . . *amino acids*.

*Id.* col. 37 l. 65–col. 38 l. 5 (emphases added).

Claim 40 is to a kit, where a powder mixture contains a surfactant:

- 40. A kit, comprising:
  - (i) a powder mixture comprising

- (a) sincalide,
  - (b) at least one stabilizer,
  - (c) a surfactant,
  - (d) a chelator,
  - (e) a bulking agent/tonicity adjuster, and
  - (f) a buffer;
- (ii) a container to hold said powder mixture; and
  - (iii) optionally, a physiologically acceptable fluid.

*Id.* col. 39 ll. 53–62 (emphasis added).

Claim 44 depends from claim 40 and recites that an amino acid can be selected as a surfactant:

44. The kit of claim 40, wherein said *surfactant* is selected from the group consisting of . . . *amino acids*.

*Id.* col. 40 ll. 10–18 (emphases added).

The specification provides further context regarding the meaning of the three terms. For example, the specification explains that buffers “are employed to stabilize the pH of sincalide formulations of the invention, and consequently, reduce the risk of chemical stability<sup>2</sup> at extreme pH values.” *Id.* col. 9 ll. 45–47. The specification provides a nonexclusive list of buffering agents “useful in the preparation of formulation kits,” which includes amino acids. *Id.* col. 9 ll. 48–65. The list of exemplary buffering agents in the specification is substantially similar to the buffering

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<sup>2</sup> We presume that this is a typographical error and the patentee intended to write “instability.”

agents listed in the dependent claims for buffer. *See, e.g., id.* col. 37 ll. 51–60.

The specification also includes a section entitled “Surfactants/Solubilizers/Surface Active Agents,” which explains that “[t]he addition of a nonionic surfactant . . . may reduce the interfacial tension or aid in solubilization thus preventing or reducing denaturation and/or degradation at air/liquid or liquid/solid interfaces of the product in solution.” *Id.* col. 11 ll. 26–34. The specification further provides two non-exclusive exemplary lists of surfactants/solubilizers, which include amino acids. *Id.* col. 11 ll. 35–63. The lists of exemplary surfactants/solubilizers in the specification overlap with the dependent claims for surfactants/solubilizers and surfactants. *E.g., id.* col. 37 l. 65–col. 38 l. 5, col. 40 ll. 11–18.

With respect to the term buffer, the district court adopted the following construction:

An excipient that: stabilizes the pH of sincalide formulations of the invention, and consequently, reduces the risk of chemical stability at extreme pH values. Buffering agents useful in the preparation of formulation kits of the invention include phosphoric acid, phosphate (e.g. monobasic or dibasic sodium phosphate, monobasic or dibasic potassium phosphate, etc.), citric acid, citrate (e.g. sodium citrate, etc.), sulfosalicylate, acetic acid, acetate (e.g. potassium acetate, sodium acetate, etc.), methyl boronic acid, boronate, disodium succinate hexahydrate, ***amino acids***, including amino acid salts (such as histidine, glycine, lysine, imidazole), lactic acid, lactate (e.g. sodium lactate, etc.), maleic acid, maleate, potassium chloride, benzoic acid, sodium benzoate, carbonic acid, carbonate (e.g. sodium carbonate, etc.), bicarbonate (e.g. sodium bicarbonate, etc.), boric acid, sodium borate, sodium chloride, succinic acid, succinate (e.g. sodium succinate),

tartaric acid, tartrate (e.g. sodium tartrate, etc.), tris(hydroxymethyl) aminomethane, biological buffers (such as N-2-hydroxyethylpiperazine, N'-2-ethanesulfonic acid (HEPES), CHAPS and other 'Good's' buffers).

*Claim Construction Order*, 2019 WL 4885888, at \*10 (emphasis added). The district court thus imported into its definition the list of exemplary buffering agents from the specification. It rejected Maia's proposal to construe the term buffer to mean "[a] compound that stabilizes the pH of a sincalide formulation." *Id.* at \*3.

The district court construed the term surfactant/solubilizer to mean:

A surfactant and/or a solubilizer. The addition of a nonionic surfactant, such as polysorbate, to the formulation, may reduce the interfacial tension or aid in solubilization thus preventing or reducing denaturation and/or degradation at air/liquid or liquid/solid interfaces of the product in solution.

Surfactants/solubilizers include compounds such as free fatty acids, esters of fatty acids with polyoxyalkylene compounds like polyoxypropylene glycol and polyoxyethylene glycol; ethers of fatty alcohols with polyoxyalkylene glycols; esters of fatty acids with polyoxyalkylated sorbitan; soaps; glycerol-polyalkylene stearate; glycerol polyoxyethylene ricinoleate; mono- and copolymers of polyalkylene glycols; polyethoxylated soya-oil and castor oil as well as hydrogenated derivatives; ethers and esters of sucrose or other carbohydrates with fatty acids. Fatty alcohols, these being optionally polyoxyalkylated; mono-, di-, and triglycerides of saturated or unsaturated fatty acids; glycerides or soya-oil and sucrose; sodium caprolate, ammonium sulfate, sodium dodecyl sulfate (SDS), Triton-100 and anionic

surfactants containing alkyl, aryl or heterocyclic structures.

Examples of preferred surfactants/solubilizers for use in the present invention include, but are not limited to, pluronics (e.g., Lutrol F68, Lutrol F 127), Poloxamers, SDS, Triton-100, polysorbates such as TWEEN® 20 and TWEEN® 80, propylene glycol, PEG and similar compounds, Brij58 (polyoxyethylene 20 cetyl ether), cremophor EL, cetyl trimethylammonium bromide (CTAB), dimethylacetamide (DMA), NP-40 (Nonidet p 40), and N-methyl-2-pyrrolidone (Pharmasolve), glycine and other *amino acids*/amino acid salts and anionic surfactants containing alkyl, aryl or heterocyclic structures, and cyclodextrins. TWEEN® 20 is the most preferred surfactant in formulations of the invention.

*Id.* at \*10 (emphasis added). As it did with the term buffer, the court imported a list of preferred surfactants/solubilizers from the specification into its definition of the term. It rejected Maia's proposal to construe surfactant/solubilizer to mean "[a] surfactant that is also a solubilizer. A solubilizer is a compound that aids in solubilization, thus preventing or reducing sincalide denaturation and/or degradation cause by peptide aggregation, precipitation, surface adsorption, or agitation at air/liquid or liquid/solid interfaces in solution." *Id.* at \*2.

Lastly, the district court construed the term surfactant to mean "[a]n excipient that *may* reduce the interfacial tension." *Id.* at \*10 (emphasis added). The court rejected Maia's proposal to construe surfactant to mean "[a] compound that reduces the tension of the air/liquid or liquid/solid interface." *Id.* at \*5. The court also rejected Bracco's proposal to import a list of exemplary surfactants/solubilizers from the specification into its definition. *Id.* at \*7.



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In view of the district court's claim constructions, the parties stipulated to infringement of claims 1–3, 6, 10–17, 19, 21–23, 26, 30–37, 40–41, 44, and 48–55 (“the stipulated claims”) and dismissal of the remaining claims and defenses without prejudice. J.A. 1–8, 3666–3678. The court made no evidentiary findings regarding infringement in its final judgment. Maia appealed to this court. We have jurisdiction over the appeal pursuant to 28 U.S.C. 1295(a)(1).

#### DISCUSSION

Maia argues that we should vacate the district court's construction of the terms buffer, surfactant/solubilizer, and surfactant, adopt Maia's proposed constructions for the terms, and remand to the district court for further proceedings. At issue in this dispute is whether the district court erroneously included amino acids in its definitions of buffer and surfactant/solubilizer, erroneously construed the backslash between surfactant/solubilizer to mean “and” or “or,” and erroneously included “may” in its definition of surfactant.

Claim construction is a question of law that we review de novo. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 839 (2015). We review de novo the district court's findings of fact on evidence “intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history),” and review for clear error underlying fact findings related to extrinsic evidence. *Id.* at 841.

As an initial matter, we note that the district court did not specify in its claim construction order which claims it was construing. *Claim Construction Order*, 2019 WL 4885888, at \*10. However, that does not matter here, as we are dealing with the same claim limitations in all of the claims, and can readily review their constructions.

In order to resolve the disputes, we turn to the claim language of the stipulated claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). Both

the dependent and independent claims recite the disputed terms buffer, surfactant/solubilizer, or surfactant. The scope of the dependent claims is expressly defined by naming the intended components, through Markush claiming. For example, dependent claims 3, 23, and 41 recite that a “buffer is selected from the group consisting of a [list of excipients, including amino acids].” ’046 patent col. 37 ll. 51–60, col. 38 ll. 58–67, col. 39 l. 63–col. 40 l. 5. The dependent claims that recite a surfactant and a surfactant/solubilizer are substantially similar. *See, e.g., id.* col. 39 ll. 5–12 (“[S]urfactant/solubilizer is selected from the group consisting of . . .”), col. 41 ll. 5–12 (“[S]urfactant is selected from the group consisting of . . .”). The Markush groups are “closed” because “[u]se of the transitional phrase ‘consisting of’ to set off a patent claim element” indicates that the claim “exclude[s] any elements, steps, or ingredients not specified in the claim.” *Multilayer*, 831 F.3d at 1358 (quoting *AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001)). Thus, the dependent claims need no formal construction because, through the Markush claim drafting, the possible components are named and the scope of the dependent claims is thus definite and clear.

The independent claims also recite use of buffers, surfactants/solubilizers, and surfactants in sincalide formulations, methods of making sincalide formulations, and sincalide kits. *See, e.g.,* ’046 patent col. 37 ll. 41–49, col. 38 ll. 51–55, col. 39 ll. 53–62. However, unlike the dependent claims, the scope of the independent claims is not expressly defined by naming the possible components. We will therefore construe the district court’s claim constructions as applicable to the disputed independent claims.

### I. *Buffer*

Maia argues that the district court wrongly imported a list of exemplary buffers from the specification into its definition of the term buffer. Maia asserts that the plain and ordinary meaning of buffer within the context of the

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patent specification is functional: “a compound<sup>3</sup> that *stabilizes* the pH of a sincalide formulation.” Appellant Br. at 43–44 (emphasis added); *see also* ’046 patent col. 9 ll. 45–47 (“Buffering agents are *employed to stabilize* the pH of sincalide formulations of the invention . . .”) (emphasis added). According to Maia, the court eliminated the functional aspect of buffer by construing it to include excipients such as amino acids that do not necessarily have buffering effects. Maia asserts that the court’s broad construction of buffer is contrary to its plain and ordinary meaning.

Maia emphasizes that its amino acids do not have buffering effects. It asserts, however, that because the district court defined buffer broadly to necessarily include all amino acids, even those that do not actually act as buffers, it had no choice but to stipulate to infringement. Maia effectively interprets the court’s construction to mean: an excipient that stabilizes the pH of a sincalide formulation and consequently, reduces the risk of chemical [in]stability at extreme pH values or [*all amino acids regardless of function*]. Appellant Rep. Br. at 22. In other words, Maia does not consider the stipulation to be an admission that its amino acids actually function to stabilize the pH of a sincalide formulation. Rather, the stipulation is only an admission that Maia’s product has amino acids. Maia thus argues that if this court removes the “predetermined” list of excipients, which includes amino acids, from the definition of buffer, we would need to remand the case for an infringement analysis as to whether Maia’s amino acids have buffering effects.

Bracco responds that the district court properly defined buffer to include a list of excipients from the specification.

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<sup>3</sup> Maia’s proposed construction refers to a buffer as a compound. Appellant Br. at 43–44. The court construed buffer to be an “excipient.” According to Maia, the distinction is not material to the case. Appellant Rep. Br. at 16.

Bracco first argues that the specification provides a list of excipients, including amino acids, that the “inventors used to define” buffer, and therefore the list must be included in the definition of buffer. Appellee Br. at 27 (citing ’046 patent col. 9 ll. 45–65). Bracco also points to dependent claims, like claim 3, which recite that “a buffer is selected from the group consisting of” a substantially similar list of exemplary buffers as those listed in the specification. Appellee Br. at 27.

According to Bracco, any error in claim construction is harmless. It rejects Maia’s argument that it only stipulated to having amino acids in its product, not that its amino acids have buffering effects. Bracco asserts that Maia is misconstruing the district court’s construction of the three terms in the stipulation “as somehow reading out the functions required by the terms.” Appellee Br. at 16. Bracco states that when Maia stipulated to infringement, Maia effectively agreed that “each of [its] two amino acids is a ‘buffer’ excipient with a ‘buffer’ effect, which is [a]n excipient that: stabilizes the pH of sincalide formulations . . . .” *Id.* at 16–17. Bracco thus argues that the court’s removal of the exemplary list has no effect on the infringement analysis. Maia is foreclosed, Bracco argues, from asserting that its amino acids do not have buffering effects in view of the stipulation. Bracco also asserts that extrinsic evidence demonstrates that Maia’s amino acids function as buffers. However, Bracco does not cite any portion of the claim construction order or final judgment demonstrating that the court took into account evidentiary findings regarding the function of Maia’s amino acids.

We agree with Maia that the district court technically erred in importing a list of excipients into its definition of buffer. Listing numerous compounds that meet the language of a functional term in a claim confuses construing what the function is with what compounds perform that function. The latter is not the task of claim construction, which is to provide definitional meaning to claim language.

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The court correctly did that when it stated that a buffer, for purposes of this invention, is “[a]n excipient that: stabilizes the pH of sicalide formulations of the invention, and consequently, reduces the risk of chemical [in]stability at extreme pH values.” *Claim Construction Order*, 2019 WL 4885888, at \*10. That construction by the district court was correct, and the court’s technical error of then listing from the specification a long list of compounds meeting that meaning does not invalidate that functional construction. And claim 3 then recites that the buffer in claim 1 includes one or more amino acids. That technical error was thus harmless. Maia then stipulated to infringement.

The key language of its stipulation reads as follows: “Under the Court’s construction of the disputed claim terms of the ’046 patent, . . . Maia’s 505(b)(2) NDA Product would literally infringe the 36 claims.” J.A. 3673; *see also* J.A. 5–6. That stipulation forecloses the argument for non-infringement.

Maia argues that it had no choice but to stipulate to infringement because the district court’s construction removed the functional aspect of buffer and predetermined that Maia’s amino acids have buffering effects. But the district court did not “remove” the functional definition of buffer. The court correctly included the functional definition in its claim construction. Maia asks us to effectively reinterpret the court’s construction to mean: an excipient that stabilizes the pH . . . buffering agents to include . . . [*all amino acids regardless of function*]. But that was not the stipulation.

Maia also points to a “whereas” clause in the stipulation stating that “the [district court’s] construction, explicitly defining ‘buffer’ . . . to include ‘amino acids,’ *alone* forms the basis for Maia’s admission and stipulation.” Appellant Rep. Br. at 23 (citing J.A. 3671) (emphasis added). But that is also not what the stipulation says, and we do not rely on a self-serving “whereas” clause to override the clear import

of the statement. That clause is directly contradictory to Maia's admission in the other portion of the stipulation that its product meets "every element and claim term" of the claims. J.A. 3669. Moreover, even Maia admits that the "whereas" clause is neither binding nor conclusive. Appellant Rep. Br. at 23.

Maia similarly argued that the claims are invalid as inoperable, because, it asserts, amino acids are not buffers. However, it relinquished those arguments when it stipulated to infringement and dismissal of its counterclaims of invalidity. J.A. 6, 3673. Consequently, contrary to Maia's assertion, it did have an opportunity to assert that its amino acids do not function as "buffering agents" because they do not "stabilize the pH." To the extent that Maia believed the district court's construction had a particular meaning, it never sought clarification from the court, and that issue, in light of the stipulation, is now beyond the scope of this appeal. J.A. 3670. Having entered into a stipulation, Maia is now bound by it. *See Inventio AG v. Otis Elevator Co.*, 497 F. App'x 37, 41 (Fed. Cir. 2012) (rejecting a party's argument that it did not stipulate to a certain fact because the wording of the stipulation "suggests otherwise, and it is to that stipulation [the party] is bound"); *United States v. Penland*, 370 F. App'x 381, 383 (4th Cir. 2010) (rejecting party's attempt to disavow "unambiguous language set forth in the [s]tipulation"); *United States v. Kieffer*, 794 F.3d 850, 852 (7th Cir. 2015) (asserting that a party "may not disavow [its] stipulations by quibbling over semantics").

Because the district court's claim construction is essentially correct and Maia stipulated to infringement if that were so, we affirm the judgment of infringement without remand. *See, e.g., SUFI Network Servs., inc. v. United States*, 755 F.3d 1305, 1312 (Fed. Cir. 2014) (remand can be unnecessary where "no further record development is appropriate"); *Shinyei Corp. of Am. v. United States*, 524 F.3d 1274, 1284 n.3 (Fed. Cir. 2008) (holding that "because

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the issues on appeal are legal, not factual, we see no need to remand”).

## II. *Surfactant/Solubilizer*

We turn next to Maia’s argument that the district court erred in construing the term surfactant/solubilizer. Maia again argues here that the court wrongly imported a list of exemplary surfactants/solubilizers from the specification into the definition. Maia also argues that the court improperly construed the backslash between surfactant/solubilizer to mean “and” or “or” rather than “and.” We address each argument in turn.

With regard to the first issue, Maia argues that the district court “eviscerated” the functional aspect of the term surfactant/solubilizer by importing a list of exemplary excipients into its definition regardless as to whether they actually function as such. We agree with Maia that the district court technically erred in importing a list of excipients into its definition of surfactant/solubilizer. But, as with the term buffer, inclusion of the list of exemplary surfactant/solubilizer agents, while technically incorrect, is essentially correct in its functional definition. As a result, the court’s technical error is harmless.

Our analysis here is similar to our analysis regarding the district court’s error in construing buffer. The district court correctly included the functional definition in its claim construction. Its construction reads that a surfactant/solubilizer “may reduce the interfacial tension or aid in solubilization thus preventing or reducing denaturation and/or degradation at air/liquid or liquid/solid interfaces of the product in solution.” *Claim Construction Order*, 2019 WL 4885888, at \*10. Inclusion of the sentence “the addition of a nonionic surfactant, such as polysorbate,” along with an exemplary list of surfactant/solubilizer agents, does not invalidate the functional portion of the construction. Moreover, as with buffer, claim 6 recites that the surfactant/solubilizer includes amino acids. ’046 patent col. 37

l. 65–col. 38 l. 5. Maia’s product includes amino acids and thus it stipulated to infringement. When Maia stipulated to infringement under the court’s claim construction, it stipulated to infringing *every limitation* of the claims, not just to having amino acids. Having entered into a stipulation, Maia is bound by it.

We now turn to Maia’s second argument. Maia argues that the district court wrongly construed surfactant/solubilizer to mean a surfactant “and” or “or” a solubilizer, rather than a surfactant that is also a solubilizer. As support for its position, Maia argues that the specification sets forth a pattern of using a backslash to describe one excipient that has multiple functions. For example, in Table 1, mannitol is reported to function as a “bulking agent/cake forming agent/tonicity adjuster.” ’046 patent cols. 3–4 Table 1. According to Maia, the table indicates that mannitol is a bulking agent [and] cake forming agent [and] tonicity adjuster. Appellant Br. at 34. Maia further argues that the district court’s construction of “surfactant/solubilizer” to mean a surfactant or solubilizer would allow the claims to encompass sincalide formulations without surfactants. According to Maia, that impermissibly broadens the scope of the claims beyond that supported by the specification because every embodiment and description of the invention in the patent requires a surfactant. Maia points to Table 1 and example 7, both of which include sincalide formulations comprising surfactants, and statements in the specification that the formulation includes a surfactant.

Bracco responds that the specification supports its construction of the backslash to mean “and” or “or.” With respect to Maia’s argument that the specification only discloses embodiments comprising surfactants, Bracco argues that Maia attempts to impermissibly read preferred embodiments into the claim. It asserts that the patent’s disclosure contains no disclaimer of sincalide formulations without surfactants and that, on the contrary, there are several examples of formulations in the specification that



do not contain surfactants, including those described in tables 8 and 9. With regard to Maia’s argument that the specification uses the backslash in Table 1 to define a single excipient that has more than one function, Bracco asserts that the backslash could also be construed in that context to mean “or.” For example, in Table 1, mannitol can be a bulking agent [or] a cake forming agent [or] a tonicity adjuster. Appellee Br. at 46.

We agree with Bracco that the district court correctly construed the backslash in surfactant/solubilizer to mean “and” or “or.” Beginning with the claim language, the plain reading of the claims is that the backslash means “and” or “or.” Claim 1, in relevant part recites: “A stabilized, physiologically acceptable formulation of sincalide comprising: . . . (c) a *surfactant/solubilizer* . . .” ’046 patent col. 37 ll. 41–49 (emphasis added). Claim 7 depends from claim 1 and recites: “The formulation of claim 1, wherein said *surfactant* is a nonionic surfactant.” *Id.* col. 38 ll. 6–7 (emphasis added). Dependent claim 7’s recitation of a formulation with only a surfactant lends credence to Bracco’s argument that the backslash can mean “or” and not necessarily “and.”

We next turn to the specification. Maia argues that this specification requires a construction of the backslash to mean only “and.” However, Maia’s argument is grounded solely on this specification’s ambiguous language and its disclosure of a few preferred embodiments of the patent that include sincalide formulations comprising surfactants. For example, Maia argues that the specification sets forth a pattern of using a backslash when describing multiple functions performed by the same excipient, as exemplified by Table 1. However, as Bracco points out, the backslash in Table 1 can also be interpreted to mean “or.” Additionally, all of Maia’s quotes from the specification reference a preferred embodiment. Appellant Br. at 35–36 (quoting ’046 patent col 1 ll. 56–62 (“In *one aspect*, the invention features sincalide formulations that include . . . a surfactant . . .”), col. 2 ll. 1–2 (“In *various embodiments* of

the invention, the surfactant is a nonionic surfactant . . . .”) (emphases added). Maia omits that the specification’s disclosure that “[t]he sincalide formulations of the invention *can include* a variety of excipients, *such as, for[] example* . . . surfactants,” indicates that surfactants are not necessary. ’046 patent col. 4 ll. 8–12 (emphases added). Here, although the specification discloses a few preferred embodiments of sincalide formulations with surfactants, Maia has not demonstrated that the patentee has a “clear intention to limit the claim scope.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014).

We thus conclude that the district court correctly construed the backslash in surfactant/solubilizer to mean “and” or “or.”

### III. *Surfactant*

Lastly, Maia argues that the district court erred in construing the term surfactant to mean “an excipient that *may* reduce the interfacial tension.” Maia asserts that in construing surfactant, the court improperly imported into the definition ambiguous and non-definitional language from the specification—“[t]he addition of a nonionic surfactant. . . *may* reduce the interfacial tension.” See ’046 patent col. 11 ll. 27–34 (emphasis added). Maia argues that because every excipient “may” or “may not” reduce interfacial tension, under the court’s construction, a surfactant encompasses “every excipient in the universe,” including excipients that increase interfacial tension or are nonfunctional. Appellant Br. at 20. Maia argues that as a result, the court’s construction is contrary to the plain and ordinary meaning of the term.

According to Maia, the plain and ordinary meaning of surfactant in view of the specification as a whole is a compound that “must” reduce the interfacial tension at the *air/liquid or liquid/solid interfaces*. Appellant Rep. Br. at 18. As support for Maia’s narrower construction, it states that the only disclosed surfactant effect in the specification

is the *reduction* of interfacial tension at the *air/liquid or liquid/solid interface* rather than any increase in interfacial tension. Maia points to the specification's disclosure that a nonionic surfactant may "*reduce* the interfacial tension . . . at *air/liquid or liquid/solid interfaces* . . ." See '046 patent col. 11 ll. 27–34. (emphases added). Maia also points to Example 3 of the patent, entitled "Effect of Surfactants on Sincalide Formulations," to support its argument. Example 3 states, in relevant part, that use of even trace amounts of a surfactant "still produced a significant effect on the *air/liquid interface*." '046 patent col. 22 ll. 28–30 (emphases added). Maia states that the "effect" refers to an increase in potency attributed to the surfactant's *reduction* of surface tension at the air/liquid interface. Maia further cites several dictionaries that define surfactant to mean an excipient that necessarily reduces interfacial tension at the air/liquid or liquid/solid interface.

Bracco responds that the district court's construction is accurate in light of the specification's explicit disclosure that a surfactant "*may* reduce the interfacial tension." Bracco disagrees with Maia's position that the court's use of "may" in the definition renders the term meaningless. According to Bracco, a person of skill would interpret "may" to mean "capable of under certain circumstances." Appellee Br. at 14. As support, Bracco cites expert testimony. Thus, Bracco argues that the court's construction would include only surfactants that can, or are capable of, reducing interfacial tension, but would not include "everything in the universe." *Id.* at 13.

Bracco also argues that Maia is improperly loading additional limitations onto the term from the specification by requiring that surfactant be construed as an excipient that *must* reduce interfacial tension at certain interfaces. Bracco contends that the patentee has made no clear and unmistakable disclaimer that the definition of surfactant should be limited in the manner that Maia proposes. With regard to Maia's argument that the specification discloses

several statements and examples that surfactants reduce interfacial tension at the air/liquid or liquid/solid interface, Bracco responds that language referring to one preferred embodiment of a surfactant, does not so limit all surfactants. *Id.* at 39 (“[T]he addition of a nonionic surfactant, *such as polysorbate*, to the formulation, may reduce the interfacial tension . . . at air/liquid or liquid/solid interfaces.” (quoting ’046 patent col. 11 ll. 29–34)) (emphasis added).

Bracco further contends that Maia misrepresents Example 3 as supporting its argument that the only surfactant effect disclosed in the patent is reduction of interfacial tension. According to Bracco, Maia purports to quote from Example 3’s disclosure that a nonionic surfactant “still produced a significant effect on the air/liquid interface,” and misleadingly ascribes that “effect” to increase in potency resulting from a surfactant’s reduction of interfacial tension, while cropping the next line, which actually explains that the effect was the elimination of “foaming in the formulation.” ’046 patent col. 22 ll. 28–31. Bracco additionally asserts that Maia’s requirement that surfactants function at the air/liquid or liquid/solid interface does not comport with claim 40, which is directed to a powder mixture kit that has no liquid present.

With regard to the extrinsic evidence proffered by Maia, Bracco asserts that a person of ordinary skill, which Bracco contends is a peptide drug formulator, would not look to dictionaries to learn about the formulation of a peptide drug; according to Bracco, formulation of peptide drugs presents highly specialized technical issues and a dictionary would not be of use to a skilled peptide formulator. Bracco points out that several of Maia’s dictionaries reject Maia’s narrow construction of “surfactant” in favor of defining it as “usually” effecting other properties and other interfaces. J.A. 587. Lastly, Bracco asserts that Maia’s construction does not take into account evidence that a person of skill would consider a surfactant to have other effects

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including inhibition in aggregation, improvement in solubility, and reduction of adsorption.

We agree with Bracco that the district court correctly construed the term surfactant. First, contrary to Maia's assertion, the court's use of the word "may" in its construction does not render surfactant meaningless. We agree with Maia that "may," standing alone, presents some ambiguity. However, the plain and ordinary meaning of "may" within the context of this specification is properly understood as indicating an inherent measure of likelihood or possibility. It is not used by a person of skill to describe an event that has no likelihood of occurring. For example, the specification discloses that "[t]he addition of a nonionic surfactant . . . *may* reduce the interfacial tension" and continues to provide an exemplary list of surfactants/solubilizers. '046 patent col. 11 ll. 26–63 (emphasis added). It is unlikely that the patentee intended to provide an exemplary list of surfactants/solubilizers that could never be capable of reducing interfacial tension. Even Maia acknowledges that "may" encompasses possibility or probability in its brief. Appellant Br. at 19 ("It is undisputed that the term 'may' is permissive, used to indicate possibility."). It follows that the district court's definition includes excipients that reduce interfacial tension, or are capable of reducing interfacial tension, but excludes excipients that can never reduce interfacial tension. Thus, the term is not meaningless, as Maia alleges.

We further disagree with Maia's argument that the specification expressly indicates that surfactants *must* reduce interfacial tension at the air/liquid or liquid/solid interface. First, the specification's disclosure that one type of surfactant "*may* reduce the interfacial tension," supports the district court's construction that surfactants need not necessarily reduce interfacial tension. '046 patent col. 11 ll. 29–34 (emphasis added). Maia recites a few lines from the description section and from a preferred embodiment as support for its limitation. However, none of Maia's

references indicates that the patentee intended to limit the claim scope in the manner that it asserts. For example, Maia argues that Example 3 demonstrates that the purpose of surfactants is to increase potency through reduction of interfacial tension, although Bracco rightly points out that the “effect” could be referring to foaming. *Id.* col. 22 ll. 28–31. We have repeatedly “cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification,” where, like here, the patentee has not made a clear disavowal of the claim scope. *Imaginal Systematic, LLC v. Leggett & Platt, Inc.*, 805 F.3d 1102, 1109–10 (Fed. Cir. 2015) (quoting *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1346–47 (Fed. Cir. 2015)); see also *Ericsson, Inc. v. D-Link Sys. Inc.*, 773 F.3d 1201, 1218 (Fed. Cir. 2014) (“[I]t is important that we avoid importing limitations from the specification into the claims.”) (internal quotation marks omitted).

Moreover, the district court’s construction is supported by the extrinsic evidence. In construing surfactant, the court relied on Dr. Forrest’s testimony that a peptide formulator in 2002 was aware that surfactants usually, but not necessarily, reduce interfacial tension. The court found his testimony “more thorough and reli[ant] upon a more authoritative list of sources” than Maia’s expert, Dr. Klibanov, who asserted that surfactants *must* reduce interfacial tension at certain interfaces. *Claim Construction Order*, 2019 WL 4885888, at \*8. We do not see, nor does Maia allege, any clear error in the court’s reliance on Dr. Forrest’s testimony over Dr. Klibanov’s testimony.

#### CONCLUSION

We have considered the parties’ remaining arguments but find them unpersuasive. For the foregoing reasons, we conclude that while the district court technically erred in construing the terms buffer, surfactant/solubilizer, and surfactant, its construction is essentially correct. We therefore *affirm* the judgment of infringement.

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**AFFIRMED**