

United States District Court,
N.D. California.

NORIAN CORPORATION,
Plaintiff.

v.

STRYKER CORPORATION,
Defendant.

No. C01-00016-WHA

Dec. 7, 2004.

Background: Owner of patents for methods of bone repair sued competitor for infringement. The District Court, 252 F.Supp.2d 945, found patents enforceable, but not infringed. The United States United States Court of Appeals for the Federal Circuit, 363 F.3d 1321, for the Federal Circuit, 363 F.3d 1321, reversed in part and remanded. On remand, the United States District Court for the Northern District of California, William Alsup, J., again found noninfringement, and owner again appealed. The Court of Appeals, 432 F.3d 1356, affirmed. Thereafter, competitor moved for summary judgment of non-infringement.

Holding: The District Court, Alsup, J., held that phrase "a solution consisting of water and a sodium phosphate," as used in patent, required a solution made from one and only one sodium phosphate. Motion granted.

6,002,065. Not Infringed.

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William Overend, Reed Smith LLP, San Francisco, CA, Morgan W. Tovey, Michael B. Harlin, McAndrews Held & Malloy, Chicago, IL, for Defendant.

**ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT ON NON-
INFRINGEMENT OF CLAIMS 8-10 OF U.S. PATENT NO. 6,002,065**

ALSUP, **District Judge.**

INTRODUCTION

In this patent case, defendant moves for summary judgment on non-infringement, arguing that "a solution

consisting of water and a sodium phosphate" in claims 8-10 of plaintiff's United States Patent No. 6,002,065, ("the '065 patent"), should be construed to require a solution made from one and only one sodium phosphate. This order construes "a" in its singular sense. Because there remains no genuine factual dispute as to whether defendant's product infringes the '065 patent, defendant's summary judgment motion is **GRANTED**.

STATEMENT

On January 3, 2001, plaintiff Norian Corporation filed against defendant Stryker Corporation, alleging that defendant's BoneSource(R) product infringed two of its patents: United States Patent No. 5,336,264, ("the '264 patent"), and the '065 patent. The '264 patent is entitled "Situ Prepared Calcium Phosphate Composition and Method" and is directed to methods for preparing calcium phosphate compositions analogous to hydroxyapatite, $\text{Ca}_5(\text{PO}_4)_3\text{OH}$, a naturally occurring building block of bones and teeth. The '065 patent is entitled "Kits for Preparing Calcium Phosphate Minerals" and is directed to kits for preparing rapidly setting calcium phosphate compositions to be used as "bone cements" in medical or dental procedures.

BoneSource(R), the accused product sold by defendant, is a kit which consists of a vial of powdered material, a syringe filled with liquid, and a spatula. The powdered material is a mixture of tetracalcium phosphate, $\text{Ca}_4(\text{PO}_4)_2\text{O}$, and monetite, CaHPO_4 . The liquid in the syringe is a 0.25 M sodium phosphate mixing solution.

On April 20, 2001, this Court issued an order denying defendant's summary judgment motion as to claims 1-8 of the '264 patent but granting summary judgment on non-infringement as to claims 1-10 of the '065 patent. Specifically, the order held that the phrase "consisting of" limited items in the claimed "kit" to those explicitly listed and that the presence of a spatula in defendant's BoneSource(R) kits rendered them outside the scope of the '065 patent. The remainder of the lawsuit focused exclusively on the '264 patent.

In April 2004, the Federal Circuit reversed this Court's summary judgment on the issue of non-infringement and remanded for further proceedings with respect to the '065 patent. In construing the phrase "consisting of" in claim 8 of the '065 patent, the Federal Circuit held that "[t]he invention is a kit containing specified chemicals, and the claims are explicitly limited in that no other chemical can be included in the composition." *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed.Cir.2004). The opinion further noted that "[i]t is undisputed that the BoneSource(R) kit contains the same chemicals as set forth in claims 8-10 of the '065 patent. Infringement is not avoided by the presence of a spatula, for the spatula has no interaction with the chemicals, and is irrelevant to the invention." *Id.* at 1332.

In its current motion for summary judgment, defendant now argues that "a solution consisting of water and a sodium phosphate" in claim 8 of the '065 patent should be construed to mean that the solution must be made from one and only one sodium phosphate. Defendant contends that its BoneSource(R) kits do not infringe the '065 patent because the solution in the syringe "contains two different sodium phosphates- monobasic sodium phosphate monohydrate and dibasic sodium phosphate heptahydrate" (Br.6).

ANALYSIS

1. LEGAL STANDARD FOR SUMMARY JUDGMENT.

Summary judgment is proper where the pleadings, discovery and affidavits show "that there is no genuine

issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FRCP 56(c). "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). "Summary judgment is as appropriate in a patent case as in any other." *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 835 (Fed.Cir.1984). Although the determination of patent infringement is a fact-intensive issue, "comparison of a properly interpreted claim with a stipulated or uncontested description of an accused device or process would reflect such an absence of material fact issue as to warrant summary judgment of infringement or noninfringement." *D.M.I. Inc. v. Deere & Co.*, 755 F.2d 1570, 1573 (Fed.Cir.1985).

2. LEGAL STANDARD FOR CLAIM CONSTRUCTION.

Claim construction is a matter of law to be decided by a judge, not a jury. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). When interpreting claims, the Court must keep in mind that claim construction "begins and ends in all cases with the actual words" used by the patentee. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed.Cir.1998). The Federal Circuit has cautioned judges that "no matter how great the temptations of fairness or policy making, courts do not redraft claims." *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed.Cir.1995).

It is commonly accepted doctrine in patent law that intrinsic evidence-i.e., the claims themselves; the specification and drawings of the patent; and its prosecution history-is "the most significant source of the legally operative meaning of the disputed claim language." *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). For most cases, "an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term;" in such cases, "reliance on any extrinsic evidence is improper." *Id.* at 1583.

As the Federal Circuit recently noted, "[l]anguage in some of [their] recent cases suggests that the intrinsic record, except for the claims, should be consulted only after the ordinary and customary meaning of claim terms to person skilled in the pertinent art is determined." *Astrazeneca AB. v. Mutual Pharm. Co., Inc.*, 384 F.3d 1333, 1337 (Fed.Cir.2004) (citing *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1204 (Fed.Cir.2002)). Under this approach, the ordinary meaning of claim terms is primarily determined using technical or general-usage dictionaries; other intrinsic evidence "is relevant only insofar as it provides clear lexicography or disavowal of the ordinary meaning." *Ibid.*

3. "A SOLUTION CONSISTING OF WATER AND A SODIUM PHOSPHATE."

Claim 8 of the '065 patent reads:

A kit for preparing a calcium phosphate mineral, said kit consisting of:

at least one calcium source and at least one phosphoric acid source free of uncombined water as dry ingredients; and

a solution consisting of water and a sodium phosphate, where the concentration of said sodium phosphate in said water ranges from 0.01 to 2.0 M and said solution has a pH in the range of about 6 to 11.

Dependent claims 9 and 10 further limit the claimed invention to narrower ranges of molarity and pH, respectively.

Defendant argues that the use of the indefinite article "a" in the phrase "a sodium phosphate" should be construed to require a solution made from one and only one sodium phosphate. According to a Stryker employee, "[t]he aqueous mixing solution of all BoneSource(R) kits contains two sodium phosphates" (Zitelli Decl. para. 5). These are (1) dibasic sodium phosphate heptahydrate, $\text{Na}_2\text{HPO}_4 \cdot 7\text{H}_2\text{O}$; and (2) monobasic sodium phosphate monohydrate, $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$. At trial, Norian's counsel also read a stipulation into the record, indicating that Stryker's kits contained "one or more syringes filled with a solution of dibasic sodium phosphate heptahydrate and monobasic sodium phosphate monohydrate and a spatula" (Frantzen Decl. Exh. 17 at 396:16-19). Based on its proposed construction of the claim language, defendant moves for summary judgment on the issue of non-infringement.

As described in further detail below, the Court agrees with defendant's proposed construction of the claims 8-10 of the '065 patent. Because an analysis of the intrinsic evidence alone is sufficient to construe the meaning of "a solution consisting of water and a sodium phosphate," the Court declines to consider extrinsic evidence offered by either party.

A. "SOLUTION" MEANS "A HOMOGENEOUS MIXTURE WHEREIN THE SOLUTE IS FULLY DISSOLVED IN THE SOLVENT."

At first blush, a solution could be defined simply as "a homogeneous mixture of two or more substances." See <http://www.chemistry-dictionary.com/Solution>. In this case, however, the prosecution history indicates that the patentee distinguished its invention from United States Patent No. 5,092,888, ("the Iwamoto patent"), on the basis that the prior art described therein was a colloid, meaning it had solid particles dispersed in a liquid (Frantzen Decl. Exh. 9 at 6-7). The Examiner noted that the critical feature of the present invention was "the lack of any solid particles in the liquid;" in other words, it was a "true solution" (Frantzen Decl. Exh. 12 at 7). Thus, in construing the term "solution," the Court holds that the solute must be fully dissolved in the solvent.

B. "CONSISTING OF" LIMITS THE SOLUTION TO CONTAIN NO CHEMICAL COMPOUNDS IN ADDITION TO "WATER AND A SODIUM PHOSPHATE."

As the Federal Circuit construed claim 8 of the '065 patent the transitional phrase "consisting of" restricts the invention to "a kit containing specified chemicals, and the claims are explicitly limited in that no other chemical can be included in the composition." Norian, 363 F.3d at 1331. Indeed, the prosecution history indicates that the transitional phrase was changed from "comprising" to "consisting essentially of" to "consisting of" in order to overcome a rejection based on United States Patent No. 5,149,368, ("the Liu patent"), which utilized a solution containing citric acid (Frantzen Decl. Exh. 13 at 6-7). The Court hereby adopts the Federal Circuit's claim construction.

"Consisting of" limits the scope of claims 8-10 of the '065 patent to a solution containing water and sodium phosphate, but no other chemical compounds aside from trace impurities. Thus, the '065 patent only covers kits containing aqueous solutions, meaning that the solvent used must be water. As for the solute, sodium phosphate must be used as opposed to some other chemical compound.

C. ALTHOUGH "A" NORMALLY MEANS "ONE OR MORE," "A" IS LIMITED TO ITS SINGULAR MEANING IN CLAIMS 8-10 OF THE '065 PATENT

The Federal Circuit has held that an indefinite article "a" or "an" in claim language generally carries the meaning of "one or more." *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed.Cir.2000). "Unless the claim is specific as to the number of elements, the article 'a' receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article." *Ibid.* Here, however, the patentee evinced a clear intent to limit the solution in claims 8-10 of the '065 patent to contain only one sodium phosphate.

Because the '065 patent uses the transitional phrase "consisting of" rather than "comprising," defendant argues that "a sodium phosphate" is limited to its singular meaning. The Court agrees. First, in defining the phrase "a sodium phosphate" as used in the '065 patent, the Court notes that claim 1 of the '065 patent limits the invention to a kit containing "a solution, wherein said solution consists of water and a solute selected from the group consisting of a sodium phosphate and a sodium carbonate." The patentee's use of a Markush group demonstrates a clear intent to limit the phrase "a solute" to mean "only one solute." *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1281 (Fed.Cir.2003) (holding that "a" indicated only one member of the Markush group because the patentee failed to expressly indicate the possible selection of multiple members with qualifying language such as "and mixtures thereof" or "at least one member of the group"). FN1

FN1. Claim language describing an element as being a member "selected from the group consisting of A, B, and C" is commonly referred to as a Markush group. *See Manual of Patent Examining Procedure* s. 2173.05(b) (8th ed.2003).

Thus, claim 1 limits the claimed invention to a solution to containing only one solute, which may either be a sodium phosphate or a sodium carbonate. The prosecution history of claim 1 further confirms this interpretation; it was amended "to limit the claimed kit to one in which the solution is made of water and a *single* solute" (Frantzen Decl. Exh. 9 at 4) (emphasis added). Naturally, if the invention is limited to a single solute, only one form of sodium phosphate or sodium carbonate may be added to water.

Examining the language of claim 8 itself further reinforces the interpretation that "a" was intended to be singular. This claim—as well as claim 9—refers to "said sodium phosphate," which suggests only one sodium phosphate is in the solution. *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1024 (Fed.Cir.1997) (finding that "[t]his term itself, 'said chamber,' reinforces the singular nature of the chamber"). Furthermore, claim 8 utilizes the language "at least one" where patentee intended to include more than one calcium source or phosphoric acid source. *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 1579 (Fed.Cir.1996) (holding that "pusher bar" and "pusher assembly" used in the same claim were presumed to have different meanings). The prosecution history also suggests that, like claim 1, claim 8 is "limited in an analogous fashion" to solutions made of water and a single solute (Frantzen Decl. Exh. 9 at 4). *Compare Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977-78 (Fed.Cir.1999) (finding that the prosecution history showed that the patentee "gave up a construction of the feed tube/probe limitation that could include an apparatus with separate flow paths for liquid and air").

Indeed, nowhere in the specification did the inventor describe an embodiment of the invention utilizing a solution made from more than one sodium phosphate. In the prosecution history, the patentee pointed to Examples 2 and 3 in the specification, "where solutions of different sodium phosphates and sodium carbonates are disclosed" (Frantzen Decl. Exh. 9 at 4). Yet the Court is unable to find a specific embodiment in Examples 2 or 3 where the sodium phosphate solution contained more than one form of

sodium phosphate. *Compare* North Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1576 (Fed.Cir.1993) (finding no indication in the specification that "linkage to a terminal portion" was intended include end-to-end linkages because all references to polysaccharide linkages spoke of linkage only at one terminal).

Plaintiff argues that Example 2 references an "off-the-shelf" buffer solution made by Sigma. Even without considering defendant's proffered declaration from Haynes, it does not appear that the Sigma Diagnostics 1.0 M Phosphate Buffer contains any sodium phosphates. FN2 Indeed, while "off-the-shelf" Sodium Phosphate Buffers made from more than one form of sodium phosphate may be available from various chemical supply companies, the results chart merely labeled this one a "PO₄ buffer solution," which suggests the absence of sodium (Frantzen Decl. Exh. 1 at 10:2). Neither do the dibasic sodium phosphate solutions of 0.1 M, 0.15 M, and 0.2 M concentrations used in Example 2 appear to include a second form of sodium phosphate. According to the results chart, these were "Na₂HPO₄ solution[s]" (*id.* at 10:12).

FN2. Defendant proffers a declaration from John Haynes, an employee at Sigma, who states that the "off-the-shelf" buffers do not contain any sodium phosphates.

Example 3 is of no greater support to plaintiff's argument. Although the claimed invention is not necessarily limited to the forms of sodium carbonate and sodium phosphate listed in the chart, each solution tested only contained one solute (*id.* at 10:35-43). While it is true that the specification does mention one instance in which "[a] 0.30 M sodium phosphate solution is prepared by combining 0.5704 g of trisodium phosphate dodecahydrate [Na₃ PO₄->12H₂O] and 0.04024 g of dibasic sodium phosphate heptahydrate [Na₂ HPO₄->7H₂O] and dissolved in deionized water to provide the proper molarity," it does so in the context of describing how to prepare the colloid control (*id.* at 10:46-50). As discussed above, plaintiff expressly disclaimed colloids to distinguish its invention from the Iwamoto patent.

Plaintiff argues that dibasic sodium phosphate heptahydrate, Na₂HPO₄-> 7H₂O, and monobasic sodium phosphate monohydrate, NaH₂PO₄->H₂O, both disassociate when dissolved in water and exist as hydrogen ions H⁺, sodium ions Na⁺, and multiple phosphate ions H₂PO₄⁻, HPO₄²⁻, and PO₄³⁻ in solution. Thus, a person of ordinary skill in the art would understand "a general disclosure of sodium phosphate to encompass the use of a single solute of any of the forms of sodium phosphate or a mixture of multiple forms of sodium phosphate because each would all lead to the production of similar ions in solution" (Frantzen Decl. Exh. 13 at 4).

While it is true that a person of ordinary skill in the art would understand "a sodium phosphate solution" to encompass solutions containing more than one form of sodium phosphate, the claim reads "a solution consisting of water and a sodium phosphate" not "a sodium phosphate solution." The Court is required to focus on the precise language used in claim 8 and declines to redraft it on plaintiff's behalf. As described above, the intrinsic evidence demonstrates a clear disavowal of the ordinary meaning of "a sodium phosphate solution." Thus, the two phrases are not synonymous.

The prosecution history also shows that the patentee explicitly surrendered the additional scope encompassed by the phrase "a sodium phosphate solution." Claim 8 was amended from "a solution, wherein said solution is selected from the group consisting of water and a sodium phosphate solution and a sodium carbonate solution" to read "a solution consisting of water and a sodium phosphate" (Frantzen Decl. Exh. 9

at 3). Claim 9 was also amended to replace the phrase "said sodium phosphate solution" with "said sodium phosphate" (*id.*).

Perhaps recognizing the shortcomings of the existing claim language, the patentee is currently attempting to rectify this mistake in reissue proceedings which are still pending. New independent claims using the phrase "one or more forms of sodium phosphate" instead of "a sodium phosphate" were submitted to the Patent Office (Frantzen Decl. Exh. 11 at 4). For the reasons stated above, however, this Court questions whether there is any original support in the specification for these new claims. The "off-the-shelf" phosphate buffer in Example 2 does not appear to contain any sodium and each solution in Example 3 only contains a single solute. The Court was unable to find a specific embodiment of a solution containing more than one form of sodium phosphate described in the specification.

Plaintiff's primary argument that defendant's proffered construction improperly reads process limitations into composition of matter claims is also unpersuasive. As Stryker correctly points out, the claim language itself references the specific ingredients of the solution-i.e., *what* is in the solution; thus, defendant is not arguing that the process of *how* the solution is made is at issue (Reply Br. 11-12). Compare AFG Indus., Inc. v. Cardinal IG Co., Inc., 375 F.3d 1367, 1373 (Fed.Cir.2004) (distinguishing the determination of what a particular structure is from the "the method of creation of that structure" and holding the latter "not determinative" of the former). Here, defendant is merely arguing that its BoneSource(R) kits contain two forms of sodium phosphate. Its argument of non-infringement does not depend on which one is added to the water first, or any other limitation on *how* the solution is made. The decisions cited by plaintiff on this issue are inapposite.

CONCLUSION

For the aforementioned reasons, this court construes "a solution consisting of water and a sodium phosphate" in claims 8-10 of the '065 patent to mean that the aqueous solution in the claimed kit may include only one form of sodium phosphate. Accordingly, defendant's motion for summary judgment of non-infringement based on the stipulated fact that its accused product contains a solution made from two forms of sodium phosphate is GRANTED. Because this order renders the damages question moot as to the '065 patent, there are no remaining issues to be decided by this Court. The clerk is instructed to close the file.

IT IS SO ORDERED.

N.D.Cal.,2004.

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