



**NORIAN CORPORATION, Plaintiff-Appellant, v. STRYKER CORPORATION,
Defendant-Cross Appellant.**

02-1490, -1506, -1507

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

363 F.3d 1321; 2004 U.S. App. LEXIS 6545; 70 U.S.P.Q.2D (BNA) 1508

April 6, 2004, Decided

SUBSEQUENT HISTORY: Rehearing denied by Norian Corp. v. Stryker Corp., 2004 U.S. App. LEXIS 14522 (Fed. Cir., June 15, 2004)

Rehearing, en banc, denied by Norian Corp. v. Stryker Corp., 2004 U.S. App. LEXIS 14523 (Fed. Cir., June 15, 2004)

Summary judgment granted by Norian Corp. v. Stryker Corp., 433 F. Supp. 2d 1051, 2004 U.S. Dist. LEXIS 29053 (N.D. Cal., Dec. 3, 2004)

PRIOR HISTORY: [**1] Appealed from: United States District Court for the Northern District of California. Judge William Alsup.

Norian Corp. v. Stryker Corp., 252 F. Supp. 2d 945, 2002 U.S. Dist. LEXIS 26032 (N.D. Cal., 2002)

DISPOSITION: Affirmed in part, reversed in part and remanded.

COUNSEL: Brian M. Poissant, Pennie & Edmonds, LLP, of New York, New York, argued for plaintiff-appellant. With him on the brief were Daniel L. Malone and Eric C. Stops. Of counsel was Carl Bretscher, Pennie & Edmonds LLP, of Washington, DC.

Gregory J. Vogler, McAndrews, Held & Mallow, Ltd., of Chicago, Illinois, argued for defendant-cross appellant. With him on the brief were Timothy J. Malloy, Sandra A. Frantzen, and John L. Abramic.

JUDGES: Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and SCHALL, Circuit Judge. Opinion for the court filed by Circuit Judge NEWMAN. Concurring in part, dissenting in part opinion filed by Circuit Judge SCHALL.

OPINION BY: NEWMAN

OPINION

[***1510] [*1324] NEWMAN, Circuit Judge.

Norian Corporation charged Stryker Corporation with infringement of Norian's United States Patent No. 5,336,264 (the '264 patent) and United States Patent No. 6,002,065 (the '065 patent). Trial was held in part to a jury and in part to the bench. The United States District Court for the Northern District of California held that [**2] the claims in suit are invalid or not infringed.¹ We affirm the judgment as to the '264 patent, and reverse as to the '065 patent.

¹ Norian Corp. v. Stryker Corp., 252 F. Supp. 2d 945 (N.D. Cal. 2002).

BACKGROUND

The '264 patent is directed to the repair of bones or teeth with certain rapidly setting calcium phosphate compositions. At issue are claims 1, 7, and 8 of the '264 patent:

1. A method for preparing a rapid setting calcium phosphate composition capable of rapidly setting up in a viable mammalian host, said method comprising:

combining with mixing dry precursors for producing a calcium phosphate mineral composition, said precursors comprising a calcium source and a phosphoric acid source free of uncombined water;

combining said combined precursors with a lubricant at a pH in the range of 6-11, wherein said lubricant comprises a member selected from the group consisting of phosphate and carbonate and is from about 15 to 70 weight percent of the total composition;

to form [**3] a rapidly setting flowable composition. [***1511]

7. A bone tissue comprising ex vivo a composition prepared according to the method of claim 1.

8. A method for making bone repair, said method comprising: introducing at a bone site for repair, a composition prepared according to the method of claim 1.

The '065 patent is for a kit containing the ingredients that are combined to produce the rapidly setting calcium phosphate composition. The claims in suit are:

8. 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 [**1325] and said solution has a pH in the range of about 6 to 11.

9. The kit according to claim 8, wherein said sodium phosphate is present in said water at a concentration ranging from about 0.05 to 0.5 M.

10. The kit according to claim 8, wherein said solution has a pH in the range from about 7 to 9.

For the period from December 1998 until October 1999 Stryker sold a mixture of tetracalcium [**4] phosphate and dicalcium phosphate in association with the trademark BoneSource (R), accompanied by instructions to the user to obtain the sodium phosphate component from an independent source and combine it with the BoneSource (R) mixture to form a rapidly setting cement. In October 1999 Stryker began to market a BoneSource (R) kit that contained the sodium phosphate component as well as the mixture of tetracalcium phosphate and dicalcium phosphate; the kit also provided instructions for combining the components and a spatula for mixing them.

Norian filed suit against Stryker in January 2001, charging willful infringement of the '264 and '065 patents. Stryker presented counterclaims of noninfringement, invalidity, and unenforceability. The district court held, on motions for summary judgment, that (1) Stryker did not infringe the '065 patent; (2) Stryker induced infringement of claims 1, 7, and 8 of the '264 patent, if the claims were valid; and (3) there was not inequitable conduct by Norian in the patent procurement. The court construed the claims, and the remaining issues concerning the '264 patent were tried to a jury.

The jury found that (1) claims 1, 7, and 8 of the '264 patent [**5] are invalid on the ground of anticipation by a document called the 1991 IADR Extended Abstract; (2) the subject matter of claims 1, 7, and 8 was not invented by others before the filing date of the '264 patent; (3) claims 1, 7, and 8 are invalid on the ground of obviousness; and (4) if the '264 patent were valid no damages are payable. On post-trial motions, the district court granted judgment as a matter of law to set aside the jury verdict on the issue of anticipation, the court holding that the claims are not anticipated. The verdicts on all other grounds were sustained, and a new trial was denied.

CLAIM CONSTRUCTION

The district court instructed the jury as to the following meanings of various terms in the claims: The term "phosphoric acid source" means "an acidic chemical that acts as a source of phosphate." "'Calcium source' means a chemical compound or substance that includes a source of calcium." "The term 'combined with mixing' [means] that the powders are stirred together so that they are thoroughly intermingled." "The parties agree that the lubricant must have a pH between six and eleven, and it must include a phosphate or a carbonate." "'Rapidly setting' means that [**6] the calcium phosphate composition may harden almost immediately, usually the maturing process should take at least two minutes, usually about eight minutes and not more than thirty minutes, usually not more than about twenty-five minutes." "The term 'flowable' means that the resulting composition has sufficient fluidity to be administered through a syringe, packed or used as paste."

The only disputed claim construction concerns the term "phosphoric acid source." The district court observed that "the most natural reading of the term 'phosphoric acid source' would be a source of phosphoric acid," but held that "that is not the way the term is defined in the specification." The court held that "phosphoric acid source" means "an acidic chemical [*1326] that acts as a source of phosphate," explaining that the '264 specification makes clear that the term "phosphoric acid source" [***1512] is an "acidic neutralizing phosphate source" including acid and acid salts. We agree that this meaning is required by the specification, which states:

The composition is formed in substantially two stages: a first stage which involves mechanical intimate mixing and milling of a calcium source, e.g., tetracalcium [**7] phosphate, tricalcium phosphate, calcium carbonate, or calcium oxide, and a phosphoric acid source substantially free of uncombined water, desirably having at least 2 protons per phosphate and not more than about 1 water of hydration per molecule, and, in addition other optional additives; and a second stage which involves mixing . . . to provide the final product, which sets up to a calcium phosphate mineral, e.g., a hydroxyapatite, having desirable mechanical properties.

The first stage involves the mechanical mixing of the primary calcium sources. The acidic neutralizing phosphate source will be free of uncombined water and may be orthophosphoric acid crystals or monocalcium phosphate monohydrate $\text{Ca}(\text{H}[\text{2}]\text{PO}[\text{4}])[\text{2}] \cdot \text{H}[\text{2}]\text{O}$ or another calcium phosphate acid source by itself or in combination e.g., monetite

'264 patent, col. 3, lines 7-29.

The meaning of a technical term in a patent claim is determined in accordance with its usage in the specification, elaborated if appropriate by the prosecution history and with due consideration to usage in the field of the invention. A technical term in a patent document has the meaning that it would be understood to have [**8] by persons knowledgeable in the field of the invention and the prior art. A technical term is not properly removed from its context in order to seek its meaning. See *Network, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001) ("The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose."). Whether a term appearing in a patent claim is subject to limitations beyond its abstract general meaning is determined in the context of the invention described in the specification, the prosecution history, and the prior art. See *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299 (Fed. Cir. 1999); *Hoechst Celanese Corp. v. B.P. Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996).

The district court observed that the specification uses the terms "phosphoric acid source," "acidic neutralizing phosphate source," and "calcium phosphate acid source" interchangeably, illustrating such materials with orthophosphoric acid and monocalcium phosphate. The district court's claim construction accords with the chemical descriptions in the specification. [**9] No contradictory information appears in the patent prosecution; the record fully supports the district court's construction. We confirm that "a phosphoric acid source" means acidic phosphates that are sources of the phosphoric component of the composition.

VALIDITY - THE '264 PATENT

The jury was correctly instructed that a party seeking to invalidate a patent must do so by clear and convincing

evidence. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984).

A. *Obviousness*

The jury found claims 1, 7, and 8 of the '264 patent invalid on the ground of obviousness; the district court denied Norian's post-trial motions on this issue. We review the jury verdict to determine whether there was substantial evidence to [*1327] support findings of fact necessary to establish invalidity on the ground of obviousness, with due attention to the evidentiary burdens. See *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001) ("This court reviews a jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the [**10] verdict, for substantial evidence."); *Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 988 (Fed. Cir. 1989) (reviewing the verdict in light of the burden of proof).

The jury held the claims invalid on the basis of U.S. Patent Re. 33,161 (Brown) taken alone or in combination with U.S. Patent No. 5,092,888 (Iwamoto). Norian acknowledges that Brown teaches the dry components of the claims, but argues that neither the Brown nor the Iwamoto reference discloses or suggests a lubricant comprising a phosphate or a carbonate. Stryker argues that a reasonable jury [***1513] could have found that either Brown alone, or Brown in combination with Iwamoto, provides the motivation needed to include a lubricant as claimed. Stryker points out, based on the testimony of Dr. Nancollas, that Specimen 6 in Example 5 of the Brown reference shows every step of the method of Norian's claim 1, with the exception of the pH range of the lubricant. Brown's Example 5 reads:

Specimens 6-9 shown in Table II were prepared by grinding $\text{Ca}_4(\text{PO}_4)_2\text{O}$, $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$, and $\text{Ca}_5(\text{PO}_4)_3\text{OH}$ to a mean particle size of 5 m. One gram of a mixture containing equimolar amounts of [**11] $\text{Ca}_4(\text{PO}_4)_2\text{O}$, $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$ and the appropriate weight percent of $\text{Ca}_5(\text{PO}_4)_3\text{OH}$ was mixed with 0.5 ml of 20 mM H_3PO_4 to form a paste. This paste was then allowed to harden. The setting times as a function of apatite

seed content are shown in Table II.

Brown, col. 12, lines 22-32. Comparing this teaching with Norian's claim 1, $\text{Ca}_4(\text{PO}_4)_2\text{O}$ is a "calcium source" and $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$ is a "phosphoric acid source free of uncombined water"; and for Brown's Specimen 6 the weight percent of $\text{Ca}_5(\text{PO}_4)_3\text{OH}$ is zero as shown in Brown's Table II. Thus, Brown's teaching of "one gram of a mixture containing equimolar amounts of $\text{Ca}_4(\text{PO}_4)_2\text{O}$, $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$ and the appropriate weight percent of $\text{Ca}_5(\text{PO}_4)_3\text{OH}$ " could reasonably be found to be a mixture of the "dry precursors" recited in claim 1. A reasonable jury could have found that combining the mixture of $\text{Ca}_4(\text{PO}_4)_2\text{O}$ and $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$ with 0.5 ml of 20 mM H_3PO_4 , as described by Brown, constitutes "combining said combined precursors with a lubricant" comprising "a member selected from the group consisting of phosphate and carbonate. [**12] " We note the testimony of Stryker's expert Dr. Nancollas that H_3PO_4 is phosphoric acid, and that phosphoric acid is a "phosphate solution." Trial Transcript at 1085, 1214-15. The jury could reasonably have found that in Brown the percentage of the weight of the lubricant solution as compared with the overall composition is within the 15-70% range of claim 1. Table II of Brown states that Specimen 6 has a setting time of 22 minutes, which is within the scope of "rapidly setting" as the phrase was construed by the district court.

Brown's Example 5 does not specifically state the pH of the lubricant, which is illustrated as a dilute solution of an acid (20 mM H_3PO_4). However, Brown does teach that the precursors may be mixed "in a dilute aqueous solution that is either slightly acidic or slightly basic." Brown, col. 10, lines 45-47. Brown also explains that monosodium phosphate may be added to the liquid to be mixed with the dry powder in order to "modify the Ca/P ratio and pH of the solution's singular point." Brown, col. 11, lines 4-5, 11-13. In addition, [*1328] Iwamoto teaches, in the context of preparation of a calcium phosphate composition useful for bone repair, that "sodium [**13] phosphate . . . can be added to adjust the setting time and the strength." Iwamoto, col. 4, lines 22-24. Dr. Nancollas testified that the level of ordinary skill in this art was high, Trial Transcript at 1029, and that a person of ordinary skill would have understood from Iwamoto's teaching that the setting time would be reduced by the presence of phosphate. *Id.* at 1093. Because Iwamoto expressly discussed the Brown patent,

Iwamoto col. 1, lines 37-44, and employed the dry precursors of Brown in an example, *id.* at col. 5, lines 55-60, the jury could reasonably have found that a person of ordinary skill in the art would have been motivated to choose a lubricant having a pH of 6-11 as claimed for the purpose of obtaining a rapidly setting calcium phosphate composition.

We agree with the district court that a reasonable jury could have found facts sufficient to provide clear and convincing evidence of obviousness of claim 1. We also agree with the district court that a reasonable jury could have also held claim 7 (bone tissue) and claim 8 (bone repair) invalid on the ground of obviousness, for both Brown and Iwamoto taught calcium phosphate compositions useful as biomedical cements [**14] or restorative materials.

B. Prejudicial Statements

Norian moved for a new trial on the issue of obviousness, contending that its case was prejudiced because the jury was allowed to hear evidence of Norian's admitted misstatements to the examiner concerning the teachings of the Brown reference. Norian points to the summary judgment granted by the district court before trial, holding that inequitable conduct had not been established. Thus Norian argues that it was prejudicial error to admit this evidence. We review denial of a motion for a new trial for abuse of discretion. See *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1284 [***1514] (Fed. Cir. 2000); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 626 (Fed. Cir. 1985).

Norian's counsel admitted at trial that he had discovered, in preparing for trial, that during prosecution relating to the Brown reference he had made "a factual misstatement as to its teaching." *Norian*, 252 F. Supp. 2d at 961. The district court ruled that this was not a material misrepresentation made with deceptive intent, remarking that the Brown patent was the subject of [**15] two rejections and was thoroughly explored during prosecution. However, the district court permitted the evidence of Norian's misdescription of the Brown reference, and instructed the jury "in determining whether Stryker has carried that burden [to overcome the presumption of validity by clear and convincing evidence] in this case, you may consider the proceedings before the examiner and the extent to which and the manner in which the prior art was considered by or before

the examiner." *Id.* at 960 (alteration in original). The court explained its purposes to the parties as follows:

This is not for purposes of inequitable conduct, that the Court's already ruled out of the case; but it is for purposes of allowing the jury to test the strength of the presumption that goes with the presumption of validity. I acknowledge that there's some overlap in purpose, but it's not going to be for inequitable conduct purposes. If that's all it is, it will be excluded; but so long as the questioning relates to information the jury may legitimately use in deciding whether or not the examiner properly focused on the prior art or was misled as to the prior art, not for purposes [**16] of enforcement, but for purposes of whether or not the examiner really did understand [*1329] what he was ruling, then that's -- the case law says that's proper.

Trial transcript at 790, quoted in *Norian*, 252 F. Supp. 2d at 960.

Norian argues that in accordance with *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956 (Fed. Cir. 1997), the district court's actions were improper. Norian states that absent evidence sufficient to establish the factual premises of inequitable conduct, evidence as to what the examiner might have believed about the prior art based on flawed arguments presented by the applicant, can be unduly prejudicial and should not be admitted. In *Magnivision* this court stated:

Procedural lapses during examination, should they occur, do not provide grounds of invalidity. Absent proof of inequitable conduct, the examiner's or the applicant's absolute compliance with the internal rules of patent examination becomes irrelevant after the patent has issued.

115 F.3d at 960. Norian is correct that the presumption of validity is not subject to being diluted by "procedural lapses" during prosecution. *Id.* Similarly, flawed [**17] prosecution arguments do not affect patent validity, whether or not they raise questions of inequitable conduct.

After a patent has issued, validity is determined objectively based on prior art and the other requirements of patentability. There may of course be estoppels generated by prosecution amendment and argument, but the presence and "strength" of the presumption of validity does not warrant inquiry into the examiner's understanding or competence or gullibility. See *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1992) (a patent is presumed valid, in part because of the expertise of patent examiners and the presumption that they have done their jobs properly).

Thus the issue of validity does not warrant findings of whether the examiner "really did understand what he was ruling." Trial transcript at 790, quoted in *Norian*, 252 F. Supp. 2d at 960. Introspection and speculation into the examiner's understanding of the prior art or the completeness or correctness of the examination process is not part of the objective review of patentability. See *Kahn v. General Motors Corp.*, 135 F.3d 1472, 1480 (Fed. Cir. 1998) [**18] (the presumption of validity does not change even when evidence not previously before the examiner is presented at trial). Misleading statements by patent applicants, if intentionally made and material to patentability, can produce unenforceability, not invalidity.

We conclude that the district court erred in instructing the jury that the presumption of validity varied with the jury's view of whether the examiner believed the applicant's misstatements or otherwise did not "properly focus on the prior art." However, the district court states, without contradiction, that no objection was made to this jury instruction. *Norian*, [***1515] 252 F. Supp. 2d at 960. It is rare indeed for appellate relief to be granted when no objection was raised at trial. See *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 238-39, 84 L. Ed. 1129, 60 S. Ct. 811 (1940) ("Counsel for the defense cannot as a rule remain silent, interpose no objections, and after a verdict has been returned seize for the first time on the point that the comments to the jury were improper and prejudicial."). The district court denied a new trial, stressing that no objection was raised.

Under such circumstances, [**19] the question devolves into "whether an error occurred in the conduct of the trial that was so grievous as to have rendered the trial unfair." *DMI, Inc. v. Deere & Co.*, 802 F.2d 421,

427 (Fed. Cir. 1986). In the [*1330] absence of objection to the jury instruction, and in view of the entirety of the patent prosecution, as discussed by the district court, we are not persuaded that the error was prejudicial or the trial unfair. The district court's denial of *Norian's* motion for a new trial is affirmed.

C. Anticipation

The jury found that claims 1, 7, and 8 of the '264 patent were invalid based on anticipation by a 1991 International Association for Dental Research (IADR) Extended Abstract, Number 2410, entitled "Composite of Calcium Phosphate Cement and Protein Bioadhesive -- Setting Reactions, Compressive and Diametral Tensile Strength." Both parties agreed that the '264 invention was described in the Abstract; the issue was whether the Abstract was "prior art," that is, "described in a printed publication" more than a year before the filing date. See 35 U.S.C. § 102(b) ("A person shall be entitled to a patent unless . . . (b) the invention [**20] was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."). Whether a document is a prior publication is a question of law. See *Reading & Bates Constr. Co. v. Baker Energy Res. Corp.*, 748 F.2d 645, 649-50 (Fed. Cir. 1984).

Norian argued that the Abstract did not meet the criteria of § 102(b) because it was available only upon individual request to the authors, and that such request and dissemination had not been shown. The district court granted *Norian's* motion for judgment as a matter of law, on the ground that there was not clear and convincing evidence that the Abstract was actually available at the IADR meeting. See *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1568 (Fed. Cir. 1988) ("dissemination and public accessibility are the keys to the legal determination whether a prior art reference was 'published' [under 35 U.S.C. § 102(b)]"; *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986) (public accessibility is "the touchstone in determining [**21] whether a reference constitutes a 'printed publication' bar under 35 U.S.C. § 102(b)").

The district court cited the evidence that (1) Dr. Chow, a co-author of the Abstract who testified that he had attended the IADR meeting and had taken along a copy of the Abstract to be given to a meeting organizer, could not recall whether he attended the presentation and

could not recall whether copies of the Abstract were actually available to hand out, and (2) Dr. Tagaki, another co-author who testified that he had attended the presentation, was not questioned about the availability of the Abstract. Although there was testimony that it was the general practice at IADR meetings for presenters to hand out abstracts to interested attendees, the lack of substantial evidence of actual availability of the Abstract adequately supports the court's conclusion that dissemination of the Abstract was not established. That holding is affirmed.

D. Inequitable Conduct

The district court granted Norian's motion for summary judgment that inequitable conduct had not been established. Stryker by cross appeal challenges this ruling.

A patent may be rendered unenforceable if **[**22]** an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1573-74 (Fed. Cir. 1991); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, **[*1331]** 863 F.2d 867, 872 (Fed. Cir. 1988) (*en banc*). When both materiality and deceptive intent have been established by clear and convincing evidence, decision of the ultimate issue of inequitable conduct is within the discretion of the district court. A discretionary decision is subject to review to determine whether "it was based on a clearly erroneous finding of fact or a misinterpretation or misapplication of law, or manifested a clear error of judgment." **[***1516]** *Glaverbel Societe Anonyme & Fosbel, Inc. v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1557 (Fed. Cir. 1995).

As mentioned ante, the attorney who prosecuted the '264 application testified that while preparing for the trial, he discovered that some statements he had made to the examiner to distinguish the Brown reference appeared to be inaccurate. The attorney **[**23]** had told the examiner that Brown did not disclose combining the calcium sources with the acid sources in a dry mixture, but at trial he stated that an example in the Brown reference did teach a dry mixture followed by addition of water to form a slurry. Stryker argued that the erroneous statement to the examiner constituted inequitable conduct. The district court observed that the Brown patent had twice been the basis of rejections by the examiner, and that its import

had been "significantly and actively debated." The court held that deceptive intent was not established by clear and convincing evidence. We agree that a genuine issue as to deceptive intent had not been established, thereby precluding a ruling of inequitable conduct. The judgment on this issue is affirmed.

INFRINGEMENT - THE '065 PATENT

The district court granted Stryker's motion for summary judgment of non-infringement of the '065 patent, holding that because the BoneSource (R) kit contained a spatula, and Norian's '065 claims did not recite a spatula, the claims could not be infringed as a matter of law.

The parties do not dispute that the BoneSource (R) kit contains all of the elements set forth in claims 8-10 of **[**24]** the '065 patent, plus a spatula. The district court held that the claim signal "consisting of" means that nothing can be included in the kit beyond what is claimed, and therefore that Stryker's kit cannot infringe as a matter of law. "Consisting of" is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. See *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1382-83 (Fed. Cir. 2000). However, while "consisting of" limits the claimed invention, it does not limit aspects unrelated to the invention. It is thus necessary to determine what is limited by the "consisting of" phrase.

"Consisting of" as used in claim 8 limits the kit to the claimed chemicals and no other chemicals; that is, the kit "consists of" only the chemicals described as contained in the kit:

8. A kit for preparing a calcium 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 **[**25]** said solution has a pH in the range of about 6 to 11.

The invention is a kit containing specified chemicals, and the claims are explicitly limited in that no other chemical can be included in the composition. See *In re Gray*, 19 C.C.P.A. 745, 53 F.2d 520, 521, 1932 Dec. Comm'r Pat. 85 (CCPA 1931) (because the chemical composition claim used the term "consists" it was [*1332] "therefore drawn to an alloy of silver and indium without other elements"). While the term "consisting of" permits no other chemicals in the kit, a spatula is not part of the invention that is described. Cf. *Mannesmann Demag Corp. v. Engineered Metal Prods.*, 793 F.2d 1279, 1282-83 (Fed. Cir. 1986) ("The presence of additional elements is irrelevant if all the claimed elements are present in the accused structure.").

It 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. The summary judgment is reversed. We remand for further proceedings with respect to the '065 patent.

WILLFULNESS OF INFRINGEMENT

[**26] After Norian presented its case-in-chief the district court granted Stryker's motion to dismiss the issue of willful infringement under Fed. R. Civ. P. 50. A grant of judgment as a matter of law receives plenary review, applying the same standard as that of the district court, viz. whether a reasonable jury could have reached a verdict in favor of Norian on this question, on the evidence presented by Norian. See *Sextant Avionique, SA v. Analog Devices, Inc.*, 172 F.3d 817, 824, [***1517] (Fed. Cir. 1999) ("We review a district court's decision on a motion for JMOL de novo, reapplying the JMOL standard."). JMOL may be granted after the plaintiff's case when the jury could not reasonably find willfulness on the evidence presented.

Norian argues that willfulness could be found because Stryker provided no evidence that it had relied on an opinion of counsel that its activities were not infringing. The district court ruled that the burden of proving willful infringement was on Norian, and that it was not Stryker's burden to come forward with an exculpatory opinion, when Norian had not presented a *prima facie* case of willful infringement. [**27] Norian offered no evidence on this issue in its case-in-chief. The district court held that the initial burden is on the patentee to present evidence of willful infringement.

Norian argues that because Stryker did not present evidence that it had obtained an exculpatory opinion of counsel, the jury could properly have inferred that Stryker had not obtained such an opinion or that any opinion it did obtain was unfavorable. Norian cites *Great Northern Corp. v. Davis Core & Pad Co.*, 782 F.2d 159, 167 (Fed. Cir. 1986) for the proposition that failure to obtain an opinion of counsel on the issue of infringement is sufficient to support a finding of willfulness. However, absent an initial presentation of evidence on the issue by Norian, this burden of coming forward in defense did not arise. There is no evidentiary presumption that every infringement is willful. Willful infringement is not established by the simple fact of infringement, even though Stryker stipulated that it had knowledge of the Norian patents. *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1351-52 (Fed. Cir. 2000) (accused infringer's knowledge of asserted patent, without [**28] more, is insufficient to support a conclusion of willfulness). The patentee must present threshold evidence of culpable behavior. There was no evidence that Stryker invoked the attorney-client privilege as to its counsel, who, according to Stryker, had been deposed and was listed as a witness by Norian, along with three other witnesses on this issue, none of whom was called by Norian. The district court summarized:

No evidence of copying was presented. No evidence of failure to obtain an opinion of counsel was presented. No evidence was presented as to whether or [**1333] not Stryker had acted reasonably once it acquired knowledge of the patent.

Transcript at A013579-80.

We affirm the district court's ruling. Removal of the question from the jury under Rule 50 was not error; we affirm the grant of JMOL on this issue.

DAMAGES

Norian's expert testified that a reasonable royalty would have been 15%, while Stryker's expert testified to a reasonable royalty of 3%. The jury found that damages had not been proved as to the '264 patent, and the district court upheld this finding. However, the statute requires that damages to a successful claimant in a patent infringement suit shall [**29] not be less than a

reasonable royalty:

35 U.S.C. § 284. Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

The jury's finding of no damages cannot be supported. However, because we have affirmed the verdict of invalidity of claims 1, 7, and 8 of the '264 patent, this issue is moot as to the '264 patent. On remand, damages as to the '065 patent may be ascertained.

Costs

Each party shall bear its costs.

AFFIRMED IN PART, REVERSED IN PART AND REMANDED

CONCUR BY: SCHALL (In Part)

DISSENT BY: SCHALL (In Part)

DISSENT

SCHALL, Circuit Judge, concurring-in-part, dissenting-in-part.

I join that part of the court's opinion that affirms the judgment of the district court that claims 1, 7, and 8 of the '264 patent are invalid by reason of obviousness. However, I respectfully dissent from that part of the court's opinion that reverses the district court's grant of summary judgment of non-infringement of claims 8-10 of the '065 [**30] patent.

I.

The '065 patent claims kits for preparing calcium phosphate minerals. The district court [***1518] granted summary judgment of non-infringement in favor of Stryker after it construed the phrase "consisting of" in independent claim 8 of the patent as a closed transition phrase that limits the scope of claim 8 to kits having only the chemical components enumerated in the claim and no other components. Because the accused device includes a spatula, an additional mechanical component, the court

concluded that Stryker does not infringe. *Norian Corp. v. Stryker Corp.*, 2001 U.S. Dist. LEXIS 25727, No. C 01-0016 WHA (N.D. Cal. Apr. 20, 2001).

On appeal, the court determines that the transition phrase "consisting of" speaks only to the types of components listed in claim 8. It does so after noting that all of the elements in claim 8 are chemical components. As a result, the court concludes that the patentee drafted the claim to cover kits that include the enumerated chemical components, but no other chemical components. However, the court further concludes that claim 8 does not exclude additional, unrecited components that are unrelated or irrelevant to the invention. Based upon that claim construction, the court [**31] holds that Stryker's accused kit, which undisputedly includes the listed chemical components plus a spatula, i.e., an unrelated mechanical component, infringes claim 8. In light of that claim construction, the court reverses the district court's grant of summary judgment of non-infringement of claims 8-10 of the '065 patent and remands for proceedings on damages.

[*1334] II.

Claim interpretation begins with the intrinsic evidence, i.e., the claims themselves, the written description, and, if in evidence, the prosecution history. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). The terms used in a claim bear a "heavy presumption" that they have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art. *Id.* I begin with the language of claim 8, which provides as follows:

8. 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 [**32] from 0.01 to 2.0 M and said solution has a pH in the range of about 6 to 11.

'065 patent, col. 12, ll. 12-22. ¹

1 Claims 9 and 10 read as follows:

9. The kit according to claim 8, wherein said sodium phosphate is present in said water at a concentration ranging from about 0.05 to 0.5 M.

10. The kit according to claim 8, wherein said solution has a pH in the range from about 7 to 9.

'065 patent, col. 12, ll. 23-26.

On appeal, the parties dispute the meaning of the phrase "consisting of." In particular, they dispute the effect of the patentee's use of the phrase in the preamble of claim 8. Norian argues that the district court construed "consisting of" too narrowly by holding that it limits the claim to those kits with the enumerated items and no others. Instead, Norian argues that the phrase "consisting of" should only serve to limit the chemical components to those listed in the claim, but should not serve to exclude any mechanical components. Norian bases its argument on the fact that **[**33]** claim 8 lists only chemical components, suggesting that the patentee only intended to limit the chemical components and not any other types of components. As a result, Norian contends that Stryker cannot avoid infringement by selling a kit that has all of the enumerated chemical components merely because it also includes a spatula, i.e., a mechanical component. For its part, Stryker argues that the district court properly construed the disputed phrase to limit claim 8 to those kits that have only the enumerated items. As such, it urges us to affirm the district court's grant of summary judgment of non-infringement of claims 8-10 of the '065 patent.

Our case law makes it clear that "'closed' transition phrases such as 'consisting of' are understood to exclude any elements, steps, or ingredients not specified in the claim." *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001); see also *Manual of Patent Examining Procedure* § 2111.03 (8th ed. 2001). Thus, we have held that "consisting of" is a narrow phrase that limits the scope of a claim to the enumerated elements in that claim. See *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1327-28 **[***1519]** (Fed. Cir. 1999) **[**34]** (quoting *Manual of Patent Examining Procedure* § 2111.03 (6th ed. 1997));

Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc., 212 F.3d 1377, 1383 (Fed. Cir. 2000) ("In simple terms, a drafter uses the phrase 'consisting of' to mean 'I claim what follows and nothing else.'").

In my view, the court errs in holding that Norian's use of the phrase "consisting of" limits only chemical, but not mechanical, components. Our precedent indicates that such language limits all components. **[*1335]** *Vehicular Techs.*, 212 F.3d at 1383. In addition, Norian chose to claim a kit as opposed to a chemical composition in claims 8-10, and a kit is generally understood to be a packaged set or collection of related items. Norian even recognized that a kit can include mechanical items, such as packaging, by stating in claims 1 and 4 of the '065 patent that "said dry ingredients and solution are present in separate containers." '065 patent, col. 11, ll. 18-19; col. 12, ll. 2-3.

I think it is important for us to construe the "consisting of" language in claim 8 in line with our prior jurisprudence because of the public notice function that a patent and its claims serve. *Springs Window Fashions LP v. Novo Indus., LP*, 323 F.3d 989, 995 (Fed. Cir. 2003) **[**35]** ("The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent. A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement."). The public relies on the words of a patentee's claims to determine the scope of the claims and to form a business strategy. If Norian erred by employing the phrase "consisting of" rather than "comprising," and thereby mistakenly acquired claims that were not as broad as it intended, it must bear the consequences. *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997) ("However, as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure."). I do not believe that we should change the meaning of a well established phrase to save a patentee from a decision to limit its claims.

Moreover, Norian amended claim 8 **[**36]** during prosecution of the '065 patent, creating a clear record for the public. The Examiner rejected the pending claims as obvious in light of the prior art Iwamoto reference.

Iwamoto discloses in claim 1 a colloidal solution containing a calcium source and a phosphate source in a sodium phosphate solution. In response to the rejection, Norian amended claim 8 (original claim 26) by changing the term "comprising" to "consisting essentially of" and finally to "consisting of." The inventor explained the last amendment by stating that it would leave "no question that the claims exclude from their scope any kits in which the liquid is a colloid or sol In other words, the claimed kits of the present application are limited to kits in which the setting liquid is a solution." These statements do not, as Norian suggests, alter the effect of the amendment.

In view of the case law discussed above, a reasonable competitor reviewing claims 8-10 and the amendments made by Norian to distinguish the claimed invention from Iwamoto would conclude that the claims do not cover kits that contain any items beyond those specifically listed in the claims. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000) [****37**] (stating that "the prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct"). Norian chose to overcome the asserted prior art by changing the language of claim 8. However, in so doing, it excessively narrowed the scope of the patent. As amended by Norian, the preamble of

claim 8 reads, "A kit for preparing a calcium phosphate mineral, said kit consisting of" Norian could have protected itself against the infringement defense mounted by Stryker by amending the preamble of claim 8 so that it read [****1336**] instead, "A kit for preparing a calcium phosphate mineral, said kit comprising" Alternatively, Norian could have amended the preamble of claim 8 so that it read instead, "A kit for preparing a calcium phosphate mineral, the chemical composition of said kit consisting of" As the claim language stands, however, Stryker was entitled to rely on Norian's use of [****1520**] the limiting phrase "consisting of" to determine whether its kits would likely infringe Norian's claims.

In my view, claim 8 should be [****38**] limited to kits that include (i) at least one calcium source and at least one phosphoric acid source free of uncombined water as dry ingredients and (ii) a solution consisting of water and at least one sodium phosphate with a specified concentration and pH. Because there is no genuine issue of material fact regarding the presence of an additional component in Stryker's kit, i.e., a spatula, I believe that Stryker is entitled to judgment of non-infringement as a matter of law. Thus, I would affirm the decision of the district court granting Stryker summary judgment of non-infringement of claims 8-10 of the '065 patent.

For the foregoing reasons, I respectfully dissent.