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Paper 90
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.
Petitioner,

v.

CONVATEC TECHNOLOGIES, INC.
Patent Owner

Case IPR2013-00097
Patent 6,669,981 B2

Before LORA M. GREEN, RAE LYNN P. GUEST, and SHERIDAN K. SNEDDEN *Administrative Patent Judges.*

GUEST, *Administrative Patent Judge*.

SNEDDEN, *Administrative Patent Judge, concurring-in-part.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

A. Introduction

On December 21, 2012, Smith & Nephew, Inc. ("Smith & Nephew"), filed a Petition under 35 U.S.C. §§ 311-319, for *inter partes* review of claims 1-8 and 10-20 of U.S. Patent No. 6,669,981 B2 (Ex. 1001, "the '981 patent"). Paper 4 ("Pet."). ConvaTec Technologies, Inc. ("ConvaTec") filed a Preliminary Response on April 1, 2013. Paper 11. On May 31, 2013, we granted the Petition, and instituted an *inter partes* review of claims 1-8 and 10-20. Paper 12 ("Dec. on Inst.").

After institution of this proceeding, ConvaTec filed its Patent Owner's Response ("PO Resp."). Paper 29. ConvaTec also filed a Corrected Motion to Amend ("Mot. Amend") in which ConvaTec moved to substitute proposed claims 21 and 22 for 1 and 17, respectively. Paper 28. Both ConvaTec and Smith & Nephew filed Motions to Exclude. Paper 55; Paper 60. Oral hearing was held on March 5, 2014.[1]

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Smith & Nephew has shown by a preponderance of the evidence that claims 1-8 and 10-20 of the '981 patent are unpatentable. ConvaTec's Motion to Amend is *denied*.

B. The '981 Patent

The '981 patent describes methods of enhancing the photostability of silver in antimicrobial materials for use in wound dressing and medical

[1] A transcript of the oral hearing is included in the record as Paper 83.

devices. Ex. 1001, 1:10-12. Silver-containing materials are generally sensitive to light, and can cause uncontrolled discoloration of the silver-containing material. *Id.* at 1:32-35. The silver-containing materials made in accordance with the '981 patent, however, are disclosed as being substantially photostable, but will release silver when rehydrated. *Id.* at 3:23-25.

The '981 patent discloses a method wherein antimicrobial materials are prepared by subjecting a material containing hydrophilic, amphoteric, or anionic polymers to a solution comprising an organic solvent and a source of silver ("the silver solution"). *Id.* at 2:56-3:4. Examples of appropriate organic solvents include ethanol, methanol, acetone, and isopropyl alcohol. *Id.* at 4:18-21.

The polymer is subjected to the silver solution for a time that is sufficient to incorporate the desired silver concentration into the polymer. *Id.* at 3:13-15, *see id*. 4:11-13. The '981 patent also refers to a "silver-loading step," where "loading" is defined as "ionic exchange of the cation to the polymer with silver ions." *Id.* at 5:38-46.

In the next step, during the course of, or following, the period where the polymer is subjected to the silver solution, the polymer is further subjected to agent(s) that facilitate the binding of the silver and the polymer together; "binding" is defined as "the formation of a photostable compound." *Id.* at 3:15-23, 5:49-50. Chlorides are examples of such facilitating agents. *Id.* at 3:18-21.

C. Exemplary Claims

Claims 1 and 17 are the independent claims among the challenged claims of the '981 patent. All the claims are directed to methods of

preparing a light stabilized antimicrobial material. The independent challenged claims, which are illustrative of the claims at issue in this *inter partes* review, recite:

> 1. A method of preparing a light stabilized antimicrobial material comprising the steps of
>
> a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in the light stabilized antimicrobial material;
>
> b) subjecting a polymer to the solution for a time sufficient to incorporate the desired silver concentration into the polymer, wherein the polymer is selected from the group consisting of a polysaccharide, a modified polysaccharide, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyvinyl ether, a polyurethane, a polyacrylate, a polyacrylamide, a collagen, a gelatin, and a mixture thereof; and
>
> c) subjecting the polymer, during or after step (b), to one or more agents which facilitate the binding of the silver on the polymer;
>
> wherein the silver is substantially photostable in the light stabilized antimicrobial material when dry, but will dissociate from the light stabilized antimicrobial material upon hydration of the light stabilized antimicrobial material.
>
> 17. A method of preparing a light stabilized antimicrobial material comprising the steps of
>
> a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in the light stabilized antimicrobial material;
>
> b) subjecting a polymer to the solution for a time sufficient to incorporate the desired silver concentration into the polymer; and
>
> c) subjecting the polymer, after step (b), to one or more agents which facilitate the binding of the silver on the polymer;
>
> wherein the silver is substantially photostable in the light stabilized antimicrobial material when dry, but will dissociate

> from the light stabilized antimicrobial material upon hydration of the light stabilized antimicrobial material.

Claims 2-8 and 10-16 depend from claim 1, either directly or indirectly. Claims 18-20 depend directly from claim 17.

Dependent claims 2 and 18 add step (d) using the light stabilized material in a medical device.

Dependent claims 3 and 19 add step (d) using the light stabilized material in a wound dressing.

Dependent claim 4 adds step (d) using the light stabilized material in an ostomy device.

Dependent claim 5 specifies that the source of silver is a silver salt, while dependent claim 6 lists specific silver salts. Dependent claims 7 and 8 list specific agents that facilitate the binding of the silver to the polymer. Dependent claim 10 limits the method to specific polysaccharides, and dependent claim 11 limits the method to the listed organic solvents. Dependent claim 20 limits the method of claim 17 to certain polymers.

Dependent claims 12 and 13 specify the desired silver concentration. Dependent claims 14 and 15 limit the time sufficient to incorporate the desired silver concentration into the polymer, and claim 16 limits the amount of time that the polymer is subjected to the agent that facilitates the binding of the silver to the polymer.

D. Challenges to the Patentability of Claims

We instituted this *inter partes* review in connection with the following challenges to the patentability of claims in the ’981 patent:

1. Claims 1-3, 5-8, 12, 13, and 17-19 are anticipated, or rendered obvious, by Kreidl.[2]

2. Claim 11 is rendered obvious by the combination of Kreidl and Bahia.[3]

3. Claims 12-16 are rendered obvious by Kreidl, Walder,[4] Ronan,[5] and Romans.[6]

4. Claims 10 and 20 are rendered obvious by the combination of Kreidl, Bahia, and Ronan.

5. Claims 1, 2, 5-8, 10, 12-15, 17, 18, and 20 are anticipated or rendered obvious by Ronan, as evidenced by Kreidl and Romans.

6. Claims 3, 11, and 19 are rendered obvious by the combination of Ronan and Bahia.

7. Claims 1-8, 10, 11, and 17-20 are anticipated under 35 U.S.C. § 102(e) by Gibbins '751.[7]

8. Claims 12-15 are rendered obvious by the combination of Gibbins '751, as combined with Walder, Ronan, Romans, and Kreidl.

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[2] Kreidl et al. ("Kreidl"), U.S. Patent No. 2,396,514 (issued Mar. 12, 1946) (Ex. 1002).

[3] Bahia et al. ("Bahia"), WO 94/16746 A1, published August 4, 1994 (Ex. 1005).

[4] Walder, U.S. Patent No. 5,848,995 (issued Dec. 15, 1998) (Ex. 1004).

[5] Ronan et al. ("Ronan"), U.S. Patent No. 5,820,918 (issued Oct. 13, 1998) (Ex. 1006).

[6] Romans, U.S. Patent No. 3,092,552 (issued June 4, 1963) (Ex. 1003).

[7] Gibbins et al. ("Gibbins '751"), U.S. Patent No. 6,605,751 B1 (issued Aug. 12, 2003) (Ex. 1007).

9. Claim 16 is rendered obvious by the combination of Gibbins '751 and Kreidl.

II. ANALYSIS

A. Claim Interpretation

We interpret patent claim language in an *inter partes* review by ascribing to that language its broadest reasonable meaning in light of the specification of the patent. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Under that standard, we construe claim terms using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). We presume that claim terms have their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question.") (internal quotation marks and citation omitted). A patentee may rebut that presumption, however, by acting as his own lexicographer, providing a definition of the term in the specification with "reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We expressly interpret below only those claim terms that require analysis to resolve arguments related to the patentability of the challenged claims in this proceeding.

1. "to incorporate the desired silver concentration into the polymer"

ConvaTec contends that the above quoted phrase requires a chemical interaction between silver ions solubilized from a silver salt and a polymer. PO Resp. 7. ConvaTec contends also that the phrase "incorporate the desired silver concentration into the polymer" is construed properly to involve an ionic interaction. *Id.* To support that position, ConvaTec contends that the specification of the '981 patent associates the "incorporate . . . into" step with "loading" of silver onto the polymer, as required by independent claims 1 and 17, where "loading" is expressly defined in the '981 patent to mean "ionic exchange of the cation to the polymer with silver ions." *Id.* at 6-7 (citing Ex. 1001 at 5:38-40).

We agree with ConvaTec that the claims encompass an ionic interaction between free silver ions and a polymer; we do not agree, however, that the claims are limited to that single type of interaction. The claims do not recite the term "loading," and we decline to construe the claims to be limited to the express definition given to that term. Further, the '981 patent provides a list of suitable polymers that includes substances incapable of ionic interaction with silver ions including, for example, unmodified polysaccharides (i.e. cotton) and polyurethane. Ex. 1001, 3:61-4:7; Ex. 1045 ¶ 52; Ex. 2029 ¶¶ 30, 58. Rather, we interpret the phrase "incorporate . . . into" as requiring the silver to associate with the polymer in a way, regardless of the type of interaction (*e.g.*, ionic, Van der Waals, etc.), such that it can interact with the polymer and the agent that facilitates the binding of silver into the polymer so as to form a substantially photostable complex. Thus, in addition to ionic exchange, the term "incorporate . . .

into" includes other types of adsorptive interactions with the polymer that result in a substantially photostable complex, such as adsorption of the silver on the polymer, with the subsequent conversion of the silver cation to insoluble silver chloride.

2. "a solution comprising an organic solvent"

The '981 patent discloses that silver is dissolved in an organic solvent to solubilize the source of silver, such as a silver salt. Ex. 1001, 5:34-36. The organic solvent also functions to prevent hydration of the polymer, and as such should include less than 50% w/w water to alcohol so as to prevent hydration of the polymer. *Id.* at 4:63-64. ConvaTec further relies on the declaration of Dr. Kevin Edgar to establish that the presence of an organic solvent creates an environment favorable for ion exchange. PO Resp. at 7; *see* Ex. 2029 ¶¶ 17-18.

The express language of the claims, however, merely requires a solution comprising an organic solvent, and does not recite expressly any specific range as to the ratio of, for example, water to alcohol. The claims may encompass a ratio of water to alcohol that favors the ionic exchange of silver onto an ionized polymer, but are not so limited. The claims, thus, broadly encompass any solution comprising an organic solvent in an amount sufficient to prepare a silver solution, regardless of whether the amount of organic solvent is sufficient to create an environment favorable for ionic exchange.

3. "binding of silver on the polymer"

The '981 patent expressly defines "binding" as "the formation of a photostable compound." Ex. 1001, 5:50-51. As with the

"incorporate . . . into" language discussed above, the term "binding" has not been defined in the specification as being particularly limited to binding of the silver to the polymer via ionic exchange. Accordingly, the term "binding" can refer to any formation of a photostable compound on the polymer.

4. "substantially photostable"

The '981 patent defines "photostable" as "[c]ontrolled colour change to a desired colour with minimal change thereafter." *See*, *e.g.*, Ex. 1001, 5:47-49. The '981 patent does not define what is or is not a "desired color," and it does not exclude any particular color as a "desired color."

ConvaTec seeks a definition of "desired color" that excludes any colors other than a white or a "grayish white," and particularly excludes purple as a "desired color." PO Resp. 13-14, 42-43. ConvaTec relies substantially on the testimony of Dr. Tania Phillips[8] (Ex. 2028) in support of that interpretation. *Id.*

Smith & Nephew contends that the term "photostable" should be interpreted broadly due to a lack of evidence to support what a skilled artisan would have considered to be a "desired color," as required by the claims. Paper 45:7-10.

[8] Dr. Phillips testifies to having extensive experience in the field of wound care, as both a practicing clinician and researcher, for almost 30 years, and being very familiar with issues related to the wound care and management field. Ex. 2028 ¶ 9. Dr. Phillips appears to be qualified to testify as to wound care practices at the time of the invention described in the '981 patent.

Dr. Phillips testifies that if she "were presented with an AQUACEL® Ag dressing[9] that was purple out of its package, or turned purple shortly after exposure to light, [she] would assume that the dressing was expired and not in optimal condition for clinical use." Ex. 2028, ¶ 16. Dr. Phillips further testifies that

> It is my experience that the "desired color" of a silverised antimicrobial material in the '981 patent and '828 patent is white. . . . [i]nstead, a color change from "white" to "purplish" is in my opinion a discoloration, and does not equate with a "substantially photostable" product, or a "photostable" product that has minimal color change from the "desired color" of white.

Ex. 2028 ¶ 21. Dr. Phillips also references a table found in Gibbins '751, which lists "Ag Aquacel" when dry as "[w]hite, good, eventually purplish," to support her testimony that white is a desired color for a silverized antimicrobial material. Ex. 2028, ¶ 18 (citing Ex. 1007, 33:36); Ex. 2041, 88:17-20.

We are not persuaded by Dr. Phillips' testimony. Dr. Phillips only testifies as to the desired color for the AQUACEL® Ag product, with which she is familiar in clinical practice, and not to desired colors of wound dressings in general. We note that the claims and specification of the '981 patent are not limited to any particular product. The specification also does not limit "desired colour" to any particular desired colors for any particular product. *See, e.g.*, Ex. 1001, 5:46-48 (defining "photostable" as requiring a "[c]ontrolled colour change to a desired colour," without specifying a

[9] AQUACEL® Ag dressing is a silverised wound dressing product marketed by ConvaTec that is said to be covered by the '981 patent. Ex. 2045, ¶ 2.

desired color). Upon cross-examination, Dr. Phillips further states that there was nothing inherently wrong with purple if the wound dressing did not change further after turning purple.[10]

Dr. Phillips' testimony is based on her experience,[11] as well as the statements of the Gibbins '751 patent. Dr. Phillips' testimony does not address what was recognized as a "desired color" in the art of wound dressings as a whole. Dr. Phillips testifies that she has no knowledge of the technical details of why color change may occur in a silverized wound dressing[12] on which to base her opinion as to what would be a "desired color" in the art of wound dressings as a whole.

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[10] Exhibit 2041, 88:21-89:14 ("I would say that in my experience, I have not used a mauve tinted dressing as a silverized dressing. However, if there was a new dressing introduced that was purple and it was exposed to the air and it did not change color significantly during air exposure and it was as effective as all the other silver containing antimicrobial dressings, then I would have to see the data on it, but the color, per se, would not be an objection."); Exhibit 1046, 65:18-21 ("I think if the dressing had a purplish tinge and it was exposed to light and it didn't change color and didn't look any different, then it would be acceptable.") (emphasis removed).

[11] Ex. 1046, 65:7-21 ("Q. What about white with a purplish tinge to it, would that also be a desired color? A. I haven't seen that color in any of the dressings I'm currently using."); Exhibit 1046, 61:20-62:4 ("Q. You have no understanding as to whether any other practitioners have a different understanding as to the desired color of wound dressings? [] A. I can only comment on my own experience. Q. Did you ask any other practitioners whether they think purple is a desirable color for a wound dressing? A. I did not.") (objection omitted).

[12] Exhibit 1046, 39:17-21("I'm a clinician. I'm somebody who uses the dressings in practice. I can see when they change color, but I could not give you the scientific details why they change color.").

Moreover, Dr. Phillips' testimony seems to suggest that any change of color is undesirable,[13] and reads Gibbins '751's color change of the dry product from white to purple as being unacceptable.[14] The claims recite, however, that the material must be "substantially photostable . . . upon drying," and the '981 patent defines the term "photostable," as having a "[c]ontrolled colour change to a desired colour with minimal change thereafter." There is nothing to suggest that a controlled color change of a dry product from white to purple would not be encompassed by the scope of the definition of the '981 patent.

Dr. Phillips also characterizes desirability based on whether the material "was expired and not in optimal condition for clinical use." Ex. 2028 ¶ 16. The '981 patent defines photostability, however, not in terms of suitability for use, antimicrobial activity, or chemical stability, but in terms of controlled color change, with minimal change thereafter. Dr. Phillips' testimony that a color change from white or greyish white would appear "unsuitable for clinical use" or "expired" also is controverted by Gibbins '751's disclosure that, despite the purple color, *Staph. aureus* was nonetheless inhibited. Ex. 1007, 34:42-54.

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[13] Exhibit 2028 ¶ 16; Exhibit 1046, 61:7-16 ("Well, I think in my experience working with wound dressings, I know that most, in fact, all the silver wound products that I've worked with are in the color spectrum between white to gray. So if I open a packet with a wound dressing that's a silverite that I know is in this color spectrum and the color has changed to purple or brown or green, I think that's outside the normal color change that I would expect to see within those dressings.").

[14] Ex. 2028 ¶¶ 18-19; Ex. 2041, 88:7-20.

Accordingly, we interpret the term "desired color" reasonably broadly to encompass any color that may be desirable to one of ordinary skill in the art for any purpose. On the testimony of record, we do not find any reason to conclude that one of ordinary skill in the art would not consider purple as a desired color.

There is no discussion in the '981 patent as to whether or not a "minimum color change" is a change of color to an undesirable color or simply a change in the shade or spectrum of a single color. The broadest reasonable meaning therefore includes both, and thus, we construe term "photostable" to permit a minimal color change from a desired color, and also to permit minimal discoloration to an undesired color.

As to "substantially," the Federal Circuit has noted that "the term 'substantially' is capable of multiple interpretations." *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc*., 347 F.3d 1314, 1323 (Fed. Cir. 2003) (citation omitted). "[S]ubstantially" can be interpreted as "'significantly' or 'considerably,'" or also "'largely' or 'essentially.'" *Id*. at 1322-23 (citing *Webster's New 20th Century Dictionary* 1817 (1983)). In view of those possible meanings, the broadest reasonable interpretation of "substantially," when read in the context of the '981 patent, is that the claim is open to at least some degree of additional color change beyond that described in the definition of the term "photostable."

In view of the above discussion, we determine that the broadest reasonable interpretation of the term "substantially photostable" is that the material may undergo a controlled color change to desired color, some minimal discoloration, even to an undesirable color, from the controlled

color, and even some degree beyond a "minimal discoloration," and still be considered "substantially [i.e., essentially] photostable."

B. Patentability of Original Claims

To prevail in its challenges to the patentability of claims, the petitioner must establish facts supporting its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). The Court of Appeals for the Federal Circuit summarized the analytical framework for determining whether prior art anticipates a claim as follows:

> If the claimed invention was "described in a printed publication" either before the date of invention, 35 U.S.C. § 102(a), or more than one year before the U.S. patent application was filed, 35 U.S.C. § 102(b), then that prior art anticipates the patent. Although § 102 refers to "the invention" generally, the anticipation inquiry proceeds on a claim-by-claim basis. *See Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1319 (Fed. Cir. 2007). To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation. *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). But disclosure of each element is not quite enough—this court has long held that "[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim*." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (citing *Soundscriber Corp. v. United States*, 175 Ct.Cl. 644, 360 F.2d 954, 960 (1966) (emphasis added)).

Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323, 1334–35 (Fed. Cir. 2008). We must analyze prior art references as a skilled artisan would. *See Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.*, 556 F.3d 1282 (Fed. Cir. 2009) (to anticipate, "[t]here must be no difference

between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention").

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). The level of ordinary skill in the art usually is evidenced by the references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

For an obviousness analysis, prior art references must be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)). Moreover, "it is proper to take into account not only specific teachings of the reference, but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). That is because an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."

KSR, 550 U.S. at 418; *see also In re Translogic Tech., Inc.*, 504 F.3d. at 1259 .

We analyze the instituted grounds of unpatentability in accordance with the above-stated principles.

1. Claims 1-3, 5-8, 12, 13, and 17-19 as anticipated and/or obvious over Kreidl (Ex. 1002)

Kreidl discloses a disinfectant material being impregnated with light-stabilized silver halide compositions. Ex. 1002, 1, 1:2-5, 39-46. Kreidl discloses a method in which bandage gauze is soaked in silver nitrate solution, dried, and then placed in a sodium chloride solution. *Id.* at 3, 2:37-46. In Example 5 of Kreidl, a bandage gauze is dipped into a solution of 1% silver nitrate and dried. *Id.* at 6, 1:20-21. The bandage is then placed into a 20% sodium chloride solution for an hour, and washed. *Id.* at 6, 1:20-23. According to Kreidl, the gauze bandage does not discolor when exposed to light. *Id.* at 6, 1:23-24.

Example 6 is very similar to Example 5, except the bandage is immersed in a 5% sodium chloride solution for 24 hours. *Id.* at 6, 1:25-29. The time the gauze spends in the halide solution depends on the concentration of the halide, such that using a 20% sodium chloride solution only requires one hour, while a 5% solution requires 24 hours. *Id.* at 3, 2:57-61.

Kreidl also teaches that wherever solutions are mentioned, the term "is not to be limited to aqueous solutions but is meant to comprise other suitable solvents such as alcohol, glycerine, carbon tetrachloride, and the like." *Id.* at 6, 2:20-26. While Kreidl states that aqueous solutions are

preferred for silver halide preparations, it nonetheless discloses further that mixed solvents, such as diluted alcohol, may be used. *Id.* at 6, 2:26-31.

a. Claims 1, 2, 3, 5, 8, and 17-19

ConvaTec contends that Kreidl does not anticipate claims 1 and 17, and contends further that the claims are not rendered obvious by Kreidl, because the bandage gauze of Kreidl is made from cotton fibers. PO Resp. 15-16, 18-20. According to ConvaTec, cotton—being made primarily of pure cellulose containing no readily ionizable groups—is incapable of carrying out ion exchange reactions, and thus, Kreidl does not disclose a chemical association of silver ions with the polymer. *Id.* (citing Ex. 2029 ¶ 30).

ConvaTec presents evidence that the process of Kreidl results in the impregnation of precipitated and insoluble silver chloride into fibrous cotton gauze in a process referred to as *in situ* incorporation. *See e.g.*, Ex. 1026 ¶¶ 14, 15, 20, 26, 27, 39. The insoluble silver chloride precipitate occurs when the sodium chloride is added either before or at the same time as the silver source, because the silver ions are more attracted to the chloride ions than to any negative charges associated with the polymer. *Id.*; Ex. 2029 ¶ 23. Nonetheless, both parties agree that, due to the proximity of silver chloride to the polymer, there necessarily will be adsorption of silver chloride to the polymer. Ex. 1026 ¶ 26; *see* Ex. 2029 ¶ 32.

ConvaTec further argues that "Kreidl does not appreciate the use of organic solvents for shifting the ion exchange equilibria, and 'driv[ing] the exchange of sodium for silver' in the incorporation of silver into the polymer." PO Resp. 17, 21.

ConvaTec's arguments are substantially directed to an interpretation of the phrase "incorporate . . . into" and "binding" as requiring an ionic exchange of the silver onto only anionic polymer fibers. We reject that interpretation of the claim language, as set forth above, and thus, we are not persuaded by ConvaTec's arguments. Although ConvaTec's evidence shows that ionic exchange is not possible for the cotton fibers and the lower alcohol content described in Kreidl, the claims are not so limited, and encompass any adsorption of the silver taught by Kreidl to the cotton, which is an unmodified polysaccharide expressly recited in the claims. Both parties agree that adsorption of silver chloride onto the cotton fiber occurs, which is encompassed by the term "incorporate . . . into" and "binding" recited in the claims. Ex. 1026 ¶ 26; Ex. 2029 ¶ 32.

Kreidl expressly states that the resulting silverized antimicrobial materials do not discolor when exposed to light. Ex. 1002, 6, 1:23-24. ConvaTec has not presented any persuasive evidence to undermine that teaching.

ConvaTec further argues that Kreidl does not exemplify a solution comprising an organic solvent, and the use thereof constitutes inappropriate picking and choosing of embodiments for a finding of anticipation. PO Resp. 17 (citing Ex. 2029 ¶ 31 (calling the use of an organic solvent an "afterthought")). Alternatively, ConvaTec argues that Kreidl's preference for aqueous solutions teaches away from the skilled artisan adding an organic solvent. *Id.* at 20-21.

Smith & Nephew contends that Kreidl expressly discloses the use of an organic solvent, particularly diluted alcohol, with the silver source. Pet.

31-34, 39-42; Ex. 1002, 6, 2:20-31. As discussed above, the claims do not require any particular concentration of an organic solvent.

We are not persuaded that the use of an organic solvent in addition to water is not taught expressly by Kreidl. The disclosure in Kreidl is not limited to the examples, and a disclosure that the described solutions may comprise an organic solvent is sufficient. *See Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1325 n.6 (Fed. Cir. 2003) ("The anticipation analysis asks solely whether the prior art reference discloses and enables the claimed invention, and not how the prior art characterizes that disclosure or whether alternatives are also disclosed.").

Moreover, it would have been obvious to one of ordinary skill in the art to have selected an organic solvent as part of the silver nitrate solution taught by Kreidl based on the explicit teaching in Kreidl. We are not persuaded that the disclosure of an aqueous solution as preferred constitutes a teaching away. *Merck & Co v. Biocraft Labs.*, 874 F.2d 804, 807 (Fed. Cir. 1989) ("[A]ll disclosures of the prior art, including unpreferred embodiments, must be considered.") (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976)). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure of non-preferred embodiments. *In re Susi*, 440 F.2d 442, 446 n.3 (CCPA 1971).

ConvaTec presents no additional arguments as to dependent claims 2, 3, 5, 8, 18, and 19 other than those discussed above as to claims 1 and 17. Based on our review of the evidence presented by Smith & Nephew, we conclude that Smith & Nephew has established by a preponderance of evidence that Kreidl anticipates claims 1, 2, 3, 5, 8, and 17-19 under 35 U.S.C. § 102(b). We conclude further that when weighed with the evidence

of secondary considerations, discussed below, Smith & Nephew has shown by a preponderance of the evidence that claims 1, 2, 3, 5, 8, and 17-19 would have been obvious over Kreidl.

b. Claims 12 and 13

Claim 12 is drawn to the method of claim 1, "wherein the desired silver concentration is between 0.1 and 20 wt %," and claim 13 recites that "the desired silver concentration is between 1 and 20 wt %." Smith & Nephew note Kreidl teaches that "'[a]s a rule, for a standard bandage gauze[,] not more than about 4% silver nitrate should be retained on the fiber . . . .'" Pet. 32-34 (quoting Ex. 1002, 3, 2:41-44). Smith & Nephew contends, citing the Declaration of Dr. Stephen L. Coulter ("Coulter Declaration," Ex. 1026 ¶ 27), that levels of silver below 4% are within the ranges of silver claimed in claims 12 and 13. Pet. 34. ConvaTec argues that claims 12 and 13 are not anticipated by Kreidl, as Kreidl does not disclose the level of silver in the finished product, but "merely discloses that a bandage gauze was 'dipped into 1% AgNO3 solution.'" PO Resp. 24 (citing Ex. 1002, 6: 1:20-29).

ConvaTec does not challenge the Coulter Declaration in its Response, nor does ConvaTec show why the Declaration is incorrect in its conclusions. We thus credit the Declaration of Dr. Coulter.

For those reasons, we conclude that Smith & Nephew has established by a preponderance of evidence that Kreidl renders claims 12 and 13 unpatentable as anticipating under 35 U.S.C. § 102(b). We conclude further that Smith & Nephew has shown by a preponderance of the evidence that claims 12 and 13 would have been obvious over Kreidl.

2. Claim 11 as obvious over Kreidl (Ex. 1002) in view of Bahia (Ex. 1005)

Claim 11 depends from claim 1 and further recites "wherein the organic solvent is selected from the group consisting of industrial methylated spirit, denatured ethanol, methanol, acetone, isopropyl alcohol and ethanol."

Kreidl describes a solution comprising a "diluted alcohol" but does not disclose any of the recited alcohols of claim 11. Ex. 1002, 6, 2:30-31. Smith & Nephew contends:

> Bahia discloses that industrial methylated spirits and industrial alcohol (ethanol) are suitable solvents for use in processing wound dressings, Bahia at 13:24-25, and that an antiseptic can be added in alcohol containing wash compositions. Bahia at 13:10-18, 14:29-33. It would have been obvious to use industrial methylated spirits or ethanol as the alcohol in the process of Kreidl as these were well known forms of alcohol used to wash wound dressings at the time of the invention as demonstrated by Bahia.

Pet. 35-36.

ConvaTec's arguments for patentability are similar to those discussed above regarding the anticipation of claim 1, namely that, unlike Bahia, Kreidl considers the use of an alcohol as an "afterthought," while the carboxymethylcellulose ("CMC") described in Bahia would be capable of ionic exchange with silver ions and would dissolve in an aqueous solution. PO Resp. 22-23. According to ConvaTec, the teachings of Bahia cannot be combined properly with the teachings of Kreidl because of the "vast differences between the . . . processes disclosed in Bahia and Kreidl." *Id.* at 24.

As above, ConvaTec's arguments are presented as if the claims require an ionic exchange between the silver and the polymer, which we have determined they do not. Moreover, ConvaTec provides no persuasive evidence that Smith & Nephew's reasoning is in error. Thus, we agree with Smith & Nephew that it would have been obvious to one of ordinary skill in the art to have used the ethanol of Bahia as the alcohol solvent described for the bandage gauze in Kreidl, because Bahia is evidence that ethanol was a known solvent for wound dressings. *See KSR*, 550 U.S. at 417 (The question to be asked is "whether the improvement is more than the predictable use of prior art elements according to their established functions.").

We conclude that, when weighed with the evidence of secondary considerations, discussed below, Smith & Nephew has shown by a preponderance of the evidence that claim 11 would have been obvious over Kreidl in view of Bahia.

3. Claims 12-16 as obvious over Kreidl (Ex. 1002), Walder (Ex. 1004), Ronan (Ex. 1006), and Romans (Ex. 1003)

a. Claims 12 and 13

As to claims 12 and 13, those claims have been discussed above in the analysis of the challenge over Kreidl alone. Therefore, we need not address those claims further.

b. Claims 14 and 15

Claims 14 and 15 specify the time during which the dressing material is exposed to a silver nitrate solution. Smith & Nephew acknowledges that Examples 5 and 6 of Kreidl do not disclose the duration in which the gauze is exposed to the silver nitrate solution. Pet. 37. Smith & Nephew relies on

Walder, Ronan, and Romans, which each teach exposing a polymer to a silver nitrate solution for a duration of time encompassed by the ranges set forth in claims 14 and 15. *Id.* Smith & Nephew, therefore, contends that it would have been within the level of skill of the ordinary artisan to "have readily appreciated that the amount of time for which the polymer must be exposed to silver nitrate will depend on the type and dimensions of the polymer subject to *in situ* silver chloride precipitation and the level of silver chloride in the final product," rendering claims 14 and 15 obvious. *Id.* (citing Coulter Dec., Ex. 1026 ¶¶ 68, 70).

ConvaTec's arguments that each of Walder, Ronan, and Romans fails to teach ionic exchange of silver with a polymer (PO Resp. 25-28) are not persuasive for the reasons discussed above.

ConvaTec further argues that Walder cannot properly be combined with Kreidl, because Walder describes only an aqueous silver nitrate solution. PO Resp. 25. ConvaTec also argues that Romans cannot properly be combined with Kreidl because Romans is directed to "non-analogous products, such as ointments and skin antiseptics," and discloses a preferred silver concentration outside of the claimed range. PO Resp. 28.

ConvaTec's arguments are not persuasive. ConvaTec has not shown why the aqueous solution of Walder or the differences described in Romans are a basis for determining that the skilled artisan would not consider the silver nitrate exposure times disclosed therein as being suitable for the process described in Kreidl, as Smith & Nephew has shown that each of Walder, Ronan, and Romans is directed to incorporating the antimicrobial properties of silver into a polymer. Moreover, ConvaTec's arguments fail to

direct us to any persuasive additional arguments regarding the teachings of Ronan.

We thus conclude that, when weighed with the evidence of secondary considerations, discussed below, Smith & Nephew has shown by a preponderance of the evidence that claims 14 and 15 would have been obvious over Kreidl, Walder, Ronan, and Romans.

c. Claim 16

Claim 16 further recites the time during which the polymer is exposed to the binding agents in step (c) of claim 1. Smith & Nephew notes that Kreidl teaches exposing the gauze to a sodium chloride solution for one hour when a 20% sodium chloride solution is used, and for 24 hours when a 5% sodium chloride solution is used. Pet. 38. Smith & Nephew asserts that Kreidl teaches that the amount of time the material is soaked in a sodium chloride solution is a result-effective variable. *Id.* (citing Ex. 1002, 3, 2:44-51). Smith & Nephew contends it would have been obvious to optimize the time the gauze of Kreidl is soaked in the sodium chloride solution, such as soaking for 5 to 30 minutes, because Kreidl specifically teaches that it is a result-effective variable. *Id.* (citing Coulter Dec., Ex. 1026 ¶ 70).

ConvaTec's Response demonstrates no error in Smith & Nephew's challenge to patentability to claim 16 over those arguments discussed above. PO Resp. 24-29. Namely, ConvaTec's arguments do not respond to Smith & Nephew's evidence and argument that the amount of time the material is exposed to an agent that facilitates the binding of silver is a result-effective variable based on the teachings of Kreidl.

We thus conclude that, when weighed with the evidence of secondary considerations, discussed below, Smith & Nephew has shown by a

preponderance of the evidence that claim 16 would have been obvious over Kreidl, Walder, Ronan, and Romans.

4. Claims 10 and 20 as obvious over Kreidl (Ex. 1002), Bahia (Ex. 1005), and Ronan (Ex. 1006)

Claims 10 and 20 further recite that the polymer comprises "a carboxymethylcellulose [CMC], an alginate, or a mixture thereof." Smith & Nephew has presented a detailed argument that "it would have been obvious to replace the cotton gauze of Kreidl with the gel fiber [CMC] dressing of Bahia, or to apply the Kreidl process to provide the silver chloride as an antiseptic in the gel fiber dressing of Bahia." Pet. 50-52. ConvaTec's Response demonstrates no error in Smith & Nephew's challenge to the patentability of these dependent claims over those arguments discussed above with respect to claims 1 and 17 as well as claim 11 above. Namely, ConvaTec argues that Ronan's aqueous solution would not allow for incorporation of silver ions into the polymer by ionic exchange. PO Resp. 29-30. ConvaTec further argues that, unlike Bahia, Kreidl considers the use of an alcohol as an "afterthought," while the CMC described in Bahia would be capable of ionic exchange with silver ions and would dissolve in an aqueous solution. PO Resp. 30-31.

As above, ConvaTec's arguments are presented as if the claims require an ionic exchange between the silver and the polymer, which we have determined they do not. We agree with Smith & Nephew that it would have been obvious to one of ordinary skill in the art to have used the CMC polymer of Bahia for the bandage gauze in Kreidl, because the skilled artisan would have been aware of the advantages of Bahia's wound dressing, namely in promoting healing, ease of handling, and translucency. Pet. 51.

See KSR, 550 U.S. at 417 (The question to be asked is "whether the improvement is more than the predictable use of prior art elements according to their established functions.").

We thus conclude that, when weighed with the evidence of secondary considerations, discussed below, Smith & Nephew has shown by a preponderance of the evidence that claims 10 and 20 would have been obvious over Kreidl, Bahia, and Ronan.

5. Claims 1, 2, 5-8, 10, 12-15, 17, 18, and 20 as anticipated or obvious over Ronan (Ex. 1006), as evidenced by Kreidl (Ex. 1002) and Romans (Ex. 1003)

Ronan discloses a method of making an antiseptic article, in which the article is immersed in an infiltration solution comprising an aqueous solution of silver acetate, and then immersed into a solution that contains an anion, such as chloride. Ex. 1006, 4:40-56. The infiltration solution may contain up to about 50% of a water miscible solvent such as an alcohol, glycol, ether, or ester solvent. *Id.* at 5:20-25.

Ronan provides an example in which calcium alginate hydrogel tubing is soaked for one hour in an aqueous 1% silver acetate solution, and then soaked in an aqueous calcium chloride solution for an hour. *Id.* at 7, Example 3.

ConvaTec contends that Ronan discloses insoluble alginate cross-linked hydrogels that are not designed for ion-exchange, and thus, Ronan does not disclose or suggest "incorporation" of silver onto anionic polymers substrates. PO Resp. 32 (citing Ex. 2029 ¶¶ 37-38).

As discussed above with respect to Kreidl, ConvaTec's arguments are substantially directed to an interpretation of the phrase "incorporate . . . into"

as requiring an ionic exchange of the silver onto only anionic polymer fibers. We are not persuaded by ConvaTec's arguments because we reject this interpretation for the reasons discussed above. Although ConvaTec's evidence shows that Ronan's alginate cross-linked hydrogels would likely be destroyed by ion exchange, the claims are not so limited, and encompass adsorption or other bonding of the silver, taught by Ronan, to the alginate cross-linked hydrogels, which is a type of polymer expressly recited in claims 10 and 20. Both parties agree the silver chloride is provided in the alginate polymers of Ronan, which is encompassed by the term "incorporated . . . into" recited in the claims. Ex. 1026 ¶ 46; Ex. 2029 ¶ 39.

Ronan does not state expressly that the resulting silverized antimicrobial materials do not discolor when exposed to light. Smith & Nephew contends that because Ronan discloses a process substantially similar to the process taught by the '981 patent, it would result inherently in a material that is substantially photostable. Pet. 39-40 (citing Coulter Dec., Ex. 1026 ¶ 50). We agree with Smith & Nephew that Ronan describes a process that is essentially the same as the claimed process. The realization of a new benefit of an old process does not render that process patentable. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377-78 (Fed. Cir. 2005); *see also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (stating in the context of a claimed process that was drawn to the same use comprising the same steps of the prior art, "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent"). ConvaTec has not presented any persuasive evidence or argument to undermine this reasoning. *See*, *e.g.*, PO Resp. 34.

Smith & Nephew contends that Ronan expressly discloses the use of organic solvents, particularly alcohols, glycols, ether, and ester solvents, with the silver source. Pet. 39; Ex. 1006, 5:20-25.

ConvaTec argues that Ronan does not exemplify a solution comprising an organic solvent. According to ConvaTec, the disclosure in Ronan of "infiltration solutions" that may contain organic solvents "does not constitute a disclosure of preparing a solution comprising an organic solvent," and the use thereof constitutes inappropriate picking and choosing of embodiments for a finding of anticipation. PO Resp. 33. Alternatively, ConvaTec argues that Ronan's requirement for water soluble salts teaches away from the skilled artisan adding an organic solvent. *Id.* at 35 (citing Ex. 1006, 3:59-64).

We disagree with ConvaTec that the use of an organic solvent in addition to water is not taught by Ronan. The disclosure in Ronan is not limited to the examples, and a disclosure that the described solutions may comprise an organic solvent is sufficient. *See Hewlett-Packard*, 340 F.3d at 1325 n.6.

Moreover, we agree with Smith & Nephew (Pet. 43) that it would have been obvious to substitute the aqueous solvent with a solvent that contained 50% alcohol as Ronan teaches that such a substitution may be made. We are not persuaded that the disclosure of water soluble salts constitutes a teaching away from including miscible organic solvents. *Merck*, 874 F.2d at 807; *In re Susi*, 440 F.2d at 446 n.3.

Smith & Nephew has presented a detailed argument that each of claims 1, 2, 5-8, 10, 12-15, 17, 18, and 20 are anticipated by or, in the alternative, would have been obvious over the teachings of Ronan. Pet. 39-

43. ConvaTec's Response demonstrates no error in Smith & Nephew's challenge to patentability to any particular claim so challenged. PO Resp. 31-36. For those reasons, we conclude that Smith & Nephew has established by a preponderance of evidence that Ronan anticipates claims 1, 2, 5-8, 10, 12-15, 17, 18, and 20 under 35 U.S.C. § 102(b). We conclude further, that when weighed with the evidence of secondary considerations, discussed below, Smith & Nephew has shown by a preponderance of the evidence that claims 1, 2, 5-8, 10, 12-15, 17, 18, and 20 would have been obvious over Ronan.

6. Claims 3, 11, and 19 as obvious over Ronan (Ex. 1006) and Bahia (Ex. 1005)

Claims 3 and 19 depend from claims 1 and 17, respectively, and recite "further comprising: (d) using the light stabilized antimicrobial material in a wound dressing." Claim 11 depends from claim 1, and recites "wherein the organic solvent is selected from the group consisting of industrial methylated spirit, denatured ethanol, methanol, acetone, isopropyl alcohol and ethanol."

Ronan describes "medical devices," which "include films, stents, catheter or cannulas, plugs and constrictors." Ex. 1006, 5:26-29. Ronan further describes "[l]inear device or pre-device shaped configurations such as fibers, rods, tubes or ribbons." *Id.* at 5:36-37. Ronan does not expressly teach a "wound dressing," as recited in claims 3 and 19. Smith & Nephew argues:

> Bahia . . . demonstrates that gel forming polymers similar to those disclosed by Ronan can be made into wound dressings. Accordingly, it would have been obvious to a person having ordinary skill in the art to apply Ronan's process for making

> antiseptic medical devices to the wound dressings of either [sic] Bahia.

Pet. 44.

Ronan describes a solution comprising an "alcohol" but does not disclose any of the recited alcohols of claim 11. Smith & Nephew argues:

> Bahia discloses that industrial methylated spirits is a suitable solvent for use in processing wound dressings, Bahia at 13:24-25, and that an antiseptic can be added in alcohol containing wash compositions. Bahia at 13:10-18, 14:29-33. It would have been obvious to use industrial methylated spirits or ethanol as the alcohol in the process of Ronan as these were well known forms of alcohol used to wash wound dressings at the time of the invention as demonstrated by Bahia.

Id. at 43-44

ConvaTec's arguments that Ronan does not teach, but instead discourages, the use of organic solvents (PO Resp. 36) are not persuasive for the reasons discussed above with respect to anticipation based on Ronan.

ConvaTec argues further that, unlike the alginate fibers of Ronan, the CMC described in Bahia would be capable of ionic exchange with silver ions, and thus, would dissolve in an aqueous solution. *Id*. at 37. According to ConvaTec, the teachings of Bahia cannot be combined properly with the teachings of Ronan, because the Bahia process does not contain silver, and Ronan's process is "very different" and there are different "considerations necessary in treating anionic polymers." *Id.*

ConvaTec's arguments directed to ionic exchange between the silver and the polymer are not persuasive for the reasons discussed above. Further, ConvaTec has shown no error in the reasoning that it would have been obvious to one of ordinary skill in the art to have used the alginate material described in Ronan for a wound dressing. Specifically, Bahia evidences that

the use of alginate hydrogels as wound dressings was known in the art, and the skilled artisan would have used the ethanol of Bahia as the alcohol solvent described in Ronan, because Bahia is evidence that ethanol was a known solvent for such wound dressings. *See KSR*, 550 U.S. at 417.

We thus conclude that, when weighed with the evidence of secondary considerations, discussed below, Smith & Nephew has shown by a preponderance of the evidence that claims 3, 11, and 19, would have been obvious over Ronan and Bahia.

7. Claims 1-8, 10, 11, and 17-20 are anticipated under 35 U.S.C. § 102(e) by Gibbins '751 (Ex. 1007)

Gibbins '751 discloses methods for incorporating silver chloride into various substrates by nucleation of silver chloride into the matrix. *See, e.g.*, Ex. 1007, 31:26 (Section heading "AGCL Colloid Nucleation in Solvent for Aquacel"); Ex. 1026 ¶ 51.

Gibbins '751 discloses a solution of a chloride salt, such as sodium chloride, that is made using water combined with an alcohol solvent, such as ethanol or isopropyl alcohol, wherein the aqueous portion of the solution is not greater than 50%. Ex. 1007, 18:13-17, 28-30. A polymeric material is immersed into the chloride bath, and then immersed into a similar solution of water and an alcohol solvent that contains silver ions. *Id.* at 18:20-25. Gibbins '751 specifically teaches that the immersion sequence may also be reversed without affecting the success of the method. *Id.* at 18:30-32.

Example 24D of Gibbins '751 added silver to Aquacel® fibers.[15] *Id.* at 31, Example 24. In Example 24D of Gibbins '751, the polymer was added to a solution of sodium chloride comprising ethanol as the solvent, to which was added, after "a few seconds," a silver nitrate solution comprising ethanol as the solvent. *Id.* at 32:61-67. Gibbins '751 noted that, while the silver Aquacel® eventually turned purplish, the material did not discolor appreciably in light. *Id.* at 33:35-50.

Gibbins '751 also provides Examples 25(a) through 25(n). *Id.* at 34:4-39. In each example, reagents were prepared and used to impregnate CMC (Aquacel). *Id.* at 33:66 to 34:1. From those Examples, Gibbins '751 states that "[t]he stability of the material to light is controlled by the amount of NaCl, and the location and concentration of Cu ions in the material." *Id.* at 33:62-65.

Examples 25(a)-25(h) use the following notation, with X used to describe amounts that vary between the different examples:

> X g NaCl in 2 ml H_2O, add to 50 g EtOH, add dressing, add X mL $AgNO_3$ sol., add X µl Cu.

Id. at 34:4-20. We interpret that notation as describing providing a sodium chloride solution in 2 ml water, to which 40 g ethanol is added. The CMC dressing is added. A silver nitrate solution then was added, followed optionally with a copper solution in ethanol. *See* Ex. 1045 ¶ 6. These examples systematically vary the sodium chloride concentration, the silver nitrate concentration, and the copper concentration.

[15] Aquacel® is a trade name for carboxymethoylcellulose (CMC). Gibbins '751, 33:67-34:1; Exhibit 1045 ¶ 65.

Examples 25(i)-25(l) use the following notation, with X used to describe amounts that vary between the different examples:

> X g $AgNO_3$ to 100 µl H_2O, add to 25 g EtOH/0.0888 g NaCl in 2 ml H_2O, add X µ1 Cu, add to 25 g EtOH, add dressing, add $AgNO_3$ solution.

Id. at 34:21-33. We interpret that notation to describe first preparing a silver nitrate solution in 100 µl of water, which is added to 25 g of ethanol. Then a sodium chloride solution is prepared in 2 ml water, optionally adding copper, and added to 25 g ethanol. The CMC dressing is then added to the sodium chloride solution, followed by the silver nitrate solution. *See* Ex. 1045 ¶ 7. The concentration of silver nitrate and the copper concentration are varied in these examples.

Examples 25(m) and 25(n) use the following notation with X used to describe amounts that vary between the two examples:

> 0.006795 g $AgNO_3$ to 100 µl H_2O, add to 25 g EtOH, add dressing/X NaCl in 2 ml H_2O, add 0 µl Cu, add to 25 g EtOH, add to $AgNO_3$ solution.

Id. at 34:34-39. What this notation means is at issue in this proceeding. Based on a consistent reading of this notation with the other examples, we agree with Smith & Nephew that this notation describes first, preparing a silver nitrate solution in 100 µl of water, to which is added to 25 g of ethanol. The CMC dressing is then added to the silver nitrate solution. A sodium chloride solution then is prepared in 2 ml water, without adding copper, and added to 25 g ethanol. The sodium chloride solution is then added to the silver nitrate solution. *See* Pet. 52-56; Paper 45, 6-7 (Ex. 2047 (redacted version of Paper 45)); *see* Ex. 1045 ¶¶ 8, 9, 20.

Gibbins ’751 at column 34, line 40, further states “[a]dd 10 g H_2O to 25 g EtOH, add dressing.” That disclosure may be a control example, which

only adds water to ethanol, followed by adding a CMC dressing, and no silver nitrate or sodium chloride is added.

Each of the Examples was exposed to light and *Staph. aureus* to determine antimicrobial activity. Ex. 1007, 34:42-44.

Gibbins '751 states that:

> Samples that contained higher concentrations of silver discolored more quickly in light with most samples eventually turning a purplish color. The exceptions were samples "n" and "o" which remained white. With the exception of the sample developed from the combination in "o", the samples had an acceptable feel and texture. Sample "o" was stiff following processing. All samples produced the same size zone of inhibition on the staph plate except for sample "o", which had no zone of inhibition.

Id. at 34:46-54. We note that there is no example "o" identified by Gibbins '751, but that Gibbins '751 does include a possible additional control example, as discussed above. *Id.* at 34:10. The results would be consistent with sample "o" being a control example with no expected antimicrobial activity or color change, as no silver was added.

Smith & Nephew argues that Example 25(m), as well as the disclosure in Gibbins '751 that the steps of Example 24 can be prepared in the opposite order without affecting the success of the method, anticipates claims 1-8, 10, 11, and 17-20 of the '981 patent. Pet. 53-57.

ConvaTec argues that Gibbins '751 intends the "immersion" or "impregnation" of "an insoluble silver chloride precipitate," which is not "the incorporation of silver ions into polymers by ion exchange." PO Resp. 39-40. According to ConvaTec, even though the CMC dressing of Gibbins '751 is capable of ionic exchange with silver, only by immersing the dressing in silver first, absence the presence of chloride ions, is the silver

allowed to ionically exchange with the dressing, and Gibbins '751 "failed to teach, disclose, or appreciate that the order of addition . . . was important and critical" to ionic exchange. *Id.* (citing Ex. 2029, ¶ 42); *see* Ex. 2029 ¶ 43. As Dr. Edgar explains, "[t]he presence of soluble sodium ions from sodium chloride will retard the exchange of sodium counterions on the anionic polymer for soluble silver ions." Ex. 2029 ¶ 42. Dr. Edgar concludes that the sequence of addition of reagents, i.e., substrate in sodium chloride, then addition of silver salt "is precisely the opposite of the sequence that would promote the incorporation or loading of a desired silver salt concentration into the polymer." *Id.*

ConvaTec's arguments are not persuasive. First, as discussed in detail above, ConvaTec's arguments are presented as if the claims required an ionic exchange between the silver and the polymer, which we have determined they do not.

Second, claim 1 of the '981 patent states that the addition of the agent (e.g., chloride) in step (c) may be performed "during or after step (b)," step (b) being the step of subjecting the polymer to the silver and organic solvent solution. Thus, independent claim 1 of the '981 patent, as well as the claims dependent thereon, are not limited to separately subjecting the polymer to the silver first, followed by subjecting the polymer to the chloride agent.

ConvaTec argues that step (b) requires a "time sufficient to incorporate the desired silver concentration into the polymer," which requires some ionic exchange of the silver prior to step (c), but that the ionic exchange does not have to be complete before beginning step (c). PO Resp. 12 (citing Ex. 2029 ¶ 26).

ConvaTec's argument is not persuasive because, as discussed above, the "incorporation . . . into" step of step (b) is not limited to ionic exchange. Moreover, the fact that claim 1 specifically states that step (c) can take place "during or after step (c)," as well as the evidence provided by Dr. Edgar, further supports our interpretation of the "incorporating . . . into" language of claims 1 and 17 of the '981 patent as including interactions in addition to ionic exchange.

Finally, because Gibbins '751 discloses the same steps in the same order recited in the claims of the '981 patent, the silver ions would necessarily ionically exchange with the CMC polymer prior to the addition of the sodium chloride agent, based on the evidence provided by ConvaTec.

ConvaTec contends that neither Example 24, nor Example 25(m), discloses the same process recited in the claims of the '981 patent, but rather should be understood to mean that the "dressing is <u>in</u> 0.0888 (presumably grams) of sodium chloride dissolved in 2 milliliters of water prior to mixing with the silver nitrate solution." PO Resp. 41; *see* Ex. 2029 ¶¶ 46-48. ConvaTec argues that the "/" in the Examples means "in." For example, the stock silver aqueous solution is described in Gibbins '751 as "0.11325 g Ag/50 mL H2O," which means "0.11325 grams of silver in 50 milliliters of water." PO Resp. 41 (citing Ex. 1007, 34:2); *see* Ex. 2029 ¶ 48.

While we agree that the stock solutions are characterized by a "/" which appears, in that instance to mean "in," we are not persuaded that the "/" means the same thing in the Examples. We find that it is the last step of each Example that best explains the order. *See* Ex. 1045 ¶¶ 23-24.

Examples 25(a)-25(h) include no "/" designations and clearly state that each of the components are additive. Examples 25(i)-25(l) recite

preparing the silver nitrate solution first, a "/," then preparing the sodium chloride solution, with the "add dressing" as an additive step of the sodium chloride solution. What is most instructive, however, is that Examples 25(i)-25(l) each recites "add $AgNO_3$ solution" as the last additive step of the sodium chloride solution, clarifying that, despite the fact that the silver nitrate solution was prepared first; it was added to the sodium chloride solution after the dressing. *See* Ex. 1045 ¶ 24.

Examples 25(m) and 25(n) are similar to these earlier examples in that they recite preparing the silver nitrate solution first, a "/," then preparing the sodium chloride solution. They are distinguished, however, in that Examples 25(m) and 25(n) recite adding the dressing before the "/" as an additive step in preparing the silver nitrate solution, and finally recite "add *to* $AgNO_3$ solution" as the last step for preparing the sodium chloride solution (emphasis added). *Id.*

Smith & Nephew's interpretation of the notation used in Gibbins '751 is further supported by Example 24B, which previously concluded that "[i]t was not appropriate to pre-mix separate solutions that are later combined to form the bath for the immersion of hydrophilic matrix material for impregnating with silver" because "a heavy rapidly forming precipitate developed in the mixture." Ex. 1007, 32:22-27. Thus, ConvaTec's interpretation would have Examples 25(i)-25(j) adding the dressing to a pre-mixed solution, in contravention of the earlier teaching in Gibbins '751 against pre-mixing.

Further, Smith & Nephew's interpretation is consistent with the further disclosure in Gibbins '751 that the order of immersion may be reversed without consequence to the success of impregnation (Ex. 1007,

18:30-32). Example 25(m) and Example 25(k) recite the dressing being immersed in the silver nitrate and sodium chloride solutions in the opposite order and Gibbins '751 reports no distinctions in the results for those Examples. *See* Ex. 1007, 34:28-30, 34-36, 45-54; Ex. 1045 ¶ 28.

We credit the testimony of Dr. Coulter as to the interpretations of the Examples 25(a)-25(n). Patent Owner states that "like all of the other examples in Example 25, the Aquacel substrate in 25(m) is contacted to sodium salt ***prior to*** admixing with soluble silver salt," but does not address the distinctions between the notations of Examples 25(a)-25(n). PO Resp. 41 (emphasis original).

Moreover, even if the steps of Example 25(m) are in the same order as Example 24D, we find it persuasive that Gibbins '751 expressly teaches reversing the order. The reverse order of Example 24D clearly reads on the steps of claims 1 and 17. Thus, we agree with Smith & Nephew that the same process is recited in claims 1 and 17 and is described in the '981 patent in the reverse order of Example 24D and that the resulting material necessarily would be "substantially photostable."

ConvaTec further argues that, even if the steps of Example 25(m) are in the same order as recited in the claims of the '981 patent, Gibbins '751 "failed to produce a substantially photostable product." PO Resp. 42. In addition to the testimony of Dr. Edgar, ConvaTec relies on the testimony of Dr. Phillips in arguing that "that the 'purplish' or 'purple' color change from white of Examples 24 and 25 [of Gibbins '751] was not, in her experience, 'substantially photostable.'" PO Resp. 42-43 (citing Ex. 2028 ¶¶ 16, 18-21; Ex. 2029 ¶ 49).

As discussed above, the term "photostable" is defined in the '981 patent as having a "controlled colour change to a desired colour with minimal change thereafter." As discussed above, we interpret the term "desired colour" broadly to encompass any color that may be desirable to one of ordinary skill in the art for any purpose, and do not find sufficient evidence to particularly exclude purple as a "desired colour." Further, as also discussed above, with the definition allowing for "minimal change thereafter," and the qualifier "substantially" in the claim, we interpret the phrase "substantially photostable" to mean that the material may undergo a controlled color change to a desired color, with some minimal discoloration, even to an undesirable color, from the desired color, and even some degree beyond a "minimal discoloration," and still be considered "substantially photostable."

Accordingly, we do not find ConvaTec's arguments persuasive. Gibbins '751 states that "[s]amples that contained higher concentrations of silver discolored more quickly in light with most samples eventually turning a purplish color. The exceptions were samples 'n' and 'o' which remained white." Ex. 1007, 34:46-49. Gibbins '751 states also that its materials "possess antimicrobial activity and do not appreciably discolor in the presence of light." *Id.* at 33:49-50. A controlled color change to "purplish" would not be excluded from the phrase "substantially photostable" because purple is not excluded as a "desirable color" within the meaning of the '981 patent.

Even if purple were shown to be an undesirable color, Gibbins '751 reports a change to "purplish" or having "purple, specks." *Id.* at 33:37-43; 34:46-49. Such a description indicates only a substantially minimal color

change to purple that is encompassed by the broad language recited in the claims and the broad definition of "photostable" in the '981 patent.

Smith & Nephew has presented a detailed argument that each of claims 1-8, 10, 11, and 17-20 are anticipated by the teachings of Gibbins '751. Pet. 52-56. ConvaTec's Response demonstrates no error in Smith & Nephew's challenge to the patentability of any particular claim so challenged. PO Resp. 38-44. For those reasons, Smith & Nephew has established by a preponderance of evidence that Gibbins '751 anticipates claims 1-8, 10, 11, and 17-20 under 35 U.S.C. § 102(e).

8. Claims 12-15 as obvious over Gibbins '751 (Ex. 1007), Walder (Ex. 1004), Ronan (Ex. 1006), Romans (Ex. 1003), and Kreidl (Ex. 1002)

Claim 12 is drawn to the method of claim 1, "wherein the desired silver concentration is between 0.1 and 20 wt %," and claim 13 recites that "the desired silver concentration is between 1 and 20 wt %." Smith & Nephew argue that Walder, Ronan, and Romans teach "that the levels of silver within the claimed ranges would have been considered desirable at the time of the invention[,]" and that "silver concentrations within the claimed ranges would have been desirable for antimicrobial effect[,] and a skilled person would have sought to optimize these levels." Pet. 56.

Claims 14 and 15 specify the time during which the material is exposed to a silver nitrate solution. Smith & Nephew acknowledges that Gibbins '751 does not expressly disclose the duration in which the gauze is exposed to the silver nitrate solution. Pet. 57. Smith & Nephew relies on Walder, Ronan, and Romans, each of which teaches exposing a polymer to a silver nitrate solution for a duration of time encompassed by the ranges set

forth in claims 14 and 15. *Id.* Smith & Nephew contends, therefore, that it would have been within the level of skill of the ordinary artisan to "have readily appreciated that the amount of time for which the polymer must be exposed to silver nitrate will depend on the type and dimensions of the polymer subject to *in situ* silver chloride precipitation and the level of silver chloride in the final product," rendering claims 14 and 15 obvious. *Id.* (citing Coulter Dec., Ex. 1026 ¶¶ 68, 70).

ConvaTec argues that Walder, Ronan, and Romans cannot properly be combined with Gibbins '751 because (1) they each describe only an aqueous silver solution; (2) "Walder relates to anti-infective urinary catheters" and Romans is directed to "non-analogous products, such as ointments and skin antiseptics;" and (3) Romans discloses a preferred silver concentration outside of the claimed range. PO Resp. 44-45. According to ConvaTec, because of

> the significant differences in the methods described in claims 1-8, 10, 11 and 17-20 of the '981 patent and the processes described in Walder, Ronan, and Romans, a person of skill in the art would have had no reasonable expectation of success in the claimed processes over the cited combination.

Id.

ConvaTec's arguments are not persuasive. ConvaTec failed to show the differences between the processes described in Walder, Ronan, and Romans are a basis for determining that the skilled artisan would not consider the silver concentrations or silver nitrate exposure times disclosed therein as being suitable for the process described in Gibbins '751, given that each of Walder, Ronan, and Romans is directed to incorporating the antimicrobial properties of silver into a polymer. Moreover, ConvaTec's arguments do not respond to Smith & Nephew's evidence and argument that

the silver concentration and the amount of time for which the polymer must be exposed to silver nitrate are result-effective variables based on the teachings of Walder, Ronan, and Romans.

We thus conclude that, when weighed with the evidence of secondary considerations, discussed below, Smith & Nephew has shown by a preponderance of the evidence that claims 12-15 would have been obvious over Gibbins '751, Walder, Ronan, Romans, and Kreidl.

9. Claim 16 as obvious over Gibbins '751 (Ex. 1007) and Kreidl (Ex. 1002)

Claim 16 further recites the time during which the polymer is exposed to the binding agents in step (c) of claim 1. Smith & Nephew notes that Gibbins '751 does not disclose the duration of exposure to sodium chloride in its process. Pet. 57-58. Smith & Nephew asserts that Kreidl teaches that the amount of time the material is soaked in a sodium chloride solution is a result-effective variable. *Id.* at 58 (citing Ex. 1002, 3, 2:44-51). Smith & Nephew contends it would have been obvious to optimize the time the gauze of Kreidl is soaked in the sodium chloride solution, such as soaking for 5 to 30 minutes, because Kreidl specifically teaches that it is a result-effective variable. *Id.* (citing Coulter Dec., Ex. 1026 ¶ 70).

ConvaTec argues that Kreidl discloses exposure times are far outside the claimed range: "For example, when having about 1% silver nitrate retained on the fibers of such a bandage gauze a cold treatment in a 20% sodium chloride solution for one hour or in a 5% solution for twenty-four hours will give good results." PO Resp. 46 (citing Ex. 1002, 3, 2:57-61).

ConvaTec's arguments do not respond to Smith & Nephew's evidence and argument that the amount of time the material is exposed to an agent that facilitates the binding of silver is a result-effective variable based on the teachings of Kreidl. The time periods outside of the claimed range recited in Kreidl are exemplary only, and do not overcome the suggestion in Kreidl that the skilled artisan would have optimized the time the gauze is soaked in the sodium chloride solution, depending on the temperature, concentration, or desired completeness of the ensuing reaction.

We thus conclude that, when weighed with the evidence of secondary considerations, discussed below, Smith & Nephew has shown by a preponderance of the evidence that claim 16 would have been obvious over Gibbins '751 and Kreidl.

10. Secondary Considerations of Nonobviousness

Before we can determine that the obviousness determinations above render the challenged claims unpatentable, we must consider the evidence of obviousness anew in light of any evidence of secondary considerations of nonobviousness presented by ConvaTec. *See Graham*, 383 U.S. at 17-18 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012) ("This objective evidence must be 'considered as part of all the evidence, not just when the decision maker remains in doubt after reviewing the art.'") (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983)).

ConvaTec presents the following evidence of commercial success, industry acclaim, long-felt but unsolved need, and copying. PO Resp. 47-58.

(1) Commercial Success

Commercial success involves establishing success in the marketplace of a product encompassed by the claims, as well as a nexus between the commercial product and the claimed invention. "Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Tech. Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). "For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

While objective evidence of nonobviousness lacks a nexus if it exclusively relates to a feature that was "known in the prior art," *Ormco Corp.* 463 F.3d at 1312, the obviousness inquiry centers on whether "the claimed invention as a whole" would have been obvious, 35 U.S.C. § 103; *Rambus Inc. v. Rea*, 731 F.3d. 1248, 1257-58 (Fed. Cir. 2013).

With regard to whether a nexus has been established between the products upon which commercial success has been based and the claimed invention, ConvaTec's arguments are based on ConvaTec's AQUACEL® Ag product line. PO Resp. 48-49. Ms. Fiona Adams testified that she is "aware of and familiar with the AQUACEL® Ag line," which she "understand[s] contain products manufactured using the methods claimed in the '981 and '828 patents." Ex. 2030 ¶¶ 3-4 (*see* Ex. 2045 (redacted version

of Ex. 2030)). Ms. Adams testifies as to the reason for success of AQUACEL® Ag as follows:

> ConvaTec's success with AQUACEL® Ag products came about because it created a new commercial opportunity that was not realized previously in the wound dressing field. Although silverised wound dressings, including Smith & Nephew's ACTICOAT product, were previously available, the market was not established. It was only with the introduction of AQUACEL Ag products and its unique features that customers expanded the market and purchased these products. AQUACEL Ag products created a commercially viable opportunity for this segment, doubling the size of the market in the US within just two years and taking dominant share in under a year from launch.

Id. at ¶ 9.

The patent owner has the burden of showing that the commercial success derives from a feature recited in the claims, in this case, for example, the particular process steps or the resulting photostability. *Tokai Corp., v. Easton Enters. Inc.*, 632 F. 3d 1358, 1369 (Fed. Cir. 2011). In order to establish a proper nexus, the patent owner must offer proof that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter. *See Microsoft v. Proxyconn, Inc.*, IPR2012-00026, slip op. at 4 (PTAB Mar. 8, 2013) (Paper 32). We have considered the testimony of Ms. Adams (Ex. 2045), which purports to show that the AQUACEL® Ag product line includes the features of claims 1 and 17 of the '981 patent. ConvaTec has not shown, however, that the sales of the AQUACEL® Ag product line are a result of the claimed invention.

Ms. Adams provides no supporting evidence that the features recited in the claims of the '981 patent are responsible for the success of the

commercial AQUACEL® Ag products. Ms. Adams provides no details of the manufacturing process for AQUACEL® Ag products as supporting evidence that the products are manufactured using the steps recited in the claims. Upon cross-examination, Ms. Adams testified that she has no technical knowledge of the patents and could not confirm whether specific products in the AQUACEL® Ag line were covered by the claims of the '981 patent. Ex. 1049, 29:18-31:9; *see* Ex. 1048, 105:14-20. Considering we have no evidence of the manufacturing process for any of the products in the AQUACEL® Ag product line, we have no means to assess whether any of the products are covered by the claims of the '981 patent.

We have considered ConvaTec's evidence of commercial success, but find it of insufficient weight and relevance to deem it persuasive as to the merits of the claimed invention, particularly when we consider it within the totality of the evidence before us.

(2) Industrial Acclaim

ConvaTec presents evidence that the company has received praise for "the development of innovative technologies that produce a major improvement in business performance and/or patient benefit." PO Resp. 49 (citing Ex. 2013). For example, ConvaTec presents evidence that "many studies and publications have praised the Aquacel Ag line and demonstrated its effectiveness in antimicrobial wound care," namely due to "the reduction of pain, dressing changes, and decreased length of hospital stays." PO Resp. 49; *see generally id.* at 50-53 (citing Ex. 2030 ¶¶ 12-21 and supporting documentation). ConvaTec also presents evidence of "the dramatic recovery of patients treated with AQUACEL® Ag." *Id.* at 54 (citing Ex. 2025).

As with commercial success, evidence of industrial acclaim is only relevant to a determination of nonobviousness when it is directed to the merits of the invention claimed. Secondary considerations may presumptively be attributed to the claimed invention only where the product being claimed '"embodies the claimed features, and is coextensive with them."' *Ormco Corp,* 463 F.3d at 131 (quoting *Brown & Williamson Tobacco Corp. v. Phillip Morris, Inc.,* 229 F.3d 1120, 1130 (Fed. Cir. 2000)).

Although ConvaTec cites comments lauding ConvaTec as an innovator, as well as the effectiveness of the AQUACEL® Ag product line, ConvaTec has not explained how such praise is directed to any particular feature of the method recited in the claims. For example, ConvaTec has not shown that the evidence of praise is directed to a particular step recited in the claims or to the photostability of the product. We have thus considered ConvaTec's evidence of industrial acclaim, but find it of insufficient weight and relevance to deem it persuasive as to the merits of the claimed invention, particularly when we consider it within the totality of the evidence before us.

(3) Long-felt but unmet need

The relevance of long-felt need and the failure of others to the issue of obviousness depend on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *Orthopedic Equipment Co. v. All Orthopedic Appliances, Inc.,* 707 F.2d 1376 (Fed. Cir. 1983); *see In re Gershon*, 372 F.2d 535, 539 (CCPA 1967). Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies v. Kenney Mfg. Co.,* 864 F.2d 757, 768 (Fed. Cir. 1988) ("[O]nce another supplied the key element, there

was no long-felt need or, indeed, a problem to be solved"). Third, the invention must in fact satisfy the long felt need. *In re Cavanagh*, 436 F.2d 491, 496 (CCPA 1971) ("[I]t was still incumbent upon appellant, if he wished by this method to rebut the inference of obviousness arising from the similarity of his process to the prior art, to bring forward evidence of his satisfaction of the need.").

ConvaTec presents evidence of the need for "a less painful and traumatic treatment of burn wounds" and that the AQUACEL® Ag product line has "reduced number of required dressing changes, decreased pain, and earlier patient discharge as compared with the traditional SSD [silver sulfadiazine] treatment." PO Resp. 55 (citing Ex. 2026, Ex. 2017, Ex. 2016). ConvaTec then argues that its evidence of "clinical and research results," "commercial success," and dominant market share are additional evidence of "a long-felt need in the field for an efficacious and cost-effective silverized wound dressing which reduced patient discomfort and decreased hospital stays." *Id.* at 55-56.

ConvaTec's evidence of a long-felt but unmet need is not persuasive. While ConvaTec describes advantages of the AQUACEL® Ag product line over a traditional "silver sulfadiazine (SSD) ointment," ConvaTec has not demonstrated that advantages of the claimed invention are not met by silverized hydrogels of the prior art, such as that taught by Gibbins '751. Moreover, ConvaTec has not shown that the evidence of long-felt and unmet need is solved by the particular steps recited in the claims, or to the photostability of the product, to the extent they are distinguishable from the prior art of record.

We have considered ConvaTec's evidence of long-felt but unmet need, and find it of insufficient weight and relevance to deem it persuasive as to the merits of the claimed invention, particularly when we consider it within the totality of the evidence before us.

(4) Copying

Although, "copying by a competitor may be a relevant consideration in the secondary factor analysis[,]" "[n]ot every competing product that arguably falls within the scope of a patent is evidence of copying." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). Copying, as objective evidence of nonobviousness, requires evidence of effort to replicate a specific product. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Iron Grip*, 392 F.3d at 1325.

ConvaTec argues that "[d]irect evidence of copying by Petitioner Smith & Nephew also exists . . . ." PO Resp. 56. ConvaTec provides evidence of an FDA statement that Smith & Nephew's Durafiber Ag is "substantially equivalent" to ConvaTec's Aquacel Ag product and has "*similar design, materials, and manufacturing methods*." *Id*. (citing Ex. 2001). ConvaTec also produces evidence that "Smith & Nephew admitted [in a submission against the European equivalent of the patent at issue in the instant proceeding] that it has no other non-infringement argument in relation to the process it uses to produce its silverised Durafiber wound dressing" other than arguments based on amended claim language not present in this proceeding. *Id.* at 57 (citing Ex. 2002).

ConvaTec's evidence of copying is not persuasive. A statement of "similar manufacturing methods" is not sufficient to demonstrate that Smith & Nephew's Durafiber product is identical to AQUACEL® Ag, is made

using the particular steps of the claimed invention, or even that it has the recited photostability. Moreover, even if Smith & Nephew's Durafiber Ag is made using the exact same process as any of ConvaTec's AQUACEL® Ag products, ConvaTec has not shown that the AQUACEL® Ag product line is manufactured according to the steps of the claims of the '981 patent, or has the claimed photostability. Further, ConvaTec has not produced any evidence of the actual manufacturing process for Smith & Nephew's Durafiber Ag product, and we are not persuaded that a decision not to pursue an alternative litigation strategy in its submission against the European equivalent of the patent at issue in the instant proceeding is sufficient evidence of a process that includes the steps and recited photostability of the claims of the '981 patent.

We have considered ConvaTec's evidence of copying but find it of insufficient weight and relevance to deem it persuasive as to the merits of the claimed invention, particularly when we consider it within the totality of the evidence before us.

Determination with respect to obviousness

After weighing all the evidence of obviousness and nonobviousness of record, on balance, we conclude that the strong evidence of obviousness outweighs the weak evidence of nonobviousness. For the foregoing reasons, we determine that Smith & Nephew has demonstrated by a preponderance of the evidence that claims 1-8 and 10-20 are unpatentable over the prior art of record.

C. Motion to Amend

ConvaTec filed a Motion to Amend. Paper 28. For the reasons set forth below, ConvaTec's Motion to Amend is *denied*.

As the moving party, ConvaTec bears the burden of proof to establish that it is entitled to the relief requested. 37 C.F.R. § 42.20(c). Entry of the proposed amendment, therefore, is not automatic, but only upon ConvaTec's having demonstrated the patentability of the proposed substitute claims.

ConvaTec requests cancellation of claims 1 and 17, to be replaced with proposed substitute claims 21 and 22, reproduced below, with underlined text indicating material inserted relative to original claims 1 and 17, and bracketed text indicating material deleted relative to original claims 1 and 17:

> 21. A method of preparing a light stabilized antimicrobial material comprising the steps of
>
> a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in a light stabilized antimicrobial material;
>
> b) subjecting a polymer to the solution for a time sufficient to incorporate the desired silver concentration into the polymer, wherein the polymer is <u>a gel forming fiber</u> selected from the group consisting of a polysaccharide, a modified polysaccharide, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyvinyl ether, a polyurethane, a polyacrylate, a polyacrylamide, a collagen, a gelatin, and a mixture thereof; and
>
> c) subjecting the polymer, during or after step (b), to one or more agents which facilitate the binding of the silver on the polymer; wherein the silver is [substantially] photostable in the light stabilized antimicrobial material when dry, but will dissociate from the light stabilized antimicrobial material upon hydration of the light stabilized antimicrobial material.

> 22. A method of preparing a light stabilized antimicrobial material comprising the steps of
>
> a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in the light stabilized antimicrobial material;
>
> b) subjecting a polymer comprising a gel-forming fiber to the solution for a time sufficient to [incorporate] load the desired silver concentration into the polymer; and
>
> c) subjecting the polymer, after step (b), to one or more agents which facilitate the binding of the silver on the polymer; wherein the silver is substantially photostable in the light stabilized antimicrobial material when dry, but will dissociate from the light stabilized antimicrobial material upon hydration of the light stabilized antimicrobial material.

Paper 28 at 2-4 (emphasis removed, alterations added).

1. Written Description Support

Pursuant to 37 C.F.R. § 42.121(b)(1), a motion to amend in an *inter partes* review must set forth "[t]he support in the original disclosure of the patent for each claim that is added or amended."

In our Order dated July 3, 2013, we pointed ConvaTec's attention to . *Nichia Corp. v. Emcore Corp.*, IPR2012-00005, slip op. at 4 (PTAB June 13, 2013) (Paper 27), for a discussion of the burden for identifying written descriptive support for the proposed substitute claims. Paper 17 at 4.

As set forth in *Nichia*, "37 C.F.R. § 42.121(b)(1) requires the patent owner to set forth the support in the *original disclosure* of the patent for each proposed substitute claim." *Id.* at 3. Specifically,

> [T]he Board noted that the written description test is whether the original disclosure of the application relied upon reasonably conveys to a person of ordinary skill[ ] in the art that the inventor had possession of the claimed subject matter as of the

> filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Therefore, the written description support must be shown in the *original disclosure of the application* . . . that issued as the . . . patent, unless [patent owner] indicates, in its motion, that there was no change to the original disclosure when the patent issued.

Id.

ConvaTec, in its Motion to Amend, points to issued claims 1 and 17, as well as sections of the issued '981 patent, as support for proposed substitute claims 21 and 22. Mot. Amend 5-6. As noted above, however, that is not sufficient, as ConvaTec did not state where support could be found in the disclosure as originally filed for the substitute claims, nor did ConvaTec state in its Motion that the specification of the issued patent was identical to the specification originally filed in Application Number 09/997,545 (the '545 application"). ConvaTec's Motion to Amend, therefore, fails on that point alone.

Moreover, proposed substitute claim 21 adds the limitation that the "polymer is a gel forming fiber," wherein the fiber may be "a polysaccharide, a modified polysaccharide, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyvinyl ether, a polyurethane, a polyacrylate, a polyacrylamide, a collagen, a gelatin, and a mixture thereof." ConvaTec points to column 3, line 41, through column 4, line 7, of the '981 patent for support. Mot. Amend 5. As proposed substitute claim 21 lists both a "polysaccharide" and a "modified polysaccharide," the term "polysaccharide" must necessarily be limited to an unmodified polysaccharide, such as cellulose.

The section of the ’981 patent relied upon by ConvaTec states that preferred gel-forming fibers include Aquacel™, orthose, Versiva™, DuoDerm™, or a blend of two or more fibers such as Carboflex™. Ex. 1001, 3:46-56. The ’981 patent discloses further:

> Polymers suitable for the present invention include, but are not limited to, polysaccharides or modified polysaccharides, polyvinylpyrrolidone, polyvinyl alcohols, polyvinyl ethers, polyurethanes, polyacrylates, polyacrylamides, collagen, gelatin, or mixtures thereof. In preferred embodiments, the polymers contain carboxymethylcellulose (CMC) such as sodium CMC. In one embodiment, the polymer can be a polysaccharide comprising a carboxymethylcellulose or alginate, or a mixture of carboxymethylcellulose and alginate. In other embodiments, the polymers contain gel-forming fibers comprising sodium CMC, and which can be incorporated into wound dressings such as Aquacel™ (ConvaTec, Skillman, N.J.).

Id. at 3:62-4:7.

ConvaTec does not explain, however, how that section of the patent supports a gel forming fiber of an unmodified polysaccharide, such as cellulose; nor does ConvaTec explain how that section provides support of a gel forming fiber of several other of the listed polymers in proposed substitute claim 21, which were not identified in the ’981 patent as being “gel-forming fibers,” namely polyvinylpyrrolidones, polyvinyl alcohols, polyvinyl ethers, polyurethanes, or polyacrylates. In fact, cellulose is an unmodified polysaccharide, and the cotton gauze of Kreidl is primarily made up of cellulose. ConvaTec’s expert, Dr. Edgar, testified that Kreidl does not teach anything about using gel forming fibers as substrates. Ex. 2029 ¶ 30.

As we conclude that ConvaTec has not established that the disclosure of the issued '981 patent provides written descriptive support for proposed substitute claim 21, we do not address it further.

2. Claim Interpretation

Proposed substitute claim 22 replaces the term "load" for the term "incorporate." ConvaTec cites the '981 patent as defining the "term 'load' or 'loading' . . . to mean 'ionic exchange of the cation to the polymer with silver ions." Mot. Amend 6 (*citing* Ex. 1001, 5:46-48).

3. Patentability over Prior Art

ConvaTec notes that proposed substitute claim 22 requires that the polymer is a gel forming fiber, and also requires that the silver be loaded into the polymer. Mot. Amend 12. ConvaTec contends that the references cited by Smith & Nephew in its Petition "fail to disclose or suggest an ion exchange reaction between cations in the polymer and silver ions as required by proposed substitute claim 22." Instead, the references teach the formation of insoluble silver chloride precipitate on or at the surface of the material. *Id.* at 13. It is insufficient, however, for ConvaTec simply to explain why the proposed substitute claims are patentable in consideration of the grounds of unpatentability on which the Board instituted review. Mot. Amend 12-15. ConvaTec's Motion does not discuss other prior art known to ConvaTec, the level of ordinary skill in the art, and also does not explain the basic knowledge and skill set already possessed by one of ordinary skill in the art, with respect to the new claim features. We agree with the reasoning in *Idle Free Sys., Inc. v. Bergstrom, Inc.*, IPR2012-00027, slip op. at 33 (PTAB January 7, 2014 (Paper 66)) that limiting the discussion to the

references relied upon in the instituted grounds of unpatentability does not provide a meaningful analysis.

Specifically, for proposed substitute claim 22, ConvaTec focuses on the added feature of requiring loading of the silver ion onto the polymer via ionic exchange. ConvaTec does not discuss, however, what was known by the ordinary artisan about loading cations, such as silver cations, on a gel by ionic exchange. Importantly, ConvaTec does not explain what would have been known to the ordinary artisan as to the effect, if any, on the photostability of silver cations, as a result of loading the silver cation on a polymer by ionic exchange. Without having discussed sufficiently prior art references that may have been known to ConvaTec, the level of ordinary skill in the art, and what was known previously regarding the new claim features, ConvaTec fails to demonstrate the patentability of proposed substitute claim 22. Thus, the Motion fails as to proposed substitute claim 22 for that reason as well. Moreover, as discussed above in the analysis of the patentability challenges of the original claims, Patent Owner's argument as to proposed substitute claim 22 also fails on the basis that Gibbins '751 teaches a substantially identical process, and thus would inherently produce a light stabilized antimicrobial material as required by proposed substitute claims 22.

Finally, ConvaTec contends that its "strong evidence of secondary considerations" is sufficient to rebut any conclusion of obviousness, and specifically refers to the success of its AQUACEL® Ag product line. Mot. Amend 15-16. ConvaTec's evidence of secondary considerations has been discussed above, and has been found not to be convincing as to the patentability of the original claims. And similarly, as in that discussion,

ConvaTec has not demonstrated how the evidence of commercial success, industry acclaim, long-felt but unsolved need, and copying, is due to the features provided by the method of the proposed substitute claims.

D. Motion to Exclude Evidence

1. Smith & Nephew's Motion to Exclude Evidence

A party wishing to challenge the admissibility of evidence must identify the grounds of the objection and explain why the evidence is not admissible. 37 C.F.R. § 42.64(c). Here, Smith & Nephew seeks to exclude testimony of Ms. Fiona Adams (Ex. 2030 (Ex. 2045 (redacted version))) and Ex. 2012 related to the commercial success of ConvaTec's Aquacel Ag line of products without identifying any rule of evidence or other authority to support its position that the testimonial evidence in question is inadmissible. Paper 55, 2. Rather, Smith & Nephew's rationale for excluding Ms. Adams' testimony is that ConvaTec has never established that any of the Aquacel Ag products are covered by the claims of the '981 patent. Contending that the evidence is inadequate for a determination of nexus, however, is not sufficient to establish the impropriety of the evidence, much less the inadmissibility of the evidence under the Federal Rules of Evidence. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,758 (August 14, 2012) (A motion to exclude may not be used to challenge the sufficiency of the evidence to prove a particular fact.).

Accordingly, Smith & Nephew's Motion to Exclude is *denied*.

2. ConvaTec's Motion to Exclude Evidence

ConvaTec seeks to exclude the following: (1) testimony of Dr. Stephen Coulter (Ex. 1045); (2) Ex. 1037; and (3) Ex. 1038. Paper 60 ("PO

Mot. Exclude"). As the movant, ConvaTec has the burden of proof to establish that it is entitled to the requested relief. 37 C.F.R. § 42.20(c).

ConvaTec argues that the declaration testimony of Dr. Stephen Coulter should be excluded because he is not qualified to testify as an expert with respect to the claimed subject matter of the '981 patent, specifically with regards to the photostability of a wound dressing. *Id.* at 2-4. ConvaTec points to paragraph 30 of the Coulter Declaration (Ex. 1045) as being the inadmissible portion of Dr. Coulter's testimony. ConvaTec further argues that Dr. Coulter's testimony reveals that he does not understand what a person of ordinary skill in the art would consider to be a "desired color" for a silverized wound dressing. *Id.*

We are not persuaded by ConvaTec's arguments. Initially, ConvaTec's objections to Dr. Coulter's testimony go to the weight and sufficiency of his testimonial evidence, rather than its admissibility. *See Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1221 (Fed. Cir. 2006) (*citing Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1344-45 (11th Cir. 2003)); *In re TMI Litig.*, 193 F.3d 613, 692 (3d Cir. 1999) ("So long as the expert's testimony rests upon 'good grounds,' it should be tested by the adversary process—competing expert testimony and active cross-examination . . . ." (quoting *Ruiz–Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir.1998))); *Wilmington v. J.I. Case Co.*, 793 F.2d 909, 920 (8th Cir.1986) ("Virtually all the inadequacies in the expert's testimony urged here by [the defendant] were brought out forcefully at trial . . . . These matters go to the weight of the expert's testimony rather than to its admissibility."). It is within our discretion to assign the appropriate weight to be accorded to Dr. Coulter's

testimonial evidence. Moreover, we have reviewed Dr. Coulter's testimony, and note that the testimony in question is not relied upon in our claim construction of the term "photostable" or in our determination of what would be considered a "desired color" for a silverized wound dressing to a person of ordinary skill in the art. Thus, the objection to paragraph 30 of Dr. Coulter's testimony is moot.

Smith & Nephew relies on Exhibits 1037 and 1038, in its opposition to ConvaTec's Motion to Amend, as evidence to support its conclusion that Example 25(m) of Gibbins '751 discloses the same order of addition of silver source (silver nitrate) and agent (sodium chloride) as claimed in the '981 patent. Paper 44, 9. ConvaTec argues that the Petitioner's Exs. 1037 and 1038 should be excluded because they are inadmissible hearsay, are not properly authenticated, or are otherwise improper under Federal Rule of Evidence 901. Paper 60, 4-6.

We find it unnecessary to consider the objections to the admissibility of Exhibits 1037 and 1038. Exhibits 1037 and 1038 were not relied upon in our determination as to the meaning of Example 25(m) of Gibbins '751. Even excluding Smith & Nephew's evidence, we have determined that Smith & Nephew has demonstrated, by a preponderance of the evidence, that the challenged claims of the '981 patent are unpatentable.

Accordingly, ConvaTec's motion to exclude is *dismissed* as moot.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1-8 and 10-20 of the '981 patent are unpatentable;

FURTHER ORDERED that ConvaTec's Motion to Amend is *denied*,

FURTHER ORDERED that Smith & Nephew's Motion to Exclude is *denied*;

FURTHER ORDERED that ConvaTec's Motion to Exclude is *dismissed as moot*; and

FURTHER ORDERED that because this is a final decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

SNEDDEN, *Administrative Patent Judge, concurring-in-part.*

I concur in the majority's conclusion that claims 1-8 and 10-20 are anticipated or obvious, but I dissent from the majority in their interpretation of the term "photostable." The '981 patent defines "photostable" as "controlled colour change to a desired color with a minimal change thereafter." Ex. 1001, 5: 47-49. Under the majority's claim construction, the "desired colour" referenced within the meaning of "photostable" includes any color, including purple, desirable for any purpose, including aesthetic purposes. It is clear from the evidence on this record, however, that the interpretation of "desired colour" should be interpreted from a more technical viewpoint—that is, color is a measure of photostability.

In this regard, the evidence on this record supports a finding that purple is not a "desired colour." Gibbins '751, for example, explains that products containing silver undergo light-mediated discoloration, which leads to discoloration of skin touching the product. Ex. 1007, 4:28-31. Gibbins '751 suggests that purple, in particular, is an undesirable color in the field of medical devices containing silver. In Example 24 of Gibbins '751, various samples of silver impregnated materials are made and subjected to a light-stability test. *Id.* at 31-33. The results are:

Dressing	Dry	Wet
Ag Aquacel	White, good, eventually purplish	Brown
Hi Ag-Aquacel	Purple, specks	Dark gray
Aquacel C	White	Clear

Id. at 33:36-42. The references to "eventually purplish" and "purple, specks" indicate that purple is the color of silver after exposure to light.

Such discoloration is undesirable for silverized medical devices meant for coming into contact with skin.

ConvaTec also presents evidence that purple is not a "desired colour" within the meaning of "photostable." Ex. 2028 ¶ 16; Ex. 1046, 61:5-16. Dr. Phillips, for example, testified that a silverized wound dressing that was purple out of its package, or turned purple shortly after exposure to light, would be considered expired or not in optimal condition for clinical use.[16] Ex. 2028 ¶ 16. Dr. Phillips testified that the "desired colour" of a silverized wound dressing is white to a "grayish white." *See*, *e.g.*, Ex. 2028 ¶ 21; *see*, Ex. 1046, 64:24–65:6, 86:13–87:3. Smith & Nephew presents no evidence as to what color(s) would be desirable or undesirable to a person of ordinary skill in the art. Thus, the weight of the evidence on the present record suggests that, to a person of ordinary skill in the art, the "desired colour" of a silverized wound dressing for purposes of photostability is white to a grayish white, and that purple, specifically, is not a desirable color.

Further, I disagree with the majority's determination that "minimal change," as referenced within the meaning of "photostable," may refer to a

[16] Although the majority finds Dr. Phillips' testimony to be controverted by the disclosure in Gibbins '751 that a purplish color did not render the product ineffective for inhibiting the growth of *Staph. aureus*, there is insufficient evidence on this record suggesting that the clinical effectiveness of a product with regard to its antimicrobial properties is a surrogate for photostability. Rather, Gibbins '751 suggests that the problem with silverized products related to photostability is discoloration because discoloration in the product causes discoloration of skin touching the product. Ex. 1007, 4:28-31. Thus, a purple dressing is "unsuitable for clinical use" because of its discoloration, not solely because the antimicrobial effectiveness of the products may be reduced to some unknown but less than optimal degree.

change of color from a desirable color to an undesirable color. ConvaTec provides testimonial evidence that a color change from the "desired colour" (*e.g.*, white) to purple would not be understood to be a "minimal change" to a person of ordinary skill in the art. Pet. 13, 43; Ex. 2028 ¶ 16-21 (Dr. Phillips concluding that "a color change from 'white' to 'purplish' is in my opinion a discoloration, and does not equate with a 'substantially photostable' product . . . that has minimal color change from the 'desired color' or white."); Ex. 2029 ¶ 50 (Dr. Edgar stating "I fully agree with Dr. Phillips' statements from a scientific point of view that a change in color of the product from 'white' to 'purple' would not be considered 'substantially photostable' or 'photostable.'"); *see* Ex. 1050, 19-20. Smith & Nephew presents no evidence as to what would be considered a "minimal change" to a person of ordinary skill in the art. Thus, the weight of the evidence suggests that a change of color from a desirable color to an undesirable color would not be considered a "minimal change."

The claims, however, simply do not require silver to be photostable, but require the silver to be "substantially photostable." Here, I agree with the majority that "substantially," in the context of the '981 patent, means "largely" or "essentially." Under the broadest reasonable interpretation of "substantially photostable," silver may undergo some minimal discoloration to an undesirable color and still be considered "substantially [i.e., essentially] photostable."

Using the above claim construction, I disagree with the majority's reliance on Example 25 of Gibbins '751, but agree with the outcome because Example 24 of Gibbins '751 discloses the results of an experiment producing a product that is substantially photostable. Specifically, Example

24 describes an experiment in which the prepared product produced purple specks when subjected to a light-stability test. Ex. 1007, 33:37-43. A person of ordinary skill in the art would understand a "speck" to represent a color change within the meaning of the terms "substantially photostable." This disclosure in Example 24, combined with other teachings in Gibbins '751 suggesting that the order of steps used in Example 24 may be reversed (*id.* at 18: 30-32), reaches the "substantially photostable" element of the claims.

The results of Example 25 of Gibbins '751, however, describe an experiment in which the prepared products eventually turned "purplish." *Id.* at 34:46-54. There is insufficient evidence presented on this record to support a finding that a disclosure of a product "eventually turning a purplish color" would be considered a minimal color change. *See id.*

With regard to the Motion to Amend, although substitute claim 21 deletes the term "substantially," potentially addressing the problem of finding a product producing only purple specks to be within the scope the claim, I agree with the majority opinion that ConvaTec's Motion to Amend remains deficient. With regard to substitute claim 22, the term "substantially" is not deleted, and thus, the substitute claim fails to cure the deficiency discussed in this concurring opinion. Accordingly, I join the majority with regard to the denial of the Motion to Amend.

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