

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ANNETTE BIANCHI,
JULIAN NIKOLCHEV, DAVID HUNG,
EYAL RON, LINDA K. GONT,
SUSAN LOVE, and TINA PATEL

Appeal No. 2006-2546
Application No. 10/425,177

ON BRIEF

Before GRIMES, LINCK, and LEBOVITZ, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a composition that undergoes a gel transition.

The examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 134. We reverse.

Background

The specification relates to gel compositions that can be used “for delivery to a breast milk duct for mapping a duct or ducts before surgical excision of any part of the breast or ductal system.” Page 1, lines 10-12. Specifically, the specification describes “a biocompatible composition comprising a polymer that has a solubility greater than

0.5 grams per 100 ml of solvent, a molecular weight in a range of between about 1 and 500 kilodaltons and a weight/weight ratio of polymer to solvent in a range between about 0.5:100 to 100:0.5.” Page 2, lines 21-24. “[T]he composition is liquid in a solvent and undergoes a gel transition inside a target breast milk duct within about 30 minutes of delivery of the composition to the target duct.” Page 2, lines 24-26.

The specification states that the polymer can comprise, for example, polyvinyl alcohol, polyvinyl pyrrolidone, polyalkylene glycols, or polyethylene oxide. Page 6, line 32, to page 7, line 5. In the Examples, the specification describes using PLURONIC® F-127. Page 28, line 21.

The gel can “comprise an additive to provide detection of the gel inside the target duct. . . . The additive can be a dye.” Page 3, lines 17-20. “The additive can provide visual detection of the gel by the naked eye, or can be an additive that is capable of detection by a special sensor or machine or other mechanism that is sensitive to the presence of such an additive and which can detect material that has the additive and distinguish such material from other material not containing the particular additive.”

Page 14, lines 15-19.

Discussion

1. Claim construction

Claims 10-13 and 16-22 are pending and on appeal. We will focus on claim 10, the broadest claim on appeal, which reads as follows:

10. A biocompatible composition comprising a polymer that has a solubility greater than 0.5 grams per 100 ml of solvent, a molecular weight in a range of between about 1 and 500 kilodaltons and a weight/weight ratio of polymer to solvent in a range of between about 0.5:100 to 100:0.5, wherein the composition is a liquid in a

solvent and undergoes a gel transition inside a target breast milk duct within about 30 minutes of delivery of the composition to the target duct, and further comprises an additive to provide detection of the gel inside the target breast milk duct.

Thus, claim 10 is directed to a biocompatible composition that contains a polymer with a solubility, molecular weight, and weight ratio of polymer to solvent within specified ranges. In addition, claim 10 recites that the composition is a liquid in a solvent and undergoes a gel transition inside a target breast milk duct within about 30 minutes of its delivery to the duct.

Claim 10 also recites that the composition contains “an additive to provide detection of the gel inside the target breast milk duct.” “[The additive can provide visual detection of the gel by the naked eye, or can be an additive that is capable of detection by a special sensor or machine or other mechanism.” Specification, page 14, lines 15-19. Thus, we interpret the claim to require an additive that is capable of providing detection of the gel inside a breast milk duct; e.g., by visual detection or by using a special sensor, machine, or other mechanism.

2. Krezanoski

The examiner rejected claims 10 and 16-21 under 35 U.S.C. § 102(b) as anticipated by Krezanoski.¹ The examiner argued that:

Krezanoski discloses a liquid composition comprising polyoxyethylene-polypropylene block copolymer wherein the composition has a sol-gel transition temperature in the range from about 25 °C to about 40 °C; the polymer has a molecular weight of 7,500 Daltons to about 15,500 Daltons and the solubility is greater than about 10 gram[s] per 100 ml water (abstract, column 2, line 64 to column 3 and line 19, column 5, lines 28-33 and Examples I-VIII).

¹ Krezanoski, U.S. Patent No. 4,188,373, issued February 12, 1980.

Examiner's Answer, pages 3-4. At column 3, lines 1-19, Krezanoski describes a composition comprising "from about 10% to about 26%" by weight polyoxyethylene-polyoxypropylene block copolymer and "from about 74% to about 90%" by weight water.

In addition, the examiner argued that "[t]he pharmaceutical composition of Krezanoski contains pharmaceutically active drug or medicament material (column 3, lines 37-47) [and] further contains various additives such as auxiliary non-ionic surfactants, salts to adjust osmotic pressure, buffer systems to control pH, and preservatives (column 3, lines 20-31)." Examiner's Answer, page 4. The examiner reasoned that "[t]he additive of Krezanoski meets the broad limitation of the claimed additive." Id. Specifically, the examiner argued that "the recitation of 'to provide a detection of the gel inside the target breast milk duct' is an intended use of the additive and future intended use of a component in a composition is not given patentable weight." Examiner's Answer, page 3.

Appellants argue that the additive of claim 10 "is not merely 'an additive' but is an additive that has the capacity to 'provide detection of the gel inside the target breast milk duct.'" Appeal Brief, page 4. "Nowhere in Krezanoski is there any mention of an additive to aid in the detection of a breast duct." Appeal Brief, page 5.

We agree with Appellants that the examiner has failed to set forth a prima facie case that Krezanoski describes a composition comprising "an additive to provide detection of the gel inside the target breast milk duct." In particular, we do not agree with the examiner that the phrase "to provide detection of the gel inside the target breast milk duct" is merely an intended use of the additive. Instead, we conclude that this

phrase limits the additive to an additive that is capable of providing detection of the gel inside a breast milk duct.

The examiner has not adequately explained how any of the additives described in Krezanoski would be capable of providing detection of the gel inside a breast milk duct. Thus, we agree with Appellants that the examiner has not set forth a prima facie case that Krezanoski anticipates claim 10. We therefore reverse the rejection of claims 10 and 16-21 under 35 U.S.C. § 102(b) over Krezanoski.

3. Snow

The examiner rejected claims 10-13, 17-19, 21, and 22 under 35 U.S.C. § 102(e) as anticipated by Snow.² The examiner argued that “Snow discloses [a] pharmaceutical composition comprising [a] physiologically tolerable contrast agent that contains at least two chromophores and at least one polyalkylene oxide moiety (column 9, lines 1-12).” Examiner’s Answer, page 4. “[I]n one embodiment the chromophoric group is attached to a surfactant molecule (column 9, lines 13-15). The surfactant is disclosed to be polyalkyleneoxide block copolymer that may be branched (column 9, lines 52-57); PLURONIC and TETRONIC block copolymers are used with the chromophores (column 10, lines 35-44).” Id. The examiner argued that “[t]he chromophores of Snow . . . would provide detection of the gel inside the target breast milk duct.” Id., page 6. In addition, the examiner argued that Snow, at column 54, lines 11-21, contemplates administering the composition as an aqueous solution or suspension. Id., page 8.

² Snow et al., U.S. Patent No. 6,350,431, issued February 26, 2002, from an application filed October 28, 1999.

The examiner argued that polyalkylene oxide meets the limitations recited for the polymer of claim 10. Examiner's Answer, page 9. The examiner also noted that Snow states that the compounds can include polymers such as "polyvinylpyrrolidone, . . . polyvinyl alcohol (column 44, lines 51-67), . . . hyaluronic acid, dextran, polydextrose . . . (column 46, lines 23, 25, 50), [and] polyethylene glycols (PEG); and these are some of the polymers recited in claims 16 and 17." Examiner's Answer, paragraph bridging pages 5 and 6. The examiner reasoned that:

Since the polymer of Snow and the claims are the same, these same polymers would have the function or properties of solubility and molecular weight ascribed in claim 10 and the composition containing these same polymers and chromophores would have the mutually exclusive [sic, recited?] properties capable of undergoing the same gel transition inside a target breast milk duct within the 30 minutes of administration/delivery.

Id.

Appellants argue that "[t]here is no teaching or suggestion in Snow *et al.* of a polymer that is a liquid in a solvent and is able to undergo a gel transition." Appeal Brief, page 6. In particular, Appellants argue that "[o]ne skilled in the art would recognize that the concentration and weight of a polymer are important parameters in determining the ability of a polymer to undergo a solid-liquid transition. The mere mention of a polymer such as polyalkylene oxide is insufficient to determine whether or not the polymer has the ability to undergo a gel transition." Appeal Brief, page 7.

We agree with Appellants that the examiner has failed to set forth a prima facie case that Snow describes a composition that "undergoes a gel transition inside a target breast milk duct within about 30 minutes of delivery of the composition to the target duct."

Snow describes “a physiologically tolerable water-soluble light imaging contrast agent compound having a molecular weight in the range 500 to 500000 and containing at least two chromophores having delocalized electron systems as well as at least one polyalkylene oxide moiety having a molecular weight in the range of 60 to 100000.”

Col. 2, lines 2-7. In addition, Snow describes a physiologically tolerable contrast agent comprising at least one chromophoric group attached to a surfactant molecule; e.g., a surfactant molecule comprising Pluronic® block copolymers. Col. 9, line 13, to col. 10, line 11. Snow also states that the contrast agent compounds can include linking groups such as polyvinylpyrrolidones, polyvinyl alcohols, and polyethylene glycols. Col. 44, lines 57-65; col. 46, lines 8-45. Furthermore, Snow describes solutions, such as aqueous solutions, containing these compounds. Col. 54, lines 1-19.

The examiner has not pointed to any disclosure indicating that compositions described in Snow would undergo the gel transition recited in the claims. Instead, the examiner argued that this property is inherent in the compositions described in Snow. “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”

In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting Hansgirg v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939), emphasis in original).

To support the inherency position, the examiner relied on the fact that Appellants are claiming compositions containing categories of polymers, such as polyvinyl alcohols, polyvinylpyrrolidones, and polyethylene glycols, that are also described in Snow. However, the fact that the claimed compositions contain certain types of polymers does not provide a reasonable basis to conclude that all compositions

containing those types of polymers will undergo the gel transition recited in the claims.

For example, the fact that Appellants are claiming compositions containing polyethylene oxide does not provide a reasonable basis to conclude that all compositions containing polyethylene oxide undergo the gel transition recited in the claims.

In particular, the examiner has not provided a reasonable basis on which to conclude that any composition containing polyalkylene oxide described in Snow will necessarily undergo the gel transition recited in the claims. Even if the broad disclosure of Snow may encompass compositions that undergo a gel transition as recited in the claims, such a generic disclosure is not sufficient for Snow to anticipate claim 10.

Cf. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (“A prior art reference that discloses a genus still does not inherently disclose all species within that broad category.”). Thus, the examiner has not provided a reasonable basis to conclude that a composition undergoing the claimed gel transition is necessarily present in the teachings of Snow.

The examiner has not set forth a reasonable basis to conclude that Snow inherently discloses a composition that “undergoes a gel transition inside a target breast milk duct within about 30 minutes of delivery of the composition to the target duct.” Thus, we agree with Appellants that the examiner has not set forth a prima facie case that Snow anticipates claim 10. We therefore reverse the rejection of claims 10-13, 17-19, 21, and 22 under 35 U.S.C. § 102(e) over Snow.

Other Issues

For the reasons discussed above, we conclude that Krezanoski would not have suggested the claimed composition to those of skill in the art. On return of this case,

however, the examiner should consider whether the prior art as a whole would have suggested a composition meeting the limitations of the instant claims. For example, Hoeg³ teaches compositions that, like those of Krezanoski, gel rapidly under physiological conditions. See, e.g., Hoeg at column 9, line 59 to column 10, line 8. Unlike Krezanoski, Hoeg expressly suggests including detectable agents in the disclosed compositions. See, e.g., column 15, lines 17-22. See also Example X (column 19), in which a fluorescein-containing composition was administered to rabbit eyes and “monitored using a slit lamp technique”: “an incremental increase in fluorescence” was detected.

On return of this case, the examiner should consider whether Hoeg or other prior art would have suggested to those of ordinary skill in the art the composition defined by any of the instant claims.

³ Hoeg et al., U.S. Patent 5,441,732, issued August 15, 1995.

Summary

The examiner has not shown that the claimed composition is anticipated by either of the applied references. We therefore reverse the rejections of claims 10-13 and 16-22.

REVERSED

Eric Grimes)
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