

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

Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARY E. EWASYSHYN, BARRY I. CAPLAN,
ANNE-MARIE BONNEAU and MICHEL H. KLEIN

Appeal No. 1999-1162
Application No. 08/427,837

ON BRIEF

Before WILLIAM F. SMITH, ROBINSON and MILLS, Administrative Patent Judges.
MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 9, 19 and 20, which are all of the claims pending in this application.

We affirm-in-part.

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Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejections, we make reference to the Examiner's Answer (Paper No. 14, September 12, 1997) for the examiner's complete reasoning in support of the rejection, and to the appellants' Brief (Paper No. 13, July 10, 1997) for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Claim Interpretation

Our appellate reviewing court stated in Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert denied, 481 U.S. 1052 (1987):

Analysis begins with a key legal question -- what is the invention claimed? Courts are required to view the claimed invention as a whole. 35 U.S.C. § 103. Claim interpretation, in light of the specification, claim language, other claims and prosecution history, is a matter of law and will normally control the remainder of the decisional process. [Footnote omitted.]

To that end, we also note that during ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

The term "highly immunogenic" found in claim 9 is not defined, per se, in the specification. The examples in the specification do not provide a quantitative value

relative to “immunogenicity” of the claimed composition. Thus, in the present case we interpret the term “highly immunogenic” as used in claim 9, consistent with providing a protective antibody response (Example, VII, page 9) or production of neutralizing antibodies (Example V, pages 7-8). We also find that the claimed composition encompasses a composition wherein the immunogenicity is sufficient to provide an effective vaccine (specification, page 1).

We interpret the terms “copurified” and “prepared by copurification” in claim 9, as directed to a method of preparation of the claimed composition and not limiting of the characteristics of the composition. The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969).

Grounds of Rejection

1. Claim 9 stands rejected under 35 U.S.C. §102(b) as unpatentable over Ray.
2. Claims 9, 19 and 20 stand rejected under 35 U.S.C. § 102(e) as unpatentable over Wathen.
3. Claims 9, 19 and 20 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as now claimed.

DECISION ON APPEAL

35 U.S.C. § 102(b)

Claim 9 stands rejected under 35 U.S.C. § 102(b) as unpatentable over Ray.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). The inquiry as to whether a reference anticipates a claim must focus on what subject matter is encompassed by the claim and what subject matter is described by the reference. As set forth by the court in Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984), it is only necessary for the claims to "'read on' something disclosed in the reference, i.e., all limitations of the claim are found in the reference, or 'fully met' by it."

The examiner relies on Ray as describing a mixture of affinity purified hemagglutinin-neuraminidase (HN) and fusion (F) glycoproteins of human parainfluenza virus type 3 (PIV3) used to investigate the induction of a protective immune response following immunization of hamsters. Answer page 5 and Ray, page 786. Thus, it would appear that this embodiment of Ray anticipates the claimed composition (Claim 9). As indicated in the claim interpretation herein, the patentability of the claimed product does not depend on its method of production, and we give no patentable weight to the term

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“copurified” in the claim as the term defines a method of preparation of the claimed composition. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). In re Marosi, 710 F.2d 799, 803, 218 USPQ 289, 292-93 (Fed. Cir. 1983).

In our view, for the reasons set forth above, the examiner has provided sufficient evidence to establish a prima facie case of anticipation. After the PTO establishes a prima facie case of anticipation, the burden shifts to the appellants to prove that the subject matter shown to be in the prior art does not possess the characteristics of the claimed invention. See In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986).

Appellants have submitted a Declaration by Michel Klein as evidence of differences in properties between the composition of Ray and the composition of the claimed invention. The Declaration indicates that the affinity chromatography procedure used in the isolation and purification of the glycoproteins of the present invention does not lead to denaturing of the glycoproteins by acid conditions and/or chaotropic agents. Declaration, page 10. The Declaration refers to an affinity chromatography procedure involving lentil-lectin or concanavalin A covalently linked to cross-linked Sepharose (column) or cellulosic microporous membranes, and elution of the viral glycoproteins from the column with an

appropriate competing sugar. Declaration, page 4. To the extent that appellants urge that these isolation and purification steps would likely yield a product differing from the composition of Ray, we note simply that the existence of different characteristics resulting from these process steps has not been established and any alleged differences are not reflected in the claim before us.

The declarant does suggest that the composition of the invention differs from the composition of Ray, because the vaccine composition of Ray requires a dosage of 80 ug for the induction of an immune response, whereas the claimed composition only requires a dose of 30 ug. Declaration, page 10. However, the examiner responds to this argument, finding that Ray describes a 20 microgram dosage of its composition, when intranasally administered, induced significant resistance to challenge infection. Ray, page 784, Table 1. For this reason, the examiner concludes that “evidence of a difference in immunogenicity” between the composition of Ray and the claimed composition has not been demonstrated. Answer, page 8. We agree.

Thus, on this record the Appellants have not come forward with sufficient evidence to satisfy the burden of showing that the claimed composition does not possess the characteristics of the prior art composition of Ray. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977); In re Ludtke, 441 F.2d 660, 664, 169 USPQ 563, 566-

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67 (CCPA 1971). Therefore, the rejection of Claim 9 under 35 U.S.C. § 102(b) as unpatentable in view of Ray is affirmed.

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35 U.S.C. § 102(e)

Claims 9, 19 and 20 stand rejected under 35 U.S.C. § 102(e) as unpatentable over Wathen.

The examiner relies on Wathen as describing a recombinantly produced PIV3 HN and F, or HNF chimeric glycoproteins which are immunogenic and purified by ConA or lectin affinity chromatography, and may be admixed with aluminum phosphate as adjuvant for purposes of vaccine administration. Answer, page 6.

Wathen does not describe a “mixture of HN and F glycoproteins”, as required by claim 9, as the disclosure of Wathen appears to be limited to a single, recombinant, chimeric glycoprotein comprised of HN linked to F. Wathen, column 2, lines 49-50, column 8, lines 1-10, and column 16, lines 43-47.

Thus, Wathen does not anticipate the claimed composition and the rejection of Claims 9, 19 and 20 under 35 U.S.C. § 102(e) as unpatentable over Wathen is reversed.

35 U.S.C. § 112, first paragraph

Claims 9, 19 and 20 are rejected under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as now claimed.

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The purpose of the written description requirement under 35 U.S.C. § 112, first paragraph is to convey with reasonable clarity to those skill in the art, that, as of the filing date sought, appellants were in possession of the invention now claimed. Vas-Cath Inc. v. Makurar, 935 F.2d 1555, 1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). The description of the invention is provided using descriptive means such as words, structures, figures, diagrams, formulas, etc. The exact terms need not be used in haec verba. Lockwood v. American Airlines, Inc., 107 F.2d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); citing: Eiselstein v. Frank, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995). Thus, as stated above, all that is necessary to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, is to convey to those skilled in the art, that, as of the filing date the applicants were in possession of the invention. Vas-Cath Inc. v. Makurar, supra.

It is the examiner's position that the term "non-immunopotentiating" in claim 9 is not supported by the original specification and represents new matter. An applicant may by amendment make explicit a disclosure which was implicit or inherent in the application as filed. In re Reynolds, 443 F.2d 384, 389, 170 USPQ 94, 98 (CCPA 1971). The term "non-immunopotentiating" was added to Example VIII at page 11, line 20 of the specification by a preliminary amendment (Paper No. 3, April 26, 1995). The use of the term "non-immunopotentiating" following the term "i.e." reasonably suggests an equivalent meaning

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for the phrase “no short term immunopathological effects.” Read in this manner, the term “non-immunopotentiating” appears to restate a specific phrase finding support in the original disclosure. Thus, we do not find the term “immunopotentiating” to introduce new matter into the specification and claims. The specification and claims appear to convey to those skilled in the art, that, as of the filing date the appellants were in possession of the invention. Therefore, the rejection of claims 9, 19 and 20 under 35 U.S.C. § 112, first paragraph is reversed.

OTHER MATTERS

Having affirmed the rejection of claim 9 under 35 U.S.C. § 102(b) and reversed the rejections of claims 9, 19 and 20 under 35 U.S.C. § 102(e) and 35 U.S.C. § 112, first paragraph, claims 19 and 20 are free of prior art and not subject to rejection.

With regard to claims 19 and 20, we recognize that Wathen describes in Example 9, column 19, lines 35-56, that aluminum phosphate may be used as an adjuvant or immunomodulating agent for a PIV3 vaccine. While we could evaluate claims 19 and 20 under 35 U.S.C. § 103 in relation to the combination of Ray and Wathen, we choose not to do so. This Board serves as a board of review. 35 U.S.C. § 6(b). It is the responsibility of the Examiner, not the Board to set forth the ground for a rejection in the first instance. See Ex Parte Braeken, 54 USPQ2d 1110, 1112 (Bd. Pat.

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App. & Int. 1999). Thus, we leave it to the examiner in the first instance to determine if a rejection of claims 19 and 20 over the combination of Ray and Wathen is appropriate. Should the examiner determine that the claims are unpatentable, the examiner should issue an appropriate communication explaining in detail the basis of such a rejection and provide appellants with an opportunity to respond.

CONCLUSION

The rejection of claim 9 under 35 U.S.C. § 102(b) is affirmed. The rejections of claims 9, 19 and 20 under 35 U.S.C. § 102(e) and 35 U.S.C. § 112, first paragraph are reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

WILLIAM F. SMITH))
Administrative Patent Judge))
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))
)) BOARD OF PATENT
DOUGLAS W. ROBINSON)) APPEALS AND
Administrative Patent Judge))
)) INTERFERENCES

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DEMETRA J. MILLS
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