

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 39

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* RICHARD A. CONE and KEVIN J. WHALEY

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Appeal No. 95-2710  
Application 08/011,837<sup>1</sup>

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ON BRIEF

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Before WARREN, OWENS and KRATZ, *Administrative Patent Judges*.  
OWENS, *Administrative Patent Judge*.

*DECISION ON APPEAL*

This is an appeal from the examiner's final rejection of claims 52, 54, 55 and 58-62. Claims 1-50, which are the only other claims remaining in the application, have been withdrawn

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<sup>1</sup> Application for patent filed February 1, 1993. According to appellants, the application is a continuation of Application 07/305,048, filed February 1, 1989, now abandoned.

from consideration by the examiner as being directed toward a nonelected invention.

*THE INVENTION*

Appellants' claimed invention is directed toward methods for prophylaxis in a female mammal and for passively immunizing skin surfaces and mucus epithelial surfaces, by introducing into the vaginal cavity or uterus of the female mammal, or applying to the skin or mucus epithelial surfaces, at least one pan semen antibody which is capable of binding, directly or indirectly, to cells and pathogens in semen, thereby trapping the cells and pathogens in semen.<sup>2</sup>

Appellants state that the methods are useful for contraception and prophylaxis against sexually transmitted diseases (specification, page 1, lines 7-11). Claims 52 and 58 are illustrative and read as follows:

52. A method of prophylaxis in a female mammal which comprises continuously introducing into the vaginal cavity or uterus of said female mammal, over a prolonged period of time at a controlled rate a prophylactically effective amount of at

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<sup>2</sup> According to appellants' specification (page 16, lines 29-32), pan semen antibodies are "antibodies that not only immobilize sperm in semen but also immobilize virtually all other cells in semen by coagulating [sic, coagulating] them with the sperm."

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least one pan semen antibody capable of binding, directly or indirectly, to cells and pathogens in semen, thereby trapping said cells and pathogens in semen, including sexually transmitted disease pathogens and cells infected with sexually transmitted disease pathogens, in mucus secretions present in said vaginal cavity or uterus;

by means of a biologically compatible prolonged released carrier therefor,

wherein said at least one pan semen antibody is contacted with and binds, directly or indirectly, to said cells and pathogens in semen and thereby effects said trapping.

58. A method of passively immunizing skin surfaces and mucus epithelial surfaces comprising applying to said surfaces a pharmaceutical composition comprising

at least one pan semen antibody capable of binding, directly or indirectly, to viruses and cells in semen, thereby trapping said cells and viruses in mucus secretions present on said skin or mucus epithelial surfaces, wherein said antibody is present in an amount sufficient to effect said trapping, and

a pharmaceutically acceptable carrier,

under conditions such that said trapping is effected.

#### *THE REFERENCE*

Shinzo Isojima et al. (Isojima), "Establishment and characterization of a human hybridoma secreting monoclonal antibody with high titers of sperm immobilizing and agglutinating activities against human seminal plasma", 10 *J. Reprod. Immunology* 67-78 (1987).

#### *THE REJECTIONS*

The claims stand rejected as follows: claims 52, 54, 55

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and 58-61 under 35 U.S.C. § 101 as lacking patentable utility; claims 52, 54, 55 and 58-62 under 35 U.S.C. § 112, first paragraph, on the ground that the specification is speculative;<sup>3</sup> claims 52, 54, 55 and 58-61 under 35 U.S.C. § 102(b) as being anticipated by appellants' admitted prior art or Isojima.<sup>4</sup>

*OPINION*

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with appellants that the aforementioned rejections are not well founded. We therefore do not sustain these rejections.

*Rejection under 35 U.S.C. § 101*

Before utility is determined, the claims must be interpreted to define the invention to be tested for utility. See *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983), *cert denied*, 469 U.S. 835 (1984).

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<sup>3</sup> We assume that the examiner's statement that the specification is speculative means that the examiner considers the specification to fail to provide an enabling disclosure.

<sup>4</sup> In the answer (pages 4-5), the examiner erroneously includes canceled claim 51 in the rejections under 35 U.S.C. §§ 101 and 102(b).

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During prosecution, claims are to be given their broadest reasonable interpretation. See *In re Morris*, 127 F.3d 1048, 1055, 44 USPQ2d 1023, 1028 (Fed. Cir. 1997); *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Regarding utility, a predecessor of our reviewing court stated in *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974):

[A] specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented *must* be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter *unless* there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

The examiner argues that appellants claim a method for preventing the sexual transmission of AIDS (answer, page 5). As indicated by appellants' specification (page 10, lines 16-20; page 13, lines 27-35; page 16, line 27 - page 17, line 16; page 27, lines 11-13), appellants' claimed methods encompass binding cells which carry AIDS. The examiner errs, however, by arguing as though appellants claim methods for treating AIDS, rather than methods which prevent the transmission of AIDS (answer, pages 5-6).

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Appellants provide figures which show that appellants' antibodies agglutinate sperm and other cells (page 8, lines 2-28; page 17, lines 18-20), and state that all five tested antibodies coagulated virtually all cells present in semen, either directly or by binding to factors secreted by the seminal vesicles (page 17, line 30 - page 18, line 2). Also, Isojima discloses (page 67) that H6-3C4 has strong sperm immobilizing and agglutinating activities.

The examiner provides no evidence or sound technical reason which indicates that one of ordinary skill in the art would have questioned the objective truth of the statements in appellants' specification that their pan semen antibodies bind to cells and pathogens in semen, including cells that carry AIDS, thereby trapping the cells and pathogens. Hence, the examiner has not carried his initial burden of establishing a *prima facie* case of lack of utility.

For the above reasons, we do not sustain the rejection under 35 U.S.C. § 101.

*Rejection under 35 U.S.C. § 112, first paragraph*

The examiner argues that there is no evidence of record

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of an antibody which can agglutinate sexually transmitted disease pathogens and sperm (answer, pages 4, 7 and 8). Appellants argue that their specification discloses five antibodies which are useful for carrying out the claimed methods and provides six criteria for screening additional pan semen antibodies (brief, pages 7-10). The specification, appellants argue (brief, page 9), discloses at page 16, lines 26-33, antibodies which immobilize sperm and also immobilize virtually all other cells in semen by coagulating them with the sperm (see also, reply brief, pages 4-5).

With respect to enablement, a predecessor of our appellate reviewing court stated in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971):

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. . . .

. . . .

. . . it is incumbent upon the Patent Office,

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whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

The examiner has not carried his initial burden of setting forth evidence or sound technical reasoning which indicates that one of ordinary skill in the art would not have been enabled by appellants' specification to provide prophylaxis and passive immunization of skin surfaces and mucus epithelial surfaces using the disclosed antibodies and other antibodies selected according to the guidelines in appellants' specification.

For the above reasons, we do not sustain the rejection under 35 U.S.C. § 112, first paragraph.

*Rejection under 35 U.S.C. § 102(b)*

The examiner argues that in appellants' specification at page 11, lines 14-23, appellants acknowledge that antibodies which immobilize sperm, usually by agglutination, were known in the art (answer, pages 4 and 9). Appellants argue that they have admitted that certain antibodies were known in the

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art to bind sperm cells in semen, but have not admitted that pan semen antibodies were known which bind to and trap all cells and pathogens in semen (brief, page 11). Appellants' argument is not well taken in view of the fact that the antibodies used by appellants were known by and obtained from others (specification, page 12, lines 14-36). Appellants also argue that they have not admitted that methods were known to apply a pan semen antibody into the vaginal cavity or uterus or to skin surfaces or mucus epithelial surfaces (brief, page 11).

The examiner argues that Isojima teaches that H6-3C4, which is one of the antibodies recited in appellants' claims 59-61, was known in the art to immobilize sperm and cause contraception, and that agglutination of pathogenic cells would be inherent with the administration of the antibody (answer, page 4). Appellants argue that Isojima does not disclose an antibody that binds to cells other than sperm cells or to pathogens in semen (brief, page 12). Appellants' argument is not persuasive because Isojima discloses H6-3C4 (page 67) which, appellants state (specification, page 17, lines 30-33), agglutinates virtually all cells present in

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semen. Appellants also argue that Isojima does not disclose application of a pan semen antibody into the vaginal cavity or uterus or to the skin surfaces and mucus epithelial surfaces (brief, page 13).

In order for a claimed invention to be anticipated under 35 U.S.C. § 102(b), all of the elements of the claim must be found in one reference. See *Scripps Clinic & Research Found. v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). The examiner has the initial burden of establishing a *prima facie* case of anticipation by pointing out where all of the claim limitations appear in a single reference. See *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138-39 (Fed. Cir. 1986).

Each of appellants' claims requires a step of applying the at least one pan semen antibody, either into the vaginal cavity or uterus of a female mammal or to the skin surfaces and mucus epithelial surfaces. Appellants do not acknowledge that this step was known in the art. Also, the examiner does not point out, and we do not find, where Isojima describes

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such an application step. The examiner's argument based on *Ex Parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Int. 1993) that "[t]he agglutination of pathogenic cells would be inherent with the administration of the claimed antibody" (answer, page 4) is not well founded because the examiner does not point out where the relied-upon prior art discloses "the administration of the claimed antibody". In *Novitski*, 26 USPQ2d at 1390, the board considered the claimed invention to be anticipated. In the present case, the examiner does not indicate where Isojima describes appellants' claimed methods within the meaning of 35 U.S.C. § 102(b).

For the above reasons, we find that the examiner has not carried his burden of establishing a *prima facie* case of anticipation of the method recited in any of appellants' claims. Accordingly, we do not sustain the rejection under 35 U.S.C. § 102(b).

#### DECISION

The rejections of claims 52, 54, 55 and 58-61 under 35 U.S.C. § 101 as lacking patentable utility, of claims 52, 54,

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55 and 58-62 under 35 U.S.C. § 112, first paragraph, on the  
ground that the specification is speculative, and of claims  
52, 54,

55 and 58-61 under 35 U.S.C. § 102(b) as being anticipated by  
appellants' admitted prior art or Isojima, are reversed.

*REVERSED*

	CHARLES F. WARREN	)	
	Administrative Patent Judge	)	
		)	
		)	
		)	
	TERRY J. OWENS	)	BOARD OF
PATENT	Administrative Patent Judge	)	APPEALS AND
		)	INTERFERENCES
		)	
		)	
	PETER F. KRATZ	)	
	Administrative Patent Judge	)	

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