

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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

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Appeal No. 1996-3794  
Application No. 08/212,698

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ON BRIEF

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Before OWENS, LIEBERMAN, and KRATZ, Administrative Patent Judges.

LIEBERMAN, Administrative Patent Judge.

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claims 13 through 22 and 26 through 34 which are all the claims in the application.

**THE INVENTION**

The invention is directed to a composition for use in the disinfection of a blood sample or a blood component sample, and in a method for disinfecting a blood sample or

blood component sample. The composition consists essentially of an anionic surfactant, at least one non-anionic surfactant, a stabilizer and a buffer solution.

### **THE CLAIMS**

Claim 13 is illustrative of appellant's invention and is reproduced below.

13. A composition for use in the disinfection of a blood or blood component sample, wherein said sample is contained in a blood bag and wherein said composition controls hemolysis of and maintains the chemical and physical characteristics of the cells present in said sample such that said sample can be used for a transfusion, said composition consisting essentially of, in combination, an anionic surfactant, at least one non-anionic surfactant, a stabilizer, and a buffer solution.

### **THE REFERENCES OF RECORD**

As evidence of obviousness, the examiner relies upon the following reference.

Hicks et al. (Hicks) "The Lancet" pp. 1422-1423, (Dec. 21/28, 1985).

### **THE REJECTIONS**

Claims 13 through 22 and 26 through 34 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hicks.

Claims 13 through 22 and 26 through 34 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention.

Claims 13 through 22 and 26 through 34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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## OPINION

We have carefully considered all of the arguments advanced by appellant and the examiner and agree with appellant that each of the aforementioned rejections under 35 U.S.C. §§ 103 and 112 are not well founded. Accordingly, we do not sustain the examiner's rejection.

### The Rejections under § 112

Any analysis of the claims for compliance with 35 U.S.C. § 112 should start with the second paragraph, then proceed with the first paragraph. In re Angstadt, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976). The legal standard for definiteness under the second paragraph of 35 U.S.C. § 112 is whether a claim reasonably apprises those of ordinary skill in the art of its scope. In re Warmerdam, 33 F.3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). Furthermore, the definiteness of the language employed must be analyzed not in a vacuum, but in light of the teachings of the particular application. In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

It is the examiner's position that claims 13 and 19 are directed to the term, "disinfection," which is unsupported by the remainder of the claim. See Supplemental Answer, mailed January 25, 1996, page 4. The issue however is not whether the term, "disinfection" is supported by the remainder of the claim, but whether the teachings of the specification are such that one of ordinary skill in the art would be apprised of the scope of

the claimed subject matter. In this respect, we find that appellant's specification teaches compositions used in the disinfection of a blood sample or blood component sample on pages 11 -15 of the specification. We further find that appellant's specification teaches the claimed method for disinfecting blood or blood component samples by using the composition of the claimed subject matter. See pages 15-17 of the specification.

Based upon the above considerations, we find that the examiner has failed to establish that one of ordinary skill in the art would not be apprised of the scope of the claims set forth above. Accordingly, the rejection under the second paragraph of 35 U.S.C. § 112 is reversed.

We turn next to the examiner's rejection under the first paragraph of 35 U.S.C. § 112 on the grounds of lack of enablement. See Supplemental Answer, mailed January 25, 1996, page 3. When rejecting a claim under the enablement requirement of section 112, the PTO bears the initial burden of setting forth a reasonable explanation as to why it believes the scope of protection provided by the claimed subject matter is not adequately enabled by the description of the invention provided in the specification of the application. This includes providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If this burden is met, the burden then shifts to the appellant to provide suitable proof that the specification is enabling. In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Marzocchi, 439 F.2d 220, 223, 169 USPQ

367, 369 (CCPA 1971). It is the examiner's position that the appellant has not provided any information regarding the maintenance of the immunological characteristic of the cell. See Supplemental Answer, mailed January 25, 1996, page 3. However, as determined *supra*, it is well settled that the burden rests with the examiner to establish lack of enablement. In the absence thereof, appellant is under no burden to provide suitable proof that the specification is enabling. As the balance of the examiner's rejection is directed to speculation that an interaction between the surfactant and the surface of the molecules in solution might result in changing the physical and chemical characteristics of the cells present, we conclude that the examiner has not met his burden of providing a reasonable explanation for lack of enablement. See Supplemental Answer, mailed January 25, 1996, page 3. Moreover, we find that the specification on pages 10-18 and the examples fully enable the subject matter claimed by appellant. Accordingly, we reverse the rejection under 35 U.S.C. § 112, first paragraph.

### **The Rejection under Hicks**

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The examiner relies upon a reference to Hicks to reject the claimed subject matter and establish a *prima facie* case of obviousness. The basic premise of the rejection is that the reference to Hicks discloses that nonoxynol-9

can be used to inactivate the HTLV virus in human blood. As the nonoxynol-9 being the active ingredient, it would have been within the skill of the art to modify the composition by the addition of anionic surfactant, stabilizer and buffer. See Supplemental Examiners Answer, pages 5 and 6. We disagree.

A proper analysis of the claimed invention under § 103 requires consideration of two factors. The initial question is whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed invention and whether the prior art would have revealed that in so doing or carrying out, those of ordinary skill would have had a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). Our findings indicate with respect to the first factor, no suggestion or teaching in the prior art of Hicks for the presence of an anionic surfactant, a stabilizer or a buffer. The absence of that suggestion in and of itself is sufficient to conclude that no prima facie case of obviousness had been established. Accordingly, we do not sustain the rejection under § 103.

### **DECISION**

The rejection of claims 13 through 22 and 26 through 34 under 35 U.S.C. § 103 as being unpatentable over Hicks is reversed.

The rejection of claims 13 through 22 and 26 through 34 under 35 U.S.C. § 112, first paragraph as failing to adequately teach how to make and/or use the invention is reversed.

The rejection of claims 13 through 22 and 26 through 34 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is reversed.

The decision of the examiner is reversed.

REVERSED

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

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CUSHMAN, DARBY & CUSHMAN  
NINTH FLOOR  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005-3918