

***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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* LAKSHMAN R. SEHGAL,  
RICHARD E. DE WOSKIN,  
GERALD S. MOSS,  
STEVEN A. GOULD,  
ARTHUR L. ROSEN  
and HANSA SEHGAL

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Appeal No. 96-0352  
Application 08/031,563<sup>1</sup>

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HEARD: AUGUST 2, 1999

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Before KIMLIN, JOHN D. SMITH and GARRIS, *Administrative Patent Judges*.

JOHN D. SMITH, *Administrative Patent Judge*.

***DECISION ON APPEAL***

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<sup>1</sup> Application for patent filed March 15, 1993. According to appellants, is application is a continuation of Application 07/616,727, filed November 21, 1990, now U.S. Patent No. 5,194,590, granted March 16, 1993, which is a continuation of Application 07/315,130, filed February 23, 1989, now abandoned, which is a continuation of Application 06/876,689, filed June 20, 1986, now U.S. Patent No. 4,826,811, granted May 2, 1989.

Appeal No. 96-0352  
Application 08/031,563

This is an appeal pursuant to 35 U.S.C. § 134 from the final rejection of Claim 1.

The references of record relied upon or discussed in the brief and the answer are:

Scheinberg	4,049,673	Sept. 20, 1977
Chiang et al. (Chiang)	4,485,174	Nov. 27, 1984
Jacobson et al. (Jacobson)	4,711,852	Dec. 8, 1987
Bonaventura et al. (Bonaventura)	4,761,209	Aug. 2, 1988
Saunders	4,835,097	May 30, 1989
Sehgal et al. (Sehgal patent)	5,194,590	Mar. 16, 1993

Appealed claim 1 stands rejected under 35 U.S.C. § 101 as claiming the same invention as that defined by patented claim 1 of the Sehgal patent. Alternatively, appealed claim 1 stands rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over patented claim 1 of the Sehgal patent. We reverse.

Patented claim 1 of the Sehgal patent reads as follows:

1. Essentially tetramer free, cross linked, polymerized hemoglobin wherein the hemoglobin is from human blood.

Appealed claim 1, reproduced below, includes a further limitation concerning a specific amount of methemoglobin reductase activity:

1. Essentially tetramer free, cross linked, polymerized hemoglobin wherein the hemoglobin is from human blood and having methemoglobin reductase enzyme activity ranging from about 1.0 to about 2.0 units of enzyme activity.

The examiner's 35 U.S.C. § 101 double patenting rejection is based on the examiner's contention that the "enzyme function" of the appealed claim is an inherent property of the

product defined by the patented claim. We find that the references of record do not support the examiner's contention that the claimed enzyme activity is necessarily and inevitably an inherent property of the polymerized hemoglobin defined by the patented claim.

Hemoglobin is a complex molecule contained in red blood cells and is involved in the transport of oxygen and carbon dioxide in the blood. The hemoglobin molecule has been described as consisting of heme (a pigment of iron in the ferrous state) and globin (a protein formed of two alpha chains and two beta chains having 141 and 146 amino acids respectively). See Saunders at column 1, lines 36-42. Oxygen combines rapidly and reversibly with hemoglobin to form oxyhemoglobin, and when the iron of the hemoglobin molecule is oxidized to the ferric state, methemoglobin is formed. See Saunders at column 1, lines 43-47. As acknowledged by the examiner in the answer at page 9 and as taught by Saunders at column 1, lines 47 and 48, the enzyme, methemoglobin reductase, acts to reduce the formed methemoglobin back to oxyhemoglobin. Scheinberg also confirms that the above reactions take place and that methemoglobin reductase enzyme is present in red blood cells. See Scheinberg at column 4, lines 22-31.

The examiner relies on the disclosure in the Sehgal patent at column 15, lines 53-59 as factual support for his conclusion that the patented product inherently possesses the claimed enzyme activity. This portion of the patent refers to a specifically exemplified polymerized hemoglobin product produced by a complex and detailed process and indicates that the methemoglobin reductase activity in

the exemplified product “was essentially unchanged by the process”, and that the “starting lysate as well as the final product” had enzyme activities in the range now claimed. We point out that the starting lysate used to produce this product was obtained from a preferred blood source, outdated human blood. See Sehgal patent at column 5, lines 1-5 and column 9, lines 5-25. However, it would appear that a polymerized hemoglobin produced from a non-preferred blood source using the Sehgal process would not necessarily possess an enzyme activity in the range claimed.

In light of the above, it is evident that patented claim 1 of the Sehgal patent is a broad claim directed simply to a polymerized hemoglobin which may be characterized as a polymerized protein, i.e., a single substance, while appealed claim 1 is directed to a two-component composition, i.e., a polymerized hemoglobin in combination with the enzyme, methemoglobin reductase in specified amounts (the claimed enzyme activity is observed only if the enzyme is present). Accordingly, it is evident that patented claim 1 of the Sehgal patent could be infringed without literally infringing appealed claim 1, for example, by a polymerized hemoglobin purified of all methemoglobin reductase or by a polymerized hemoglobin having methemoglobin reductase in concentrations such that the enzyme activity is outside the claimed range of appealed claim 1. Applying the infringement test set forth in *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970), it is apparent that “the claims do not define identically the same invention”. Therefore, the rejection under 35 U.S.C. § 101 is reversed.

We also reverse the examiner's alternative rejection of appealed claim 1 on the grounds of obviousness-type double patenting. The examiner contends that methemoglobin reductase enzyme is often added to hemoglobin to maintain its structural and functional stability, and "because of prior art knowledge that establishes the importance of methemoglobin reductase activity in the amounts claimed," modifications and variations of the product defined by patented claim 1 of the Sehgal patent would have been obvious to one of ordinary skill in the art. See the answer at page 12.

We have reviewed the five references of record which are "presented to merely make of record prior art knowledge<sup>2</sup> and what the skilled worker already knows" (answer, page 12), but we find no explicit disclosure of the "importance of methemoglobin reductase activity" in the range claimed here. In this regard, we point out that Scheinberg teaches that chemical reductants which function analogously to the enzyme "need not be stoichiometrically equivalent to or greater than the quantity of oxygen" (emphasis added) to which a hemoglobin product used to absorb carbon monoxide would be exposed during processing or use. See this reference at column 3, line 66 to column 4, line 41. Thus, we agree with appellants that no reference of record suggests that a polymerized hemoglobin product as defined by the patented claim should be prepared to have the "specific enzyme activity", i.e., "from about 1.0 to about 2.0 units of enzyme activity". Thus, the rejection for obviousness-type double

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<sup>2</sup> Consistent with the practice suggested in In re Hoch, 428 F.2d 1341, 1342, n.1, 166 USPQ 406, 407, n. 1, (CCPA 1970), these references should have been included in the examiner's statement of rejection. In light of the prosecution history and our disposition of this appeal, we will not exercise our discretion to remand this application to the examiner to modify the statement of rejection.

Appeal No. 96-0352  
Application 08/031,563

patenting cannot be sustained. The decision of the examiner is reversed.

**REVERSED**

EDWARD C. KIMLIN	)	
Administrative Patent Judge	)	
	)	
	)	BOARD OF PATENT
	)	APPEALS AND
JOHN D. SMITH	)	INTERFERENCES
Administrative Patent Judge	)	
	)	
	)	
BRADLEY R. GARRIS	)	
Administrative Patent Judge	)	

JDS/dal

Appeal No. 96-0352  
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