

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte ZHI YANG

\_\_\_\_\_  
Appeal No. 1996-1916  
Application 07/912,122

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ON BRIEF  
\_\_\_\_\_

Before WINTERS, WILLIAM F. SMITH and SCHEINER, Administrative Patent Judges.  
SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 4 and 7, all the claims pending in the application. Claims 1 and 7 are representative of the subject matter on appeal and read as follows:

1. A cDNA sequence (SEQ ID NO:3) encoding soluble *Flk-2*.
7. Soluble *Flk-2* (SEQ ID NO:4) as a purified composition.

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The reference relied on by the examiner is:

Lemischka

5,185,438

Feb. 9, 1993

Claims 1 through 4 and 7 stand rejected under 35 U.S.C. § 112, first paragraph as based on a non-enabling disclosure. In addition, claims 1 through 3 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies on Lemischka. We reverse both rejections.

### DISCUSSION

#### Enablement

Flk-2 is a tyrosine kinase and "putative stem cell growth factor receptor" with a ligand-binding extracellular domain, a transmembrane domain, and an intracellular catalytic domain.<sup>1</sup> The present invention is directed to a 1.9 kb cDNA molecule identical to portions of the 3.4 kb cDNA molecule encoding murine Flk-2; an expression cassette containing the 1.9 kb cDNA molecule; and a vector containing the cassette (claims 1 through 3). The invention further encompasses the protein encoded by the 1.9 kb cDNA molecule, and a method of producing the protein (claims 4 and 7). The 1.9 kb cDNA transcript appears to be "an alternative spliced form of [*Flk-2*]" which "lacks the transmembrane sequence as well as portions of the extracellular and intra-cellular

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<sup>1</sup> U.S. Patent No. 5,185,438 to Lemischka. See column 3, lines 48-60.

sequences” of the 3.4 kb cDNA transcript, and appellant concludes that the 1.9 kb transcript encodes a secreted, soluble form of Flk-2 (specification, pages 2 and 9). Soluble Flk-2 lacks 59% of the extracellular domain of the Flk-2 transmembrane receptor, thus, the examiner considers it to be “extremely unpredictable that an extracellular domain consisting of only 41% of the previously known receptor would retain ligand binding function” or “be able to achieve a conformation such as to form structures necessary for antibody recognition.” Further, the examiner believes “[i]n the absence of any structural or functional characterization of the encoded protein, it would require undue experimentation to use the claimed DNA to make protein, make antibodies to that protein, determine the individual specificities of all such antibodies, and then determine how to use such based upon those specificities.” Accordingly, claims 1 through 4 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification “does not enable how to use the claimed DNA or protein.” Examiner’s Answer, page 4.

It is well settled that the specification need only teach one skilled in the art how to make and use the claimed invention, and that it is the examiner’s initial burden to provide reasons why a supporting disclosure does not enable a claim. As stated in

In re Marzocchi, 439 F.2d 220, 223, 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

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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.

In this case, the specification teaches a number of uses for the claimed DNA and protein (pages 3 and 6):

Nucleic acid encoding [*Flk-2*] may be obtained from host hematopoietic stem cells by using as a probe, at least twelve, usually at least eighteen, nucleotides of the subject sequence. The subject sequence, which is the mouse sequence, may be used to identify other mammalian analogs by hybridiz[ation] . . .

The cDNA may be used for expression of the [*Flk-2*] in any convenient expression host . . .

\* \* \*

The subject proteins find use in culture and *in vivo* in competing with *Flk-2* receptor for *Flk-2* ligand. Thus, the subject compositions may be used for modulating the growth of hematopoietic progenitor cells. In addition, the subject proteins or fragments thereof of at least about 12 amino acids . . . may be used for the production of antibodies . . . Particularly, the soluble *Flk-2* may be used to produce antibodies which are specific for the juncture or sequences proximal to the juncture between about amino acids 680 and 700 . . . The antibodies may be used for identifying cells carrying *Flk-2*, removing soluble *Flk-2* from culture fluids or natural fluids, purifying *Flk-2*, and the like. The antibodies may also be used for assaying for the presence of *Flk-2*.

Thus, the dispositive issue is whether the examiner has met the initial burden of establishing a reasonable basis to doubt the objective truth of statements in the specification regarding the use of the claimed DNA and protein.

As further stated in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971):

[I]t is incumbent upon the Patent Office, 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.

In our judgment, a mere assertion of unpredictability is insufficient ground for questioning the truth or accuracy of appellant's disclosure, or for shifting the burden to appellant to provide rebuttal evidence substantiating statements made in the specification.

To the extent that the examiner argues that appellant's disclosure does not enable any person skilled in the art to make and use the claimed invention without undue experimentation, we disagree. Given the straightforward, routine protocol outlined in the specification, together with what is well known in the art, we are persuaded that any experimentation necessary to practice the claimed invention would be routine, not undue.

We hold that the examiner has not set forth a reasonable basis for questioning the enablement of the claims on appeal. Accordingly, the rejection of claims 1 through 4 and 7 is reversed.

#### Obviousness

Claim 1 is directed to cDNA of a particular sequence (SEQ ID NO:3) encoding soluble Flk-2. Claim 2 is directed to an expression cassette comprising cDNA (SEQ ID NO:3) encoding soluble Flk-2; claim 3 is directed to a vector containing the expression

cassette of claim 2. Claims 1 through 3 stand rejected under 35 U.S.C. § 103 as unpatentable over Lemischka.

Lemischka discloses DNA encoding Flk-2, a 992 amino acid “receptor protein tyrosine kinase” with a ligand-binding extracellular domain, a transmembrane domain, and an intracellular catalytic domain (column 3, lines 48-60). The reference also discloses a form of Flk-2 lacking the transmembrane region (amino acids 545-564), the catalytic domain (amino acids 565-992), and a portion of the extracellular domain (amino acids 1-27); i.e., a form of Flk-2 corresponding to amino acids 28-544 of the 992 amino acid receptor (column 3, lines 48-56 and column 6, lines 15-20). The presently claimed cDNA, on the other hand, has a sequence identical to the Flk-2 receptor, but for “a 511 amino acid deletion beginning with the amino acid 221 Val and ending with the 731 Gln, so that the Lys at 220 is joined to the Ala at 732” (specification, pages 2 and 9).

The examiner argues that “there is no sequence with which the claimed DNA would hybridize that would not also hybridize to the DNA as disclosed by Lemischka” and concludes that “the claimed DNA is, with respect to its use as hybridization probe, functionally equivalent to and therefore *prima facie* obvious over the DNA disclosed by Lemischka” (Examiner’s Answer, page 6).

We find ourselves in agreement with appellant that “[t]his is not the standard for obviousness” (Reply Brief, page 2). As argued by appellant, the claimed cDNA “has a

specific deletion in the transmembrane region, as well as portions of the extracellular and intracellular sequences” (Id., page 3). The examiner concedes that Lemischka “does not disclose the particularly claimed sequence,” but does not provide reasons why one of ordinary skill in the art would have found it obvious to modify the prior art sequence to arrive at the specifically claimed cDNA (Examiner’s Answer, page 6).

35 U.S.C. § 103 requires that obviousness be determined on the basis of the claimed “subject matter as a whole.” Where, as here, the determination of obviousness is based on less than the entire claimed subject matter, the examiner’s conclusion of obviousness cannot be sustained. Accordingly, we find that the examiner’s initial

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burden of establishing a prima facie case of obviousness has not been met, and the rejection of claims 1 through 3 under 35 U.S.C. § 103 is reversed.

REVERSED

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Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
William F. Smith	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
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Toni R. Scheiner	)	
Administrative Patent Judge	)	

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