

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 52

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte XANDRA O. BREAKEFIELD,  
and ROBERT L. MARTUZA

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Appeal No. 2001-1686  
Application No. 08/363,998

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HEARD: February 7, 2002

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Before WINTERS, WILLIAM F. SMITH, and GREEN, Administrative Patent Judges.

GREEN, 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 54, 55, 57, 59-61 and 72-77. Claim 54 is representative of the subject matter on appeal, and reads as follows:

54. A method of expressing a gene sequence in a neuronal cell of the central nervous system, said method comprising:
- directly administering into said neuronal cell a herpes simplex virus 1 (HSV-1) mutant as a vector for gene delivery, said HSV-1 mutant comprising:
- (a) a deletion in an immediate early gene whereby said deletion in an immediate early gene is replaced by

- (b) a gene sequence operably linked to a promoter sequence so that said gene sequence will be expressed in said neuronal cell, and

expressing said gene sequence in said neuronal cell.

The claims stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not enable any person skilled in the art to use the invention commensurate in scope with the claims. Upon careful review of the record before us and consideration of the issue on appeal, we reverse.

#### BACKGROUND

The specification asserts that the “delivery and expression of heterologous or native genes into cells of the nervous system to alter normal cellular biochemical and physiologic processes in a stable and controllable manner is of substantial value in the fields of medical and biological research.” Specification, page 1. In order to perform such delivery, the specification teaches the use of herpes simplex virus 1 (HSV-1) mutants as vectors for gene delivery, wherein the virus is mutated so that it has a deletion(s) in a gene(s) necessary for viral replication in neuron. See id. at 4.

As noted by the specification, HSV-1 is a double-stranded DNA virus that is replicated and transcribed in the nucleus of the cell. The virus contains approximately 70 genes, and the five immediate early genes encode infected cell proteins (ICPs) 0, 4, 22, 27 and 47, the major regulatory proteins of the virus. The immediate early proteins regulate expression of proteins of the early and late classes, and the proteins of the early class are responsible for viral DNA

replication. Post-mitotic neurons harbor latent stage HSV-1, and once latent, the virus can be retained by the neuron for the life of the cell. See id. at 11-12.

The claims are drawn to methods of administering a mutant HSV-1 to a neuronal cell of the central nervous system, wherein one of the immediate early genes has been replaced by a gene operably linked to a promoter, resulting in the expression of the gene in the neuronal cell. See Claim 54. According to appellants, the method has both in vitro and in vivo uses, including studying DNA sequences and cellular factors that regulate expression of neural specific genes, production of animal models, and gene therapy. See Appeal Brief, pages 10-11.

#### DISCUSSION

The claims stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope of the claims. The Answer contends that

the specification, while being enabling for methods of studying cell type specific differences in processing and cellular fate; methods to study DNA sequences and cellular factors which regulate expression of neural specific genes; and methods for studying cellular fate and interactions between the central and peripheral nervous system by directly administering into said neuronal cell an HSV-1 mutant as a vector for gene delivery comprising a deletion in an immediate early gene replaced by a gene sequence operably linked to a promoter sequence so that the gene sequence will be expressed in the neuronal cell, and expressing the gene sequence [in] [sic] said neuronal cells, does not reasonably provide enablement for to [sic] study neurological diseases, to study neuronal physiology or to control expression of protein and assess its capacity to modulate cellular events in the central and peripheral nervous systems; to elucidate the processing, regulation and functional domains of neural peptides; to study mutations such as

the shiver and jumpy mutations; to study the effects of genes encoding growth factors, oncogenic proteins or toxic peptides; methods of making animal of [sic] models for nervous system diseases or human painful conditions; to study in vivo neural proteins to monitor changes in receptor density, cell number, fiber growth, electrical activity or neurotransmission; and methods of treatment, that is gene therapy.

Answer, pages 2-3.

The answer then carefully goes through the pertinent Wands factors, setting forth facts why certain disclosed uses are not enabled by the specification. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). According to the examiner, the issue on appeal is “whether or not the claims as written have to be enabled for all of the disclosed uses.” Answer, page 22. The Answer asserts that the answer to that question is yes, contending that “[m]ethod claims, in this regard, do not have the same standard as product claims, which only need to be enabled for one disclosed use.” Id. While we commend the examiner for her thorough analysis in the Answer, we reverse, but do not reach the issue as framed by the examiner.<sup>1</sup>

According to the rejection, the specification fails to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope of the claims. The examiner acknowledges that the specification would enable the skilled artisan to practice

some of the disclosed embodiments of the claimed invention, but argues that other disclosed embodiments would not be enabled. A claim may, however, encompass inoperative embodiments and still meet the enablement requirement of 35 U.S.C. § 112, first paragraph. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976), In re Cook, 439 F.2d 730, 732, 169 USPQ 298, 300 (CCPA 1971).

In In re Cook, 439 F.2d 730, 169 USPQ 298 (CCPA 1971), one of the issues addressed by the court was whether claims to an “optical objective of the ‘zoom’ type” met the requirements of 35 U.S.C. § 112, first paragraph, on the grounds that the “disclosure was said to be insufficient because it would require many months for a skilled lens designer, working with the aid of a computer, to design, within the ambit of the claims, a satisfactory zoom lens assembly other than the six specifically disclosed.” Id. at 732, 169 USPQ at 300.

In finding that the disclosure was sufficient with regard to that particular basis of rejection, the court stated that

many patented claims read on vast numbers of inoperative embodiments in the trivial sense that they can and do omit “factors which must be presumed to be within the level of ordinary skill in the art,” and therefore read on embodiments in which such factors may be included in such a manner as to make the embodiment operative rather than inoperative.

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<sup>1</sup> To the best of our knowledge, the question of whether the specification has to enable all of the disclosed uses of a method claim has not been addressed by our reviewing court, the Court of Appeals for the Federal Circuit, nor its predecessor court, the Court of Custom and Patent Appeals. Because we need not reach it here, we decline to do so.

\* \* \* \*

We agree that appellants' claims are not too broad "to the point of invalidity" just because they read on even a large number of inoperative embodiments, since it seems to be conceded that a person skilled in the relevant art could determine which conceived but not-yet-fabricated embodiments would be inoperative with expenditure of no more effort than is normally required of a lens designer checking out a proposed set of parameters.

Id. at 735, 169 USPQ at 302 (citations omitted); see also Angstadt, 537 F.2d at 504, 190 USPQ at 219 ("Without undue experimentation . . . the combinations which do not work will readily be discovered and, of course, nobody will use them and the claims do not cover them.")

The issue thus becomes whether a person skilled in the relevant art could determine which uses disclosed in the specification are enabled and distinguish them from those that are not using the ordinary effort in the field of endeavor to which the claim is drawn, i.e., the art of protein expression. We find that the person skilled in the art could discern the uses of the claimed method of protein expression enabled by the specification from those that are not.

Our finding is based, in significant part, on the thorough reasoning provided by the scope of enablement rejection set forth by the examiner in her answer. In the Appeal Brief, appellants set forth both therapeutic, as well as non-therapeutic uses for the claimed method of expressing a gene sequence in a neuronal cell of the central nervous system. See Appeal Brief, pages 10-11. In response, the examiner, as set forth supra, details those uses for the claimed method that are enabled, and then distinguishes those uses that the examiner contends are not enabled. See Examiner's Answer, pages 2-3. Thus, the

statement of the rejection provides support for our finding that an artisan skilled in the art would be able to distinguish those uses of the claimed method disclosed by the specification that are enabled from those that are not.

In making the scope rejection that the disclosure is enabled for some, but not all of the disclosed uses, the examiner appears to be concerned that the claim may encompass the inventive efforts of later developers. That is a concern, however, under potential infringement of the claim and not the patentability of the claim. See In re Hogan, 559 F.2d 595, 607, 194 USPQ 527, 538 (CCPA 1977).

CONCLUSION

For the reasons stated above, the rejection of claims 54, 55, 57, 59-61 and 72-77 under 35 U.S.C. § 112, first paragraph, on the basis that the specification fails to enable the entire scope of the claims, is reversed. Nonetheless, we decline to decide the specific issue framed by the examiner, that is, whether or not method claims must be enabled for all disclosed uses in the specification in order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

REVERSED

SHERMAN D. WINTERS	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
WILLIAM F. SMITH	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
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LORA M. GREEN	)	
Administrative Patent Judge	)	

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