

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte JOHN L. RIDIHALGH

Appeal No. 2001-1150
Application No. 09/167,764

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER, 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 1, 3-5 and 8-10. Claims 1 and 6 are representative of the subject matter on appeal, and read as follows:

1. A therapeutic agent for treating patients afflicted with chronic fatigue syndrome (CFS), which comprises:
in a pharmaceutically-acceptable carrier, cytokine-producing cells having been produced by the step of subjecting cells derived from autologous lymph nodes excised from patients afflicted with CFS to mitogenic stimulation in the presence of interleukin-2 (IL-2) and anti-CD3 monoclonal antibody in serum-free media for their expansion.

6. A method for treating patients afflicted with chronic fatigue syndrome (CFS), which comprises:

administering to said patient the autologous therapeutic agent of claim 1.

The examiner cites the following references:

Caplan, "Chronic fatigue syndrome or just plain tired?" CMAJ, Vol. 159, pp. 519-20 (1998)

Goldenberg, "Fibromyalgia, chronic fatigue syndrome, and myofascial pain syndrome," Current Opinion in Rheumatology, Vol. 9, pp. 135-43 (2000)

Levine, "What We Know About Chronic Fatigue Syndrome and Its Relevance to the Practicing Physician," Am. J. Med., Vol. 105 (3A), pp. 100S-103S (1998)

All of the claims stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. After careful review of the record and consideration of the issue before us, we reverse.

DISCUSSION

Claims 1, 3-6 and 8-10 stand rejected under 35 U.S.C. § 112, first paragraph, on the ground that they contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection cites Levine to demonstrate that chronic fatigue syndrome (CFS) exhibits a variety of symptoms, thus precluding the use of a laboratory test for diagnosis and requiring individualizing the treatment of the syndrome to the symptoms of the individual. Examiner's Answer, pages 5-6. Levine, as well as

Caplan, are cited for their teaching that there is no “magic bullet” for the treatment of CFS. Because of the varying symptoms of CFS, the rejection asserts that there is not an art recognized definition of a therapeutic effect for CFS, and that the specification fails to enable the skilled artisan to determine whether any improvement was due to the administration of lymphocytes. See id. at 6-7.

The examiner notes that while “[t]he specification discloses treating six patients with autologous lymphocytes isolated from the patient’s lymph node and stimulated with antibody against CD3 and with IL-2,” the results varied between patients and not all of the patients demonstrated improvement. Id. at 4-5. In addition, the examiner, relying on Goldenberg, faults the data in the specification for not having a control, i.e., for failing to compare patients receiving the treatment method of the invention to patients receiving a placebo. See id. at 6-7.

The rejection concludes:

Applicants have not provided adequate guidance for one of skill to determine when a therapeutic effect has been obtained or whether the autologous lymphocytes administered to CFS patients are responsible for any of the observed effects (either positive or negative). Given the lack of a definition of a therapeutic effect for CFS in the specification and in the art at the time of filing, the heterogeneity in CFS and variability of symptoms of CFS over time, the art recognized need to compare CFS treatments to placebos taken with the data provided in the specification, it would require one of skill undue experimentation to determine how to use the cells or methods claimed to treat CFS.

Examiner’s Answer, pages 7-8.

Appellant argues that “the Examiner just plain does not believe the data,” and that the declaration of Dr. Klimas establishes that the specification provides

adequate guidance to allow one skilled in the art to practice the claimed invention. We agree.

The burden is on the examiner to set forth a prima facie case of unpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). “[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 35 U.S.C. 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 re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). “[It] 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.” Id. at 224, 169 USPQ at 370.

With respect to pharmaceutical inventions, the Court of Appeals for the Federal Circuit has stated:

On the basis of animal studies, and controlled testing in a limited number of humans (referred to as Phase I testing), the Food and Drug Administration may authorize Phase II clinical studies. See 21 U.S.C. § 355(i)(1); 5 C.F.R. § 312.23 (a)(5), (a)(8) (1994). Authorization for a Phase II study means that the drug may be administered to a larger number of humans, but still under strictly supervised conditions. The purpose of a Phase II study is to determine primarily the safety of the drug when administered to a larger human population, as well as its potential efficacy under

different dosage regimens. See 21 C.F.R. § 312.21(b). FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. . . . Usefulness in patent law, and in particular the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

In re Brana, 51 F.3d, 1560, 1568 34 USPQ2d 1436, 1442-43 (Fed. Cir. 1995)

(citations omitted).

In this case, the inventor has presented data from Phase I clinical studies in humans. See Klimas Declaration, Paper No. 5, ¶ 11. Moreover, as noted by the examiner, most of the patients demonstrated some type of improvement upon receiving treatment. See Examiner's Answer, page 5 ("Upon treatment, patients reported little improvement (page 12, line 1), modest improvement (page 14, line 3), marked improvement after one week, but only 50% showed improvement overall (page 16, line 3; page 18, line 2; page 20, line 3; page 22, line 3."). There is no need for the inventor to demonstrate that the treatment will be efficacious in every patient exhibiting CFS, i.e., a "magic bullet" for the treatment of CFS. See, e.g. Brana, 51 F.3d at 1568, 34 USPQ2d at 1442 ("We hold as we do because it is our firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value

in the treatment of humans.”). Thus, the examiner has not provided “acceptable evidence or reasoning which is inconsistent” with the specification that one of skill in the art would not be able to practice the claimed invention, and therefore has not met the initial burden of demonstrating nonenablement.

CONCLUSION

Because the examiner has failed to set forth a prima facie rejection that the specification fails to set forth an enabling disclosure, it is reversed.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
)	
Toni R. Scheiner)	APPEALS AND
Administrative Patent Judge)	
))INTERFERENCES
)	
)	
)	
Lora M. Green)	
Administrative Patent Judge)	

LG/dym

Jerry K. Mueller
Mueller and Smith
7700 Rivers Edge Drive
Columbus OH 43235

