

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte STUART A. LIPTON

Appeal No. 2001-1905
Application No. 08/245,827

ON BRIEF¹

Before ADAMS, MILLS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 11 and 13-15, which are all the claims pending in the application.

Claim 11 is illustrative of the subject matter on appeal and is reproduced below:

11. A method for treating a human patient to limit NMDA receptor-mediated injury to CNS neurons by providing a pharmacologically acceptable composition comprising glutathione and administering said composition to said patient in an amount sufficient to limit said neuronal injury.

¹ Pursuant to appellant's request (Paper No. 44, received July 6, 1999) an oral hearing for this appeal was scheduled for February 21, 2002. However, we note appellant waived (Paper No. 47, received January 15, 2002) the request for oral hearing. Accordingly, we considered this appeal on Brief.

The references relied upon by the examiner are:

BIOCHEMISTRY (Lehninger), pp. 795 (Lehninger ed., 2nd ed., Worth Publishers, Inc., N.Y., 1975)

Sucher et al. (Sucher), "Rapid Communication: Redox Modulatory Site of the NMDA Receptor-Channel Complex: Regulation by Oxidized Glutathione," J. Neuroscience Research, Vol. 30, pp. 582-591 (1991)

Jackowski, "Review Article: Neural injury repair: hope for the future as barriers to effective CNS regeneration become clearer," British J. Neurosurgery, Vol. 9, pp. 303-317 (1995)

GROUND OF REJECTION

Claims 11 and 13-15 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

We reverse.

DISCUSSION

To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). We note, however, that "nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

Whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The Answer addresses the Wands factors, however in our opinion, the examiner's rationale is merely a rambling accumulation of conclusions. Therefore, for the reasons discussed infra, we find that the examiner failed to meet his burden of establishing a prima facie case of non-enablement.

According to the examiner (Answer, page 4):

The sole description of the invention contemplating [the] use of glutathione consists of two sentences on page 8 of the specification:

"[a]pplicants [sic] have also discovered that both reduced and oxidized glutathione (0.5-10mM) can protect against toxicity mediated at NMDA receptors by a mechanism not related to the site of oxidation discussed above. Thus glutathione can be used in vivo or in vitro as

discussed in the application for those aspects which act to oxidize the NMDA receptor.”
[Alteration original].

With regard to the “state of the art,” the examiner finds (id.) that “neuronal injury results in neuronal cell death” and that according to Jackowski “CNS neurons do not regenerate.” However, as appellant points out (Reply Brief, bridging sentence, pages 9-10) regenerating dead neurons is irrelevant to the claimed methods. We agree. Therefore we are not persuaded by the examiner’s position (Answer, page 10) that the claimed invention encompasses regeneration. As appellant explains (Brief, page 10) “the present invention is not directed to regenerating dead neurons in the CNS; it is directed to limiting neuronal injuries, e.g., providing live neurons a better chance of surviving an insult.”

Addressing the “predictability of the art” the examiner concludes (Answer, pages 5-6) that since Lehninger teaches “glutathione is well known in the art to be already present in high concentrations (approximately 5mM) in all animal tissues ... the objective truth of being able to treat stroke with 0.5-10mM glutathione is questionable, because the human population still suffers from stroke.” However, as appellant points out (Brief, bridging sentence, pages 10-11) the examiner’s argument is flawed in that it does not take into consideration that the administration of glutathione according to the claimed invention will “involve raising the level of glutathione in vivo [sic].”

The examiner finds (Answer, page 6) that “[n]o assays are disclosed, nor is any guidance provided for determining when, or if, a patient is ‘effectively

treated' in vivo." The examiner, however, fails to address appellant's argument (Brief, page 6), with reference to page 7, lines 3-8 of the specification, that:

The specification provides adequate teaching and guidance regarding the medical conditions being treated. For example, the specification states that

Such patients will include those discussed above which are susceptible to, or suffer from, strokes, anoxia and certain degenerative diseases. They will also include those patients which have no symptoms but are found to have abnormally high levels of glutamate or related compounds in the CNS...

The examiner finds (Answer, page 6) that the in vitro examples provided in the specification "would not reasonably be extrapolated by the skilled artisan to knowing how to use glutathione to effectively treat any patient, as claimed in vivo..." However, we remind the examiner as set forth in In re Strahilevitz, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982), working examples are not required to satisfy section 112, first paragraph. Nevertheless, in support of his position, the examiner finds that "glutathione does not cross the blood brain barrier." See Answer, pages 6, 7 and 11. However, as appellant points out (Brief, page 12) the examiner's "assertion is entirely based on the [e]xaminer's own speculation and is not supported by any evidence and/or scientific reports." In relying on what they assert to be general knowledge to negate patentability examiner's must articulate that knowledge and place it of record. Failure to do so is not consistent with either effective administrative procedure or effective judicial review, examiners cannot rely on conclusory statements, but must set forth the rationale on which they rely. Cf. In re Lee, 277 F.3d 1338, 1343-1344, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002).

Furthermore, as appellant explains (Reply Brief, fn. 5) “[t]here are sound medical reasons that undercut the [e]xaminer’s assumptions. There is a specific uptake system for glutathione which renders general experience with charged amino acids irrelevant. Finally, during stroke, the blood brain barrier is somewhat disrupted, making experience with a healthy subject irrelevant.” The examiner provides no response to appellant’s argument.

Finally, the examiner finds (Answer, page 7), with reference to Sucher, “that ‘[e]xtracellular application of oxidized glutathione (GSSG), but not reduced glutathione (GSH), inhibited responses mediated by activation of the NMDA subtype of glutamate receptor in cultures of rat cortical and retinal ganglion cell neurons’...” [alteration original]. The examiner then contrasts this with the claimed invention finding (id.) that “the instant specification states that ‘[a]pplicants have also discovered that both reduced and oxidized glutathione ... can protect against toxicity mediated at NMDA receptors...’” [alteration original].

We are not persuaded by the examiner’s position. First, it appears that the examiner concedes that “oxidized glutathione” can be used according to the claimed invention. Further, as appellant points out (Brief, bridging paragraph, pages 11-12) “[i]t is generally believed that no matter which form of glutathione is administered to a patient, an equilibrium between the oxidized and the reduced forms of glutathione will be readily established in vivo [sic].” We note that appellant’s specification (bridging paragraph, pages 3-4) supports this position in that it discloses that “[u]seful agents need not be oxidizing agents in their own right, and include those agents which will be acted upon in vivo to produce

oxidizing agent at the in vivo site of the NMDA receptor....” The examiner provides no evidence to dispute this fact, and we find the examiner’s argument (Answer, page 12) that the claims do not recite the term “equilibrium” lacks merit.

On reflection, we are not persuaded by the examiner’s conclusions. Based on the foregoing discussion, we find that the examiner failed to meet his burden of establishing a prima facie case of non-enablement. Accordingly, we reverse the rejection of claim 11 and 13-15 under 35 U.S.C. § 112, first paragraph.

Having determined that the examiner has not established a prima facie case of obviousness, we find it unnecessary to discuss the Declaration evidence relied on by appellants to rebut any such prima facie case. Furthermore, we recommend the examiner review Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371, 52 USPQ2d 1129,1136 (Fed. Cir. 1999), wherein our appellate reviewing court provided a model analysis of enablement issues and illustrated

the type of fact finding which is needed before one is in a proper position to determine whether a given claim is enabled or non-enabled.

REVERSED

Donald E. Adams)	
Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
Demetra J. Mills)	
Administrative Patent Judge)	APPEALS AND
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