

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte BENJAMIN SREDNI, and MICHAEL ALBECK

Appeal No. 2001-0918
Application No. 08/758,106

ON BRIEF

Before WINTERS, ADAMS, and MILLS, 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 1 and 4-7, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal is set forth in the appendix to the appellants' brief. The examiner does not rely on prior art to support her rejection.

GROUND OF REJECTION

Claims 1 and 4-7 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure that is insufficient to support or enable the claimed invention.

We reverse.

DISCUSSION

According to the examiner (Answer, page 4), “[t]he successful treatment of alopecia or baldness is generally accepted in the art as being ‘incredible’.” With reference to In re Ferens, 417 F.2d 1072, 163 USPQ 609 (CCPA 1969) and In re Oberweger, 115 F.2d 826, 47 USPQ 445 (CCPA 1940), the examiner finds (Answer, bridging paragraph, pages 4-5), “[n]umerous methods and compositions, alleged to have the same usefulness as the instant invention, have proven in the past to be uniformly ineffective and unreliable.” Based on these unsupported assertions, the examiner finds (Answer, page 5):

The evidence in the instant specification is deemed inadequate to support the scope of the claims for the following reasons: 1) No correlation between the test performed [from which appellants’ data relates only to alopecia induced by chemotherapeutic agents] and treatment of male pattern baldness in patients has been demonstrated. 2) Treatment of disease has not been adequately demonstrated[, and] 3) The showing in the specification of a single tellurite compound is not deemed sufficient to support the scope of claims 1 and 4-7.

The examiner, however, fails to support her position with factual evidence. Instead, she relies on prior decisions (Ferens and Oberweger) dating back 23 years prior to appellants’ earliest effective filing date of August 13, 1992. In this regard, we remind the examiner that it is the facts appearing in the record, rather

than prior decisions in and of themselves, which must support the legal conclusion of whether the specification provides an enabling disclosure of the claimed invention. Cf. In re Cofer, 354 F.2d 664,667, 148 USPQ 268, 271 (CCPA 1966) (while the court in Coffer make this observation with regard to the question of obviousness under 35 U.S.C. § 103, in our opinion this principle is equally applicable to the question of enablement.).

As set forth In re Glass, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974), the sufficiency of appellants' disclosure under 35 U.S.C. § 112, first paragraph is judged as of its filing date. In this regard, our appellate reviewing court recognized that "[i]n view of the rapid advances in science, ... that what may be unpredictable at one point in time may become predictable at a later time." See Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1375, fn. 10, 52 USPQ2d 1129, 1138, fn. 10 (Fed. Cir. 1999). On this record, appellants appear to highlight this point, when they "asked the Examiner to take Official Notice that the product Rogaine was approved for the treatment of male pattern baldness by the Food and Drug Administration...." Brief, page 3. The examiner does not dispute, "minoxidil is accepted in the art as an effective treatment for baldness." Answer, page 8. Thus, this record has factually established that in the time period since the Ferens decision there is an effective treatment for baldness, minoxidil.

What has not been factually established on this record is why one of ordinary skill in the art would question appellants' presumptively accurate disclosure. 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, 188 F.3d at 1371-72, 52 USPQ2d at 1136. 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.

To assist the fact finder in meeting her initial burden our appellate reviewing court has outlined a number of factors that should be considered. As set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988), 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.

On this record, the examiner provides no analysis of the Wands factors. In addition, the examiner does not rely on any factual evidence to support her

position. Instead, we find only the examiner's unsupported conclusions, as to why the specification does not enable the claimed invention. In this regard, we emphasize as set forth in Marzocchi, 439 F.2d at 224, 169 USPQ at 370 that 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. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained her initial burden of establishing a prima facie case of non-enablement. Having found that the examiner failed to meet her burden of establishing a prima facie case of non-enablement, we do not consider the Sredni Declaration relied upon by appellants' to rebut any such prima facie case.

Since the examiner failed to adequately support her position with a fact-based reasoned analysis of the issue of enablement we are constrained to reverse the rejection of claims 1 and 4-7 under 35 U.S.C. § 112, first paragraph.

REVERSED

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

Appeal No. 2001-0918
Application No. 08/758,106

Page 7

JAMES V COSTIGAN
HEMAN GIBSON & COTIGAN
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-2601

DEA/jlb