

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 45

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GLENN D. BRAUNSTEIN and SONG-GUANG REN

Appeal No. 1998-2195
Application No. 08/277,241

HEARD: MARCH 22, 2001

Before, WILLIAM F. SMITH, SCHEINER, and GRIMES, Administrative Patent Judges.

GRIMES, 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 28, 30-32, and 34-37, all of the claims remaining in the application. Claim 28 is representative and reads as follows:

28. A method for evaluating inhibition of human chorionic gonadotropin (hCG) production of a subject's trophoblast cells comprising the steps of isolating a regulatory polypeptide
 - a) which inhibits, in a dose dependent manner, the production of hCG by human trophoblasts in vitro;

- b) which substantially inhibits the stimulation of hCG secretion by human trophoblasts caused by exogenous cyclic AMP in vitro;
- c) which does not substantially inhibit the production of human placental lactogen (hPL) by human trophoblasts in vitro; and
- d) which exhibits a molecular weight of about 7,000 to about 10,000 daltons, as determined by ultrafiltration and gel exclusion chromatography;

from human decidual cells of said subject; and quantifying the amount of the regulatory polypeptide produced in vitro by said subject's human decidual cells.

The examiner does not rely on any references.

Claims 28, 30-32, and 34-37 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled by the specification.

We reverse.

Background

Appellants' specification discloses a protein, referred to as decidual inhibitory protein (DIP), which inhibits production of human choriongonadotropin (hCG). Decreased hCG levels during pregnancy are associated with abnormal pregnancies and can result in spontaneous abortion. Specification, page 2. The specification states that DIP can be "measured in vivo or in vitro to diagnose the cause of hCG inhibition as an indication of potential miscarriage." Page 1.

Discussion

The examiner concedes that "[t]he specification has established that the protein of the claims (DIP) does indeed inhibit the secretion of hCG," and that "the specification provides enablement for a bioassay for the measurement of

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DIP.” Answer, page 4. The examiner nonetheless the claimed method as non-enabled because

Appellants have failed to establish a direct correlation between the levels of DIP production and the levels of hCG production. Further, the instant specification does not provide a value or range of values for DIP concentrations against which a practitioner could compare a sample value and thereby achieve some meaningful result.

Answer, page 17. Thus, the examiner’s position is that the specification enables those skilled in the art to carry out the physical steps of the claimed method— isolating and quantifying the DIP produced by a subject’s decidual cells—but the results of the method would not allow the skilled artisan to evaluate hCG inhibition because the specification does not correlate a given level of DIP production to a given level of hCG inhibition.

Appellants argue that the examiner has not met her burden of showing, by evidence or scientific reasoning, that the specification is not enabling. In particular, Appellants argue that

[s]ince it is disclosed that DIP controls trophoblast hCG production by inhibiting production in a dose dependent manner, (See Figs. 4 and 5), clinicians can measure the quantity or concentration of DIP and evaluate whether they are within a normal range under the circumstances. The importance of the test is that by measuring the level or concentration of DIP, the clinician will know if the trophoblast cells are receiving the “right signal” from the decidua regarding the level of hCG the trophoblast cells should be producing.

Appeal Brief, page 25.

Appellants also argue that it was routine in the art to measure the levels of effector substances to evaluate the functional state of hormone producing tissues. This has been done despite the individual variability in hormone and effector substance

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concentration, and [despite the fact] that “exact mathematical relationships” are not known between any hormone and its regulatory peptide.

Appeal Brief, page 30. Appellants have provided an excerpt from a laboratory medicine textbook to support their assertions concerning the state of the art.

The examiner bears the burden of establishing that the claimed invention is not enabled by the specification. See 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.

See also In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971):

[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 this case, we conclude that the examiner has not met her burden of providing acceptable evidence or reasoning to establish that the claimed method is not enabled by the specification. It is true, as the examiner points out, that the specification does not disclose a normal range of DIP levels. Thus, those skilled in the art would have been required to perform some experimentation, in order to

determine what range of DIP levels are normal, and what (elevated) levels correlate to inhibition of hCG production and consequent risk in pregnancy.

However, the examiner has conceded that the specification provides a bioassay to measure DIP and that DIP inhibits hCG production. Answer, page 4. We also note that Appellants have previously been granted a patent on DIP itself, the claim defining DIP in part by its dose-dependent inhibition of hCG. See claim 1 of U.S. Patent 5,140,100.¹

Based on these uncontested facts, a person of ordinary skill in the art would reasonably expect that a higher level of DIP would generally correlate to a lower level of hCG. Appellants have submitted evidence that diagnostic tests for other hormones are based on similar relationships with those hormones' effector substances. See Noe et al., *The Logic of Laboratory Medicine* (1985), pages 158-162, cited in Appellants' Brief. Thus, based on the evidence that similar assays are accepted in the art as diagnostic and the high level of skill in the art, we conclude that determining of the normal range of DIP levels would not have required more than routine experimentation.

"Enablement . . . is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1987) (citations omitted). "The key word is 'undue,'

¹ Claim 1 of the '100 patent reads: "A substance having an inhibitory effect on the production of human chorionic gonadotropin (hCG) comprising a regulatory polypeptide being characterized in that it: (a) inhibits, in a dose dependent manner, the production of hCG by human trophoblasts in vitro . . .".

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not ‘experimentation.’” In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). The record does not establish that practicing the claimed method would have required undue experimentation. Since it is the examiner’s burden to show nonenablement and that burden has not been carried here, we reverse the rejection under 35 U.S.C. § 112, first paragraph.

Summary

We reverse the rejection for non-enablement because the examiner has not shown, by convincing evidence or scientific reasoning, that those skilled in the art would have had to carry out an undue amount of experimentation in order to practice the claimed method.

REVERSED

WILLIAM F. SMITH)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
TONI R. SCHEINER)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
ERIC GRIMES)	
Administrative Patent Judge)	

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LYON & LYON
633 WEST FIFTH STREET, SUITE 4700
LOS ANGELES, CA 90071-2066

EG/jlb