

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 28

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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Ex parte JOACHIM GANTE,  
HORST JURASZYK,  
PETER RADDATZ,  
HANNES WURZIGER,  
SABINE BERNOTAT-DANIELOWSKI, and  
GUIDO MELZER

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Appeal No. 2000-0600  
Application No. 08/642,268

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ON BRIEF<sup>1</sup>

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Before WILLIAM F. SMITH, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

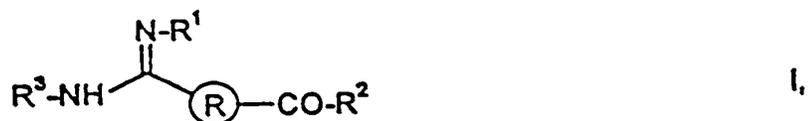
This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 2, 5-11, and 13-19. The examiner has indicated that claim 3, the only other pending claim, is allowed. See Final Office Action, page 3.

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<sup>1</sup> We recognize appellants' request for an oral hearing (Paper No. 23, received June 23, 1999). However, in accordance with 37 CFR §1.194(c), the Board decided that an oral hearing was not necessary in this appeal.

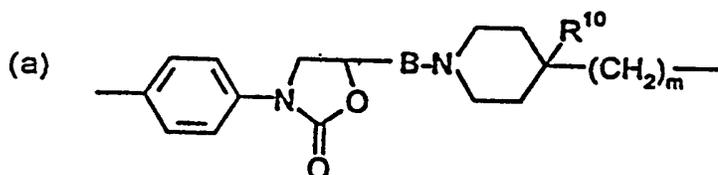
Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A compound of the formula I

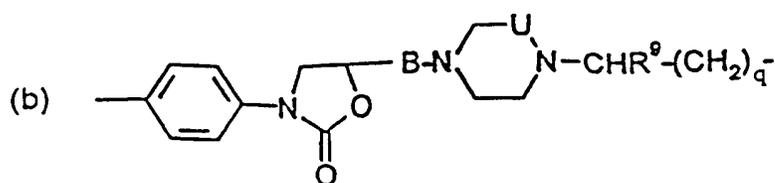


in which

R is



with B = CH<sub>2</sub>, CO or CS, R<sup>10</sup> = OH or H and  
m = 0, 1, 2, 3 or 4; or



with B = CH<sub>2</sub>, CO or CS, U = CH<sub>2</sub> or CO and  
R<sup>9</sup> = H, CO<sub>2</sub>H or CO<sub>2</sub>A, and q = 0, 1, 2 or 3

R<sup>1</sup> is H, A, Ar-CO, A-CO, OH, OA or AO-CO;

R<sup>2</sup> is OH, OA, OAr, OHet, NHOH, NH<sub>2</sub>, NHA or NA<sub>2</sub>;

R<sup>3</sup> is A-CO, Ar-CO, Het-CO, Het-O-CO, Ar-O-CO, A-O-CO, Ar-SO<sub>2</sub> or A-SO<sub>2</sub>;

A is alkyl with 1 to 6 C atoms;

Ar is aryl of 6 to 10 C atoms, or diphenylmethyl or benzyl which are unsubstituted or substituted once, twice or three times by A, F, Cl, Br, I, OA, -O-CH<sub>2</sub>-O-, COOA, COOH, CF<sub>3</sub>, OH, NO<sub>2</sub>, CN, NH<sub>2</sub>, O-CO-A, NHA or NA<sub>2</sub>; and

Het is a mono- or binuclear saturated, unsaturated or aromatic heterocycle with 1 to 4 N, O and/or S atoms, which can be unsubstituted or substituted once by F, Cl, Br, CF<sub>3</sub>, A, OH, OA, CN or NO<sub>2</sub>, and their physiologically acceptable salts and solvates.

The examiner does not rely on prior art.

### GROUND OF REJECTION

Claims 1, 2, 5-11, and 13-19 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a specification that fails to enable the subject matter of the claimed invention.

Claims 7-11 and 18-19 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a specification that fails to enable the use of the subject matter of the claimed invention.

Claims 1, 2, 5-11, and 13-19 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter of the claimed invention.

Claims 7-11 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter of the claimed invention.

We reverse.

## DISCUSSION

### THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

#### Claims 1, 2, 5-11, and 13-19:

The examiner finds (Answer, page 5) appellants “provide no reasonable assurance that [the] piperazin,[ ]piperidino species having ‘het’ at R2 and/or R3 will all share the requisite profile of activity needed to be operative for practicing the invention.” According to the examiner (id.) while certain in vitro tests are disclosed on pages 4-5 of the specification it has “not been shown if a variety of hetero rings at R2,[ ]R3 have been tested or just one or two of the working examples directed to a much narrower scope- ie.[ ]piperidino,[ ]pyridyl,[ ]thienyl and furyl in the R3 group.”

We note that the examiner provides no evidence to support her position, instead, the examiner simply concludes that the specification is not sufficient to support the claimed invention. With reference to In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971), appellants argue (Brief, page 6) “that the burden of proof on this issue has been prematurely shifted to [a]ppellants.” We agree with appellants.

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.

We find no analysis of the Wands factors by the examiner. Instead, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Marzocchi, 439 F.2d at 223, 169 USPQ at 369. 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. As set forth by appellants' (Brief, page 7):

A disclosure which contains representative examples which provide reasonable assurance to one of ordinary skill in the art that the compounds falling within the scope of the claim can be made and possess utility is all that is required, absent any reasons given as to why the statements made in the specification are not accurate.

We agree. The burden of proof does not shift to appellant until the examiner first meets her burden. Marzocchi, 439 F.2d at 223-224, 169 USPQ at 369-370. On this record, the examiner has not met her burden.

Accordingly, we reverse the examiner's rejection of claims 1, 2, 5-11, and 13-19 under 35 U.S.C. § 112, first paragraph.

Claims 7-11 and 18-19:

According to the examiner (Answer, page 5) the "[s]pecification does not adequately teach one 'how to use' the instant compounds for all disorders apparently embraced by the method claims." The examiner finds (Answer, page 5)

that the specification makes reference to a number of disorders, including, “(but ... not limited to) thromboses, [ ] osteolytic disorders, kidney failure [and] antitumor agents.” However, the examiner finds (Answer, pages 5-6) that the “nature of testing relied on in the specification does not appear to be art-recognized for treating all such disorders.” In this regard, the examiner makes reference (Answer, page 6) to two prior art references – Muller and Smith. However, as set forth on page 3 of the Answer, “[n]o prior art is relied upon by the examiner in the rejection of the claims under appeal.” As set forth in In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970) (“[w]here a reference is relied on to support a rejection, whether or not in a ‘minor capacity,’ there would appear to be no excuse for not positively including the reference in the statement of the rejection”).

Accordingly, the examiner’s reliance on Muller and Smith is in error.

Notwithstanding the examiner’s error, appellants responded to the examiner’s argument (Reply Brief, page 4), therefore, we will consider the references to the extent that the examiner and appellants have relied on them. For emphasis, the following quote reproduces in full the examiner’s position relative to the cited references (Answer, page 6), “[a]t best, [ ] Muller, provided in an earlier action, suggests a correlation exists for the treatment of thrombosis-see second [to the] last paragraph on p. [ ] 113. Note also Smith cited in the specification, [ ] p. [ ] 4, for an example of a ligand binding assay that can be used does not make such assertions. See page 12270.”

While we find the examiner’s point less than clear, we find appellants’ response compelling. According to appellants’ (Reply Brief, page 4):

The [e]xaminer's Answer alleges that the assays disclosed in the specification and the examples in the art of record (e.g., Muller) are only art-recognized for, at best, the treatment of platelet aggregation and thrombosis (as is recited, e.g., in claim 8). However, the [e]xaminer has provided no reasons to cast doubt on appellants' assertion that these models are, in fact, suitable for determining how to treat the diseases encompassed by the claims (e.g., thromboses, osteolytic disorders, kidney failure, tumors). As was discussed in the Appeal Brief, the burden lies with the [e]xaminer to provide evidence which raises doubt about what applicants have disclosed as to the utility of the invention (In re Marzochi et al.), and in the absence of such evidence, the rejection cannot be maintained.

Here again we find no analysis of the Wands factors by the examiner. Instead, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. As set forth above, 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. We recognize appellants' argument (Brief, page 7):

Again, the [e]xaminer appears to set forth an initial burden upon [a]ppellants to provide tests as to the applicability of the compounds to many of the several embodiments of the claims. Appellants urge that such burden is unfounded in the absence of reasons for doubting the objective truth of the statements in the specification on how to conduct the methods, explanations why the truth or accuracy of such statements are doubted and acceptable evidence or reasoning to back up the assertions that such statements are insufficient."

We again remind the examiner that the burden of proof does not shift to appellant until the examiner first meets her burden. Marzocchi, 439 F.2d at 223-224, 169 USPQ at 369-370. In our opinion, the examiner has not met her burden on this record.

Having determined that the examiner has not met her burden of established a prima facie case of non-enablement, we find it unnecessary to discuss the Melzer Declaration, relied on by appellants to rebut any such prima facie case.

Accordingly, we reverse the rejection of claims 7-11 and 18-19 under 35 U.S.C. § 112, first paragraph.

THE REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:

The legal standard for indefiniteness under 35 U.S.C § 112, second paragraph, is whether a claim reasonable apprises those of skill in the art of its scope. See, Amgen Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991).

Claims 1, 2, 5-11, and 13-19:

According to the examiner (Answer, page 3) the “[s]cope of ‘solvates’ as recited in ... [the] claims is unknown.” The examiner finds (id.) “[g]enerally not all solvents can form solvates with all compounds ... [and] it is not routine for any and every type of solvent for form solvate(s) with specific compounds.” According to the examiner (Answer, page 4) “[i]n the absence of any guidance in the specification ... or in any relevant prior art,[ ]one cannot readily determine what is and what is not within the instant scope of solvates.”

In response, appellants argue (Brief, page 3) “[t]hat all solvents cannot form solvates with all compounds is not seen to be relevant herein. The relevant inquiry is whether it would be known to one of ordinary skill in the art what solvents form physiologically acceptable solvates with the compounds of formula I.” In this regard, appellants argue (Brief, page 4), with reference to Hybritech Inc. v. Monoclonal

Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986), “the selection of useful solvents and formation of solvates is highly routine in this art. Appellants need not provide in their specification a description of matter which is common and routine in the art. A ‘patent need not teach, and preferably omits, what is well known in the art.’” According to appellants’ (Reply Brief, page 2) “[b]ecause selection of the appropriate solvents for forming solvates was routine to one of ordinary skill in the art, the metes and bounds of the term were reasonably determinable using only ordinary skill in the art.” We agree.

Accordingly, we reverse the rejection of claims 1, 2, 5-11, and 13-19 under 35 U.S.C. § 112, second paragraph.

Claims 7-11:

According to the examiner (Answer, page 4) the “[s]cope of method claims 7-11 is unknown as no particular disorder is recited in these claims only a mechanism of action, namely diseases ‘associated with undesirable integrin binding’.” The examiner finds (id.) the “claim language is of indeterminate scope since it may read on diseases that are affected by integrin binding ... in ways not yet understood.”

In response, appellants argue (Reply Brief, page 3) “[w]hile it is possible that there may be disease conditions caused by undesirable integrin binding which cannot be treated successfully by the compounds of the invention, the existence of a few inoperable embodiments does not render the invention non-enabled or of indeterminate scope.” We agree. Cf. Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. “It is not a function of the claims to specifically exclude ... possible inoperative substances....” In re Dinh-Nguyen, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

On this record, the examiner failed to provide evidence demonstrating that the number of inoperative combinations is significant enough to force one of ordinary skill in the art to experiment unduly in order to practice the claimed invention.

The examiner also finds (Answer, pages 4-5) “[t]he level of undesirable integrin binding is not synonymous with doses of specific drugs needed for administration to treat a specific disease but rather the underlying physiological contributing factor that may lead to one or more diseases that is present in the host and this quantity is never defined.” In response appellants argue (Reply Brief, page 3) that “one of skill in the art would know that ‘undesired integrin binding’ is an amount of binding which results in disease symptoms, e.g., the disease recited in the specification, so the term is not indefinite.” We agree.

Furthermore, appellants argue (Brief, page 4) that “the ‘effective’ amount of an agent required to inhibit an integrin is the amount of the agent which, in fact, does inhibit the interaction of an integrin with its receptor and/or ligand. Since the amount which provides such activity can be readily determine by one of ordinary skill in the art, the meaning of ‘effective amount’ is known.” Again, we agree with appellants.

On reflection, we find that the examiner failed to meet her burden of establishing that the claims are indefinite. Accordingly, we reverse the examiner's rejection of claims 7-11 under 35 U.S.C. § 112, second paragraph.

REVERSED

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

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