

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DENNIS P. RILEY, RANDY H. WEISS, WILLIAM L. NEUMANN, ANIL S. MODAK,
PATRICK J. LENNON and KARL W. ASTON

Appeal No. 95-1083
Application No. 08/004,444¹

ON BRIEF

Before SOFOCLEOUS, WILLIAM F. SMITH, and ROBINSON, Administrative Patent
Judges.

ROBINSON, 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 1-3, 6-8, and 12. Claims 4, 5, and 9-11 stand withdrawn from consideration by the examiner as being directed to the non-elected invention and are not presented on appeal.

¹ Application for patent filed January 14, 1993.

Appeal No. 95-1083
Application No. 08/004,444

Claims 1-3, 6-8, and 12 stands rejected under 35 U.S.C. § 101, as lacking demonstrated utility.

Claims 1-3, 6-8, and 12 stands rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure.

Claims 1-3, 6-8, and 12 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Kimura, Fujioka, Kimura (O), Kimura (E), Weiss, Petkau, and Fretland.

We reverse.

BACKGROUND

The applicants' invention, as described at pages 2 and 40-41 of the specification, is directed to manganese (II) or manganese (III) complexes of nitrogen containing sixteen-member macrocyclic ligands which catalyze the conversion of superoxide into oxygen and hydrogen peroxide and are characterized by their ability to mimic superoxide dismutase. These complexes are stated to be useful in the treatment of numerous inflammatory disease states and related disorders, including reperfusion injury due to ischemia, inflammatory bowel disease, rheumatoid arthritis, osteoarthritis, and hypertension.

Discussion:

The Rejection under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Our appellate reviewing court recently stated in Fujikawa v. Watanasin, 93 F.3d 1559, 1563, 39 USPQ2d 1895, 1898-99 (Fed. Cir. 1996):

Appeal No. 95-1083
Application No. 08/004,444

For over 200 years, the concept of utility has occupied a central role in our patent system. See Brenner v. Manson, 383 U.S. 519, 529, 148 USPQ 689, 693 (1966). Indeed, “[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.” Id. at 534, 148 USPQ at 695. Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed. See Cross v. Iizuka, 753 F.2d 1040, 1044, 224 USPQ 739, 742 (Fed. Cir. 1985).

It was stated in Genentech Inc. v. Nova Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1995):

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.)

Whether an issue of utility is raised under 35 U.S.C. § 101 or § 112, first paragraph, the initial burden is on the Patent and Trademark Office to establish reasons why one skilled in the art would not believe the objected statements of utility and/or enablement in the specification. In re Brana 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974); In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

In setting forth the basis of the rejection under 35 U.S.C. § 101, the examiner states (Answer, page 4):

[O]ne of ordinary skill would not accept the claimed utility of treating and preventing inflammatory bowel disease, or any of the other disclosed diseases including cancer, in a host in the absence of adequate evidence in support of the same.

Appeal No. 95-1083
Application No. 08/004,444

In setting forth the basis of the rejection under 35 U.S.C. § 112, first paragraph, the examiner states (Answer, page 5):

The disclosure lacks sufficient exemplary matter to allow one of ordinary skill in the art to carry out the claimed invention without undue experimentation.

On the record before us, we find that the examiner's statements, in support of these rejections, fall short of the requirement set forth above and fail to provide adequate evidence or reasons why one skilled in the art would doubt the statements relating to the stated utility or the manner of using the claim designated manganese complexes.

The appellants attribute the usefulness of the claim designated manganese complexes to their ability to catalytically dismutate superoxide. At page 41 of the specification appellants state:

Activity of the compounds or complexes of the present invention for catalyzing the dismutation of the superoxide can be demonstrated using the stopped-flow kinetic analysis technique as described in Riley, D.P., Rivers, W.J. and Weiss, R.H., "Stopped Flow Kinetic Analysis for Monitoring Superoxide Decay in Aqueous Systems," *Anal. Biochem.*, 196, 344-349 (1991), which is incorporated by reference herein. Stopped-flow kinetic analysis is an accurate and direct method for quantitatively monitoring the decay rates of superoxide in water. The stopped-flow kinetic analysis is suitable for screening compounds for SOD activity and activity of the compounds or complexes of the present invention, as shown by stopped-

Appeal No. 95-1083
Application No. 08/004,444

flow analysis, correlate to treating the above disease states and disorders.
(Emphasis added).

Example 2, at page 50 of the specification, specifically exemplifies the use of the stopped-flow analysis to demonstrate that the manganese (II) complex of Example 1 is an effective catalyst for the dismutation of superoxide. The examiner has addressed the use of the stopped-flow analysis test by concluding (Answer, pages 4 and 5) that: "the in vitro stopped flow kinetic analysis assay have been considered but are not deemed persuasive since the same assay is not deemed predictive of utility in the treatment or prevention of inflammatory bowel disease, or any of the other diseases encompassed by the claims, in the absence of evidence in support of the same." The examiner's response fails to provide any facts or evidence to support this conclusion that the results from "stopped flow kinetic analysis" would not correlate to the treatment of the disclosed disease states and disorders.

As explained in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996):

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g. In re Goodman, 11 F.3d 1046, 1050-52, 29

Appeal No. 95-1083
Application No. 08/004,444

USPQ2d 2010, 2013-2015 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co., v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. Ex parte Jackson, 217 USPQ 804, 807 (Bd. App. 1982).

To the extent that we understand the examiner's position in these rejections, it is clear that the examiner has failed to make any of the findings which must be made before a conclusion of "lack of utility" or "lack of enablement" may be properly reached.

The examiner bears the initial burden of providing reasons for doubting the objective truth of the statements made by applicant as to the scope of enablement. In re Marzocchi, 439 F.2d 220 at 223-24, 169 USPQ at 369-70 (CCPA 1971). On the record before us, we conclude that the examiner has not established a reasonable basis for

Appeal No. 95-1083
Application No. 08/004,444

questioning the sufficiency of the supporting specification as it relates to utility or how to use the claimed invention.

While not considered as evidence in our consideration of these rejections, we note that U. S. Patents 5,637,578 and 5,874, 421 have issued to appellants since the filing of this appeal. These patents disclose and claim very closely related manganese complexes, pharmaceutical compositions and uses, as well as process of making such complexes, where the disclosed utility is the same as in the instant case.

The rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph are reversed.

The Rejection under 35 U.S.C. § 103

Claims 1-3, 6-8, and 12 stand rejected under 35 U.S.C. § 103 as obvious over Kimura, Fujioka, Kimura (O) and Kimura (E) in view of Weiss, Petkau and Fretland.³

The examiner cites Kimura, Fujioka, Kimura(O) and Kumura(E) as teaching "that compounds substantially similar to those claimed herein are known in the art." (Answer, page 6). In addition, the Kimura (O) and Kimura (E) are relied on as teaching "that the superoxide dismutase activity of substantially similar compounds is known in the art."

³ At page 7 of the Examiner's Answer the examiner discusses Bannister et al. The reliance on this reference was specifically withdrawn in the Office action of February 1, 1994 (Paper No. 8). Therefore we have not considered this reference in consideration of the rejection before us.

Appeal No. 95-1083
Application No. 08/004,444

(Answer, page 6). Weiss, Petkau and Fretland are relied on as teaching "that superoxide dismutase related compounds similar to those of the primary references are known in the art for treatment of inflammatory bowel diseases" (Answer, page 7). The examiner concludes (Answer, page 7):

One having ordinary skill in the art would have been motivated, absent evidence to the contrary, to employ the claimed compound in methods and compositions for the treatment and/or prevention of

inflammatory bowel disease since it is an inflammatory condition and since substantially related compounds were known in the art for their superoxide dismutase related activity, which activity was known to be useful in the treatment of inflammatory bowel disease.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. Id. The burden is on the examiner to provide a reason, based on the prior art, or knowledge generally available in the art as to why it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297, n.24, 227 USPQ 657, 667, n.24 (Fed. Cir. 1985). If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988).

Appeal No. 95-1083
Application No. 08/004,444

On the record before us, the examiner has not met the initial burden of establishing why it would have been obvious to those of ordinary skill in the art to substitute a manganese complex of the appealed claims for those compounds disclosed by the references relied on. As pointed out by appellants (principal brief, pages 10-11), none of the primary references disclose the specific manganese

complexes of the claims. The examiner takes the position that (Answer, page 8):

Manganese is a well known transition metal and therefore the instant compounds would be expected to possess activity complexed with Manganese as well as any other transition metal, absent evidence to the contrary.

However, appellants point to Kimura (O) and Kimura (E) as evidencing the unpredictability associated with the use of different transition metal in such complexes. (Brief, page 11). Specifically, Kimura (E), at page 177, first column, discloses that activity is unpredictable where the transition metal is selected between Cu(II) and Ni(II). The Cu complex is shown to be active and the Ni complex is inactive. This evidence reasonably appears to suggest that one of ordinary skilled in this art would not necessarily expect other transition metals, so complexed, to be similarly active. As further evidence of unpredictability, the appellants cite EP 524 161 A1 as disclosing 17 similar compounds closely related to the claim designated compounds which have no detectable superoxide

Appeal No. 95-1083
Application No. 08/004,444

dismutase activity. The examiner (Answer, page 9) found the evidence not persuasive "since the superoxide dismutase activity of the instant compounds is clearly suggested by the prior art as discussed ". However, the examiner has pointed to no manganese complex of nitrogen containing sixteen-member macrocyclic ligands, within the scope of the claimed subject matter, which have superoxide dismutase activity. In addition, the examiner has offered no facts or evidence to rebut the evidence, presented by the appellants, as to the unpredictability of substituting one transition metal for another in this type of complex. Thus, on the

record before us, we find that the examiner has failed to present facts or evidence which would support a prima facie case of unpatentability of the claimed subject matter.

The rejection of claims 1-3, 5-8, and 12 under 35 U.S.C. § 103 is reversed.

SUMMARY

To summarize, the decision of the examiner to reject claims 1-3, 5-8 and 12 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph is reversed. The rejection of claims 1-3, 6-8, and 12 under 35 U.S.C. § 103 is reversed.

REVERSED

Appeal No. 95-1083
Application No. 08/004,444

MICHAEL SOFOCLEOUS)	
Administrative Patent Judge)	
)	
)	
)	
WILLIAM F. SMITH)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
)	
)	
DOUGLAS W. ROBINSON))	
Administrative Patent Judge)	

Appeal No. 95-1083
Application No. 08/004,444

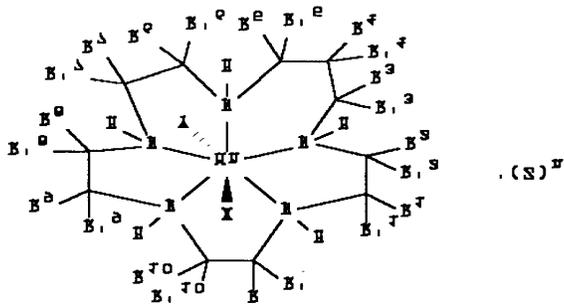
Michael J. Roth
G. D. Searle & Co.
P. O. Box 5110
Chicago, IL 60680-5110

DSR/ki

APPENDIX

1

μρεν τρε νιτκοδεν σουτσηνιτνδ μεφεκοσλσρε ιε αυ ατοωαριε
 σουτσηνιτνδ μεφεκοσλσρε μαλιτνδ 5 φο 50 σαιρου ατοωα βιολιφωφ τμαφ
 ατοωα φο μητισμ τμελ ατε ατφσμεφ ιυφεβουφουττλ ιοικω α νιτκοδεν
 οκ Κ, 8 αυφ Κ^δ οκ Κ, ^δ αυφ Κ¹⁰ οκ Κ, ¹⁰ φοδεφμετ μιτμ τρε σαιρου
 Κ^φ οκ Κ, ^φ Κ^φ οκ Κ, ^φ οκ Κ² οκ Κ, ² αυφ Κ^ε οκ Κ, ^ε Κ^λ οκ Κ, ^λ αυφ Κ⁸
 50 σαιρου ατοωα! Κ οκ Κ, αυφ Κ^τ οκ Κ, ^τ Κ⁵ οκ Κ, ⁵ αυφ Κ³ οκ Κ, ³ οκ
 ατφνικαφωφ, βατφτσηττλ ατφνικαφωφ οκ λυαατφνικαφωφ αλσριε μαλιτνδ 3 φο
 τρε σαιρου ατοωα φο μητισμ τμελ ατε ατφσμεφ ιυφεβουφουττλ ιοικω α
 Κ⁸ οκ Κ, ⁸ αυφ Κ^δ οκ Κ, ^δ αυφ Κ¹⁰ οκ Κ, ¹⁰ αυφ Κ οκ Κ, φοδεφμετ μιτμ
 αυφ Κ² οκ Κ, ² Κ^φ οκ Κ, ^φ αυφ Κ² οκ Κ, ² Κ^ε οκ Κ, ^ε αυφ Κ^λ οκ Κ, ^λ
 ασιφωφ! Κ^τ οκ Κ, ^τ αυφ Κ⁵ οκ Κ, ⁵ Κ³ οκ Κ, ³ αυφ Κ^φ οκ Κ, ^φ Κ³ οκ Κ, ³
 ασιφωφ οκ ιαφισαρε ατφσμεφ φο τρε α-σαιρου οκ β-σαιρου οφ β-αμτιο
 αικηττλ ιαφισαρε αυφ ιαφισαρε ατφσμεφ φο τρε α-σαιρου οφ α-αμτιο
 αττενιτσλσριεττλ, αττενιτσλσριεττλ, μεφεκοσλσριε, αττλ αυφ
 αλσριεττλ, αττενιτσλσριεττλ, αττενιτσλσριεττλ, αττενιτσλσριεττλ,
 αλσριεττλ, αλσριεττλ, αλσριεττλ, αλσριεττλ, αλσριεττλ,
 ιεβρεαεωφ μλατοδεν, αττενιτσλσριεττλ, αττενιτσλσριεττλ, αλσριεττλ,
 Κ, ^ε Κ, ^λ Κ, ^λ Κ⁸, Κ, ⁸ Κ^δ, Κ, ^δ Κ¹⁰ αυφ Κ, ¹⁰ ιυφεβουφουττλ
 μρετετμ Κ, ^ε Κ, ^λ Κ^τ, Κ, ^τ Κ⁵, Κ, ⁵ Κ³, Κ, ³ Κ^φ, Κ, ^φ Κ², Κ, ² Κ^ε,



ιοικωσιε:
 βιοβηλιεσφισαριεττλ ειτεσφισαριε αωονυφ οφ α σωβητεχ ιεβρεαεωφ ρλ τρε
 ιοκ ατσηνιτσλσριεττλ αττενιτσλσριεττλ αττενιτσλσριεττλ αττενιτσλσριεττλ οκ
 τ. βηατσηνιτσλσριεττλ αττενιτσλσριεττλ ιυ λυιτ φωσδε ιοικω ηαεττλ

