

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(2) is not binding precedent of the Board.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. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte MILTON P. CHARLTON and MICHAEL TYMIANSKI

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Appeal No. 94-2504  
Application 07/963,676<sup>1</sup>

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ON BRIEF

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Before WILLIAM F. SMITH, METZ, and GRON, Administrative Patent Judges.

GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

This is an appeal from an examiner's final rejection of  
Claims 1 and 11-16 under 35 U.S.C. § 112, first paragraph.

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<sup>1</sup> Application for patent filed October 20, 1992.

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Claims 1, 3, and 5-25 are pending in this application.

1. History of prosecution

A. In a first office action mailed December 7, 1992

(Paper

No. 3), the examiner required the following restriction under

35 U.S.C. § 121:

The claims are drawn to compounds that find themselves classed in various and numerous parts of class 514.

Accordingly, selection of a specific invention as defined by a specific compound is required.

The several inventions are clearly independent and distinct due to separate search, status, consideration and/or classification. Further, a reference to one invention under 35 U.S.C. § 103 would not be a reference to the others.

Applicant is required to elect one of the above, even though such be traversed, 37 C.F.R. 1.143.

It is not within the Board's jurisdiction to review the propriety of restriction requirements under 35 U.S.C. § 121.

In re Watkinson, 900 F.2d 230, 233, 14 USPQ2d 1407, 1409 (Fed. Cir. 1990). Nevertheless, we cannot help but notice that Claims 1-16 which were pending in this application at the time the restriction requirement was imposed were, as originally filed, directed to "a method of reducing the damaging effect

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of an injury to cells in mammalian tissue in vivo and treatment of epilepsy," not "to compounds" as the examiner indicated. Moreover, as filed, Claims 2-16 were all dependent upon Claim 1 which generically defined the treating agent as "a cell membrane permeant calcium buffer." Needless to say, our attempts to comprehend the examiner's restriction requirement have been unsuccessful.

In response to the restriction requirement (Paper No. 4, filed January 6, 1993), applicants interpreted the examiner's restriction requirement as requiring restriction between (I) method Claims 1-16, (II) method Claims 23-25, (III) compound Claims 17-21, and (IV) composition Claim 22, and an election of a species of buffer. Accordingly, applicants elected the method of Claim 10 and BAPTA-AM as the species of buffer.

In a second office action mailed February 5, 1993 (Paper No. 6), the examiner withdrew Claims 2-9 and 17-25 from consideration without explanation and indicated that Claims 1 and 10-16 would be examined. The examiner then summarily rejected Claims 1 and 10-16 as follows (Paper No. 6, p. 2):

Claims 1 and 10-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims should all relate to the host of the tissue and not as claimed.

Claims 1 and 11-16 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited in accord with the entire disclosure. See M.P.E.P. §§ 706.03(n) and 703.03(z).

"A cell membrane permeant calcium buffer" is broader than the specific supporting disclosure. It is also broader than the elected invention.

In response to these rejections (Paper No. 7, filed May 5, 1993), applicants canceled Claims 2 and 4 and amended Claim 1 to specify the "host" and to further define the "calcium buffer" as a chelating agent having a  $K_D$  within a designated range.

In the **FINAL** office action mailed May 13, 1993 (Paper No. 8), the examiner responded to applicants' amendment and arguments as follows:

Claims 1 and 10-16 remain examined.

Claims 1 and 11-16 remain rejected for the reasons of record under 35 U.S.C. 112, 1st paragraph.

The rejected phrase remains too broad and such is broader than the elected invention.

**THIS ACTION IS MADE FINAL.**

Appellants filed **NOTICE OF APPEAL** August 13, 1993.

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Apparently, Claim 10 was considered allowable in independent form, and Claims 3, 5-9 and 17-25 stood withdrawn from consideration by the examiner.

2. Introduction

Claims 1 and 11-16 stand finally rejected under 35 U.S.C.

§ 112, first paragraph, because the phrase "'cell membrane permeant calcium buffer' is broader than the specific supporting disclosure . . . [and] also broader than the elected invention" (Paper No. 6, page 2). All claims on appeal stand or fall (Appeal Brief (Br.), p. 3) with independent Claim 1. Claim 1 on appeal reads:

1. A method of reducing the damaging effect of an injury to cells in mammalian tissue of a host in vivo and treatment of epilepsy, said method comprising treating a host in need of such treatment with a non-toxic, damage-reducing effective amount of a cell membrane permeant calcium buffer which is a calcium ion chelating agent having a  $K_D$  selected from the range  $1 \times 10^{-4}$  to  $1 \times 10^{-8}$  Molar.

Appellants argued in their Appeal Brief (Br.) that the examiner had not adequately considered the specificity with which the "calcium buffer" utilized in the method claimed is described

(Br. 5-6, bridging para.) and submitted the Declarations of

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Daniel Alkon (Alkon) and George J. Augustine (Augustine) to support their view that the claim defines "a well-defined class of materials to those in the art and, with the disclosure given . . . the invention could be practised [sic] without difficulty using any such material as defined" (Alkon, p. 3, para. 6; Augustine, p. 3, para. 6).

In the Examiner's Answer (Ans., pp. 3-4), the examiner explained what he had meant by "broader than the specific supporting disclosure" in the first and **FINAL** office actions:

The claims do not structurally define the compounds to be used and the  $K_D$  range, a common property of structurally diverse compounds, does not distinguish one potential drug class from another. Thus, one skilled in the art would have to imagine which drug to use.

. . . . .

In this case, the compounds are not defined because cell membrane permeant calcium buffer does not evoke a mental image of a chemical structure and the  $K_D$  range is such a general property that it does not distinguish a particular class of compounds.

The examiner added (Ans., pp. 4-5, bridging para.; emphasis in original):

In addition, claims to treating injury to cells in a host are not enabled because they are overly broad. Treating injury to cells in a host reads on treating all patients since normal physiology and all diseases result in cell injury. Applicant merely showing effect for cell injury caused by select conditions, ischemia and

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epilepsy.

Applicant does not provide a general teaching that the results shown would enable one skilled in the art to treat all other diseases. The pharmaceutical arts are inherently unpredictable and method of universal treatment is highly speculative as no single medical method is known which can treat all diseases. As such, the limited nature of the examples and [sic] are not sufficient quid pro quo for the broad claims in an unpredictable art to an invention speculative in nature. Ex parte Forman 230 USPQ 546 (PTOB 1986).

In a Reply Brief filed January 5, 1994, appellants argued that the Examiner's Answer had raised new arguments. In response to the new arguments, appellants filed an Amendment Accompanying Reply Brief (Paper No. 14) which limited the claimed method to one for "reducing the damaging effect of an excitotoxic, ischemic or traumatic injury" (Amendment, p. 1). The examiner entered appellants' Reply Brief and notified appellants of that action. The examiner did not substantively respond to the extensive arguments set forth in the Reply Brief. See Paper No. 16. However, the examiner refused entry of the accompanying amendment. See the handwritten instructions on Paper No. 14. It does not appear from the record the examiner informed appellants that the amendment was not entered.

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3. Discussion

We reverse the examiner's **FINAL** rejection of Claims 1 and 11-16 under 35 U.S.C. § 112, first paragraph. Appellants filed their **NOTICE OF APPEAL** under 35 U.S.C. § 134 on August 13, 1993 (Paper No. 9) after having had Claims 1 and 11-16 twice rejected because "[a] cell membrane permeant calcium buffer' is broader than the specific supporting disclosure. It is also broader than the elected invention." See again the examiner's first office action mailed February 5, 1993 and **FINAL** office action mailed May 13, 1993.

In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971) teaches at 223, 169 USPQ 369:

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Moreover, Marzocchi adds at 224, 169 USPQ at 370:

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[I]t 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.

Here, appellants' claims stand finally rejected because "[a] cell membrane permeant calcium buffer' is broader than the specific supporting disclosure," with no explanation, evidence or reasoning in support of the rejection. We are obliged to reverse this rejection. Whether or not the claims on appeal are drawn to an invention "broader than the elected invention" is, of course, not a matter within the scope of our jurisdiction under 35 U.S.C. § 134.

We are mindful that the examiner ultimately explained the basis for the rejection in the Examiner's Answer by setting forth a new rationale. However, the examiner (1) did not substantively respond to the arguments contained in the Reply Brief and (2) refused to consider appellants' amendment at their first opportunity to amend the claims in response to the new rationale. Thus, the posture of this case is that appellants were first notified of substantive reasons why

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their claims were rejected in the Examiner's Answer without a new ground of rejection being made. Appellants filed an extensive Reply Brief in response to the new rationale and a proposed amendment. The Reply Brief was entered without a substantive comment by the examiner, leaving the record barren as to reasons why appellants' arguments were not persuasive to the examiner. The amendment was not entered, yet, appellants were not notified of that action by the examiner.

Taking a step back and reviewing the examination procedure followed in this application, it is questionable whether the administrative due process requirements of 35 U.S.C. § 132 were followed. Appellants should not have to file an appeal brief in order for the examiner to explain for the first time the substance of a rejection. However, having that unhappy set of circumstances occur here, appellants were entitled to a substantive response from the examiner to the extensive arguments set forth in the Reply Brief instead of the terse notification that the paper had been "entered and considered but no further response by the Examiner is deemed necessary." At the least, appellants should have been accorded the courtesy of a written notification that the amendment filed with the Reply Brief was not entered.

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By statute, this Board operates as a board of review.

See

35 U.S.C. § 7 ("The [board] shall . . . review adverse decisions of examiners . . . .") For this board to properly perform its review function, full and fair examination of the patentability of the claims of an application must have occurred below. This has not happened in this case. In essence, the examiner has not presented a case which we can meaningfully review.

4. Conclusion

We reverse the examiner's **FINAL** rejection of Claims 1 and 11-16 under 35 U.S.C. § 112, first paragraph.

Having read the Bibliography attached to each of the Declarations of Daniel Alkon and George J. Augustine, having considered the examiner's record of having "searched" Class 514, subclass 561, having noted the examiner's statement that "[t]he claims are drawn to compounds that find themselves classed in various and numerous parts of class 514" (Paper No. 3), having reviewed the examiner's "Search Notes," having noted the examiner's statement that "[n]o prior art are [sic]

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relied upon by the examiner in the rejection of claims under  
appeal" (Ans., p. 2), and having considered the prosecution of  
this case in its

entirety, we recommend that, upon return to the jurisdiction  
of the examiner, this application be completely examined under  
35 U.S.C. § 131.

REVERSED

	William F. Smith	)	
	Administrative Patent Judge	)	
		)	
		)	
	Andrew H. Metz	)	BOARD OF
PATENT	Administrative Patent Judge	)	APPEALS AND
		)	INTERFERENCES
		)	
	Teddy S. Gron	)	
	Administrative Patent Judge	)	

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