

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS R. TICE,
DEBORAH L. DILLON,
DAVID W. MASON,
AMANDA MCRAE-MCFARLANE
and ANNICA B. DAHLSTROM

Appeal No. 1998-0143
Application No. 08/268,177¹

ON BRIEF

Before WINTERS, ROBINSON, and SPIEGEL, Administrative Patent Judges.
SPIEGEL, 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 11 through 15. Claims 9 and 10, the only other claims pending in this application, have been indicated as allowable by the examiner.²

¹ Application for patent filed June 29, 1994. According to appellants, this application is a continuation-in-part of application 08/033,309 filed March 15, 1993, now U.S. Patent 5,360,610 issued November 1, 1994, which is a continuation of application 07/525,383 filed May 16, 1990, now abandoned.

² See page 4 of the final Office action (Paper No. 8, mailed December 21, 1995).

Claims 11 and 12 are illustrative:

11. A method for eliciting neural fiber growth within the central nervous system which comprises:
gaining access to the central nervous system of a patient;
providing a microsphere comprising an effective neural fiber growth amount of neuro-active agent encapsulated within a polymer sufficient to elicit neural fiber growth, said polymer (1) being permeable to the neuro-active agent, (2) being biocompatible with the tissues of the central nervous system, (3) being biodegradable within the tissues of the central nervous system without producing toxic byproducts of degradation, and (4) having kinetic characteristics that may be manipulated to allow for the permeation of the neuro-active agent through the polymer at a controlled rate and a predetermined period of time; and
implanting said microsphere into the central nervous system of the patient.

12. A method for delivering a pharmaceutically-active agent directly into astrocyte cells of the nervous system which comprises
(A) gaining access to the central nervous system of a patient;
(B) implanting microspheres of an encapsulated pharmaceutically-active agent in a therapeutically effective amount within the presence of astrocyte cells within the central nervous system of a patient, wherein the microspheres have a diameter of less than about 45 μm and comprise a polymer, said polymer (1) being permeable to the pharmaceutically-active agent, (2) being biocompatible with the tissues of the central nervous system, and (3) having kinetic characteristics that may be manipulated to allow for the permeation of the pharmaceutically-active agent through the polymer at a controlled rate and a predetermined period of time.

ISSUES

Claims 11-15 stand rejected under 35 U.S.C. § 112, sixth paragraph, as failing to adequately express a means or step for performing a specified function without recital of structure, material, or acts in support thereof. Claims 11-15 stand rejected under the

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judicially created doctrine of obviousness-type double patenting over claims 1-11 of U.S. Patent No. 5,360,610. Answer,³ pp. 3-4.

According to appellants, the claims stand or fall in separate groups, i.e., claim 11 and claims 12-15, with respect to each issue. Brief,⁴ p. 6. Therefore, we limit our discussion to claims 11 and 12. See 37 CFR § 1.192(c)(7) (1995).

We affirm the obviousness-type double patenting rejection of claim 11 and reverse the remaining rejections of claims 11-15.

OPINION

I. Rejection of claims 11-15 under 35 U.S.C. § 112, ¶ 6

Section 112, ¶ 6 states

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claims shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The key inquiry in assessing whether § 112, ¶ 6 applies is determining whether a claim element can be characterized by reciting at least enough structure to essentially carry out any function recited in the claim element. If it can be so characterized, § 112, ¶ 6 should not apply; if not, § 112, ¶ 6 probably does apply.

³ Paper No. 20, mailed February 19, 1997.

⁴ Paper No. 15, filed July 19, 1996.

Here, claims 11 and 12 identify the specific steps, i.e., implanting a defined microsphere "comprising an effective neural fiber growth amount" of a neuro-active agent into the central nervous system (CNS) of a patient; and, implanting defined microspheres containing a pharmaceutically-active agent "in a therapeutically effective amount" within the CNS of a patient, respectively, required to produce the claimed result, i.e., eliciting neural fiber growth within the CNS and delivering a pharmaceutically-active agent directly into astrocyte cells of the CNS, respectively. The examiner has not explained why such claims should be treated as "means-plus-function" claims.

According to the examiner, the phrase "in need thereof" should be added after the last word, "patient", to maintain proper means/function as "[t]his is merely an art recognized standard in method claims reciting therapeutically effective amounts" (Answer, p. 5). However, the examiner has not cited any legal precedent to support such a rejection under § 112, ¶ 6.⁵

Consequently, the rejection of claims 11-15 under § 112, ¶ 6 is reversed.

II. Rejection of claims 11-15 under obviousness-type double patenting over claims 1-11 of U.S. Patent No. 5,360,610

The proper inquiry for obviousness-type double patenting is to compare the claims of the patent and of the application to see whether they are patentably distinct.

⁵ We agree with the general principle espoused in In re Lundberg, 244 F.2d 543, 547-48, 113 USPQ 530, 534 (CCPA 1979), that the sixth paragraph of section 112 does not exempt an applicant from the requirements of the first two paragraphs of that section. However, none of the claims on appeal have been rejected under either of the first two paragraphs of section 112.

Here, both claim 1 of the '610 patent and claim 11 on appeal are drawn to a method for eliciting neural fiber growth within the CNS comprising implanting a polymer encapsulated neural fiber growth eliciting neuro-active agent within the CNS. More specifically, claim 1 of the '610 patent⁶ recites three species of the encapsulating polymer generically described in claim 11 on appeal.

Appellants argue that appealed claim 11 cannot be obvious unless the '610 patent supports a method using a generically defined polymer to encapsulate the neural fiber growth eliciting neuro-active agent (Brief, pp. 9-10). However, enablement and obviousness-type double patenting are two separate issues. Here, appellants chose to file the present continuation-in-part application to overcome the enablement rejection of the '610 patent rather than take the enablement issue to the Board in spite of their stated belief that the examiner's position was in error (Brief, p. 5). Further, appellants have not refuted the examiner's position that "[t]he characteristics of 'being permeable..biocompatible...biodegradable, kinetics described the description of the polymer are all art recognized as inherent to the copolymers and homopolymers used in

⁶ Claim 1 of the '610 patent reads as follows:

A method for eliciting neural fiber growth within the central nervous system which comprises implanting within the central nervous system a neuro-active neural fiber growth eliciting molecule encapsulated within a microsphere comprising the copolymer of poly(lactide-co-glycolide) or a homopolymer of polylactide or polyglycolide.

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the '610 patent" (Answer, p. 7) or presented any other arguments of nonobviousness.

Indeed, appellants' prior position had been that

[w]ith regard to the method of present Claim 11, Applicants are in agreement with the Examiner that the subject matter of this claim may be rejectable under this doctrine. Accordingly, Applicants are willing to submit a Terminal Disclaimer directed solely to Claim 11 and any subsequent claims which may be added that are dependent upon Claim 11. [Amendment filed September 11, 1995 (Paper No. 7), p. 3.]

Therefore, based upon this record, we sustain the rejection of claim 11 over claims 1-11 of the '610 patent.

As to the remaining claims, we agree with appellants that "Claims 12 to 15 are directed to a totally different invention than that described in the '610 patent or as described in Claim 11" (Brief, p. 11). As summarized by appellants,

Claims 12-15 have nothing to do with neural fiber growth ... These claims are clearly drawn to delivery of pharmaceutically-active agents directly within a specific cell type, i.e., astrocytes, by allowing such cells to "ingest" pharmaceutically-agent containing microspheres and having the agent permeate through the microsphere polymers directly into the cytoplasm of the astrocyte cells. [Reply brief, Paper No. 23, filed May 27, 1997, p. 4.]

Although the examiner is of the opinion that "delivery [of microspheres] to one cell type of the central nervous system [i.e., neurons] would involve delivery to the second [i.e., glial cells (astrocytes)]" (Answer, para. bridging pp. 9-10) (see also the Supplementary Answer, Paper No. 24, mailed August 14, 1997, p. 3, § (4) and the Second Supplementary Answer, Paper No. 26, mailed October 17, 1997, pp. 2-4), the examiner

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has not pointed to any evidence of record disclosing or suggesting that one of ordinary skill in the art would have had a reasonable basis for expecting the claimed microspheres to be ingested by, i.e., directly delivered to, any and all cells of the CNS, whether neurons or glial cells. Therefore, based upon this record, we reverse the rejection of claims 12-15 over claims 1-11 of the '610 patent.

OTHER MATTERS

According to appellants, the Declaration of record has not been executed by inventor Deborah L. Dillon because she is deceased (See the Submission of Documents letter filed September 2, 1994). The file does not currently contain a supplemental declaration executed by the administrator/executor of Ms. Dillon's estate.

CONCLUSION

To summarize, the decision of the examiner (I) to reject claims 11-15 under 35 U.S.C. § 112, sixth paragraph, is reversed, (II) to reject claim 11 under the- judicially created doctrine of obviousness-type double patenting over claims 1-11 of U.S. Patent No. 5,360,610 is affirmed, and (III) to reject claims 12-15 under the judicially created doctrine of obviousness-type double patenting over claims 1-11 of U.S. Patent No. 5,360,610 is reversed.

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No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
DOUGLAS W. ROBINSON)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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CAROL A. SPIEGEL)	
Administrative Patent Judge)	

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