

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HERBERT K. GRAHAM

Appeal No. 1997-1705
Application 08/211,352

ON BRIEF

Before OWENS, LIEBERMAN, and DELMENDO, *Administrative Patent Judges*.

OWENS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the examiner's final rejection of claims 6, 7, 10 and 13-17, and refusal to allow claims 1-4, 11 and 12 as amended after final rejection. These are all of the

claims remaining in the application.

THE INVENTION

Appellant's claimed invention is directed toward a method for treating a juvenile patient up to six years in age who suffers from muscle contractures due to cerebral palsy.

Claims 1 and 17 are illustrative and read as follows:

1. A method for treating a juvenile patient, said method comprising formulating a solution containing a presynaptic neurotoxin for the promotion of normal muscle growth in a juvenile patient of up to six years in age, suffering from dynamic contractures due to cerebral palsy, said promotion having a duration greater than a clinical activity of said presynaptic neurotoxin, and administering said formulation to said juvenile patient.

17. A method for causing relief of muscle contractures due to cerebral palsy in juvenile patients, said method comprising the administering to a juvenile patient of up to six years in age an effective amount of botulinum toxin A having clinical activity for blocking the release of synaptic vesicles containing acetylcholine, the relief from arrested muscle growth having a duration greater than the clinical activity of the presynaptic neurotoxin.^[1]

THE REFERENCES

T.K. Das & D.M. Park (Das), "Effect of treatment with botulinum toxin on spasticity", 65 *Postgrad. Med. J.* 208-10

¹In the event of further prosecution, appellant and the examiner should address on the record whether the antecedent basis in claim 17 for "the presynaptic neurotoxin" is sufficiently clear.

Appeal No. 1997-1705
Application 08/211,352

(1989).

Barry J. Snow et al. (Snow), "Treatment of Spasticity with Botulinum Toxin: A Double-Blind Study", 28 *Ann. Neurol.* 512-15 (1990).

Joseph Jankovic & Mitchell F. Brin (Jankovic), "Therapeutic Uses of Botulinum Toxin", 324 *New Eng. J. Med.* 1186-94 (1991).

THE REJECTIONS

Claims 1-4, 6, 7 and 10-17 stand rejected under 35 U.S.C. § 103 as obvious over Jankovic in view of Snow or Das, and under 35 U.S.C. § 112, first paragraph, on the ground that the original specification does not provide adequate written descriptive support for the invention as now claimed.

OPINION

We have carefully considered all of the arguments advanced by appellant and the examiner and agree with the examiner that the claimed invention would have been obvious to one of ordinary skill in the art at the time of appellant's invention over the applied references. Accordingly, we affirm the rejection under 35 U.S.C. § 103. We also affirm the rejection of claims 1-4, 7, 10-12, 15 and 16 under 35 U.S.C. § 112, first paragraph, but reverse the rejection under 35 U.S.C. § 112, first paragraph, of claims 6, 13, 14 and 17.

Appeal No. 1997-1705
Application 08/211,352

Rejection under 35 U.S.C. § 103

Appellant states that no claim is made for separate patentability (brief, page 4). Thus, the claims stand or fall together and we limit our discussion to one claim, i.e., claim 17. See *In re Ochiai*, 71 F.3d 1565, 1566 n.2, 37 USPQ2d 1127, 1129 n.2 (Fed. Cir. 1995); 37 CFR § 1.192(c)(7)(1995).

In order for a *prima facie* case of obviousness to be established, the applied prior art must have provided one of ordinary skill in the art with both a motivation to carry out appellant's claimed method and a reasonable expectation of success in doing so. See *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988).

Jankovic discloses under "Other Potential Indications" (page 1191) that "[t]he effects of botulinum toxin on spasticity in children with cerebral palsy are also being studied" and, under "Strabismus and Other Disorders of Ocular Motility" (page 1187), that "children under seven years of age may require light ketamine anesthesia and restraint" when treated with botulinum toxin. Jankovic states that he refers

to botulinum toxin A as botulinum toxin (page 1186), and teaches that "[t]he therapeutic scope of botulinum toxin has continued to expand, and it now includes a variety of neurologic disorders associated with

inappropriate muscular contractions or spasms" (page 1187).²

These teachings, taken together, would have provided one of ordinary skill in the art with motivation to administer botulinum toxin A to a child who is less than seven years old to treat the child for muscle contractures due to cerebral palsy.

The remaining question is whether one of ordinary skill in the art would have had a reasonable expectation of success in carrying out such treatment, i.e., whether there would have been a reasonable expectation of the absence of detrimental side effects which would have prevented the treatment from being useful. Under "Other Potential Indications" (page

²The clinical activity for blocking the release of synaptic vesicles containing acetylcholine recited in appellant's claim 17 is an inherent characteristic of botulinum toxin A as indicated by Jankovic (page 1186).

Appeal No. 1997-1705
Application 08/211,352

1191), which includes the statement cited above regarding the effect of botulinum toxin on spasticity in children with cerebral palsy being studied, Jankovic states that "[f]urther studies are needed to establish the efficacy and safety of botulinum toxin in these and other disorders associated with muscular spasms". However, in this section Jankovic also states that "[t]here are no absolute contraindications to injections of botulinum toxin except a history of hypersensitivity to the toxin (none yet reported) and infection at the site of injection. Thus far, no teratogenicity has been attributed to botulinum toxin, even though several women have been injected during pregnancy. Because botulinum toxin acts on the final common pathway, spasms of any cause could be temporarily relieved by this treatment." This teaching would have provided one of ordinary skill in the art with a reasonable expectation that administering botulinum toxin A to a child less than seven years old would not be accompanied by any side effects which would render such treatment inadvisable. Consequently, we conclude that such an administration of botulinum toxin A

Appeal No. 1997-1705
Application 08/211,352

would have been *prima facie* obvious to one of ordinary skill in the art. The recitation in appellant's claim 17 regarding "the relief from arrested muscle growth having a duration greater than the clinical activity of the presynaptic neurotoxin" is merely an inherent characteristic of the above-discussed administration of botulinum toxin A, and reciting an inherent characteristic of the prior art does not render appellant's invention patentable. See *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Appellant argues that he has discovered that botulinum toxin A is effective in promoting normal growth and not just the alleviation of spasticity (reply brief, page 2). Appellant's claim 17, however, is directed toward a method for causing relief of muscle contractures. As discussed above, Jankovic would have fairly suggested, to one of ordinary skill in the art, administering botulinum toxin A to a child under seven years of age to relieve muscle contractures.

Appellant argues that the claimed invention produces unexpected results (reply brief, page 6). In support of this argument appellant relies upon Case Study 1 and Example 2 of

the specification.

Regarding Case Study 1, appellant argues that it was unexpected that in a gait analysis taken at four months after a five year old girl was injected with botulinum toxin A, which was after the effects of the toxin had clinically worn off, her knee flexed to the same extent in swing that it did prior to injection (reply brief, page 6). This argument is not persuasive because appellants have not provided a comparison with the closest prior art,³ explained why the results would have been unexpected by one of ordinary skill in the art,⁴ or provided evidence which is commensurate in scope with claim 17 which encompasses relief from arrested muscle growth which has a duration which is greater than the clinical activity of the botulinum toxin A by

³ See *In re Baxter Travenol Labs.*, 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

⁴ See *In re Freeman*, 474 F.2d 1318, 1324, 177 USPQ 139, 143 (CCPA 1973); *In re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972).

as little as a fraction of a second.⁵

As for Example 2, appellant argues that it was unexpected that injection of intermuscular botulinum toxin A during the growth period of the hereditary spastic mouse allowed normal longitudinal muscle growth to take place (reply brief, page 6). This argument is not persuasive for the reasons given regarding Case Study 1 and also because appellant has not established that results for mice are indicative of results for a human.⁶

For the above reasons we conclude, based upon the preponderance of the evidence, that the method recited in appellant's claim 17 would have been obvious to one of ordinary skill in the art within the meaning of 35 U.S.C. § 103. Consequently, we affirm the rejection under this

⁵See *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 778 (Fed. Cir. 1983); *In re Clemens*, 622 F.2d 1029, 1035, 206 USPQ 289, 296 (CCPA 1980).

⁶When we give appellant's claim 17 its broadest reasonable interpretation in view of the specification and the prior art, see *In re Kroekel*, 504 F.2d 1143, 1146, 183 USPQ 610, 612 (CCPA 1974); *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238-39 (CCPA 1971), we conclude that "juvenile patients" refers to human juvenile patients.

Appeal No. 1997-1705
Application 08/211,352

section of the statute.

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

The examiner argues that there is inadequate written descriptive support in appellant's original specification for "having a duration greater than a clinical activity of said presynaptic neurotoxin" in claims 1, 6 and 17, "having a duration greater than a clinical activity of said botulinum toxin" in claim 7, and "having a clinical activity of about four months" in claim 10.

We do not find in appellant's briefs a challenge to the rejection based on the language in claim 10. We therefore affirm the rejection under 35 U.S.C. § 112, first paragraph, of claim 10 and claims 11 and 12 which depend therefrom.

Claims 1 and 7 require that the promotion of normal muscle growth has a duration greater than the clinical activity of the presynaptic neurotoxin or botulinum toxin. Appellant argues (brief, page 12; reply brief, page 8) that this language is supported by the statements in the specification that "such functional improvements persist when the tone reducing effects of the toxin have worn off" (page 4)

and "[a]t this stage the effects of the toxin had clinically worn off and it was found that the knee flexed to the same extent in swing that it did prior to injection" (page 10).⁷ These statements, however, pertain to functional improvements and knee flexure, whereas claims 1 and 7 require that normal muscle growth continues to be promoted after the clinical activity of the toxin ends. Appellant has not pointed out, and we do not find, written descriptive support in the original specification for this claim requirement. Accordingly, we affirm the rejection under 35 U.S.C. § 112, first paragraph, of claim 1 and claims 2-4 which depend therefrom, and claim 7 and claims 15 and 16 which depend therefrom. Also, this is an additional reason for affirming the rejection under 35 U.S.C. § 112, first paragraph, of claim 10 which depends from claim 7.

Claims 6 and 17 require that the relief from arrested muscle growth has a duration which is greater than the clinical activity of the presynaptic neurotoxin. This

⁷The article relied upon by appellant on page 14 of the brief is not part of the specification and is not prior art. Thus, we give it no weight in our determination of whether the specification complies with 35 U.S.C. § 112, first paragraph.

Appeal No. 1997-1705
Application 08/211,352

language appears to have adequate written descriptive support in the portions of the specification cited above, and the examiner's argued distinction between normal muscle growth and normal range of movement (answer, pages 14-15) is not a convincing argument to the contrary. We therefore reverse the rejection under 35 U.S.C. § 112, first paragraph, of claims 6 and claims 13 and 14 which depend therefrom, and claim 17.

DECISION

The rejection of claims 1-4, 6, 7 and 10-17 under 35 U.S.C. § 103 over Jankovic in view of Snow or Das is affirmed. The rejection under 35 U.S.C. § 112, first paragraph, is affirmed as to claims 1-4, 7, 10-12, 15 and 16, and reversed as to claims 6, 13, 14 and 17.

Appeal No. 1997-1705
Application 08/211,352

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

AFFIRMED

TERRY J. OWENS)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
PAUL LIEBERMAN)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
ROMULO H. DELMENDO)
Administrative Patent Judge)

Appeal No. 1997-1705
Application 08/211,352

TJO:pgg
Walter A. Hecker
2372 S.E. Bristol, Suite B
Newport Beach, CA 92660