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D E C I S I O N
of 5 July 2005

Case Number: T 0509/04 - 3.3.4

Application Number: 92919570.9

Publication Number: 0605501

IPC: S61K 38/00

Language of the proceedings: EN

Title of invention:
Method and compositions for the treatment of cerebral palsy

Patentee:
ALLERGAN, INC.

Opponent:
-

Headword:
Cerebral palsy/ALLERGAN

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty, inventive step (yes)"

Decisions cited:
G 0005/83, G 0002/88, G 0006/88, T 0290/86, T 0254/93, T 0542/96

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0509/04 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 5 July 2005

Appellant: (Proprietor of the patent)	ALLERGAN, INC. 2525 Dupont Drive Irvine, CA 92623-9534 (US)
Representative:	Hoffman Eitle, Patent- und Rechtsanwälte Arabellastrasse 4 D-81925 München (DE)
(Opponent)	ELAN PHARMACEUTICALS INC. 800 Gateway Blvd South San Francisco, CA 94080 (US)
Representative:	Chapman, Paul William Kilburn & Strode 20 Red Lion Street London WC1R 4PJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 20 February 2004 revoking European patent No. 0605501 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairwoman: U. Kinkeldey
Members: M. Wieser
G. Weiss

Summary of Facts and Submissions

I. The appeal was lodged by the Patent Proprietors (Appellants) against the decision of the Opposition Division, whereby European patent No. 0 605 501 was revoked under Article 102(1) EPC. It had been opposed by one party under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and Article 100(b) EPC for lack of sufficiency of disclosure (Article 83 EPC).

II. The Opposition Division decided that the claims of the main request and of two auxiliary requests before them did not involve an inventive step (Article 56 EPC) in the light of the disclosure in document

(E14) Southern Medical Journal, vol.83(9), 1990, 2S-53

III. The Opponents withdrew their opposition on 19 July 2004 and ceased to be a party in respect of substantive issues.

IV. The Board expressed their preliminary opinion in a communication dated 15 December 2004. Oral proceedings were held on 23 June 2005.

V. The Appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 3 filed at the oral proceedings as main request or, in the alternative, on the basis of claims 1 to 3 filed at the oral proceedings as first auxiliary request.

VI. Claim 1 of the main request read as follows:

"*The use of a presynaptic neurotoxin which is a botulinum toxin for the manufacture of a medicament for the promotion of normal muscle growth in a juvenile patient before the patient has completed its growing period and fixed contracture has occurred suffering from dynamic contractures due to cerebral palsy.*"

Dependent claims 2 and 3 referred to preferred embodiments of the use according to claim 1.

VII. The submissions by the Appellants as far as they are relevant to the present decision may be summarised as follows:

Claim 1 of the new main request was based on the application as originally filed (Article 123(2) EPC). The muscle relaxing effect of botulinum toxin in juvenile patients suffering from cerebral palsy, as known from document (E14), was different from the unknown effect of promoting normal muscle growth in these patients, which was both novel and inventive (Articles 54 and 56 EPC). The essential difference in the medical treatments carried out according to document (E14) and the patent had to be seen in their different focus.

Reasons for the Decision

Main Request
Amendments (Articles 123(2) and 123(3) EPC)
Clarity (Article 84 EPC)

1. Claim 1 is based on claims 2 to 4 and page 7, lines 1 to 4 of the application as originally filed. Claims 2 and 3 correspond to original claims 5 and 6.

   Claim 1 as granted referring to a "juvenile patient" has been restricted by introducing the feature "before the patient has completed its growing period and fixed contracture has occurred". The claims have not been amended in such a way as to extend the protection conferred.

   The requirements of Articles 123(2) and 123(3) EPC are met.

2. The claims are clear, concise and supported by the description (Article 84 EPC).

Sufficiency of disclosure (Article 83 EPC)

3. The suitability of the product to be manufactured according to claim 1 for the claimed therapeutic use in the defined group of patients, which is a functional technical feature of the claim, is disclosed in case studies 1 and 2 in column 5 of the patent (corresponding to pages 10 to 11 of the original application).

Thus, the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person according to the requirements of Article 83 EPC.

Novelty (Article 54 EPC)

4. Claim 1 refers to a therapeutic application in the form allowed by the Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985, 64), i.e. in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application.

The attained therapeutic effect, namely the promotion of normal muscle growth in a juvenile patient suffering from dynamic contractures due to cerebral palsy, wherein the patient has not completed its growing period and fixed contractures have not occurred, is not described in the documents on file.

5. Document (E14) is concerned with botulinum treatment of patients suffering from cerebral palsy. The document reports that in three groups of patients, all consisting of children, significant improvements were observed after the patients were infiltrated with 1 to 6 units/kg body weight of botulinum toxin A into the target muscle mass adjacent to the myoneural interface. The improvements detected are described as being improved gait pattern and sitting balance and decreased spasticity of the injected muscles. Document (E14) concludes that "*Botulinum-A toxin is a potential adjunctive treatment in the evaluation and short-time management of extremity spasticity and merits additional prospective evaluation.*"

The therapeutic effect of promoting normal muscle growth in patients suffering from cerebral palsy is not mentioned in document (E14) or in any other prior art document on file.

6. The attaining of a new technical effect is considered as a functional technical feature of a claim referring to the new use of a known substance. If that technical feature has not been previously made available to the public by any of the means as set out in Article 54(2) EPC, then the claimed invention is novel, even though such technical effect may have inherently taken place in the course of carrying out what has previously been made available to the public (cf decisions of the Enlarged Board of Appeal G 2/88 and G 6/88, OJ EPO 1993, 93 and 114; point (9) of the reasons for the decision).

7. These decisions have been followed by many Boards of Appeal when deciding on claims relating to the second or further medical use of a known substance.

In decision T 290/86 (OJ EPO 1992, 414)the competent Board was confronted with a situation where a prior art document and a claimed invention were both concerned with a similar treatment of the human body for the same therapeutic purpose, namely the use of compositions including lanthanum salts in the prevention of tooth decay. The Board decided that the invention, by describing the attainment of an unknown technical effect, namely the removal of plaque from teeth, compared to the reduction of the solubility of tooth enamel, described in the prior art, represents a further medical indication within the meaning of

Decision G 5/83 (OJ EPO 1985, 64). Novelty of claims referring to the use of a salt of lanthanum for the manufacture of various dental compositions for obtaining the unknown technical effect was acknowledged (cf point (6.1) of the reasons).

In decision T 542/96 of 11 May 2000 the Board had to decide whether the claimed use of xylitol and fluoride for remineralisation of teeth could be accepted as a new therapeutic application in view of the disclosure in a prior art document of the use of these compounds in toothpastes for their known caries reducing activity. Remineralisation and hardening of teeth, even when taking place independently from caries prophylaxis, improves resistance to acid attack and to mechanical shocks and thus prevents the decay of teeth. Therefore, as the two expressions remineralisation of teeth and caries prophylaxis are not synonyms but identify different and not necessarily overlapping situations, novelty was accepted (cf point (4) of the reasons).

This situation, which also applies to the claims under consideration (see points (4) to (5) above), namely the attainment of a therapeutic effect which is not described in the prior art documents on file, is different from the situation where the indication of a use only reflects an effect already described in the prior art.

8. The patent application underlying the decision T 254/93 (OJ EPO 1998, 285) referred to a combined use of a retinoid and a corticosteroid in the prevention of skin atrophy. It was known that corticosteroids when

topically applied cause skin atrophy as a biological side effect. Combined use of a corticosteroid and a retinoid was disclosed in a prior art document. Incidence of skin atrophy was prevented by application of this prior art composition. Due to the severe symptoms of corticosteroid induced skin atrophy this could not be overlooked by a skilled person. The invention was merely based on the finding that it was the retinoid that was responsible for the prevention of skin atrophy.

The competent Board decided that the mere explanation of an effect obtained when using a compound in a known composition even if the effect was not known to be due to this compound in the known composition, cannot confer novelty on a known process if the skilled person was already aware of the occurrence of the desired effect (cf point (4.8) of the reasons).

Thus, the technical circumstances underlying decision T 254/93 are different from the ones in the present case. Therefore, this decision is not considered to be relevant with regard to the patent in suit.

9. Thus, in accordance with the relevant case law of the Boards of Appeal, the subject-matter of claims 1 to 3 is novel and meets the requirements of Article 54 EPC.

Inventive step (Article 56 EPC)

10. The Opposition Division in point (7.3) of the decision under appeal found that the botulinum treatment disclosed in the patent in suit and in document (E14) was directed to the same group of patients. The same

muscles were treated and the mode of administration, the dosage and the posology were identical. They concluded that "*[E]ven if the skilled practitioner is not inevitably aware of an additional benefit (muscle growth), this effect will occur without any change in the medical practice that is already described in (E14). The present patent does not teach the skilled person to do something which he wouldn't have done without the information of the patent. For this reason, claims 1-3 lack an inventive step*".

11. The Board comes to a different conclusion for the following reasons:

In accordance with the problem and solution approach, the Boards of Appeal have developed in their case law certain criteria for identifying the closest prior art which provides the best starting point for assessing inventive step. It has been repeatedly pointed out that this should be prior art relating to subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications (cf Case Law of the Boards of Appeal of the European Patent Office, 4th Edition 2001, chapter I.D.3).

12. The invention according to claim 1 aims at the objective to provide a medicament for the promotion of normal muscle growth in a specifically defined group of patients suffering from dynamic contractures due to cerebral palsy.

This objective is met by the subject-matter of claims 1 to 3, namely by the provision of a medicament containing a botulinum toxin.

13. None of the prior art documents on file serves this purpose or objective.

Document (E14) refers to the muscle relaxing effect of botulinum toxin and mentions that this substance merits additional prospective evaluation in the treatment and short-term management of extremity spasticity (see point (5) above). Normal muscle growth in patients suffering from cerebral palsy, which is a therapeutic effect different and clearly distinguishable from muscle relaxation, is not mentioned in document (E14) or in any other prior art document on file.

14. The skilled person, neither from the disclosure in document (E14) alone nor from a combination with any other prior art document on file, would arrive at the new therapeutic application of a botulinum toxin according to claim 1 in an obvious way.

Claims 1 to 3 involve an inventive step and meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of claims 1 to 3 filed at the oral proceedings as main request and the description as granted.

The Registrar: The Chairwoman:

P. Cremona U. Kinkeldey