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**Datasheet for the decision
of 5 June 2018**

Case Number: T 2368/12 - 3.3.04

Application Number: 01966482.0

Publication Number: 1322324

IPC: A61K38/48, A61P21/00

Language of the proceedings: EN

Title of invention:

Botulinum toxin for use in the treatment of acute injuries to skeletal muscles

Patent Proprietor:

Allergan, Inc.

Opponent:

Ipsen Pharma, S.A.S.

Headword:

Botulinum toxin/ALLERGAN

Relevant legal provisions:

EPC Art. 123(2), 123(3)

RPBA Art. 13(1)

Keyword:

Main request, first and second auxiliary request - amendments
- added subject-matter (yes)

Third and fourth auxiliary request - amendments - broadening of
claim (yes)

Late-filed fifth auxiliary request - admitted (no)

Decisions cited:

Catchword:

-



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Case Number: T 2368/12 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 5 June 2018

Appellant: ALLERGAN, INC.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 12 September
2012 revoking European patent No. 1322324
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairwoman G. Alt
Members: B. Claes
P. de Heij

Summary of Facts and Submissions

- I. The appeal by the proprietor (hereinafter "appellant") lies against the decision of the opposition division to revoke European patent No. 1 322 324 entitled "*Botulinum toxin for use in the treatment of acute injuries to skeletal muscles*". The patent was granted for European patent application No. 01 966 482.0, which was published as WO 02/028425.

Claim 1 of the patent as granted read:

"1. A botulinum toxin for use in the treatment of acute injuries to skeletal muscles by local administration, by intramuscular injection, which substantially immobilizes the injured muscle."

- II. The patent was opposed on the grounds in Article 100(a) EPC, in relation to novelty (Article 54 EPC), inventive step (Article 56 EPC) and methods for treatment (Article 53(c) EPC), and in Article 100(b) and Article 100(c) EPC.
- III. In the decision under appeal the opposition division held *inter alia* that the subject-matter of claim 1 of the main request and of the first to tenth auxiliary request lacked inventive step. Claim 1 of the fifth to tenth auxiliary request was amended in such a way that the protection conferred by the patent was extended (Article 123(3) EPC). A further eleventh auxiliary request was not admitted into the proceedings.
- IV. With the statement of grounds of appeal, the appellant re-submitted the former main request and the first, fourth, seventh, tenth and eleventh auxiliary requests as the main request and the first to fifth auxiliary

requests respectively, and argued in favour of inventive step of the subject-matter of their claim 1 and that claim 1 of the third and fourth auxiliary request complied with the requirements of Article 123(3) EPC.

Claim 1 of the *main request* and of the *first auxiliary request* was identical to claim 1 as granted (see section I).

Claim 1 of the *second auxiliary request* read:

"1. A botulinum toxin, which is a botulinum toxin type A, B, C₁, D, E, F or G, for use in the treatment of acute injuries to skeletal muscles by local administration, by intramuscular injection, which substantially immobilizes the injured muscle." (emphasis added by the board)

Claim 1 of the *third auxiliary request* read:

"1. A botulinum toxin for use in the treatment of a strain injury to skeletal muscles by local administration, by intramuscular injection, which substantially immobilizes the injured muscle." (emphasis added by the board)

Claim 1 of the *fourth auxiliary request* was identical to that of the third auxiliary request but for the inserted specification that the botulinum toxin is a botulinum toxin type A, B, C, D, E, F or G (see second auxiliary request).

- V. With its reply to the statement of grounds of appeal, the opponent (hereinafter "respondent") argued *inter alia* that claim 1 of each request related to added

subject-matter (Articles 100(c) and 123(2) EPC) and that claim 1 of the third and fourth request additionally did not comply with the requirements of Article 123(3) EPC. Four further documents were submitted.

VI. In a communication pursuant to Article 15(1) RPBA and in preparation for oral proceedings the board gave its preliminary appreciation of the parties' requests and certain substantive and legal matters concerning the appeal.

VII. During the oral proceedings the appellant withdrew the fifth auxiliary request filed with the statement of grounds of appeal and filed a new fifth auxiliary request. At the end of the oral proceedings the chairwoman announced the decision of the board.

Claim 1 of the new *fifth auxiliary request* read:

"1. A botulinum toxin for use in the treatment of acute injuries to skeletal muscles by local administration, by intramuscular injection, which substantially immobilizes the injured muscle, wherein the botulinum toxin is effective to immobilize the injured muscle during phase 1 of a repair process of the injured muscle." (emphasis added by the board)

VIII. The following documents are referred to in this decision:

D4: Garret (1996), Am. J. Sports Med., Vol. 24, No. 6, pages S-2 to S-8.

D26: Noonan *et al.* (1999), J. Am. Ac. Orthop. Surg., Vol. 7, pages 262 to 269.

D30: "Annex A" filed by the patentee during the examination proceedings with letter dated 12 February 2008, internet web page.

IX. The appellant's arguments in as far as they are relevant for the decision can be summarised as follows:

*Main request and first auxiliary request - claim 1
Added subject-matter (Article 100(c) EPC)
Second auxiliary request - claim 1
Added subject-matter (Article 123(2) EPC)*

The wording of the claim in respect of the feature "acute injuries to skeletal muscles" found a basis in the first two paragraphs on page 1 of the application as filed, in particular on lines 9 to 11.

*Third and fourth auxiliary request - claim 1
Extension of conferred protection (Article 123(3) EPC)*

Since muscle strains were always acute injuries, the amendment complied with the requirements of Article 123(3) EPC.

*Fifth auxiliary request
Admission into the proceedings (Article 13(1) RPBA)*

The request was a reaction to the board's finding that claim 1 of the main request did not comply with the requirements of Article 123(2) EPC.

- X. The respondent's arguments in as far as they are relevant for the decision can be summarised as follows:

*Main request and first auxiliary request - claim 1
Added subject-matter (Article 100(c) EPC)*

There was no basis in the application as filed for the term "acute injuries to skeletal muscles" in the first two paragraphs on page 1 and in particular not in the passage on page 1, lines 9 to 11, which was part of the background section of the description and was not linked to or concerned with the invention. The passage simply enumerated examples of acute skeletal muscle injuries but neither limited the injuries of the invention to acute injuries, nor did it convey the impression of a preferred embodiment.

*Second auxiliary request - claim 1
Added subject-matter (Article 123(2) EPC)*

The reasons why claim 1 of the main request related to added subject-matter also applied to this claim.

*Third and fourth auxiliary request - claim 1
Extension of conferred protection (Article 123(3) EPC)*

The amendment contravened the requirements of Article 123(2) EPC because the term "strain injury" could read both on acute and chronic strain injuries (see e.g. documents D4, D26 and D30). A strain injury was thus not necessarily "acute".

Therefore, the claim encompassed embodiments that were not directed to the treatment of acute muscle injuries and that were thus not encompassed by claim 1 as granted.

Fifth auxiliary request

Admission into the proceedings (Article 13(1) RPBA)

The request should not be admitted into the proceedings.

The appellant had failed to explain why the request had only be filed at the end of the oral proceedings and not earlier.

The request still included the features of claim 1 as granted and was thus clearly unallowable.

The request, as compared to claim 1 of the third and fourth auxiliary request, did not simplify matters but rather increased the number of issues to be dealt with.

- XI. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, or alternatively, on the basis of one of the first to fourth auxiliary requests, all filed with the statement of grounds of appeal, or further alternatively, on the basis of a fifth auxiliary request, filed during the oral proceedings.

The respondent requested that the appeal be dismissed. It also requested that the fifth auxiliary request not be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

Main request and first auxiliary request - claim 1

Added subject-matter (Article 100(c) EPC)

2. The appellant has referred solely to the wording in the two first paragraphs of the application as filed on page 1 for alleged support for the wording of the claim in respect of the feature "acute injuries to skeletal muscles". The essential parts of the passage read:

"BACKGROUND

*The present invention relates to **methods for treating muscle injuries**. In particular, the present invention relates to a method for treating an injured muscle by administration of a neurotoxin to the injured muscle.*

*Injuries to muscles include **acute injuries to skeletal muscles** such as contusions (bruises), lacerations, ischemia, strains, and complete ruptures. These injuries may cause tremendous pain (...)" (emphasis added by the board).*

3. Upon inspection of these passages the board can accept that the first paragraph relates to the invention, i.e. methods for treating muscle injuries. The text starting in the second paragraph referred to, however, concerns the technical background section of the description in which injuries to muscles are introduced, described and enumerated. The board agrees with the respondent that the passage referred to by the appellant simply enumerates examples of acute skeletal muscle injuries

without limiting the injuries of the invention to such acute injuries.

4. The board concludes accordingly that the appellant has failed to indicate an appropriate basis in the application as filed that clearly and unambiguously discloses the feature "acute injuries to skeletal muscles" in the context of the claimed invention. For this reason alone the board must conclude that the claim fails to meet the requirements of Article 100(c) EPC.
5. In view of the above considerations claim 1 relates to added subject-matter and fails to meet the requirements referred to in Article 100(c) EPC.

Second auxiliary request - claim 1

Added subject-matter (Article 123(2) EPC)

6. This claim is identical to claim 1 as granted but for the inserted specification that the botulinum toxin is a botulinum toxin type A, B, C, D, E, F or G.
7. The reasons for the finding that claim 1 of the main request relates to added subject-matter applies thus *mutatis mutandis* to this claim.
8. The amended claim accordingly fails to meet the requirements of Article 123(2) EPC.

Third and fourth auxiliary request - claim 1

Extension of conferred protection (Article 123(3) EPC)

9. The feature "acute injuries" in claim 1 as granted has been replaced in these claims by the feature "a strain injury". The clinical indication to be treated is

accordingly reworded to be "a strain injury to skeletal muscles".

10. In the decision under appeal the opposition division held that such an amendment to the claims did not comply with the requirements of Article 123(3) EPC because the claims now related also to a therapeutic indication in which the injury, here a strain injury, was not acute.
11. The appellant contended, without submitting documentary evidence in support, that a strain injury is always an acute injury and that accordingly the amendment did not extend the conferred protection.
12. It would seem to the board, however, that the documentary evidence on file would, rather than support the appellant's contention, contradict it. Indeed, on the basis, for example, of document D4 (page S-5, right-hand column, lines 36 to 39), document D26 (page 268, middle column, lines 7 to 12) and document D30 (first page, definition of "strain"), it can be established that the skilled person in the technical field was aware that the term "strain injury" not only referred to an acute injury as it was also known that such an injury could be of a chronic nature.
13. In view of the above considerations therefore, the board can concur with the opposition division that the protection conferred by the claim now also entails the use of the botulinum toxin in the treatment of chronic injuries. The amended claim therefore does not comply with the requirements of Article 123(3) EPC.

Fifth auxiliary request

Admission into the proceedings (Article 13(1) RPBA)

14. This request was submitted during the oral proceedings. It is thus to be considered as an amendment to the appellant's case, the admission of which is at the board's discretion.
15. The board considers that, since the appellant, in reaction to the board's opinion expressed during the oral proceedings that claim 1 of the main request and of the first and second auxiliary requests related to added subject-matter, opted to maintain the third and fourth auxiliary requests, the filing of the fifth auxiliary request actually constitutes the appellant's second attempt to overcome the issue of added subject-matter. Moreover, this second attempt was undertaken at the latest possible point in time, i.e. during the oral proceedings.
16. The board furthermore notes that claim 1 of this request (see section VII) still contains the feature "acute injuries to skeletal muscles", which it considers infringes the requirements of Article 123(2) EPC (see points 2 to 6, above). Therefore the claim request cannot *prima facie* overcome this objection.
17. In view of these considerations the board decided not to admit this request into the appeal proceedings (Article 13(1) EPC).
18. The board accordingly concludes that no allowable claim request is on file for consideration by the board.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



L. Malécot-Grob

G. Alt

Decision electronically authenticated