

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 2 September 2021**

Case Number: T 2797/18 - 3.3.07

Application Number: 09768315.5

Publication Number: 2373294

IPC: A61K9/19, A61K47/10, A61K47/18,
A61K47/26, A61K47/32,
A61K47/34, A61K47/36, A61K38/48

Language of the proceedings: EN

Title of invention:
CLOSTRIDIAL TOXIN PHARMACEUTICAL COMPOSITIONS

Patent Proprietor:
ALLERGAN, INC.

Opponent:
IPSEN PHARMA S.A.S.

Headword:
Clostridial toxin/ALLERGAN

Relevant legal provisions:
EPC Art. 100(c)
RPBA 2020 Art. 11

Keyword:

Grounds for opposition - added subject-matter (no)
Remittal - (yes)

Decisions cited:

T 1966/16



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2797/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 2 September 2021

Appellant:
(Patent Proprietor)

ALLERGAN, INC.
2525 Dupont Drive, T2-7h
Irvine, CA 92612 (US)

Representative:

Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Respondent:
(Opponent)

IPSEN PHARMA S.A.S.
65, Quai Georges Gorse
92100 Boulogne-Billancourt (FR)

Representative:

Plasseraud IP
66, rue de la Chaussée d'Antin
75440 Paris Cedex 09 (FR)

Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 25 September
2018 revoking European patent No. 2373294
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman E. Duval
Members: M. Steendijk
Y. Podbielski

Summary of Facts and Submissions

- I. European patent 2 373 294 (hereinafter "the patent") was granted on the basis of 10 claims.

Independent claim 1 as granted related to:

"An animal-protein free, solid-form Clostridial toxin pharmaceutical composition comprising a Clostridial toxin active ingredient, an effective amount of a sugar excipient comprising two different sugars, and an effective amount of surfactant excipient."

- II. The patent, which resulted from the international patent application originally published as WO2010/090677, was opposed on the grounds that its subject-matter lacked inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the application as filed.

The appeal was filed by the patent proprietor (hereinafter: appellant) against the decision of the opposition division to revoke the patent. The decision was based on the appellant's main request relating to the patent as granted and auxiliary requests 1-12 filed with the appellant's letter of 2 May 2018.

- III. The opposition division was of the opinion that the subject-matter of claim 1 as granted resulted from a generalisation which extended beyond the content of the application as filed.

Claim 1 of the application as filed defined a composition comprising an effective amount of a sugar excipient and an effective amount of surfactant excipient. Paragraph [096] of the application as filed mentioned a plurality of non-protein excipients to be useful for formulating Clostridial toxin pharmaceutical compositions. In these passages the application as filed did not specifically disclose the three-excipient combination of two different sugars with a surfactant as defined in claim 1 as granted.

Paragraph [0155] of the application as filed discussed the results obtained with the six examples of specific three-excipient Clostridial toxin compositions comprising sucrose, lactose and poloxamer 188 described in table 6. The first sentence of this paragraph mentioned Clostridial toxin pharmaceutical compositions comprising two different sugars and a surfactant in an introduction to the description of these examples and did not represent a general statement of the invention. The application as filed provided no basis for generalisations, because from its content as a whole the skilled person derived that even small modifications in the composition of the stabilizing excipients resulted in large variations of the recovered potency. If the introductory sentence of paragraph [0155] were nevertheless regarded as a statement of general concept, such statement was speculative, unsupported and contrary to the disclosure of the patent as a whole. No generalization could therefore be derived from the six specific compositions of table 6 on page 86 comprising sucrose, lactose and poloxamer 188.

The independent claims of auxiliary requests 1-12 equally defined subject-matter extending beyond the

content of the original disclosure in the form of unacceptable generalisations with respect to the examples of table 6.

- IV. With the statement of grounds of appeal the appellant filed auxiliary requests 1-13. Auxiliary requests 1-12 corresponded to the auxiliary requests on which the decision under appeal was based.
- V. In its reply to the appeal the respondent objected to the admission of auxiliary request 13.
- VI. With the summons of 29 October 2020 the parties were invited to attend oral proceedings to be held on 16 November 2021.

In its communication pursuant to Article 15(1) RPBA 2020 of 16 March 2020 the Board expressed its preliminary opinion that the ground of added subject-matter was not prejudicial to the claims of the patent as granted.

The Board further expressed its intention to remit the case to the opposition division for further prosecution, should this preliminary opinion be confirmed.

- VII. The respondent (opponent) withdrew its request for oral proceedings with its letter of 5 August 2021. The oral proceedings were cancelled on 7 September 2021.
- VIII. The appellant's arguments in as far as relevant to this decision can be summarized as follows:

Claim 1 as granted was amended with respect to claim 1 as originally filed by specification that the sugar excipient comprised two different sugars.

Paragraph [0155] of the application as filed presented in its first sentence the general statement that Clostridial toxin pharmaceutical compositions comprising two different sugars and a surfactant resulted in an effective recovered potency and long-term stability of the Clostridial toxin active agent. This general statement was followed by statements of decreasing levels of generalisation introduced by the phrase "For example", which defined the types of sugars and surfactant and further aspects of the exemplified compositions. The decision under appeal incorrectly questioned the disclosure of the relevant general concept because of doubts as to its validity and thereby diverged from the established "Gold standard" for the assessment of amendments. The general concept explicitly disclosed in original paragraph [0155] was fully in line with the results presented in table 6 as well as the general statement in paragraph [0096], which referred to a composition comprising two different sugars.

IX. The respondent's arguments in as far as relevant to this decision can be summarized as follows:

The only mention of Clostridial toxin pharmaceutical compositions comprising two different sugars and a surfactant occurred in paragraph [0155] of the application as filed. This paragraph discussed the results obtained with the six specific three-excipient compositions described in table 6. These compositions were obtained by using specifically botulinum neurotoxin serotype A with specific amounts of sucrose,

lactose and Poloxamer 188 in combination with specific buffers at a specific pH.

Claim 1 as granted involved a generalization with respect to the specific compositions of table 6 by defining compositions comprising any Clostridial toxin with a combination of any two different sugars and any surfactant. The results from example 3 presented in table 6 showed unpredictable variation in the recovered potency of the Clostridial toxin compositions at different pH values and with the use of different buffers. Moreover, the results from example 2 presented in table 3 showed that in compositions comprising a sugar and a surfactant even small modifications in the amounts used resulted in dramatic changes in the recovered potency. The teaching of the application as filed, in particular the experimental section, therefore provided no basis for the generalization in claim 1 as granted.

The inadmissible generalisations with respect to the compositions of table 6 persisted in dependent claims 2-10. Claims 2 and 3 defined sugars other than sucrose and lactose, claim 4 defined surfactants other than poloxamer, claim 6 defined pH values other than 5.5 and 6.5, claim 7 defined buffers other than sodium citrate and potassium phosphate and claims 9 and 10 defined compositions further comprising a non-protein polymer excipient.

- X. The appellant requested that the decision under appeal be set aside and that the patent be maintained based on the claims as granted. The appellant further requested that the case be remitted to the first instance for examination of the further grounds of opposition.

Subsidiarily the appellant requested consideration of auxiliary requests 1-13.

- XI. The respondent requested that the appeal be dismissed. In this context the respondent requested that auxiliary request 13 be not admitted into the proceedings. The respondent requested remittal to the first instance for examination of the further grounds of opposition in the event that the Board would consider that one of the appellant's requests met the requirements of Article 123(2) EPC.

Reasons for the Decision

1. Main request / Added subject-matter
- 1.1 Claim 1 as granted results from amendment of claim 1 as originally filed by insertion of the feature that the sugar excipient comprises two different sugars.
- 1.2 The patent application as filed defined in claim 1 an animal-protein free, solid-form Clostridial toxin pharmaceutical composition comprising a Clostridial toxin active ingredient, an effective amount of a sugar excipient and an effective amount of surfactant excipient. The application as filed further envisaged in paragraph [096] the use of a plurality of non-protein excipients in formulating Clostridial toxin pharmaceutical compositions and mentions in this context *inter alia* compositions comprising two different sugars and compositions comprising at least three non-protein excipients. A similar general reference to compositions with at least three non-protein excipients can be found in paragraph [011] of

the application as filed. The decision under appeal correctly concluded that these generic descriptions of subject-matter do not specifically disclose the particular excipient combination of two different sugars and a surfactant as defined in claim 1 as granted.

- 1.3 Example 3 of the patent application presents compositions comprising three excipients (see heading of example 3 on page 83) following the report of mixed results in examples 1 and 2 concerning compositions with one or two excipients.

Paragraph [0155] of the application as filed is part of this example 3. The first sentence of this paragraph states:

"Clostridial toxin pharmaceutical compositions comprising two different sugars and a surfactant resulted in an effective recovered potency and long-term stability of the Clostridial toxin active ingredient."

The Board observes that, when taken in isolation, the formulation of this first sentence of paragraph [0155] in the past tense might arguably be taken to indicate that this sentence only refers to the specific compositions, which actually *resulted* in the effective recovered potency as subsequently reported in table 6 on page 86. This interpretation seems to underlie the reasons for the decision under appeal (see page 4, lines 23-29).

However, the first sentence of paragraph [0155] referring to results with compositions comprising two

different sugars and a surfactant is followed by a second sentence stating:

"For example, compositions comprising sucrose, lactose and Poloxamer 188 resulted in initial recovered potency of about 81 % to about 114% (Table 6)."

The Board agrees with the appellant that from the use of the expression "*For example*" in this subsequent sentence the skilled person understands that the statement in the preceding first sentence discloses the more general concept of compositions comprising two different sugars and a surfactant as defined in claim 1 as granted.

- 1.4 Paragraphs [096] and [011] of the application as filed disclose generalisations relating to compositions comprising two different sugar excipients and compositions comprising at least three non-protein excipients. The decision under appeal therefore incorrectly concluded that there is no basis in the application as filed for any generalisation (see decision page 5, lines 24-30) and that an interpretation of the first sentence of paragraph [0155] as relating to a general statement of invention would be contrary to the teaching of the patent as a whole (see decision, page 6, lines 4-7).

- 1.5 The decision under appeal further stated (see page 6, lines 8-13) that even if the first sentence of paragraph [0155] were considered to represent a statement of general concept, the amendment of claim 1 as granted could still not be based on what the opposition division considered a single speculative statement lacking support in the disclosure of the patent when taken as a whole.

The Board does not share the opinion of the opposition division. For the purposes of Article 100(c) EPC it is enough that the amended subject-matter remains within the limit of what the skilled person would derive directly and unambiguously from the whole of the application as filed. As explained in sections 1.3 and 1.4 above, paragraph [0155] presents a general statement regarding the effective use of two different sugars and a surfactant, which is consistent with the content of the original disclosure as a whole and which thus unambiguously forms part of this content. In this context the alleged speculative nature of the general statement or the extent to which this statement is supported by evidence are not relevant to the criteria of Article 100(c) EPC.

- 1.6 Having regard to the general statement of concept in the first sentence of paragraph [0155] and the progressively narrower levels of generality subsequently described in that paragraph the Board is therefore satisfied that the subject-matter of claim 1 of the patent as granted can be directly and unambiguously derived from the content of the application as filed.

The wording of the granted dependent claims 2-10 had not been amended with respect to claims 2-10 as filed and does not give rise to any valid objection of added subject-matter.

The Board therefore concludes that the ground of subject-matter extending beyond the content of the application as filed is not prejudicial to the maintenance of the patent as granted.

2. Both the appellant and the respondent explicitly requested remittal of the case to the opposition division for examination of the remaining grounds of opposition in the event that the Board would not confirm the appealed decision regarding the issue of added subject-matter with respect to any of the filed requests.

Taking further account of the fact that the reasons for the decision under appeal were not based on any of the other raised grounds of opposition (lack of sufficient disclosure and lack of inventive step) the Board considers that in accordance with Article 11 RPBA 2020 and in line with T 1966/16 (point 2.2) special reasons justify that the case is remitted to the opposition division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



B. Atienza Vivancos

E. Duval

Decision electronically authenticated