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Case Number: T 1221/14 - 3.3.01

Application Number: 02807745.1

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Language of the proceedings: EN

Title of invention:
FRET PROTEASE ASSAYS FOR CLOSTRIDIAL TOXINS

Patent Proprietor:
ALLERGAN, INC.

Opponents:
Merz Pharma GmbH & Co. KGaA
IPSEN PHARMA S.A.S.

Headword:
Clostridial assays/ALLERGAN

Relevant legal provisions:
EPC Art. 123(2), 123(3), 111(1)
RPBA Art. 12(4)

Keyword:
Late-filed requests, filed with statement of grounds of appeal - admitted (yes)
Amendments - allowable (main request, first and second auxiliary requests - no; third auxiliary request - yes)
Appeal decision - remittal to the opposition division (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1221/14 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 9 May 2019

Appellant: (Patent Proprietor)	ALLERGAN, INC. 2525 Dupont Drive Irvine, CA 92612 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent)	Merz Pharma GmbH & Co. KGaA Eckenheimer Landstrasse 100 60318 Frankfurt/Main (DE)
Representative:	Herzog, Fiesser & Partner Patentanwälte PartG mbB Isartorplatz 1 80331 München (DE)

Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 March 2014 revoking European patent No. 1438586 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	M. Blasi

Summary of Facts and Submissions

I. European patent 1438586 is based on patent application 02807745.1, which was filed as an international application published as WO 2004/031773. The patent is entitled "Fret protease assays for clostridial toxins" and was granted with 16 claims.

Independent claims 1 and 2 as granted read as follows:

"1. A botulinum toxin serotype A (BoNT/A) substrate, comprising:
(a) a donor fluorophore;
(b) an acceptor having an absorbance spectrum overlapping the emission spectrum of said donor fluorophore; and
(c) a BoNT/A recognition sequence comprising a BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence derived from a SNAP-25, said BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence intervening between said donor fluorophore and said acceptor;
wherein said donor fluorophore and said acceptor are spatially separated by a distance of at most 10 nm; and
wherein, under the appropriate conditions, resonance energy transfer is exhibited between said donor fluorophore and said acceptor."

"2. A botulinum toxin serotype A (BoNT/A) substrate, comprising:
(a) a donor fluorophore;
(b) an acceptor having an absorbance spectrum overlapping the emission spectrum of said donor fluorophore; and
(c) a BoNT/A recognition sequence comprising a BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site

sequence derived from a SNAP-25, said BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence intervening between said donor fluorophore and said acceptor;
wherein either of said donor fluorophore, said acceptor, or both said donor fluorophore and said acceptor are genetically encoded;
wherein said donor fluorophore and said acceptor are spatially separated by a distance of at most 10 nm; and
wherein, under the appropriate conditions, resonance energy transfer is exhibited between said donor fluorophore."

II. Two oppositions were filed against the granted patent, both opponents requesting the revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC). By letter dated 19 October 2012, opponent 2 withdrew its opposition, and hence opponent 1 became the sole opponent.

III. In its decision taken at the oral proceedings, the opposition division revoked the patent under Article 101(3)(b) EPC. All requests on file (main request and auxiliary requests 1 to 4) were found to contravene Article 123(2) EPC.

IV. The patent proprietor (appellant) lodged an appeal against that decision. In the statement of grounds of appeal, the appellant requested that the decision of the opposition division be set aside and the patent be maintained according to the set of claims of the main request or, alternatively, according to one of the sets

of claims of the first to fifth auxiliary requests, all filed with the grounds of appeal.

Claims 1 and 2 of the **main request** are identical to claims 1 and 2, respectively, as granted.

Claims 1 and 2 of the **first auxiliary request** differ from the respective claims of the main request in that the following feature has been added to item (c):

"...
(c) ... between said donor fluorophore and said acceptor;
wherein said substrate includes at least six consecutive residues of SNAP-25, wherein the six consecutive residues include Gln-Arg;
wherein ..."

Claims 1 and 2 of the **second auxiliary request** differ from the respective claims of the main request in that the following feature has been added to item (c):

"...
(c) ... between said donor fluorophore and said acceptor;
in which the residue at position P_1-P_2-P_3-P_4-P_5 or $P_{>5}$ is substituted with an amino acid conjugated to a donor fluorophore or acceptor and in which the residue at position P_1'-P_2'-P_3'-P_4'-P_5' or $P_{>5}$' is substituted with an amino acid conjugated to a donor fluorophore or acceptor,
wherein ..."

Claims 1 and 2 of the **third auxiliary request** differ from the respective claims of the main request in that the following amendments have been made to item (c):

"...
(c) a BoNT/A recognition sequence ~~comprising a BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence derived from a SNAP-25, said BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence intervening~~ which comprises the amino acid sequence selected from the group consisting of SEQ ID NO:27, SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO:32, amino acid residues 137 to 206 of SEQ ID NO:2, and amino acid residues 134 to 206 of SEQ ID NO:2 or a peptidomimetic thereof and intervenes between said donor fluorophore and said acceptor;
..."

V. In the letter of reply to the statement of grounds of appeal, the opponent (respondent) requested that the appeal be dismissed. It also requested that the second to fifth auxiliary requests not be admitted into the proceedings.

VI. As requested by the parties, the board issued a summons to oral proceedings. In the accompanying communication, the board provided a preliminary opinion on procedural issues, in particular regarding admission of requests and a possible remittal to the opposition division for further prosecution.

VII. Oral proceedings before the board took place as scheduled. At the end of the oral proceedings, the chairman announced the board's decision.

VIII. The appellant's submissions may be summarised as follows:

Article 123(2) and (3) EPC

The claims of the main request did not add subject-matter. The passage on page 3, first paragraph, of the application as filed provided the basis for most of the features of claims 1 and 2. It disclosed the general features of the invention as comprising a "recognition sequence that includes a cleavage site", said cleavage site intervening between donor fluorophore and acceptor. As to feature (c), this was an additional definition of the BoNT/A recognition sequence. Page 4, first sentence, referred specifically to BoNT/A and also taught a sequence comprising six consecutive amino acids of SNAP-25. Portions of SEQ ID NOs:1 and 2 were given as further examples, all making clear that the substrate comprised a sequence of at least two amino acids (cleavage site), but preferably with more amino acids around. From page 11, lines 20 onwards, it was clear that in the preferred embodiments not only did the cleavage site intervene but also more residues surrounding the cleavage site. The assay was explained in the last sentence of page 11, bridging to page 12, and page 18, last paragraph, bridging to page 19, clarifying that a specific spatial conformation was required. On page 30, lines 7 to 8, the nomenclature P_1-P_1' was used. Page 31 provided an overview of different sequences that were substrate to different botulin toxins and represented the cleavage site sequence as P_4...P_4'. Page 40, lines 5 ff., made clear that recognition sequence meant a scissile bond (i.e. cleavage site) plus adjacent or non-adjacent recognition elements; examples thereof were provided in the following paragraph, consisting of specific sequences which all fell within the language of P_5-...-P_5', with the sole exception of SEQ ID NO:28. Page 27, third paragraph, referred to a cleavage site and

recognition sequence, and the fourth paragraph also included the situation where the recognition sequence intervened. Page 28, lines 4 ff. taught that "all or only a portion of the clostridial toxin recognition sequence can intervene". Page 45, lines 28 ff. referred to P_5-...-P_5' as standard nomenclature. There was no embodiment covered by the claims which was not disclosed in the application as filed. It was well-known in the art that SNAP-25 was the preferred substrate of BoNT/A.

As to the first auxiliary request, the additional feature was explicitly disclosed on page 4, lines 10 to 13. Hence, Article 123(2) EPC was complied with.

As to the second auxiliary request, the same language as on pages 45 and 46 was used in claim 1, and thus the requirements of Article 123(2) EPC were met.

Regarding the third auxiliary request, the claimed sequences were disclosed in the application as filed (pages 40 and 41) as preferred embodiments. All claimed sequences were BoNT/A recognition sequences (page 40, lines 13 to 14) and were inherently cleavable. There was a general reference to peptidomimetics on page 4, lines 10 to 14 and 17 to 20. Hence, the requirements of Article 123(2) and (3) EPC were met.

IX. The respondent's arguments may be summarised as follows:

Admission of second to fifth auxiliary requests

These requests should not be admitted into proceedings, as they were late-filed, could have been filed earlier and were not clearly allowable, since they were still

not fully compliant with Article 123(2) EPC and also raised new issues under Articles 123(3), 84 and 56 EPC.

Article 123(2) and 3 EPC

The claims of the main request added subject-matter. Pages 3 and 4 did not mention the P_5-...-P_5' sequence, let alone as intervening sequence. On page 11, second paragraph, an upper limit for the number of intervening residues was given; however claims 1 and 2 had no upper limit but rather an implicit lower limit (ten or more, due to the use of the word "comprising"). The relevant sequence of Table 1 on page 31 only comprised eight amino acids and in the list of sequences of page 40 there was no mention of fluorophores or their localisation. On page 28 no portion was defined nor were the specific (BoNT-A substrate, derived from SNAP-25) recognition sequence or cleavage site mentioned. The passage on page 45, last paragraph, was not related to a BoNT/A recognition sequence, let alone derived from SNAP-25, nor did it teach that the sequence was an intervening sequence. There was no mention of a "cleavage site sequence" in the application as filed. The same arguments also applied to the first and second auxiliary requests, since the features objected to were still present. Hence, the claims of the first and second auxiliary requests were not compliant with Article 123(2) EPC.

With regard to the second auxiliary request, a further objection was raised due to the presence of hyphens, instead of the commas given in the description as filed. Moreover, the claimed subject-matter involved a specific selection from two lists, which was not disclosed in the application as filed, and the passage did not require the intervention of ten or more amino

acids. This request thus also contravened Article 123(2) EPC.

Claims 1 and 2 of the third auxiliary request extended the scope of protection (Article 123(3) EPC) because they only required the presence of the recognition sequence but not of the cleavage site; therefore, non-cleavable variants were also encompassed. With regard to Article 123(2) EPC, there was no basis for peptidomimetics of the peptides 137 to 206 and 134 to 206 of SEQ ID NO:2 and no disclosure that the specific sequences intervened between fluorophores.

X. The appellant requested that the decision of the opposition division be set aside and the case be remitted to the opposition division for further prosecution on the basis of the claims of the main request or, alternatively, of the first to fifth auxiliary requests, all as filed with the statement of grounds of appeal.

The respondent requested that the appeal be dismissed and that the second to fifth auxiliary requests not be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. Admission of the second to fifth auxiliary requests - Article 12(4) RPBA

2.1 Pursuant to Article 12(4) RPBA, it is at the discretion of the board to admit *inter alia* requests which could

have been presented in the proceedings before the examining or opposition division. When exercising its discretion, the board has to take into account the circumstances of the particular case and the arguments put forward by the parties.

2.2 The second to fifth auxiliary requests were all filed by the appellant with the statement of grounds of appeal as new requests which had not been present during the proceedings before the opposition division. The respondent objected to their admission, arguing that they were late-filed, that they could have been filed earlier in reply to the summons to oral proceedings by the opposition division and that they were not clearly allowable.

2.3 It is apparent to the board that the new auxiliary requests have been submitted as a reaction to the decision of the opposition division, in a legitimate attempt to redress said decision. As can be derived from the file inspection, in its communication accompanying the summons to oral proceedings, the opposition division had explicitly indicated that it considered the requirements of Article 123(2) EPC to be met for the claims of the main request (which was the same main request that was subsequently refused under Article 123(2) EPC) and the division had not raised any objections under Article 123(2) EPC for any of the other requests which were then on file. At the oral proceedings before the opposition division, the appellant was confronted with the changed position of the opposition division on the issue of Article 123(2) EPC for the first time. Accordingly, the filing of the present amended claim requests with the statement of grounds of appeal is considered by the board as an appropriate reaction to the procedural

development of the present case. As to the respondent's further argument that these requests were not clearly allowable, the board notes that *prima facie* allowability may be required for admitting requests which are filed very late in the appeal proceedings (e.g. at appeal oral proceedings) but is not necessarily a requirement for those claim requests that have been filed already with the statement of grounds of appeal.

2.4 The board thus decided to admit the second to fifth auxiliary requests into the proceedings (Article 12(4) RPBA).

3. Main request - Article 123(2) EPC

3.1 Claims 1 and 2 of the main request are directed to a botulinum toxin serotype A (BoNT/A) substrate defined by a number of features (for the exact wording, see section I). Both claims are derived from claim 4 of the application as filed, differing therefrom in that item (c) has been amended as follows:

Claim 1:

"(c) a BoNT/A recognition sequence comprising a BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence derived from a SNAP-25, said BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' ~~wherein said~~ cleavage site sequence intervening ~~intervenes~~ between said donor fluorophore and said acceptor;
wherein said donor fluorophore and said acceptor are spatially separated by a distance of at most 10 nm;
and..."

Claim 2:

"(c) a BoNT/A recognition sequence comprising a BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence derived from a SNAP-25, said BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' ~~wherein said~~ cleavage site sequence intervening ~~intervenes~~ between said donor fluorophore and said acceptor;
wherein either of said donor fluorophore, said acceptor, or both said donor fluorophore and said acceptor are genetically encoded;
wherein said donor fluorophore and said acceptor are spatially separated by a distance of at most 10 nm;
and ..."

3.2 In relation to the features "wherein either of said donor fluorophore, said acceptor, or both said donor fluorophore and said acceptor are genetically encoded" (claim 2) and "wherein said donor fluorophore and said acceptor are spatially separated by a distance of at most 10 nm" (both claims), the respondent has not raised any objections under Article 123(2) EPC. A basis for these features can be found in the application as filed, e.g. on page 86, line 12 to page 87, line 4, and on page 90, last paragraph, respectively.

3.3 However, there is no apparent basis in the application as filed for the feature "a BoNT/A recognition sequence comprising a BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence derived from a SNAP-25, said BoNT/A P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' cleavage site sequence intervening between said donor fluorophore and said acceptor". The only passage in the application as filed where the sequence P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' is mentioned is on page 45, line 30, as part of a sentence that reads: "In standard nomenclature, the

sequence surrounding clostridial toxin cleavage sites is denoted P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5', with P_1-P_1' the scissile bond". This sentence does not disclose that the sequence is a recognition sequence, let alone a BoNT/A recognition sequence, much less from a SNAP-25, nor that it is a cleavage sequence intervening between the donor fluorophore and the acceptor. Hence, this sentence cannot provide a basis for the disputed feature in claims 1 and 2.

3.4 Other passages have been indicated by the appellant as a basis for this feature, however the board is not convinced by the appellant's arguments, as explained below.

3.4.1 On pages 45 and 46, the sentence following the aforementioned sentence reads: "In one embodiment, the invention provides a BoNT/A substrate or other clostridial toxin substrate in which the residue at position P_1, P_2, P_3, P_4, P_5, or $P_{>5}$ is substituted with an amino acid conjugated to a donor fluorophore or acceptor, and in which the residue at position P_1', P_2', P_3', P_4', P_5' or $P_{>5}$' is substituted with an amino acid conjugated to a donor fluorophore or acceptor". While specifically mentioning a BoNT/A substrate, this sentence does not mention SNAP-25 and the board notes that, even if, as argued by the appellant, SNAP-25 may be a well-known BoNT/A substrate, there is no teaching in the application or elsewhere on file that it is the only possible BoNT/A substrate. Moreover, this sentence allows a large number of possible alternatives for the intervening sequence, since its limits are in any of the residues surrounding the scissile bond P_1-P_1', and even in the scissile bond residues themselves, and does not even require a symmetry (in terms of size) of the intervening sequence around the scissile bond. The now

claimed sequence, which is made up of at least five residues on each side of the scissile bond, may thus be considered to be a selection of all possible alternatives which fall within the disclosure of this passage.

3.4.2 Page 4, first sentence, refers specifically to a BoNT/A substrate containing "a BoNT/A recognition sequence that includes a cleavage site, where the cleavage site intervenes between the donor fluorophore and the acceptor". The following sentence teaches that "A BoNT/A substrate of the invention can include, for example, at least six consecutive residues of SNAP-25, where the six consecutive residues include Gln-Arg". While this second sentence refers to a sequence of SNAP-25, this is not described as a BoNT/A recognition sequence that includes a cleavage site (not further defined), nor does its structure correspond to the structure defined in the claim, which would require at least five residues on each side of the scissile bond. Further down on page 4, in lines 20 to 26, it is disclosed that "In one embodiment, a BoNT/A substrate of the invention includes the amino acid sequence Glu-Ala-Asn-Gln-Arg-Ala-Thr-Lys (SEQ ID NO: 1), or a peptidomimetic thereof. In another embodiment, a BoNT/A substrate of the invention includes residues 187 to 203 of human SNAP-25 (SEQ ID NO: 2), or a peptidomimetic thereof". Again, these sequences do not necessarily satisfy the structural requirements of the claim, because it is not taught that they are recognition sequences, let alone that they intervene between the donor fluorophore and the acceptor. Even if they fulfilled said structural requirements, they would be only two examples of possible sequences and could not provide a basis *per se* for the generalised structural definition given in the claim.

3.4.3 The third paragraph on page 11 refers to possible sizes of clostridial toxin substrates of the invention. It is not specifically related to BoNT/A substrates nor does it refer to recognition sequences. Moreover, while the last sentence of this paragraph teaches that intervening sequences between the donor fluorophore and the acceptor comprise at most six, eight, ten or fifteen residues, it does not require at least five residues to be present on each side of the scissile bond, as in the claims. The following paragraph, bridging to page 12, as well as the last paragraph on page 18, bridging to page 19, teach the method of the invention. According to the appellant these passages disclosing the assay of the invention make clear that a specific spatial conformation of the substrate is required. The board however fails to see that the claimed specific spatial conformation is at all implicit to these disclosures.

3.4.4 Page 30, line 8, teaches that BoNT/A cleaves a Gln-Arg bond. Table 1 on page 31 provides examples of substrate sequences for different clostridial toxins, with the general sequence P_4-P_3-P_2-P_1 - - P_1'-P_2'-P_3'-P_4'. For the first of said sequences, the toxin is identified as BoNT/A, and the target as SNAP-25. The sequence is Glu-Ala-Asn-Gln-Arg-Ala-Thr-Lys, SEQ ID NO:1. As explained above, this sequence does not necessarily fulfil the structural requirements of the claim, because it is not taught that it is a recognition sequence, nor that it intervenes between the donor fluorophore and the acceptor, nor does it comprise five residues on each side of the cleavage site Gln-Arg. Moreover, it would be only one example of all possible sequences and could not provide *per se* a basis for the generalised structural definition given in the claims.

3.4.5 The second paragraph of page 40 teaches that a BoNT/A recognition sequence consists of a scissile bond together with adjacent or non-adjacent recognition elements sufficient for detectable proteolysis at the scissile bond by a BoNT/A. This passage does not teach that said recognition sequences can be generally represented by the sequence P_5-P_4-P_3-P_2-P_1-P_1'-P_2'-P_3'-P_4'-P_5' as in the claim. The following paragraph provides examples of known BoNT/A recognition sequences which fall within the structural definition of the claim, with the exception of SEQ ID NO:28. Although these sequences may all be represented by the general sequence of the claims, they are not a suitable basis for generalisation to all possible recognition sequences falling within the general structural definition of the claims, since there is no teaching in the application making said generalisation implicit or unambiguously derivable. Contrary to the appellant's arguments that there would be no sequence falling within the claimed subject-matter which was not disclosed in the application as filed, it cannot be excluded *a priori* that other sequences, different from those disclosed in the application, could fulfil the structural requirements of claims 1 and 2.

3.5 In summary, the application does generally disclose a BoNT/A substrate comprising a donor fluorophore, an acceptor having an absorbance spectrum overlapping the emission spectrum of said donor fluorophore, and a BoNT/A recognition sequence comprising a cleavage site, wherein said cleavage site intervenes between said donor fluorophore and said acceptor (claim 4 as filed; page 3). It also discloses that, for clostridial toxin recognition sequences, the whole recognition sequence or only a part of it can intervene between the donor

fluorophore and the acceptor (page 28, lines 4 to 7). BoNT/A substrates including at least six consecutive residues of SNAP-25 including the cleavage site Gln-Arg, such as e.g. SEQ ID NO:1 or residues 187 to 203 of SEQ ID NO:2, are disclosed (page 4, second sentence and lines 20 to 26; Table 1 on page 31). A number of specific BoNT/A recognition sequences derived from SNAP-25 and identified by their respective SEQ IDs are listed on pages 40 and 41. Finally, a more general disclosure of intervening sequences in BoNT/A substrates is given on pages 45 and 46, but without indicating that these are recognition sequences; moreover, this general disclosure encompasses a number of different possibilities regarding the length and conformation of the intervening sequence, without explicitly disclosing the claimed conformation.

3.6 There is thus no basis in the application as filed for a substrate comprising an intervening sequence as defined in claims 1 and 2 of the main request. The main request therefore contravenes Article 123(2) EPC.

4. First auxiliary request - Article 123(2) EPC

4.1 Claims 1 and 2 of the first auxiliary request essentially differ from claims 1 and 2, respectively, of the main request in that a further characterising feature was added to item (c). However, the feature which was considered to add subject-matter in the main request is still present, unchanged, in this claim request, and the added feature does not limit it in any way. In fact, the former feature already implicitly contained the limitation that the substrate included at least six consecutive residues of SNAP-25 (in fact, at least ten residues) and that these included Gln-Arg, since this was known to be the target bond for BoNT/A

(page 30, line 8) and was thus necessarily part of any natural BoNT/A recognition sequence.

4.2 Accordingly, claims 1 and 2 of the first auxiliary request also do not meet the requirements of Article 123(2) EPC.

5. Second auxiliary request - Article 123(2) EPC

5.1 As for the first auxiliary request, claims 1 and 2 of the second auxiliary request essentially differ from claims 1 and 2, respectively, of the main request in that a further characterising feature was added to item (c), while the feature which was considered to add subject-matter in the main request is still present, unchanged, and is not further limited by the new feature.

5.2 Hence, claims 1 and 2 of the second auxiliary request also contravene Article 123(2) EPC.

6. Third auxiliary request

6.1 Article 123(3) EPC

6.1.1 Claims 1 and 2 of the third auxiliary request differ from the respective claims of the main request in that the feature which has been considered to add subject-matter was deleted and the BoNT/A recognition sequence was instead defined by reference to specific amino acid sequences identified by their SEQ ID NOs.

6.1.2 The respondent essentially argued that, since the disputed feature of the main request had been deleted, there was no longer any requirement for a cleavage site to be present in the recognition sequence. Accordingly,

the claims also encompassed uncleavable recognition sequences, and were thus broader than the granted claims.

6.1.3 The board disagrees with this argument. First, the definition of a recognition sequence, as put forward in the application on page 40, lines 5 to 12, makes clear that a cleavage site (i.e. a scissile bond) is present. Second and most importantly, the presence of such a cleavage site is inherent to the amino acid sequence itself. As is apparent from the sequence listing, all of these sequences comprise the Gln-Arg motif that is identified in the application as the BoNT/A cleavage site (page 30, line 8).

6.1.4 The present claims thus fulfil the requirements of Article 123(3) EPC.

6.2 Article 123(2) EPC

6.2.1 As regards Article 123(2) EPC, the added features are described on pages 40 and 41, where all of the sequences currently in the claim are listed and disclosed as BoNT/A recognition sequences. While this passage does not explicitly refer to peptidomimetics of the peptides 137 to 206 and 134 to 206 of SEQ ID NO:2, the general disclosure of peptidomimetics on page 4, lines 10 to 14 and 17 to 20, is considered an appropriate basis for this feature also in combination with the specific sequences, which only requires the application of this general disclosure to the disclosure of the specific sequences.

6.2.2 A further argument from the respondent was that this passage did not disclose that the listed sequences had to intervene between the donor fluorophore and the

acceptor. The board notes however that the general disclosure of the invention clearly teaches that the whole recognition sequence or a part of it can intervene between the donor fluorophore and the acceptor (page 28, lines 4 to 6). Hence, this feature in the claim finds a basis in the combination of the first of these two alternatives of the general disclosure with the specific sequences.

6.2.3 Claims 1 and 2 of the third auxiliary request thus comply with Article 123(2) EPC.

6.3 There were no further objections from the respondent as regards Article 123(2) and (3) EPC. The board has no objections either. Hence, the set of claims of the third auxiliary request is considered to comply with Article 123(2) and (3) EPC.

7. Remittal - Article 111(1) EPC

7.1 The appellant requested the remittal of the case to the opposition division for further prosecution and the respondent raised no objections thereto. The board also finds it appropriate not to decide on issues which have not yet been decided upon by the opposition division and has therefore decided, exercising its discretion under Article 111(1), second sentence, EPC, to remit the case 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 on the basis of the set of claims of the third auxiliary request filed with the statement of grounds of appeal dated 21 July 2014.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated