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Datasheet for the decision of 15 November 2022

Case Number: T 1875/19 - 3.3.08

Application Number: 06806155.5

Publication Number: 1940881

IPC: C07K16/28, C07K16/30, A61K39/395, A61P35/00, C12N15/13

Language of the proceedings: EN

Title of invention:
Compositions comprising cross-species-specific antibodies and uses thereof

Patent Proprietor:
Amgen Research (Munich) GmbH

Opponents:
Aptevo Research & Development LLC
MorphoSys AG (Opposition withdrawn)

Headword:
Bispecific cross-species-specific antibodies/AMGEN

Relevant legal provisions:
EPC Art. 83
RPBA Art. 12(2), 12(4)
RPBA 2020 Art. 13(1)

Keyword:
Sufficiency of disclosure - reproducibility (no)
Statement of grounds of appeal - party's complete case (no)
Late-filed requests - requests could have been filed in first instance proceedings (yes)

Decisions cited:
T 0665/90, T 0792/00

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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 1875/19 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 15 November 2022

Appellant: (Patent Proprietor)	Amgen Research (Munich) GmbH Staffelseestraße 2 81477 München (DE)
Representative:	Schiweck Weinzierl Koch Patentanwälte Partnerschaft mbB Ganghoferstraße 68 B 80339 München (DE)
Respondent 1: (Opponent 1)	Aptevo Research & Development LLC 400 Professional Drive, Suite 400 Gaithersburg MD 20879 (US)
Representative:	Forresters IP LLP Skygarden Erika-Mann-Straße 11 80636 München (DE)
Respondent 2: (Opponent 2) - opposition withdrawn -	MorphoSys AG Semmelweisstraße 7 82152 Martinsried/Planegg (DE)
Representative:	Spiller, Stephan MorphoSys AG Semmelweisstraße 7 82152 Planegg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 17 April 2019 revoking European patent No. 1940881 pursuant to Article 101(2) and Article 101(3)(b) EPC**

Composition of the Board:

Chair	B. Claes
Members:	A. Schmitt
	M. Blasi

Summary of Facts and Submissions

I. The patent proprietor's (appellant's) appeal lies from the decision of the opposition division to revoke European patent No. 1 940 881 (patent), entitled "*Compositions comprising cross-species-specific antibodies and uses thereof*", granted on European patent application No. 06 806 155.5, which had been filed as an international application published as WO 2007/042261.

Claims 1 and 8 of the patent read:

"1. A pharmaceutical composition for the treatment of a human patient, comprising a bispecific single chain antibody which comprises
(i) a first binding domain binding to a non-chimpanzee primate CD3, and
(ii) a second binding domain binding to a cell surface antigen,
wherein said first binding domain binds to an epitope of human and non-chimpanzee primate CD3 epsilon,
wherein the epitope comprises the amino acid sequence "FSEXE" (SEQ ID NO. 204), wherein "X" represents L (Leucine) or M (Methionine), and wherein the non-chimpanzee primate CD3-epsilon comprises or consists of an amino acid sequence shown in
SEQ IN [*sic*] NO: 135 or 136."

"8. The pharmaceutical composition of any one of claims 1 to 7, wherein the VH region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:2 and the VL region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:4."

II. Two oppositions were filed against the patent. The opposition proceedings were based on the grounds for opposition in Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and in Article 100(b) and 100(c) EPC.

III. In the decision under appeal, the opposition division decided, *inter alia*, that the subject-matter of claim 1 of the patent as granted (main request, see section I.) lacked novelty, that the invention as defined in claim 1 of auxiliary request 2, which had been submitted as auxiliary request 6 on the final date for making written submissions set under Rule 116(1) EPC, was not disclosed in the application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Documents D20 and D36 demonstrated that an antibody with the complementarity-determining regions (CDRs) as defined in the claim (the antibody SP34) did not bind to the epitope FSEXE as required by the claim.

Claim 1 of auxiliary request 2 considered by the opposition division reads as follows:

"1. A pharmaceutical composition for the treatment of a human patient, comprising a bispecific single chain antibody which comprises
(i) a first binding domain binding to a non-chimpanzee primate CD3, and
(ii) a second binding domain binding to a cell surface antigen,
wherein said first binding domain binds to an epitope of human and non-chimpanzee primate CD3 epsilon,
wherein the epitope comprises the amino acid sequence "FSEXE" (SEQ ID NO. 204), wherein "X" represents L

(Leucine) or M (Methionine), and wherein the non-chimpanzee primate CD3-epsilon comprises or consists of an amino acid sequence shown in SEQ IN [*sic*] NO: 135 or 136, wherein the first binding domain comprises CDR-L1 set forth in SEQ ID NO. 118, CDR-L2 set forth in SEQ ID NO. 117, and CDR-L3 set forth in SEQ ID NO. 116 and CDR-H1 set forth in SEQ ID NO. 115, CDR-H2 set forth in SEQ ID NO. 114 and CDR-H3 set forth in SEQ ID NO. 112 or CDR-H3* comprising the amino acid sequence "VSWFAY" set forth in SEQ ID NO. 113."

The opposition division did not admit an auxiliary request 2A, which was submitted during the oral proceedings and later renumbered as auxiliary request 3, and nine further auxiliary requests, the claims of which had been submitted on the final date for making written submissions set under Rule 116(1) EPC as auxiliary requests 1 to 3, 5 and 7 to 11, into the opposition proceedings, because they did not "*prima-facie address the objection raised with regard to Article 83*".

Claim 1 of auxiliary request 3 (submitted as auxiliary request 2A) was identical to claim 1 of auxiliary request 2 except that it comprised the further feature "wherein said epitope is deduced by pepspot analysis".

Claim 1 of auxiliary request 7, which was submitted on the final date for making written submissions set under Rule 116(1) EPC, was identical to claim 1 of the patent as granted (see section I.) except that it comprised the further feature "wherein at least one of said first binding domain is human or humanized".

IV. With the statement of grounds of appeal the appellant submitted sets of claims of auxiliary requests 1 to 6,

6A, 7, 7A, 8, 8A, 9, 9A, 10, 11, 11A, 12 and 13, and documents D53, D54, D55A, D55B, D56 and D57. It also submitted arguments supporting its view, *inter alia*, that the invention as defined in the claims of the main request (patent as granted) was sufficiently disclosed in the patent. The sets of claims of auxiliary requests 1 to 5 and 8 to 11 are identical to those of auxiliary requests 1 to 5 and 8 to 11 submitted on the final date for making written submissions set under Rule 116(1) EPC. The sets of claims of auxiliary requests 6, 6A, 7, 7A, 8A, 9A, 11A, 12 and 13 contain amendments with respect to sets of claims filed before the opposition division.

Claim 8 of each of auxiliary requests 1, 2, 3, 6 and 6A has the same wording as claim 8 of the patent as granted (see section I.).

Claim 7 of each of auxiliary requests 4, 5, 8, 8A and 10 has the same wording as claim 8 of the patent as granted except for an amended claim reference (see section I.).

Claim 1 of auxiliary requests 1 and 2 is identical to claim 1 of the patent as granted (see section I.).

Claim 1 of auxiliary request 3 is identical to claim 1 of the patent as granted (see section I.) except for the additional feature "wherein said epitope is deduced by pepspot analysis".

Claim 1 of auxiliary request 4 is identical to claim 1 of the patent as granted (see section I.) except for the additional feature "wherein the second binding domain binds to a human cell surface antigen and to the

non-chimpanzee primate homolog of said cell surface antigen".

Claim 1 of auxiliary request 5 is identical to claim 1 of the patent as granted (see section I.) except for the additional feature "wherein the cell surface antigen is a tumor antigen".

Claim 1 of auxiliary request 6 is identical to claim 1 of auxiliary request 2 considered by the opposition division (see section III.).

Claim 1 of auxiliary request 7 is identical to claim 1 of the patent as granted (see section I.) except for the additional feature "wherein said first binding domain is human or humanized".

Claim 8 of auxiliary request 7 reads as follows:

"8. The pharmaceutical composition of any one of claims 1 to 7, wherein the VH region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:110 and the VL region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:148 or SEQ ID NO:168."

Claim 1 of auxiliary request 7A is identical to claim 1 of the patent as granted (see section I.) except for the additional feature "wherein said first binding domain is human". Moreover, compared to the set of claims of the patent as granted, all dependent claims referring to amino acid sequences of the antibodies have been deleted.

Claim 1 of auxiliary request 8 is identical to claim 1 of the patent as granted (see section I.) except for

the additional feature "wherein the first binding domain comprises a VH region having an amino acid sequence as shown in any of SEQ ID NO:2 or 110 and a VL region having an amino acid sequence as shown in any of SEQ ID NO:4, 148 or 168".

Claim 1 of auxiliary request 9 is identical to claim 1 of the patent as granted (see section I.) except for the additional features "wherein the VH region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:2 and the VL region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:4 or wherein the VH region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:110 and the VL region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:148 or SEQ ID NO:168."

Claim 1 of auxiliary request 10 is identical to claim 1 of the patent as granted (see section I.) except for the additional feature "wherein the cell surface antigen is a tumor antigen and wherein said tumor antigen is EGFR, EGFRvIII or Carboanhydrase IX (MN/CA IX)".

Claim 1 of auxiliary request 11 is identical to claim 1 of the patent as granted (see section I.) except for the additional feature "wherein the VH region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:110 and the VL region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:168".

Claim 1 of auxiliary requests 6A, 8A, 9A and 11A is identical to claim 1 of auxiliary requests 6, 8, 9 and

11 except for the additional feature "wherein said epitope is deduced by pepspot analysis".

Claim 1 of auxiliary request 12 reads as follows:

"1. A pharmaceutical composition for the treatment of a human patient, comprising a bispecific single chain antibody which comprises
(i) a first binding domain binding to a non-chimpanzee primate CD3, and
(ii) a second binding domain binding to a cell surface antigen,
wherein said first binding domain binds to an epitope of human and non-chimpanzee primate CD3 epsilon,
wherein the epitope comprises the amino acid sequence "FSEXE" (SEQ ID NO. 204), wherein "X" represents L (Leucine) or M (Methionine), and wherein the non-chimpanzee primate CD3-epsilon comprises or consists of an amino acid sequence shown in SEQ IN [*sic*] NO: 135 or 136, wherein the first binding domain comprises CDR-L1 set forth in SEQ ID NO. 166, CDR-L2 set forth in SEQ ID NO. 165, and CDR-L3 set forth in SEQ ID NO. 164 and CDR-H1 set forth in SEQ ID NO. 121, CDR-H2 set forth in SEQ ID NO. 120 and CDR-H3 set forth in SEQ ID NO. 119."

Claim 1 of auxiliary request 13 reads as follows:

"A pharmaceutical composition for the treatment of a human patient, comprising a bispecific single chain antibody which comprises
(i) a first binding domain binding to a non-chimpanzee primate CD3, and
(ii) a second binding domain binding to a cell surface antigen,

wherein said first binding domain binds to an epitope of human and non-chimpanzee primate CD3 epsilon, wherein the epitope comprises the amino acid sequence "FSEXE" (SEQ ID NO. 204), wherein "X" represents L (Leucine) or M (Methionine), and wherein the non-chimpanzee primate CD3-epsilon comprises or consists of an amino acid sequence shown in SEQ IN [*sic*] NO: 135 or 136, wherein the VH region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:6 and the VL region of the first binding domain comprises or consists of the amino acid sequence shown in SEQ ID NO:8."

V. In reply to the appeal, opponent 1 (respondent) submitted, *inter alia*, comments on the admittance of the auxiliary requests and lack of sufficiency of disclosure of the invention as defined in the claims of the auxiliary requests.

VI. By letter dated 15 May 2020, the appellant submitted sets of claims of auxiliary requests 1A, 4A, 5A, 7B, 10A, 12A and 13A as well as arguments, *inter alia*, concerning sufficiency of disclosure.

Claim 1 of auxiliary requests 1A, 4A, 5A, 7B, 10A, 12A and 13A is identical to claim 1 of auxiliary requests 1, 4, 5, 7, 10, 12 and 13 submitted with the statement of grounds of appeal (see section IV.) except that it comprises the further feature "wherein said epitope is deduced by pepspot analysis".

Claim 8 of auxiliary request 1A has the same wording as claim 8 of the patent as granted (see section I.).

Claim 7 of each of auxiliary requests 4A, 5A and 10A has the same wording as claim 8 of the patent as

granted except for an amended claim reference (see section I.).

Claim 8 of auxiliary request 7B has the same wording as claim 8 of auxiliary request 7 (see section IV.).

VII. The board summoned the parties to oral proceedings in line with their requests and issued a communication pursuant to Article 15(1) RPBA 2020, setting out its preliminary opinion that, *inter alia*, the decision according to which the invention as defined in claim 1 of auxiliary request 2 considered by the opposition division was not sufficiently disclosed in the application appeared to be correct. The board furthermore drew attention to the provisions of Article 12(4) 2007 RPBA and Article 13(1) RPBA 2020 in relation to the auxiliary requests submitted.

VIII. With its letter dated 29 September 2022, the respondent submitted four documents and requested that auxiliary requests 1 to 6, 6A, 7, 7A, 8, 8A, 9, 9A, 10, 11, 11A, 12 and 13 submitted with the statement of grounds of appeal and auxiliary requests 1A, 4A, 5A, 7B, 10A, 12A and 13A submitted by letter dated 14 May 2020 not be admitted into the appeal proceedings. It also provided arguments supporting its view that none of these auxiliary requests overcame the sufficiency-of-disclosure objections expressed in the decision under appeal.

IX. In reply the appellant requested that the documents submitted by the respondent on 29 September 2022 not be admitted. The respondent then replied to the appellant's letter by submitting arguments in favour of admittance of these documents.

X. Opponent 2 did not make any submissions during the appeal proceedings. On 11 November 2022, it withdrew its opposition and ceased to be a party to the appeal proceedings.

XI. At the end of the oral proceedings, the Chair announced the board's decision.

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

D17 Experimental report on SP34 binding

D17a SP34 binding experiments prepared by F. Hoffmann-La Roche AG

D20 Letter filed on 16 March 2016 by Janssen Biotech Inc. in Opposition against European Patent No. 2155783

D36 Experimental report "CD3ε epitope mapping"

D53 Experimental report "Epitope determination"

D54 Experimental report "Testing of SP34 binding to variants of CD3 in which the FSE motif alleged to be bound in D6 is mutated"

D55A Patent proprietor's request for correction of the decision dated 16 May 2019

D55B Declaration by Dr. Gerhard Weinzierl with regard to correction of the decision

D56 Experimental report "Determination of SP34 antibody affinity"

D57 UniprotKB - P07766 (CD3E_HUMAN)

XIII. The appellant's arguments, insofar as relevant to the decision, are summarised as follows.

Main request (patent as granted)
Sufficiency of disclosure (Article 100(b) EPC) - claim 8

No serious doubts substantiated by verifiable facts had been put forward in support of the allegation that the results obtained in the pepspot analysis of Example 17 of the patent were incorrect. The respondent had not therefore discharged its burden to demonstrate insufficiency of disclosure. The data of document D36 could not be used to challenge the patent's experimental results since the patent's experimental protocol had not been repeated under the same conditions in document D36 (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition, 2022 ("CLBA"), III.G.5.2.2 g) and decision T 792/00 cited therein; CLBA, II.C.9.2 and decision T 665/90 cited therein).

The experimental protocol of Example 17 in the patent made use, *inter alia*, of higher amounts of the antibody and a more sensitive signal detection and amplification method than in document D36. These parameters influenced the detection sensitivity and were therefore relevant for detecting epitopes bound specifically but less strongly. It could therefore be expected that, if a more sensitive signal detection and amplification method had been used in the experiment reported in

document D36, a stronger signal would have been detected for peptides comprising the FSEXE epitope.

Antibody I of the patent bound to several peptides, some of which contained the FSEXE epitope as defined in the claim (see Figures 16 to 18 of the patent). The claim did not exclude the antibody binding to more than one epitope on the same protein since the epitope was defined as *comprising* the amino acid sequence FSEXE and, according to paragraph [0038] of the patent, the minimum FSEXE epitope might be part of a discontinuous epitope. Antibody I of the patent bound to a peptide derived from cynomolgus CD3 epsilon comprising the full QDGNE epitope, thus demonstrating that the assay worked (see spot 1 in Figure 18B).

Document D36 demonstrated at most that antibody SP34 (hereinafter "SP34") could not bind to the FSEXE and the QDGNE epitope simultaneously and that it bound to the QDGNE epitope with the highest affinity. Besides the binding of SP34 to peptides comprising the FSEXE epitope, document D36 disclosed low-affinity binding of SP34 to two further peptides, which were also recognised in Example 17 of the patent (spots 15 and 40 of Figure 18B of the patent). Document D36 hence confirmed the data obtained in the patent's pepspot assay and also showed that the binding to the FSEXE epitope was specific. The only additional information provided by document D36 concerned the affinity of the binding events.

Document D53 also confirmed that minor deviations from the baseline level must be regarded as reflecting specific - and hence significant - binding because it disclosed detection of low-affinity binding to a peptide comprising the epitope QYPGSEI (peptide 23),

which was also detected in document D36 (peptides 51 to 57) and Example 17 of the patent (spot 15).

Consequently, all binding experiments that had been performed demonstrated that SP34 bound to both the QDGNE and the FSEXE epitopes, albeit with different affinities.

The mutation experiments described in documents D20 and D54 did not assess the complete FSEXE epitope since mutations had only been introduced at the S and the first E amino acids positions. No conclusion could be drawn from these experiments with respect to antibodies binding to the FSEXE epitope. Moreover, document D56 demonstrated that SP34 had a 20x weaker monovalent binding affinity to a peptide consisting of amino acids 1 to 27 of human CD3 epsilon than to full-length human CD3 epsilon. This proved that SP34 also bound to parts of human CD3 epsilon located outside of the first 27 amino acids.

Since the patent demonstrated how to prepare the antibody recited in the claim, i.e. how to carry out the invention, it was not necessary to include experimental conditions into the claim.

Auxiliary requests 1, 2, 4, 5, 6, 8, 9, 10 and 11
Sufficiency of disclosure (Article 83 EPC)

No specific arguments were submitted in this context in relation to these claim requests.

Auxiliary requests 1A, 3, 4A, 5A, 6A, 7B, 8A, 9A, 10A and 11A
Sufficiency of disclosure (Article 83 EPC)

Claim 1 of each of these auxiliary requests clarified that the epitope was deduced by pepspot analysis. Since antibody I of the patent detected the FSEXE epitope in a pepspot assay, the invention defined in the claim was sufficiently disclosed.

Auxiliary requests 7, 7A, 12 and 13
Admittance (Article 12(4) RPBA 2007)

The sets of claims of these auxiliary requests, submitted with the statement of grounds of appeal, overcame the objection of insufficiency of disclosure against the invention defined in claim 8 of the main request.

The respondent's request that these auxiliary requests not be admitted was presented after the summons to oral proceedings and the board's communication pursuant to Article 15(1) RPBA 2020 had been issued. It therefore represented an amendment of the respondent's case to be considered under Article 13(2) RPBA 2020. No exceptional circumstances were indicated as to why this request for non-admittance could not have been submitted earlier. It should not therefore be admitted.

Auxiliary request 7 - admittance

As the then auxiliary request 7 was presented during opposition proceedings by the final date for making written submissions set under Rule 116(1) EPC, the opposition division did not have discretion not to admit it (see CLBA IV.C.5.1.4.d) and decision T 1261/13

cited therein). Moreover, the opposition division's decision not to admit the request was legally incorrect also for the reason that the opposition division based non-admittance thereof on the circumstance that the request was allegedly not allowable (see also document D55B).

The opposition division had misinterpreted the appellant's statements made during oral proceedings with respect to sufficiency of disclosure of the auxiliary requests on file, as was evident from the appellant's request for correction of the minutes of the oral proceedings before the opposition division (see document D55A). No discussion on admittance of the then auxiliary request 7 had taken place, which violated the appellant's right to be heard (see CLBA III.B.2.6.1.a) and decision T 763/15 cited therein).

The amendment in claim 1 of the current auxiliary request 7 as compared to claim 1 of the auxiliary request 7 dealt with in the decision under appeal amounted to a correction of an obvious error. Moreover, since the references to SEQ ID NOs.2 and 4 had been deleted from auxiliary request 7, it was clear that the opposition division's decision on Article 83 EPC (see point 28 of this decision) had been addressed by this amendment. The arguments presented in point 8 of the statement of grounds of appeal with respect to sufficiency of disclosure of the invention defined in the claims of the main request applied to auxiliary request 7, in particular as no objection under Article 83 EPC had been raised against this auxiliary request. It was sufficient that the issue for which a claim request was found unallowable by the opposition division was addressed and overcome by an amendment. If

the latter was clear, no further explanation was required.

Auxiliary requests 7A, 12 and 13 - admittance

These requests were filed in a direct reaction to the decision of the opposition division and should be considered by the board (Article 12(4) RPBA 2007). Auxiliary request 7A was filed as a direct reaction to point 19 of the opposition division's decision that the subject-matter of claim 1 of the main request lacked novelty, and auxiliary requests 12 and 13 were filed in a reaction to the opposition division's decision with respect to sufficiency of disclosure in points 25 to 28 of the decision.

Auxiliary requests 12A and 13A
Admittance (Article 13(1) RPBA 2020)

Auxiliary requests 12A and 13A were submitted in direct response to the respondent's reply to the statement of grounds of appeal, in which new objections under Article 83 EPC were raised, and should therefore be admitted into the proceedings.

XIV. The respondent's arguments, insofar as relevant to the decision, are summarised as follows.

Main request (patent as granted)
Sufficiency of disclosure (Article 100(b) EPC) - claim 8

The results of the pepspot assay as carried out in Example 17 shown in Figure 18 substantiated serious doubts as to whether antibody I of the patent bound to the FSEXE epitope. Indeed the spots detected in the

assay did not distinguish between specific binding and unspecific background signal for the reason, *inter alia*, that the signal levels of unspecific background binding were not defined. Moreover, not all peptides comprising the FSEXE epitope recited in the claim were bound by the antibody (see peptides 29, 30, and 31 in Figures 17 and 18B), which cast further doubt on the specificity of binding to this epitope as interpreted in the patent.

Furthermore, evidence was on file that SP34 did not bind to the FSEXE epitope. The two experimental reports D17 and D17a demonstrated that SP34 bound to a peptide consisting of amino acids 1 to 27 of human and cynomolgus CD3 epsilon, i.e. a peptide that lacked the FSEXE epitope, whereas it did not bind to human and cynomolgus CD3 epsilon constructs that comprised the FSEXE epitope but lacked the first five N-terminal amino acids of CD3 epsilon. Document D20 showed that the mutating of amino acids in the FSEXE epitope recited in the claim did not affect the binding of SP34 to CD3 epsilon, which also confirmed that SP34 did not bind to this epitope.

The experiments disclosed in document D36 demonstrated that SP34 bound strongly to human CD3 epsilon peptides containing the QDGNE epitope whereas no significant binding to peptides comprising the FSEXE epitope was detected. Minor variations from the background level were observed for a variety of peptides, including those comprising the FSEXE epitope. However, such variations did not represent specific antibody binding due to being barely above the background level.

Document D56 cited by the appellant might disclose that SP34 did not only interact with the N-terminal 27 amino

acids of CD3 epsilon, but its teaching did not allow the conclusion to be drawn that the other "significant" interaction was with the FSEXE epitope. If the claim was construed such that the antibody bound to other epitopes in addition to binding to the FSEXE epitope and could even preferentially bind to another epitope, there was lack of guidance in the patent as to the extent of binding to the FSEXE epitope required to fall within the scope of the claim. Such a claim construction was not in accordance with the definition of antibody binding in the application (see page 7, lines 14 to 20, of the application and paragraph [0022] of the patent).

It was irrelevant that the experiments in Example 17 of the patent and document D36 had not been carried out under exactly the same experimental conditions. No such conditions were expressed in the claim and the patent did not confirm in any case that antibody I bound to the epitope recited in the claim.

Auxiliary requests 1, 2, 4, 5, 6, 8, 9, 10 and 11
Sufficiency of disclosure (Article 83 EPC)

The same objections with respect to insufficient disclosure as raised in the context of claim 8 of the main request and claim 1 of auxiliary request 2 underlying the decision under appeal applied to the invention as defined in the claims of auxiliary requests 1, 2, 4 to 6 and 8 to 11.

Auxiliary requests 1A, 3, 4A, 5A, 6A, 7B, 8A, 9A, 10A and 11A
Sufficiency of disclosure (Article 83 EPC)

Adding a method step - here the feature that the epitope was deduced by pepspot analysis - to a product claim could not remedy any insufficiency of disclosure raised in respect of the product claim. Therefore, the same objections concerning insufficient disclosure as raised in the context of claim 8 of the main request applied to the invention as defined in the claims of auxiliary requests 1A, 3, 4A, 5A, 6A, 7B, 8A, 9A, 10A and 11A.

Auxiliary requests 7, 7A, 12 and 13
Admittance (Article 12(4) RPBA 2007)

The issue of admittance of the auxiliary requests filed with the statement of grounds of appeal had already been addressed in the reply to the statement of grounds of appeal on pages 1 and 2. It was pointed out there that the opposition division had not admitted some claim requests and that the appellant's reasoning provided in relation to the auxiliary requests was scant. The request that none of the auxiliary requests be admitted into the appeal proceedings was therefore not new.

Auxiliary request 7 - admittance

The opposition division did not admit the then auxiliary request 7 into the opposition proceedings, because it considered that it did not remedy the objection of insufficiency of disclosure raised with respect to the invention as defined in claim 1 of the then auxiliary request 2 (see point 32.1 of the

opposition division's decision). However, when submitting the claims of auxiliary request 7 with the statement of grounds of appeal, the appellant did not provide any reasons as to why this claim request could alter the opposition division's negative opinion on Article 83 EPC. In the statement of grounds of appeal, the appellant merely indicated that the purpose of filing this claim request was to address the decision on lack of novelty over the murine CRIS7 antibody. No comments on sufficiency of disclosure were presented.

Defining the antibody as human or humanised did not represent a *bona fide* attempt to overcome the objections regarding sufficiency of disclosure, as this amendment did not address why the opposition division held that the then auxiliary request 2 was not allowable. Since the amino acid residues involved in CD3 epsilon epitope binding, i.e. the CDRs, were identical in the VH and VL sequences of SP34, antibody I of the patent (SEQ ID NOs.2 and 4) and the VH and VL sequences of the humanised antibody prepared in the patent (SEQ ID NOs.110 and 168 recited in claim 8 of auxiliary request 7), there were serious doubts as to whether the first binding domain of the bispecific antibody recited in the claim would bind the epitope recited in the claim for the same reasons as for SP34 and antibody I of the patent.

Auxiliary request 7A - admittance

The request amounted to a new case presented on appeal and could and should have been presented before the opposition division. Moreover, the purpose of submitting auxiliary request 7A had been to overcome the objection of lack of novelty and not that of insufficiency of disclosure, and no comments on

sufficiency of disclosure were presented with respect to this claim request.

Auxiliary requests 12 and 13 - admittance

These requests could and should have been filed during the proceedings before the opposition division because the objection of insufficiency of disclosure with respect to antibodies based on the CDRs of antibody I disclosed in the patent and prior-art antibody SP34 had been submitted at that time.

Auxiliary requests 12A and 13A
Admittance (Article 13(1) RPBA 2020)

It had been argued in the opposition proceedings that the feature of deducing the epitope by pepspot analysis did not alter the scope of the product claims because the deduction method did not alter the structural features of the bispecific antibody recited in the claims. The opposition division also arrived at this conclusion in the decision under appeal (see points 29, 30, 31 and 31.1. of that decision). The amendment was therefore *prima facie* not relevant for addressing any of the issues that were the subject of the appeal proceedings. Auxiliary requests 12A and 13A should therefore not be admitted.

XV. The parties' requests, insofar as relevant to the decision, were as follows:

The appellant requested that the decision under appeal be set aside and that the opposition be rejected (patent maintained as granted, main request), or, alternatively, that the patent be maintained in amended form based on the set of claims of one of auxiliary

requests 1 to 6, 6A, 7, 7A, 8, 8A, 9, 9A, 10, 11, 11A, 12 and 13, all submitted with the statement of grounds of appeal, or based on the set of claims of one of auxiliary requests 1A, 4A, 5A, 7B, 10A, 12A, 13A submitted with the letter dated 14 May 2020, in the order presented in the claim correspondence table enclosed with the letter dated 14 May 2020.

The respondent requested that the appeal be dismissed, that the sets of claims of auxiliary requests 1 to 6, 6A, 7, 7A, 8, 8A, 9, 9A, 10, 11, 11A, 12 and 13, all submitted with the statement of grounds of appeal, not be admitted into the proceedings and that the sets of claims of auxiliary requests 1A, 4A, 5A, 7B, 10A, 12A and 13A, submitted by the appellant with its letter dated 14 May 2020, not be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

Main request (patent as granted)
Sufficiency of disclosure (Article 100(b) EPC) - claim 8

2. The claim relates to a bispecific antibody which comprises a first binding domain characterised in that 1) it binds to an epitope of human and non-chimpanzee primate CD3 epsilon, which epitope comprises the amino acid sequence "FSEXE" (SEQ ID NO: 204), wherein "X" represents L (Leucine) or M (Methionine) (hereinafter "FSEXE epitope"), and 2) its VH region comprises the amino acid sequence set forth in SEQ ID NO:2 and its VL region comprises the amino acid sequence set forth in SEQ ID NO:4 (see sections I. and XV.).

3. SEQ ID NO:2 comprises the complementarity-determining regions (CDRs) set forth in SEQ ID NOs. 115, 114 and 112/113; SEQ ID NO:4 comprises the CDRs as set forth in SEQ ID NOs. 118, 117 and 116. The same CDRs are also contained in the amino acid sequence of the known antibody SP34 (hereinafter "SP34") and in the humanised VH and VL regions in SEQ ID NOs. 110 and 168. This was not disputed by the appellant (see, e.g., point 4.1 of the appellant's letter dated 15 May 2020). The opposition division considered that an antibody-binding domain comprising these CDRs did not bind to the FSEXE epitope (see section III.) and could therefore not be reproduced by the skilled person.

4. By definition, an epitope is the part of an antigen which is recognised by an antibody, i.e. the part to which the antibody binds. In the context of antibodies, the term "binding" designates a specific, i.e. preferential, binding of an antibody to its antigen, and, consequently, also to the epitope recognised on the antigen. In line with this meaning, the patent defines the term "binding" as "*the ability of the first and/or second binding domains of the bispecific single chain antibody ... to discriminate between the respective first and/or second molecule to such an extent that, from a pool of a plurality of different molecules as potential binding partners, only said respective first and/or second molecule is/are bound, or is/are significantly bound*" (see paragraph [0022]). Consequently, the claimed bispecific antibody must specifically recognise the FSEXE epitope in human and non-chimpanzee CD3 epsilon.

5. The binding specificity of an antibody is defined by its amino acid sequences, in particular by the CDRs in

the antibody's VH and VL regions. Therefore, the issue of whether or not an antibody having particular CDRs binds to a specific epitope is a question of fact and is independent of the experimental technique used to determine the binding.

6. In the patent, a so-called peptide-spotting ("pepspot") assay was used to determine the binding of antibody I of the patent to overlapping peptides derived from the human and cynomolgus CD3 epsilon amino acid sequences (see Example 17 and Figure 18). The results of this analysis were deemed to support the view that antibody I bound to, *inter alia*, the FSEXE epitope (see paragraph [0149]). However, as can be seen from Figures 17 and 18B, not all peptides comprising the FSEXE epitope derived from human CD3 epsilon were detected in the assay and no quantitative assessment of the binding was performed. The significance of the interpretation of the assay results provided in the patent is therefore limited.

7. Document D36 discloses the results of a CD3 epsilon epitope mapping by the binding of SP34 (see point 3. above) to an array of overlapping peptides derived from human CD3 epsilon. The signal intensities for each peptide were quantified. SP34 bound with high affinity to peptides comprising the QDGNE epitope at a terminal position. However, no significant binding to peptides comprising the FSEXE epitope (here FSELE) was detected (see the first figure of document D36). The appellant argued that SP34 also bound to the FSEXE epitope because the signal detected for two peptides comprising this epitope was above the baseline level. However, in document D36, minor variations from the background level were observed for a variety of peptides, including two of the five peptides comprising the FSEXE

epitope. The signal observed for each of these peptides is so low - in fact barely above the background level - that it cannot be regarded as reflecting the specific binding of an antibody to its epitope (see point 4. above).

8. The appellant argued that the results shown in document D36 were unsuitable to substantiate a lack of sufficiency of disclosure because they had been obtained under experimental conditions that differed from those used in the patent. The binding to the FSEXE epitope was possibly not detected in the experiments disclosed in document D36 because less antibody and a less sensitive detection system had been used compared to those used in the patent.

9. However, document D36 demonstrates high-affinity binding of SP34 to peptides comprising the QDGNE epitope, which proves that the assay conditions used in document D36 are suitable to detect specific binding of SP34 to its epitope. The use of higher amounts of antibody and an increased signal amplification system would thus be expected, at most, to increase the intensity of all signals, including the background signal, but not to detect additional significant binding events. The variations between the experimental protocols of document D36 and those of Example 17 of the patent are therefore not relevant and cannot be used to discredit the results disclosed in document D36. The appellant's argument hence does not persuade the board.

10. Decisions T 665/90 and T 792/00, which were cited by the appellant in support of its argument, are not pertinent to the case at hand because they do not concern the question of whether or not an antibody

comprising specific VH and VL amino acid sequences or CDRs recognises a particular epitope. In decision T 665/90, a process claim comprising several steps, defining specific conditions for each step, was considered. Since the patent disclosed examples describing the claimed process in detail and the appellant in that case had not demonstrated that the *detailed exemplified* processes could not be carried out, there were no reasons for the deciding board to doubt that the claimed processes could be carried out by the skilled person. In the case underlying T 792/00, the claimed invention went against prevailing technical opinion and the patent only contained a hypothetical example. The deciding board held that, under those particular circumstances, the patent proprietor could only demonstrate sufficiency of disclosure if the hypothetical example was reproducible by following the experimental protocol as stated in the patent and not by using a different experimental protocol.

11. The findings in document D36 in relation to the epitope binding of SP34 are also supported by the findings in documents D17, D17a and D20. Document D20 discusses an experimental report (document D54), which demonstrates that the mutating of amino acids F and E in the FSE part of the FSEXE epitope does not affect the binding of SP34 to human CD3 epsilon. Hence, at least two amino acids in the FSEXE epitope are not relevant for the binding of SP34 to CD3 epsilon, which thus casts doubt as to whether this amino acid motif is indeed part of the epitope recognised by this antibody.

12. Concerning documents D17 and D17a, these demonstrate, on the one hand, that SP34 strongly binds to a peptide consisting of amino acids 1 to 27 of human and cynomolgus CD3 epsilon, i.e. a peptide that comprises

the QDGNE but not the FSEXE epitope (see the figures on page 2 and the conclusions on page 3 of document D17). On the other hand, they demonstrate that SP34 binds only weakly to truncated human and cynomolgus CD3 epsilon proteins which contain the FSEXE epitope but lack the first five N-terminal amino acids of CD3 epsilon (see pages 8 and 9 of document D17a). The results of these experiments thus also suggest that SP34 does not bind to the FSEXE epitope (see point 5. above).

13. The board is likewise not persuaded by the appellant's further line of argument that the claim did not exclude that the antibody bound to a discontinuous epitope. According to this claim construction, the antibody could bind to the FSEXE motif with low affinity and to the QDGNE motif with high affinity. Such a claim construction is, however, not in line with the meaning of the term "epitope" and the definition of antibody binding in the patent (see point 4. above). Moreover, none of the evidence relied upon by either party in this context supports the notion that SP34 binds simultaneously to both the QDGNE and the FSEXE epitopes, i.e. that the two motifs were part of a discontinuous epitope. Indeed, the appellant also interpreted the available data such that the two motifs could not be bound simultaneously (see the second paragraph on page 17 of the statement of grounds of appeal). Document D56 only shows that SP34 binds to a sequence of CD3 epsilon in addition to the high-affinity binding to the QDGNE epitope, but not that this additional interaction was specific binding to the FSEXE epitope.

14. Consequently, taking into account the evidence submitted by the parties in this context, the board

considers that there are serious doubts as to whether SP34 binds to the FSEXE epitope. Since the binding specificity of an antibody is determined by its variable sequences and, more precisely, by the CDRs in these variable sequences (see point 5. above), an antibody which has the same VH and VL sequences or the same CDRs as SP34 and binds to the FSEXE epitope cannot be reproduced.

15. The board therefore agrees with the decision under appeal in the context of claim 1 of the then auxiliary request 2, namely that the invention as defined in claim 8 of the patent as granted is not sufficiently disclosed in the patent and that, therefore, the ground for opposition under Article 100(b) EPC prejudices the maintenance of the patent as granted.

Auxiliary requests 1, 2, 4, 5, 6, 8, 9, 10 and 11
Sufficiency of disclosure (Article 83 EPC)

16. While the respondent had requested that these auxiliary requests not be admitted into the appeal proceedings, the board proceeded by considering them on their merits, and - in order to reach a decision based on those merits - did not exclude them from the appeal proceedings under Article 12(4) RPBA 2007 (applicable pursuant to Article 24 and Article 25(1),(2) RPBA 2020) for reasons of procedural economy. The respondent is not adversely affected since these claim requests are not allowable.

17. Each of auxiliary requests 1, 2, 4 to 6 and 8 to 11 comprises at least one claim in which the first binding domain of the bispecific antibody is defined as binding to the FSEXE epitope and comprising the VH and VL amino acid sequences (SEQ ID NOs. 2 and 4) or the CDRs

(SEQ ID NOs. 112/113, 114, 115, 116, 117 and 118) of the patent's antibody I (see claim 8 of each of auxiliary requests 1, 2 and 6, claim 7 of each of auxiliary requests 4, 5, 8 and 10, and claim 1 of each of auxiliary requests 9 and 11; see section IV. and point 3. above).

18. The invention as defined in claim 8 of each of auxiliary requests 1, 2 and 6, claim 7 of each of auxiliary requests 4, 5, 8 and 10, and claim 1 of each of auxiliary requests 9 and 11, is therefore not sufficiently disclosed in the application (Article 83 EPC) for the same reasons as the invention defined in claim 8 of the main request (see points 2. to 14. above).

Auxiliary requests 1A, 3, 4A, 5A, 6A, 7B, 8A, 9A, 10A, 11A
Sufficiency of disclosure (Article 83 EPC)

19. While the respondent had requested that these auxiliary requests not be admitted into the appeal proceedings, the board proceeded by considering them on their merits, and - in order to reach a decision based on those merits - did not exclude auxiliary requests 3, 6A, 8A, 9A and 11A from the appeal proceedings under Article 12(4) RPBA 2007 (applicable pursuant to Article 24 and Article 25(1),(2) RPBA 2020) and admitted auxiliary requests 1A, 4A, 5A, 7B and 10A into the proceedings under Article 13(1) RPBA 2020 (applicable pursuant to Article 24 and Article 25(1) RPBA 2020). Admittance was based on considerations of procedural economy and the respondent was not thereby adversely affected since these claim requests are not allowable.

20. Claim 1 of each of auxiliary requests 1A, 3, 4A, 5A, 6A, 7B, 8A, 9A, 10A, 11A comprises - compared to claim 1 of each of auxiliary requests 1, 1, 4, 5, 6, 7, 8, 9, 10 and 11, respectively - the additional feature that the epitope is deduced by pepspot analysis (see sections IV. and VI.).

21. The amendment in the form of addition of this feature does not, however, remedy the lack of sufficiency of disclosure of the claimed invention. The reason for this is that the issue of whether or not an antibody binds to a particular epitope is a property of the antibody as such, which does not depend on the analysis method used (see also point 5. above). As set out above, there is compelling evidence on file that an antibody-binding domain comprising a VH and a VL region comprising the amino acid sequences as set forth in SEQ ID NOs. 2 and 4, respectively, or the CDRs set forth in SEQ ID NOs. 112/113, 114, 115, 116, 117 and 118, does not bind to the FSEXE epitope (see points 2. to 14. above).

22. The invention as defined in claim 8 of each of auxiliary requests 1A, 3, 6A and 7B, claim 7 of each of auxiliary requests 4A, 5A, 8A and 10A, and claim 1 of each of auxiliary requests 9A and 11A, is therefore not sufficiently disclosed in the application for the same reasons as those set out above for claim 8 of the patent as granted (Article 83 EPC). Thus, none of these claim requests is allowable.

Auxiliary requests 7, 7A, 12 and 13
Admittance (Article 12(2) and (4) RPBA 2007)

23. During oral proceedings the appellant submitted that these auxiliary requests, the claims of which were

first submitted with the statement of grounds of appeal, addressed the finding of the board concerning lack of sufficiency of disclosure of the invention as defined in claim 8 of the main request (see point 15. above).

24. Pursuant to Article 12(4) RPBA 2007, applicable pursuant to Article 24 and Article 25(1),(2) RPBA 2020, the board has the power to hold inadmissible requests which could have been presented or were not admitted in the first-instance proceedings, even though they were filed together with the statement of grounds of appeal, they relate to the case under appeal and meet the requirements of Article 12(2) RPBA 2007.
Article 12(2) RPBA 2007 stipulates that the statement of grounds of appeal must contain an appellant's complete case, set out clearly the reasons why the decision under appeal should be reversed, amended or upheld, and specify expressly all the facts, arguments and evidence relied on.

25. This power of the board to hold inadmissible certain submissions is independent of a party's request. Therefore, the appellant's first argument that auxiliary requests 7, 7A, 12 and 13 should be admitted into the appeal proceedings, or not be held inadmissible, solely because the respondent's request that none of these requests be admitted into the proceedings had not been filed with its reply to the statement of grounds of appeal does not persuade the board.

26. Moreover, submissions directed to the issue of whether or not the claim requests filed by the appellant in the appeal proceedings should be considered had been put forward by the respondent in the reply to the statement

of grounds of appeal, on pages 1 and 2 and in the sections relating to the auxiliary requests in question, and the board had no reason to exclude those submissions of the respondent from the proceedings under Article 12(4) RPBA 2007. Therefore, the fact that, besides these submissions, no explicit request relating to non-admittance or exclusion of the claim requests had been presented by the respondent at that stage of the proceedings was not a decisive factor in the circumstances of the present case.

Auxiliary request 7 - admittance

27. Claim 1 of the current auxiliary request 7 differs from claim 1 of auxiliary request 7 submitted in opposition proceedings by the final date for making written submissions set under Rule 116(1) EPC in the deletion of the expression "at least one of" in the phrase "wherein at least one of said first binding domain is human or humanized" (see sections III. and IV.).

28. The appellant argued that this amendment represented the correction of an obvious error pursuant to Rule 139 EPC. The board understands this argument to mean accordingly that the current auxiliary request 7, submitted with the statement of grounds of appeal, expresses the true intention of the appellant when it filed auxiliary request 7 during opposition proceedings.

29. According to Rule 139 EPC, second sentence, EPC, if the request for correction concerns the description, claims or drawings, the correction must be obvious in the sense that it is immediately evident that nothing other than what is offered as the correction could have been intended. However, the phrase "wherein at least one of

said first binding domain is human or humanized" cannot be held to clearly mean "wherein said first binding domain is human or humanized", since other intended meanings of the phrase are possible, for example, that at least one of the first or the second binding domain is human or humanised. Therefore, the amendment does not constitute the correction of an obvious error within the meaning of Rule 139, second sentence, EPC.

30. Consequently, the filing of the set of claims of auxiliary request 7 with the reply to the statement of grounds of appeal amounted to the submission of an amended set of claims. Admittance of auxiliary request 7 as filed on appeal is therefore governed by Article 12(4) RPBA 2007 (applicable pursuant to Article 24 and Article 25(1),(2) RPBA 2020).

31. In the statement of grounds of appeal, the appellant argued that the auxiliary request had been filed to overcome objections under Article 54 EPC. However, it has not submitted arguments as to why the opposition division's negative finding on sufficiency of disclosure in respect of the then auxiliary request 7 (see point 32.1 of the opposition division's decision) was wrong, or as to why the opposition division's decision that the invention in claim 1 of the then auxiliary request 2 was not sufficiently disclosed in the application (see points 28 to 28.3.1 and 33 of the decision) would be addressed by the claims of auxiliary request 7 filed on appeal. It was only during the oral proceedings before the board that the appellant argued that it was self-explanatory why the invention defined in the claims of auxiliary request 7 was sufficiently disclosed.

32. The board is not persuaded by this argument. The opposition division decided that the invention as defined in claim 1 of the then auxiliary request 2 was not sufficiently disclosed in the application. The first binding domain of the bispecific single-chain antibody recited in this claim was defined to comprise the six CDRs of SEQ ID NOs. 2 and 4. The same six CDRs are also present in the humanised VH and VL sequences defined by SEQ ID NOs. 110 and 168 recited in claim 8 of auxiliary request 7 (see section IV.). For this reason alone, it is not self-explanatory why auxiliary request 7 would overcome the opposition division's objections.

33. Moreover, after finding that the invention defined in claim 1 of the then auxiliary request 2 was not sufficiently disclosed in the application, the opposition division decided not to admit, *inter alia*, auxiliary request 7 submitted before the final date set under Rule 116(1) EPC into the opposition proceedings because it considered that it did not "*prima-facie address the objection raised with regard to Article 83*" since it related to "*the same binding domain (SP34)*" (see point 32.1 of the decision under appeal).

34. It can be derived from the submissions that the appellant is of the view, *inter alia*, that auxiliary request 7, being one of the auxiliary requests presented by the final date under Rule 116(1) EPC, should have been admitted into the opposition proceedings instead of not being admitted. However, the issue of whether or not the procedural handling by the opposition division was correct is an issue in itself and is not relevant to the question of whether or not the appellant should have submitted reasons as to why it considered that the claims of auxiliary request 7

presented with the statement of grounds of appeal overcame the issues on sufficiency of disclosure. The latter question is relevant for assessing whether or not the requirements of Article 12(2) RPBA 2007 have been met, i.e. requirements relevant in the context of Article 12(4) RPBA 2007 for a consideration of whether or not auxiliary request 7 should be held inadmissible.

35. As set out above in point 32., it was not self-explanatory in view of the opposition division's decision on the then auxiliary request 2 that the claims of auxiliary request 7 would indeed overcome insufficiency of disclosure, or how they would do this. Also, it was clear from the opposition division's decision that it considered that the invention defined in the claims of the then auxiliary request 7 was not sufficiently disclosed in the application for the same reasons as those presented for the invention defined in claim 1 of the then auxiliary request 2 (see point 32.1 of the opposition division's decision). Therefore, contrary to the appellant's allegation, an objection under Article 83 EPC had in fact been raised during the opposition proceedings with respect to the set of claims of the then auxiliary request 7.

36. In view of these considerations, the appellant should have presented, in the statement of grounds of appeal, its arguments as to why it considered that the opposition division erred in that its reasoning on sufficiency of disclosure with respect to the invention as defined in the then auxiliary request 2 underlying the decision under appeal applied likewise to the inve ntion as defined in the claims of auxiliary request 7 presented with the statement of grounds of appeal.

37. Consequently, since it was not substantiated in the statement of grounds of appeal why the opposition division's finding on the then auxiliary request 7 with respect to sufficiency of disclosure was wrong, the appellant had not presented its full case with the statement of grounds of appeal on this issue, contrary to the requirements of Article 12(2) RPBA 2007. The board therefore decided not to admit auxiliary request 7 into the appeal proceedings (Article 12(4) RPBA 2007).

Auxiliary requests 7A, 12 and 13 - admittance

38. These auxiliary requests were submitted with the statement of grounds of appeal and Article 12(4) RPBA 2007 applies to them.

39. In the claims of these requests, references either to any amino acid sequences of the antibody recited in the claims, including SEQ ID NOs. 2 and 4 (auxiliary request 7A), or to amino acid sequences related to antibody I (auxiliary requests 12 and 13) were deleted. The appellant argued that these requests were filed in direct response to the opposition division's decision on novelty and sufficiency of disclosure.

40. However, the oppositions filed against the patent were based, *inter alia*, on the argument that prior-art antibody CRIS7 bound to the FSEXE epitope and had the same binding domain as antibody II disclosed in the patent and was therefore prejudicial to the novelty of, *inter alia*, the subject-matter of claim 1 as granted. It was also argued that an antibody which comprised VH and VL sequences as defined in SEQ ID NOs. 2 and 4, e.g. antibody I of the patent, did not bind to the FSEXE epitope, thereby resulting in a lack of

sufficiency of disclosure. Consequently, auxiliary requests 7A, 12 and 13 do not constitute a direct response to the opposition division's decision on either novelty or sufficiency of disclosure. In fact, these claim requests could and should have been submitted in the opposition proceedings to allow the opposition division to decide on them.

41. In view of these considerations, the board decided not to admit auxiliary requests 12 and 13 into the appeal proceedings (Article 12(4) RPBA 2007).

Auxiliary requests 12A and 13A
Admittance (Article 13(1) RPBA 2020)

42. With its response to the respondent's reply to the statement of grounds of appeal on 14 May 2020, the appellant submitted sets of claims of, *inter alia*, auxiliary requests 12A and 13A (see section VI.). Pursuant to Article 13(1) RPBA 2020, applicable pursuant to Article 24 and Article 25(1) RPBA 2020, submission of these auxiliary requests constituted an amendment of the appellant's appeal case that was subject to the appellant's justification and the admittance of which was at the discretion of the board.

43. In claim 1 of these auxiliary requests the feature "wherein said epitope is deduced by pepspot analysis" had been inserted. This feature was already present in claim 1 of auxiliary request 3 dealt with in the decision under appeal (see section III.) and also in claim 1 of a number of auxiliary requests submitted with the statement of grounds of appeal (see section IV.). The appellant's argument that auxiliary requests 12A and 13A were filed in direct response to new arguments with respect to sufficiency of disclosure

raised in the respondent's reply to the statement of grounds of appeal therefore did not persuade the board. Moreover, the appellant did not specify what these allegedly new arguments were, and the board was unable to identify any.

44. The appellant also argued that the feature inserted into claim 1 *prima facie* remedied the deficiency as regards an alleged lack of sufficiency of disclosure because "*all pepspot data on file show that antibody I binds to the FSEXE epitope in this experimental setup*". This argument did not persuade the board either, since the binding specificity of an antibody is independent of the experimental technique used to determine the binding (see points 5. and 21. above).

45. The further arguments of the appellant, namely that the claim requests merely combined subject-matter of granted claims and thus did not come as a surprise to the respondent, and that consideration thereof would neither lead to any delay in the proceedings nor raise new issues - irrespective of whether these arguments hold true -, did not, in the board's view, excuse the advanced stage of the appeal proceedings at which the claim requests were submitted.

46. In light of the above considerations, the board, exercising its discretion pursuant to Article 13(1) RPBA 2020, decided not to admit auxiliary requests 12A and 13A into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

L. Malécot-Grob B. Claes

Decision electronically authenticated