

**Internal distribution code:**

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

**Datasheet for the decision  
of 12 March 2026**

**Case Number:** T 0660/24 - 3.3.04

**Application Number:** 15776419.2

**Publication Number:** 3130606

**IPC:** C07K16/30, A61K39/395,  
A61P35/00, A61P43/00

**Language of the proceedings:** EN

**Title of invention:**

Immunoactivating bispecific antibodies

**Patent Proprietor:**

Chugai Seiyaku Kabushiki Kaisha

**Opponents:**

J A Kemp LLP  
Thomann, William

**Headword:**

Immunoactivating bispecific antibodies/CHUGAI

**Relevant legal provisions:**

EPC Art. 100(c), 123(2), 113(1)  
RPBA 2020 Art. 13(2)  
EPC R. 106

**Keyword:**

Grounds for opposition - added subject-matter (yes)  
Amendments - auxiliary request 6A - added subject-matter (yes)  
Auxiliary request 12D - amendment after notification of Art.  
15(1) RPBA communication - exceptional circumstances (no)  
Objection under Rule 106 EPC - dismissed

**Decisions cited:**

T 1789/22, T 1685/07



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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

Case Number: T 0660/24 - 3.3.04

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.04**  
**of 12 March 2026**

**Appellant:** J A Kemp LLP  
(Opponent 1) 80 Turnmill Street  
London Greater London EC1M 5QU (GB)

**Representative:** J A Kemp LLP  
80 Turnmill Street  
London EC1M 5QU (GB)

**Appellant:** Thomann, William  
(Opponent 2) c/o ZSP Patentanwälte PartG mbB  
Hansastraße 32  
80686 München (DE)

**Respondent:** Chugai Seiyaku Kabushiki Kaisha  
(Patent Proprietor) 5-1, Ukima 5-chome  
Kita-ku  
Tokyo 115-8543 (JP)

**Representative:** Simmons & Simmons LLP (Munich)  
Lehel Carré  
Gewürzmühlstraße 11  
80538 Munich (DE)

**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 12 March 2024  
rejecting the opposition filed against European  
patent No. 3130606 pursuant to Article 101(2)  
EPC.**

**Composition of the Board:**

**Chairwoman**            M. Pregetter  
**Members:**            O. Lechner  
                              A. Bacchin

## **Summary of Facts and Submissions**

- I. The appeals by opponents 1 and 2 (appellants I and II) lie from the opposition division's decision to reject the oppositions against European patent No. 3 130 606 ("the patent"), entitled "Immunoactivating bispecific antibodies".
- II. The patent is based on European patent application No. 15 776 419.2, filed as an international application under the Patent Cooperation Treaty (PCT) and published as WO 2015/156268 in Japanese. Upon entry into the European regional phase, the respondent submitted an English translation of the application pursuant to Article 22(1) PCT and Rule 159(1)(a) EPC ("the application as filed").
- III. The patent was opposed in its entirety by both opponents on the grounds of Article 100(a) EPC (lack of novelty under Article 54 EPC and lack of inventive step under Article 56 EPC), as well as Article 100(b) and (c) EPC, the latter having been raised against all the claims as granted (claims 1 to 7), including the claims pursuant to Article 54(5) EPC.
- IV. In its decision, the opposition division held that none of the grounds for opposition raised under Article 100 EPC prejudiced maintenance of the patent as granted, and therefore rejected the oppositions. No decision was taken on the admission of the auxiliary requests since the opposition division found the main request allowable.
- V. The patent proprietor (respondent) replied to the appellants' statements of grounds of appeal and

resubmitted auxiliary requests 1A to 6A, 1B to 6B and 1C to 6C. In addition, new auxiliary requests 7A to 7C, 8A to 8C and 9A to 9C were filed. Auxiliary requests 1A to 1C, 2A to 2C, 3A to 3C, 4A to 4C, 5A to 5C, 6B and 6C were first filed by letter dated 4 December 2023; auxiliary request 6A was first filed by letter dated 5 December 2022.

- VI. Appellant I submitted further arguments by letter dated 10 March 2025.
- VII. The respondent submitted further arguments by letter dated 29 August 2025.
- VIII. The board summoned the parties to oral proceedings, as requested, and informed them of its preliminary opinion in a communication pursuant to Article 15(1) RPBA.
- IX. By letter dated 20 February 2026 the respondent submitted new auxiliary requests 10A to 10L, 11A to 11L and 12A to 12L.
- X. Oral proceedings were held on 12 March 2026. At the oral proceedings before the board, the respondent withdrew all claim requests except for the main request (claims as granted) and auxiliary requests 6A and 12D. The respondent also raised an objection under Rule 106 EPC that a fundamental procedural defect had occurred.

At the end of the oral proceedings the Chairwoman announced the board's decision.

XI. Claims relevant to the decision

(a) The independent claims of the main request (claims as granted) read:

"1. A cytotoxicity-inducing bispecific antibody comprising:

- (1) a cancer-specific antigen-binding Fab domain;
  - (2) a tumor necrosis factor (TNF) receptor superfamily-binding Fab domain, which is a CD137-binding Fab domain or a CD40-binding Fab domain;
- and

- (3) an FcRn-binding domain which is an antibody Fc region having decreased Fcγ receptor-binding activity,

wherein the bispecific antibody has an agonist activity against a tumor necrosis factor (TNF) receptor."

"3. A cytotoxicity-inducing pharmaceutical composition, comprising as an active ingredient the bispecific antibody of claim 1 or 2."

"5. A cytotoxicity-inducing pharmaceutical composition for use in the treatment of cancer, said composition comprising as an active ingredient a cytotoxicity-inducing bispecific antibody as defined in claim 1 or 2, to be administered simultaneously or separately with an antigen-binding molecule as defined in claim 4."

"6. A cytotoxicity-inducing pharmaceutical composition for use in the treatment of cancer, said composition comprising as an active ingredient an antigen-binding molecule as defined in claim 4, to be administered simultaneously or separately with a cytotoxicity-inducing bispecific antibody as defined in claim 1 or 2."

(b) Claim 1 of auxiliary request 6A reads:

"1. A cytotoxicity-inducing bispecific antibody consisting of:

- (i) a F(ab')<sub>2</sub> domain having (1) and (2)
  - (1) a cancer-specific antigen-binding Fab domain;
  - (2) a tumor necrosis factor (TNF) receptor superfamily-binding Fab domain, which is a CD137-binding Fab domain or a CD40-binding Fab domain;

and

- (ii) (3) an FcRn-binding domain which is an antibody Fc region having decreased Fcγ receptor-binding activity,

wherein the antigen-binding domains of (1) and (2) are directly linked to the Fc region of (3) by peptide bonds, and

wherein the bispecific antibody has an agonist activity against a tumor necrosis factor (TNF) receptor."

(c) Claim 1 of auxiliary request 12D reads:

"1. A cytotoxicity-inducing pharmaceutical composition for use in the treatment of cancer, said composition comprising as an active ingredient a cytotoxicity-inducing bispecific antibody, to be administered simultaneously or separately with an antigen-binding molecule;

wherein the cytotoxicity-inducing bispecific antibody consists of:

- (i) a F(ab')<sub>2</sub> domain having (1) and (2)
  - (1) a cancer-specific antigen-binding Fab domain;
  - (2) a tumor necrosis factor (TNF) receptor superfamily-binding Fab domain, which is a CD137-binding Fab domain;

and

(ii) (3) an FcRn-binding domain which is an antibody Fc region having decreased Fc $\gamma$  receptor-binding activity,

wherein the antigen-binding domains of (1) and (2) are directly linked to the Fc region of (3) by peptide bonds,

wherein the bispecific antibody is an immunoglobulin of the IgG1, IgG2, IgG3 or IgG4 isotype, and

wherein the bispecific antibody has an agonist activity against a tumor necrosis factor (TNF) receptor;

and wherein the antigen-binding molecule comprises:

(1) a cancer-specific antigen-binding domain; and

(2) a CD3-binding domain; and

(3) an FcRn-binding domain having decreased Fc $\gamma$  receptor-binding activity."

XII. The appellants' arguments relevant to the decision were:

*Main request - amendments - Article 100(c) EPC*

Claim 1 singled out a cytotoxicity-inducing bispecific antibody comprising (1) a cancer-specific antigen-binding Fab domain and (2) a tumour necrosis factor (TNF) receptor superfamily-binding fragment antigen-binding (Fab) domain, which is a CD137-binding Fab domain or a CD40-binding Fab domain, whereas the application as filed disclosed the Fab format only within generic lists of antigen-binding domain formats, without any preference for the Fab format and without any pointer to its selection for both binding domains in combination. This represented an unallowable

selection from two independent lists, yielding an undisclosed combination not directly and unambiguously derivable from the application as filed.

At the oral proceedings, appellant I argued that, contrary to the respondent's line of argument relying on the paragraph bridging pages 23 and 24, in particular page 24, lines 5 and 6, the application as filed did not limit the term "bispecific antibody" to Y-shaped IgG-like structures. As shown on page 2, line 15 ff, the term "bispecific antibody" also encompassed bispecific single chain antibodies, including the BiTE® format as disclosed in document D10 cited therein (corresponding to document D7 in appeal).

From page 9, line 15 ff it was also evident that antigen-binding molecules were not particularly limited in the present invention. Page 16, lines 11 to 13 listed various permissible binding-domain formats without any preference, so the selection of a cancer-specific antigen-binding Fab domain in feature (1) of claim 1 required a first selection from that generic list, and the selection of a tumour necrosis factor (TNF) receptor superfamily-binding Fab domain, which is a CD137-binding Fab domain or a CD40-binding Fab domain, in feature (2) of claim 1 required a second, independent, selection from the same open list. Figure 3 was nothing more than a purely schematic, generic IgG outline that did not individualise or single out the double Fab configuration claimed. The paragraph bridging pages 23 and 24 used a very generic language and referred to naturally occurring immunoglobulins but also to immunoglobulins produced by partial or complete synthesis. The relevant bispecific antibodies set out in Example 2 and the other examples consistently relied on Fab' fragments comprising an

intact hinge region, which enabled the formation of disulphide bridges between the heavy chains. Thus the examples could not be relied upon in any way to support the selection of the Fab binding domain format for either binding arm of the bispecific antibody specified in the claims. To arrive at the claimed selection of the Fab binding format for both binding arms of the claimed bispecific antibody required an unallowable intermediate generalisation.

*Auxiliary request 6A*

*Amendments - Article 123(2) EPC*

Auxiliary request 6A still relied on the same double Fab architecture as granted claim 1, so the two-list problem as discussed for the main request persisted.

The subject-matter of claim 1 encompassed non-standard antibody structures since the feature "*wherein the antigen-binding domains of (1) and (2) are directly linked to the Fc region of (3) by peptide bonds*" did not mention hinge regions at all and also encompassed e.g. the possibility of directly linking the constant light chain (CL) and the Fc region through a peptide bond.

Neither page 38, line 19 ff, nor page 41, lines 21 to 24 and 30 to 36, nor page 45, lines 18 to 22 of the application as filed mentioned the presence of an Fc region in general or of an F(ab')<sub>2</sub> directly linked to an Fc region by peptide bonds as claimed. Moreover, there was no pointer to preferentially combine an F(ab')<sub>2</sub> with an FcRn-binding domain which is an antibody Fc region having decreased Fcγ receptor-binding activity as claimed.

Page 45, lines 30 to 36 could not serve as a basis either since the passage related to tetravalent antigen-binding molecules characterised by the presence of two F(ab')<sub>2</sub> units directly linked to a domain comprising an Fc region with decreased FcγR-binding activity as the FcRn-binding domain. Contrary to the respondent's statement, there was no indication that the molecule described in lines 30 to 36 on page 45 was an obvious error.

Consequently, the subject-matter of claim 1 of auxiliary request 6A was not directly and unambiguously derivable from the application as filed, contrary to Article 123(2) EPC.

*Auxiliary request 12D*

*Admission - Article 13(2) RPBA*

Auxiliary request 12D should not be admitted into the proceedings, essentially for lack of exceptional circumstances within the meaning of Article 13(2) RPBA, for lack of *prima facie* allowability and because the amendments raised new issues. An objection as to added subject-matter had been raised for the subject-matter of all the claims, and thus also for the medical use claims, in opposition, and this objection was explicitly maintained in appellant II's statement of grounds of appeal (point 3.22). In reaction to the respondent's reply to the statements of grounds of appeal, appellant I, in the submission of 10 March 2025 (pages 15 and 16), made it clear that the added-subject-matter objection also applied to the medical use claims of auxiliary request 5A. The issue had therefore not been raised for the first time in the

board's communication pursuant to Article 15(1) RPBA. The respondent should have filed these amendments earlier in the proceedings.

*Objection under Rule 106 EPC*

The appellants did not comment on the respondent's objection under Rule 106 EPC.

XIII. The respondent's arguments relevant to the decision were:

*Main request*

*Amendments - Article 100(c) EPC*

Granted claim 1 did not relate to an antigen-binding molecule in general but to a bispecific antibody.

Paragraph 1 on page 1, claim 5 as well as item [5] on page 4 of the application as filed also referred to bispecific antibodies, which the skilled person would read in line with the precise definition for "antibody" provided in the paragraph bridging pages 23 and 24. According to that definition, "antibody" referred to the well-known Y-shaped immunoglobulin-type bivalent architecture, in which each binding arm inherently possessed the Fab structure. The two Fab binding arms were each extended C-terminally by a hinge domain, thereby forming two Fab' fragments, which, through disulphide bonds between their hinge domains, combined to form an F(ab')<sub>2</sub> fragment. The different immunoglobulin isotypes and subtypes listed at the end of the paragraph bridging pages 23 and 24 all had the same Fab-based structure concerning the antigen-binding parts. Figure 3 in combination with page 57, line 32 to

page 58, line 1 also depicted this general immunoglobulin structure, thereby providing a direct pointer to a configuration in which both binding arms were Fabs. The examples referred expressly to bispecific antibodies in the IgG format, each comprising two binding arms, which necessarily corresponded to Fab domains.

The general disclosure on page 9, line 15 ff of the application as filed was not relevant since it discussed antigen-binding molecules but not bispecific antibodies. The list of binding domains on page 16, lines 11 to 13 of the application as filed was merely a generic enumeration of possible formats and did not relate to bispecific antibodies such as referred to in other passages in the application as filed referred to by the appellants.

However, even if that passage on page 16 were to be considered in the context of bispecific antibodies, only a single selection would have been required, i.e. the choice of the Fab format, because "bispecific antibodies" implied an immunoglobulin-like structure, necessarily comprising two identical binding arms in the Fab format.

The respondent acknowledged that, although e.g. the passage bridging pages 23 and 24 of the application as filed had not been specifically cited during the written proceedings, the reference to such passages in the context of the added-matter discussion constituted an elaboration of an existing legal argument which could be presented at any stage (J 14/19).

*Auxiliary request 6A*

*Amendments - Article 123(2) EPC*

Claim 1 of auxiliary request 6A had been limited to a bispecific antibody consisting of a (i)  $F(ab')_2$  domain having (1) a Fab domain specific for a cancer-specific antigen and (2) a Fab domain specific for CD137 or CD40 and (ii) an antibody Fc region as defined.

The term "comprising", as used in claims 1 to 3 and 5 of the application as filed, provided a basis for an antibody "consisting of" the specified subunits, and also found a basis, e.g., on page 41, line 23 of the application as filed, which referred to "*the  $F(ab')_2$  constituting an antigen-binding molecule disclosed herein*".

Claims 1 to 3, 5 and the paragraph bridging pages 23 and 24 of the application as filed provided a basis for restricting the scope of claim 1 of auxiliary request 6A to a bispecific antibody consisting of an  $F(ab')_2$  domain. By considering the disclosure on page 41, lines 21 to 24, which provided a definition of the  $F(ab')_2$  format, together with page 10, lines 30 to 33, which provided a definition of an Fc region, the skilled person, when reading the application as filed as a whole, would have directly and unambiguously arrived at the generally known structure of immunoglobulins, as also shown in Figure 3. The passage on page 41 additionally explicitly stated "*the  $F(ab')_2$  constituting an antigen-binding molecule disclosed herein*", which provided a clear pointer to using an  $F(ab')_2$  domain for the bispecific antibody of claim 1 of the application as filed. Moreover, all IgG-based bispecific antibody constructs in the examples had Fab

binding domains arranged in an F(ab')<sub>2</sub> connected to an Fc region.

Based on this disclosure in the application as filed, no (double) selection was needed any longer for the two antigen-binding domains to be Fabs.

As provided on page 45, lines 21 to 22 and 30 to 36 of the application as filed, the F(ab')<sub>2</sub> and Fc regions of the bispecific antibody were connected via peptide bonds between the hinge and the Fc regions. This was in line with the commonly known general immunoglobulin structure disclosed in the paragraph bridging pages 23 and 24. Page 38, line 19 ff of the application as filed referred to a "*single polypeptide chain*", and page 45, line 36 referred to "*directly linked by peptide bonds*", from which the skilled person would directly and unambiguously derive that the subunits constituting the bispecific antibody according to claim 1 were directly linked by peptide bonds. Further support was provided by the bispecific antibodies of the examples, which contained "peptide bonds".

The skilled person would immediately realise that the bispecific construct disclosed on page 45, lines 30 to 36 as comprising two F(ab')<sub>2</sub> domains was obviously erroneous. Anyway, the structure described therein would not fall under the scope of claim 1 and would not have the structure of an immunoglobulin.

*Auxiliary request 12D*

*Admission - Article 13(2) RPBA*

Auxiliary request 12D should be admitted into the proceedings. No added-subject-matter objection had ever

been raised against the granted medical use claims 5 to 7 by the appellants. It was only with the board's communication pursuant to Article 15(1) RPBA (particularly in sections 35 and 36) that an added-subject-matter objection relating to the antibody structure was, for the first time, raised in the context of the medical use claims. There were therefore exceptional circumstances within the meaning of Article 13(2) RPBA justifying the filing of this auxiliary request at that stage of the appeal proceedings. The objection raised by appellant I in the submissions of 10 March 2025 in relation to the medical use claims was different, as it was not argued that the schematic drawing in Figure 3 of the application as filed failed to disclose the details of the antibody's structure. The same applied to the added-subject-matter objection concerning the agonist activity, which was expressed for the first time in section 36 of the board's communication pursuant to Article 15(1) RPBA.

The amendments introduced with auxiliary request 12D were suitable to overcome the added-subject-matter objection and did not introduce any complex issue. Thus, for this reason too, auxiliary request 12D should be admitted.

*Objection under Rule 106 EPC*

Having been informed that the board had decided under Article 13(2) RPBA not to admit auxiliary request 12D, the respondent filed the following objection in writing (see Minutes of the oral proceedings):

*"Pursuant to Rule 106 EPC, the Patentee hereby raises an objection that a fundamental procedural defect has occurred. The Board has refused to admit auxiliary*

*request 12D, although the added matter objections against claim 5-7 as granted have been raised for the first time in these appeal proceedings in the preliminary opinion of the Board. This represents a violation of the Patentee's right to be heard under Article 113(1) EPC."*

The respondent stated that on account of its right to be heard auxiliary request 12D should have been admitted into the proceedings. No further comments were made in that respect.

XIV. Requests of the parties relevant to the decision

- (a) The appellants requested that the decision under appeal be set aside and that the patent be revoked. The appellants also requested not to admit any of the auxiliary requests filed, except for auxiliary request 6A.

Appellant I further requested that

- documents D76 to D82 as filed with the statement of grounds of appeal be admitted
- the "steric hindrance" argument made by the respondent on page 53 starting with paragraph 24 of the reply to the statements of grounds of appeal not be admitted

Appellant II additionally requested that

- document D83 be admitted

- (b) The respondent requested that the appeals be dismissed and the patent be maintained as granted (main request), or alternatively, on the basis of any one of auxiliary request 6A or 12D, for which admission was requested.

## Reasons for the Decision

*Main request*

*Amendments - Article 100(c) EPC*

1. For the assessment of the ground for opposition under Article 100(c) EPC, the board relies on the English translation of the application as filed, submitted by the applicant upon entry into the European regional phase on 4 November 2016 ("the application as filed").
2. According to the established case law of the Boards of Appeal, the relevant test for assessing compliance with Article 123(2) EPC – which equally applies to the ground for opposition under Article 100(c) EPC – is whether the skilled person, using common general knowledge, would derive the subject-matter of the amended claim directly and unambiguously, explicitly or implicitly, from the application as filed, seen objectively and relative to the date of filing (the so-called "gold standard", Case Law of the Boards of Appeal of the European Patent Office, 11th edn., 2025, II.E.1.3.1).
3. Claim 1 is directed to a cytotoxicity-inducing bispecific antibody comprising *inter alia* (1) a cancer-specific antigen-binding Fab domain and (2) a TNF receptor (TNFR) superfamily-binding Fab domain.
4. The respondent argued that granted claim 1 was not directed to an antigen-binding molecule in general but specifically to a bispecific antibody. The application as filed consistently reflected this focus (page 1, paragraph 1; claim 5; item [5] on page 4 of the

application as filed), which the skilled person would read, in the light of the definition of "antibody" provided in the paragraph bridging pages 23 and 24, as referring to the classical Y-shaped immunoglobulin G (IgG) structure with Fab-based binding arms, as also illustrated in Figure 3 and in the IgG-based bispecific antibodies of the examples. The passage on page 9, line 15 ff of the application as filed was not relevant since it concerned antigen-binding molecules in general, not bispecific antibodies. Likewise, the list of binding domains on page 16, lines 11 to 13 was merely a generic enumeration of possible formats and did not relate specifically to bispecific antibodies, unlike other passages in the application as filed relied on by the appellants.

5. Page 1, paragraph 1 and page 4, item [5] disclose bispecific antibodies in general but do not mention any specific antigen-binding domain format.
  
6. Page 9, line 15 ff discloses that *"In the present invention, 'antigen-binding molecules' are not particularly limited as long as they are molecules that comprise a 'binding domain' of the present invention, and they may further comprise a peptide or protein having a length of about five amino acids or more. The peptide and protein are not limited to those derived from a living organism, and for example, they may be a polypeptide produced from an artificially designed sequence. They may also be any of a naturally-occurring polypeptide, synthetic polypeptide, recombinant polypeptide, and such."*

This passage provides a generic, open-ended definition of "antigen-binding molecules" and also of the binding domain(s) without structural limitation or pointer to

selecting the Fab format, much less to selecting this format for both binding domains.

7. The sentence on page 16, lines 11 to 13 of the application as filed, relied upon by the appellants, occurs within the paragraph beginning on page 15, line 35, in which the cancer-specific antigen-binding domain, the TNF superfamily-binding domain, the TNFR superfamily-binding domain and the T cell receptor (TCR) complex-binding domain, are collectively defined as antigen-binding domains. Page 16, lines 10 to 13 lists suitable examples of antigen-binding domain formats, including single chain variable fragments (scFv), single chain antibody, Fv, scFv2, Fab, F(ab')<sub>2</sub> and such.

This passage requires a double selection of the Fab format from a list of equally preferred binding-domain formats in order to arrive at the claimed bispecific antibody comprising two Fab domains.

8. The respondent relied on the disclosure in the paragraph bridging pages 23 and 24 of the application as filed, arguing in particular that, according to this passage, an "antibody" of the present invention, i.e. a bispecific antibody, was to be understood as having the structure of an IgG1, IgG2, IgG3 or IgG4 isotype which comprised two Fab binding arms.

As regards the respondent's reference to this specific passage, the board accepts that, although cited for the first time at the oral proceedings, it was made in support of a pre-existing argument put forward by the respondent in the context of added subject-matter and therefore does not raise an entirely new line of argument.

This paragraph discloses that "antibody" refers to a naturally occurring immunoglobulin or an immunoglobulin produced by partial or complete synthesis using e.g. genetic recombination. It is further stated that *"[s]uitable examples of the antibodies include antibodies of an immunoglobulin isotype or subclass of such isotype. Known human immunoglobulins include those of the following nine classes (isotypes): IgG1, IgG2, IgG3, IgG4, IgA1, IgA2, IgD, IgE, and IgM. Of these isotypes, antibodies of the present invention include IgG1, IgG2, IgG3, and IgG4."*

The board is not persuaded by the respondent's argument that in the context of the application as filed the term "antibody" was to be understood as relating to a naturally occurring IgG structure. Firstly, the paragraph bridging pages 23 and 24 contains three non-limiting "include" statements, which define antibodies broadly and merely identify the IgG1, IgG2, IgG3 and IgG4 isotypes as suitable examples. The repeated use of the term "include" does not provide a direct and unambiguous disclosure that bispecific antibodies of the invention are restricted to a particular immunoglobulin isotype, let alone to IgG-type antibodies comprising two identical Fab binding arms. Secondly, the same paragraph explicitly points to partially or fully synthetic and recombinantly engineered antibodies as alternatives, which precludes such a restrictive reading of the passage.

As pointed out by the appellants, page 2, line 15 ff of the application as filed expressly refers to bispecific antibodies including bispecific single chain antibody formats. Such constructs do not possess an IgG-type architecture.

Thus the respondent's contention that the skilled person would interpret the term "bispecific antibody" narrowly as denoting only a classical Y-shaped IgG molecule finds no support in the application as filed. On the contrary, as apparent from the cited passages the application as filed consistently uses the expression in a broad, format-neutral manner. Accordingly, the skilled person reading the application as filed would understand "bispecific antibody" as a functional category encompassing multiple structural formats, not as a synonym for a Y-shaped IgG with two Fab arms.

9. The board is also not persuaded that the examples can provide a suitable basis for the claimed bispecific antibodies. The bispecific antibodies of claim 1 are not limited to an IgG format, whereas the examples disclose highly specific antibody constructs realised in an IgG format and e.g. relying on particular synthetic IgG-engineering techniques (heterologous heavy-chain association, IgG-type Fc regions with decreased FcγR binding, and isotype-subclass-specific constant-region constructs).

Claim 1 generalises the antibody constructs disclosed in the examples by abstracting only the functional concepts ("two Fab domains having certain specificities" and "an Fc region with decreased FcγR-binding activity") from the structurally and functionally highly specific IgG-based synthetic constructs used in the examples. In these constructs, the structural features and the associated functional properties are interdependent in the context of the bispecific antibody as a whole. This constitutes an unallowable intermediate generalisation.

10. Figure 3 is presented in the application as filed as a purely schematic, conceptual illustration of the cancer-antigen-dependent activation mechanism and contains no technical explanation of the domains, regions or symbols depicted for the bispecific antibody shown. Accordingly, no structural details of the bispecific antibody can be directly and unambiguously derived from Figure 3. Consequently, it cannot serve as a basis for the specific combination of structural features of claim 1.
  
11. Taken individually or in combination, the cited passages of the application as filed do not allow the skilled person to directly and unambiguously derive the generalised structural definition of the bispecific antibody as defined in claim 1. While the examples do indeed disclose specific engineered IgG-based synthetic bispecific antibodies which inherently comprise two Fab domains, these examples are tied to highly specific IgG-based constructs. Nothing in the application as filed presents these engineered synthetic IgG constructs as a basis for abstracting the binding domains to two Fabs in general, detached from the particular engineered synthetic structure(s) in which they occur.

None of the other cited passages in the application as filed taken alone or read in context provide any pointer that the invention should be read as generally requiring the presence of a Fab domain, nor that the Fab format should be selected from among the numerous equally disclosed formats for both binding arms. Accordingly, the skilled person cannot derive the subject-matter of claim 1 directly and unambiguously from the application as filed.

12. In view of this finding, the board considers it unnecessary to assess the appellants' other objections.
13. Consequently, the subject-matter of granted claim 1 extends beyond the content of the application as filed, and the ground for opposition under Article 100(c) EPC prejudices maintenance of the patent as granted.

*Auxiliary request 6A*

*Amendments - Article 123(2) EPC*

14. Compared with claim 1 as granted, the subject-matter of claim 1 of auxiliary request 6A was amended to additionally specify that the cytotoxicity-inducing bispecific antibody consists of (i) an F(ab')<sub>2</sub> domain having the two Fabs as defined in features (1) and (2). In addition, the antigen-binding domains of (1) and (2) are required to be directly linked to the Fc region by peptide bonds.
15. The board agrees with the appellants that, since the nature of the linkage is not defined in claim 1, its wording encompasses both a hinge-mediated linkage of the F(ab')<sub>2</sub> to the Fc region, as observed in naturally occurring immunoglobulins, and non-natural, synthetic linkage arrangements, e.g. via peptide bonds using an artificial peptide linker between the constant light chain and the Fc region.
16. The respondent points to: claims 1 to 3 and 5; Figure 3 in combination with the examples and especially page 57, line 32 to page 58, line 1; page 10, lines 30 to 33; the paragraph bridging pages 23 and 24; page 38, line 19 ff; page 41, lines 21 to 24, and page 45,

lines 21 to 22 and 30 to 36 in the application as filed as providing a basis for the  $F(ab')_2$  format.

17. Claims 1 to 3 and 5 (as well as items [1] to [3] and [5] on page 4) of the application as filed fail to disclose the organisation of the bispecific antibody as an  $F(ab')_2$  and also do not specify how the antigen-binding domains of (1) and (2) are connected to the Fc region.
18. Page 10, lines 30 to 33 discloses that an Fc region refers to a region that excludes  $F(ab')_2$ , i.e. this passage forms part of a generic discussion on what an Fc region may look like and does not address the presence of an  $F(ab')_2$  in the claimed bispecific antibody.
19. The paragraph bridging pages 23 and 24 provides a general definition for an "antibody" which, in line with the analysis provided in point 8. above, is also not limited to naturally occurring immunoglobulin structures comprising an  $F(ab')_2$  domain, such as IgG1 to IgG4, especially because the passage also teaches that antibodies may be partially or completely synthetic, including recombinantly engineered constructs.
20. Page 38, line 19 ff provides examples of single chain antigen-binding molecules which may be an antibody-binding fragment such as a single chain  $F(ab')_2$ . It does not disclose an  $F(ab')_2$  in general.
21. The board notes that the passage cited by the respondent on page 41, lines 21 to 24 is located in the part of the application as filed relating to "[a]n *'antigen-binding molecule' of the present*

*invention*" (page 38, line 19 to page 41, line 34), which discloses  $F(ab')_2$  merely as one option among various antigen-binding formats, without any specific emphasis or pointer towards its use in the context of bispecific antibodies. The board further notes that the paragraph preceding lines 23 to 24 on page 41, i.e. from line 11 ff, provides a general description of how  $F(ab')_2$  or Fab fragments can be produced by treating an immunoglobulin with a protease. Page 41, lines 21 to 24 describes the general structure of an  $F(ab')_2$ , but fails to identify it or point to it as the binding entity to be (preferably) used in the context of bispecific antibodies of the invention. Moreover, the board observes that the subsequent passages on page 41, i.e. lines 30 to 36, describe antigen-binding molecules, preferably bispecific antibodies, in generic terms and explicitly leave the presence or absence of an Fc region open.

In view of these considerations, the skilled person would not derive directly and unambiguously from page 41, lines 23 to 24 a bispecific antibody comprising the specific  $F(ab')_2$ -based structure and arrangement of Fab or  $F(ab')_2$  domains as claimed. Rather, the cited passage forms part of a generic disclosure of antigen-binding molecule formats.

22. Page 45, lines 21 to 22 discloses in generic terms that two binding domains of the bispecific antibody may be connected either directly by peptide bonds or via linkers. While this identifies some form of connection between binding domains, the passage does not specify which binding domains are meant, does not disclose their organisation as an  $F(ab')_2$  fragment, and contains no reference to the presence of an Fc region.

The subsequent passage, from line 23 ff, states that the antigen-binding molecule may further comprise an FcRn-binding domain. Thus the presence of an Fc region is presented merely as an optional feature.

Page 45, lines 30 to 36 discloses a bispecific tetravalent construct composed of two separate  $F(ab')_2$  fragments and an Fc region. This arrangement is structurally distinct from the bispecific bivalent antibody as defined in claim 1, which requires one single bispecific  $F(ab')_2$  comprising two different Fab domains. It further mentions the presence of (3) an Fc region with decreased Fc $\gamma$  receptor-binding activity as the FcRn-binding domain. It is further mentioned that when the two  $F(ab')_2$  (1) and (2) and the Fc region-containing domain (3) are directly linked by peptide bonds the linked polypeptides will form an antibody structure.

The bispecific tetravalent antibody described in this paragraph does not relate to the bispecific bivalent antibody defined in claim 1.

23. As already explained in the context of claim 1 of the main request in point 10. above, no detailed structural information for the bispecific antibody can be derived from the schematic drawing provided in Figure 3.

The examples of the application as filed disclose bispecific antibodies of Y-shaped IgG isotypes having specific characteristics which are important for the bispecific antibody's function but which are not part of the generic definition of a bispecific antibody according to claim 1.

Even if Figure 3 were to be read together with Example 2, especially page 57, line 32 to page 58,

line 1, as suggested by the respondent, an unallowable intermediate generalisation would still be required to arrive at the subject-matter of claim 1, which omits numerous features of the bispecific IgG constructs disclosed in the examples (see point 9. above).

24. The respondent's allegation that the skilled person would consider the disclosure in lines 30 to 36 of page 45 to contain an obvious error, and would instead read it as disclosing a single  $F(ab')_2$  comprising (1) an anti-cancer-specific antigen Fab and (2) an anti-TNF superfamily- or TNFR superfamily-binding Fab, directly linked by peptide bonds to (3) an Fc region so as to form an antibody structure, lacks any evidential basis.
  
25. In summary, none of the passages in the application as filed provide a direct and unambiguous disclosure from which the bispecific antibody defined in claim 1 could be derived. To arrive at the claimed subject-matter, the skilled person would have to select (i) the Fab format for the cancer-specific antigen-binding domain, (ii) the Fab format for the CD40/CD137-binding domain, (iii) the  $F(ab')_2$  format as the organisational structure for the two antigen-binding Fab domains, (iv) the presence of an Fc region with decreased Fc $\gamma$ R-binding activity, and (v) direct peptide-bond linkage between the antigen-binding Fabs and the Fc region. The application as filed neither directly and unambiguously discloses these features in combination, nor provides any pointer towards their specific combination. The subject-matter of claim 1 therefore extends beyond the content of the application as filed.

*Auxiliary request 12D*

*Admission - Article 13(2) RPBA*

26. Auxiliary request 12D was filed after notification of the board's communication pursuant to Article 15(1) RPBA, and its admission to the proceedings is therefore subject to the provisions of Article 13(2) RPBA. This article provides for the most far-reaching restrictions on the submissions in appeal, raised only at an advanced stage of the proceedings. According to its wording, any amendment to a party's appeal case made after notification of a communication pursuant to Article 15(1) RPBA must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.
27. The claims of auxiliary request 12D are no longer directed to a cytotoxicity-inducing bispecific antibody *per se*, but to a cytotoxicity-inducing pharmaceutical composition comprising a cytotoxicity-inducing bispecific antibody as the active ingredient, and to its medical use, i.e. they are in the format according to Article 54(5) EPC.
28. The respondent essentially argued that the amendment introduced with auxiliary request 12D related to the granted medical use claims 5 to 7 and that, despite having been presented in auxiliary requests filed at the outset of the opposition proceedings, they had never been objected to under Article 123(2) EPC by the appellants, either in opposition or in appeal. This had also been confirmed in the decision under appeal (point 10.1), which clearly stated that both "*opponents*

*have raised objections of added matter only in respect of granted claim 1."*

- 28.1 Despite the respondent having submitted, in the reply to the statements of grounds of appeal (page 14, paragraph 24), that claims other than claim 1 were not objected to under Article 123(2) EPC, the appellants never reacted to this statement.
- 28.2 While appellant I, in its letter dated 10 March 2025, provided observations on the F(ab')<sub>2</sub> feature, it merely argued that Figure 3 and the disclosure of Example 2 "*relates solely to the specific preparation of an anti-GPC3/anti-CD137 bispecific antibody*", and that claim 1 of auxiliary request 6A was not limited to this specific embodiment.
- 28.3 The respondent further relied on decision T 1789/22, allegedly based on comparable circumstances, to argue that, since the granted use claims had never been attacked, the question of their compliance with Article 123(2) EPC did not form part of the appeal.
- 28.4 It was only with the communication pursuant to Article 15(1) RPBA (sections 33 to 36) that the board, for the first time, extended the objection under Article 123(2) EPC regarding the cytotoxicity-inducing property from claim 1, directed to the bispecific antibody *per se*, to the subject-matter of the medical use claims.
- 28.5 In particular, in section 35 of the communication pursuant to Article 15(1) RPBA, the board expressed the view that the subject-matter of the claims specifying that the two Fabs are organised in an F(ab')<sub>2</sub> molecule,

such as in claim 1 of auxiliary requests 6A, 7A, 8A and 9A, was not directly and unambiguously disclosed.

The board stated that "*the schematic drawing provided in Figure 3 and page 57, line 32 as well as page 58, line 1 do not explain the details of the antibodies' structure*". This new reasoning presented by the board differed from appellant I's argument and hence resulted in a new factual situation.

28.6 In addition, in section 36 of the communication pursuant to Article 15(1) RPBA the board expressed the view that the objection under Article 123(2) EPC, i.e. that the agonist activity could only be observed in the presence of cancer-specific antigen-expressing cells, also applied to at least claim 1 of auxiliary requests 1A to 9A.

28.7 There were therefore exceptional circumstances within the meaning of Article 13(2) RPBA for admitting auxiliary request 12D into the proceedings.

28.8 Moreover, the amendments were suitable to overcome the board's newly raised added-matter objection under section 35 of the communication pursuant to Article 15(1) RPBA concerning the structure of the bispecific antibody, and did not imply any complex issues.

The amendments were made to specify that "the bispecific antibody is an immunoglobulin of the IgG1, IgG2, IgG3 or IgG4 isotype", thus defining the bispecific antibody as a classical IgG-type antibody composed of an F(ab')<sub>2</sub> fragment and an Fc region. This was fully aligned with the structure presented in Figure 3 showing the classical IgG format, and with the

further details provided in at least Example 2, where bispecific anti-CD137 antibodies were constructed based on different IgG isotypes. Further support could be found in the application as filed, for example on page 24, lines 2 to 6, and in particular lines 5 to 6.

28.9 According to the respondent, consideration of the right to be heard required auxiliary request 12D to be admitted and discussed in substance during the oral proceedings.

29. The appellants objected to the admission of auxiliary request 12D, essentially for lack of exceptional circumstances justifying it. All the claims as granted had been explicitly objected to for added subject-matter since the beginning of the appeal proceedings (see for instance appellant II's statement of grounds of appeal on page 9, point 3.22, referring in general to the subject-matter of the claims as granted). Despite not expressly attacking the medical use claims as such, the appellants' arguments in appeal were directed to the combination of features, rather than to the individual claims. In addition, the statements of grounds of appeal were in response to the reasons present in the decision under appeal. The respondent had already filed several auxiliary requests during the opposition proceedings, rendering it unpredictable for the appellants to consider all possible amendments the respondent might submit in appeal.

29.1 In any case, in the appeal proceedings, appellant I, in its letter dated 10 March 2025 (pages 15 and 16), reacted to the respondent's arguments and expressly extended the added-subject-matter objection to the medical use claims by referring to auxiliary requests 5A and 6A. Explicit reference was made to issues

relating to intermediate generalisation arising from Figure 3 and the disclosure of Example 2 (which includes page 57, line 32 to page 58, line 1). The issue had therefore not been raised for the first time in the board's communication pursuant to Article 15(1) RPBA.

Therefore these amendments should have been filed earlier in the proceedings. This was even more true if the respondent had indeed considered that a different discussion with regard to added subject-matter would apply to the medical use claims.

- 29.2 However, the amendments clearly did not overcome the problems of added subject-matter of the main request, so it was irrelevant whether or not they were directed to a medical use claim. Finally, the amendments introduce new features, taken from the description (page 24 of the application as filed), which clearly raised new issues.

Contrary to the respondent's suggestion, the board had discretion not to admit this auxiliary request under Article 13 RPBA in the present circumstances.

30. The board is not persuaded by the respondent's submissions, and finds that the added-subject-matter objection against the medical use claims of auxiliary request 12D cannot be regarded as a new objection, but rather remains within the framework of the attacks raised by the appellants against claim 1 of the main request in appeal.

Already in their notices of opposition both opponents had invoked the ground for opposition under Article 100(c) EPC against claim 1 as granted and

extended this objection to claims 2 to 7 due to their dependency on or reference to claim 1. This includes claims 5 and 6 directed to a second medical use pursuant to Article 54(5) EPC.

31. The board agrees with the appellants that the objection of added subject-matter was directed against a specific combination of features rather than against individual claims (see e.g. appellant II's statement of grounds of appeal, points 3.2 and 3.22). Hence it cannot be said that the medical use claims were not attacked under Article 123(2) EPC.
32. Contrary to the respondent's arguments, appellant I's letter dated 10 March 2025 (pages 15 and 16) expressly extended the added-subject-matter objection raised against the product in claim 1 to all the claims as granted, and explicitly referred to the medical use claims in auxiliary requests 5A and 6A to 9A.
33. The fact that Figure 3, together with the disclosure in Example 2, does not provide a basis for the claimed binding domains other than each being in the  $F(ab')_2$  format was not raised for the first time by the board in the communication pursuant to Article 15(1) RPBA, but had already been addressed in appellant I's letter dated 10 March 2025 (page 16). In that submission, appellant I expressly cited Figure 3 and the disclosure of Example 2 (starting on page 57, line 27 of the application as filed) in support of the added-subject-matter objection. Indeed, the disclosure in Figure 3, together with the disclosure on page 57, line 32 to page 58, line 1, was relied upon by the respondent (page 67, point 6.3 of the reply to the statements of grounds of appeal). Thus the board, in its communication pursuant to Article 15(1) RPBA, had

merely expressed its provisional view on the parties' submissions.

34. In view of these considerations, decision T 1789/22 cited by the respondent is not applicable to the present case.

Under the special circumstances of T 1789/22, the board had to consider the rights of a non-appealing party in appeal, in particular the question of whether a non-appealing party may question the patentability of subject-matter decided upon in the first instance but not appealed by the appellant with the statement of grounds of appeal.

In the present case, however, as explained above, added subject-matter was objected to against all the claims already with appellant II's statement of grounds of appeal and was then further specified in appellant I's submissions of 10 March 2025, so the circumstances of the case are clearly different from those in T 1789/22.

35. The board also finds that the respondent had had time to react to this objection before receiving the board's preliminary opinion contained in the communication pursuant to Article 15(1) RPBA (notified on 12 January 2026). It therefore concurs with the appellants that the respondent had reason to file auxiliary request 12D earlier in the proceedings, at the latest in reply to appellant I's submissions of 10 March 2025.

36. The same applies to the objection under Article 123(2) EPC that the agonist activity can only be observed in the presence of cancer-specific antigen-

expressing cells, which also applies to at least claim 1 of auxiliary requests 1A to 9A.

This objection was not raised for the first time in the board's communication pursuant to Article 15(1) RPBA, but already in appellant II's statement of grounds of appeal (see in particular points 3.20 and 3.22).

For the reasons indicated above, the fact that the objection was formally restricted to claim 1 cannot be understood to mean that it would no longer apply to the same specific combination of features in the medical use claim(s).

Accordingly, the respondent had had reason to react by filing amendments to address this objection already before it had received the board's communication pursuant to Article 15(1) RPBA.

37. In addition, when applying the criteria set out in Article 13(1) RPBA, the board finds that the amendments introduced do not *prima facie* solve the added-subject-matter issues identified for the main request. Contrary to the respondent's arguments, the board would not expect a different assessment under Article 123(2) EPC from that made for the main request.

The board fails to see how an objection directed to added subject-matter arising from a specific combination of features in a product claim should no longer apply merely because the claim has been, *inter alia*, amended into a claim directed to a medical use of that product.

38. Moreover, contrary to the respondent's position, the subject-matter of claim 1 of auxiliary request 12D does

not result exclusively from deletions of features from the granted claims. As is apparent from the wording of claim 1 of auxiliary request 12D (see items XI.(a) and (c) above), the claim not only shifts from a product claim to a second medical use claim pursuant to Article 54(5) EPC in combination with a further antigen-binding molecule, but also introduces additional structural limitations, including that the bispecific antibody consists of an F(ab')<sub>2</sub> domain and an FcRn-binding domain, that the antigen-binding domains are directly linked to the Fc region by peptide bonds, and that the antibody is restricted to specific IgG isotypes.

These features were not present in the granted claims and go beyond a mere restriction by deletion, thereby increasing the complexity of the amendment.

39. In view of the above, auxiliary request 12D is not admitted into the proceedings.

*Objection under Rule 106 EPC*

40. After the board had stated at the oral proceedings its intention to exercise its discretion under Article 13(2) RPBA by not admitting auxiliary request 12D, the respondent raised an objection under Rule 106 EPC.
41. The respondent was of the opinion that its right to be heard under Article 113(1) EPC had been violated. The respondent had been heard on the issue of the admission of its auxiliary request and had been able to present its arguments on this matter in full. Its right to be heard regarding the admission of its amended request had therefore been neither restricted nor disregarded.

This was not disputed by the respondent either. Rather, its objection was directed against the board's discretionary decision not to admit auxiliary request 12D into the proceedings.

In the respondent's view, it had had no reason to file this auxiliary request earlier in the appeal proceedings and should have been given the opportunity to react to the board's communication pursuant to Article 15(1) RPBA or to a changed procedural situation with an auxiliary request.

Therefore the non-admission of auxiliary request 12D had infringed the respondent's right to be heard under Article 113(1) EPC.

42. The board, however, takes the view that the respondent cannot derive from its right to be heard under Article 113(1) EPC a right to file claim requests and to have them admitted at any stage of the appeal proceedings.
  
43. The parties are not entirely free in the conduct of the proceedings, but are subject to certain limits which, in *inter partes* proceedings, arise from the case law on fairness towards the other parties, as well as more generally from the requirements of due process (see also T 1685/07, Reasons 6.1).

In particular, the parties to the appeal proceedings also have a duty to conduct the proceedings diligently and expeditiously. This includes presenting all relevant facts, evidence, arguments and requests as early and as completely as possible, as required by the circumstances of the case. Such conduct ensures

predictability and enables a proper decision to be taken within a reasonable time frame.

44. Waiting until a late stage of the proceedings to file amended claims addressing the added-subject-matter objection raised against the medical use claims in the statement of grounds of appeal (of appellant II) and further specified one year before the oral proceedings by appellant I (see points 31. and 32. above, respectively) involves running the risk that such amended submissions will not be admitted into the appeal proceedings, unless there are special circumstances.
45. The board also notes that Article 13(2) RPBA does not limit the right of a party to be heard. In fact, Article 13(2) RPBA also provides that, if exceptional circumstances exist, such as in the case of a new objection raised for the first time in the board's communication pursuant to Article 15(1) RPBA or during the oral proceedings before the board, the strict approach of this provision should not be adhered to. However, as explained above in point 35., this was not the case here.

The respondent had had reason to file auxiliary request 12D earlier in the proceedings, at the latest after appellant I's submissions of 10 March 2025. Contrary to the respondent's allegations, the alleged "extension" of the added-subject-matter objection to the granted medical use claims was not introduced into the proceedings for the first time by the board in its communication pursuant to Article 15(1) RPBA, but had already been raised by the appellants. Therefore the board fails to see any violation of the respondent's right to be heard.

46. According to the respondent, auxiliary request 12D should also have been admitted because the amendment was straightforward and did not give rise to any new technical situation.

In this regard, the board is of the view that, precisely when an amendment made is straightforward and does not lead to any new technical situation, the corresponding auxiliary request ought to have been filed at an earlier stage of the proceedings.

47. For these reasons, the objection under Rule 106 EPC is rejected.

### **Order**

#### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The respondent's objection under Rule 106 EPC is dismissed.
3. The patent is revoked.

The Registrar:

The Chairwoman:



D. Grundner

M. Pregetter

Decision electronically authenticated