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Datasheet for the decision of 2 July 2020

Case Number: T 0032/17 - 3.3.04

Application Number: 10189130.7

Publication Number: 2316854

IPC: C07K16/26, C07K16/44, G01N33/82

Language of the proceedings: EN

Title of invention:
Process for the production of a hybridoma and antibody obtained therefrom, able to recognize more than one vitamin D metabolite.

Patent Proprietor:
Diasource Immunoassays S.A.

Opponents:
Nederlandsch Octrooibureau N.V.
Immundiagnostik AG
Siemens Healthcare Diagnostics Inc.
Euroimmun Medizinische Labordiagnostika AG
Adams, Harvey Vaughan John

Headword:
Bispecific antibody/ DIASOURCE

Relevant legal provisions:
EPC Art. 54, 83, 112(1)(a)
EPC R. 31
RPBA Art. 13(1), 12(4)

Keyword:
Main request - novelty (no)
Late-filed auxiliary requests 1 and 2 - admitted (no)
Late-filed facts - admitted (no)
Referral to the Enlarged Board of Appeal - (no)
Auxiliary request 3 - requirements of the EPC met (yes)

Decisions cited:
G 0002/12, G 0003/14, G 0001/15, T 0412/93, T 1120/00, T 0179/03

Catchword:

The deposit of a hybridoma under Rule 31 EPC for compliance with the disclosure requirement of Article 83 EPC does not in itself convey any technical information about the molecular structure of the monoclonal antibody produced by said hybridoma, such as its amino acid sequence (see points 5 to 17 of the Reasons).

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Case Number: T 0032/17 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 2 July 2020

Appellant: (Opponent 2)	Immundiagnostik AG Stubenwald-Allee 8a 64625 Bensheim (DE)
Representative:	Benedum, Ulrich Max Nebens IP Patente Marken Designs Oberföhringer Strasse 172 81925 München (DE)
Respondent: (Patent Proprietor)	Diasource Immunoassays S.A. Rue du Bosquet 2 1348 Louvain-la-Neuve (BE)
Representative:	Paemen, Liesbet R.J. De Clercq & Partners cvba Edgard Gevaertdreef 10 a 9830 Sint-Martens-Latem (BE)
Party as of right: (Opponent 1)	Nederlandsch Octrooibureau N.V. PO Box 29720 2502 LS The Hague (NL)
Party as of right: (Opponent 3)	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591 (US)
Representative:	Potter Clarkson The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Party as of right: (Opponent 4)	Euroimmun Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck (DE)

Party as of right: (Opponent 5)	Adams, Harvey Vaughan John Mathys & Squire LLP The Shard 32 London Bridge Street London SE1 9SG (GB)
Representative:	Miller, David James Mathys & Squire LLP The Shard 32 London Bridge Street London SE1 9SG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 26 October 2016 concerning maintenance of the European Patent No. 2316854 in amended form.**

Composition of the Board:

Chair	G. Alt
Members:	R. Morawetz
	P. de Heij
	A. Chakravarty
	R. Romandini

Summary of Facts and Submissions

I. The appeal of opponent 2 (appellant) lies from the opposition division's interlocutory decision according to which European patent No. 2 316 854 (patent) as amended in the form of the main request filed on 29 August 2016, and the invention to which it relates, meet the requirements of the EPC.

II. The patent derives from European patent application No. 10 189 130.7 ("application as filed" or "application"), published on 4 May 2011. The patent is entitled "*Process for the production of a hybridoma and antibody obtained therefrom, able to recognize more than one vitamin D metabolite.*"

Claims 1, 7 and 8 as granted read as follows:

"1. Process for the production of a hybridoma, and of a monoclonal antibody or fragments thereof, able to recognize 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3 comprising the following steps:
a) immunisation of a non-human animal with a hapten, rendered immunogenic, of formula (I),(...);
b) (...);
c) (...).

7. Hybridoma suitable for the production of a monoclonal antibody or fragments thereof able to recognize 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3.

8. Hybridoma according to claim 7, characterised in that it is selected from the group consisting of the

hybridomas deposited in the BCCM/LMBP under deposit numbers LMBP 7011CB, LMBP 7012CB, LMBP 7013CB, LMBP 7204CB and LMBP 7205CB."

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

D9 Mawer B. et al., Steroid. (1985), vol. 46, pages 741 to 754

D13 Declaration of Dr. Schumann, dated 28 February 2003

D16 Mawer B. et al., Clinica Chimica Acta (1990), pages 199 to 210

D32 Sales Catalogue, Immundiagnostik AG, dated 13 June 2007, pages 1 to 4

D33 Sales invoices, Immundiagnostik AG, dated 2005 to 2009

D34 Price list. Linscott's Directory of Immunological and Biological reagents, dated 7 March 2007

D35 Manual 25-hydroxyvitamin-D ELISA, Immundiagnostik AG (14 November 2008)

D36 25OH Vitamin D Total ELISA (DiaSource), catalogue number KAP1971

IV. Five oppositions were filed. The patent was opposed on the grounds in Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and in Article 100(b) and Article 100(c) EPC.

V. In the decision under appeal, the opposition division considered one claim request, the main request, consisting of two claims. They held that claims 1 and 2 corresponded to granted claims 8 and 12 and were thus not open to an objection under Article 84 EPC and that the claimed subject-matter was novel (Article 54 EPC) and involved an inventive step (Article 56 EPC).

VI. In the statement of grounds of appeal, the appellant referred to documents D9, D13, D16, D32, D33a to D33m, D34 and D35 (see statement of grounds of appeal, section 3). They submitted, *inter alia*, that the requirements of Article 83 EPC were not met with regard to the claimed hybridomas because the patent did not provide the necessary guidance for their generation (*ibid.*, section 5). Further, they argued that "a hybridoma-produced monoclonal antibody *able to recognize 25-hydroxy-vitamin-D_2 and 25-hydroxyvitamin-D_3 (...) was available to the public as demonstrated by the Appellant during opposition proceedings*" (emphasis in the original; *ibid.*, see page 6, fourth paragraph); "*that the contested patent contains no experimental evidence which supports any new feature or an advantage of the claimed antibodies over the cited prior art*" (*ibid.*, see page 8, second paragraph) and that the claimed antibodies were not new (*ibid.*, see page 9, first paragraph).

VII. In reply, the patent proprietor (respondent) maintained the main request dealt with in the decision under

appeal as their main (sole) request and provided arguments to the effect that the requirements of Article 83 EPC were fulfilled and that the claimed hybridomas (claim 1) and the resulting antibodies (claim 2) were novel over the cited prior art and that the claimed antibodies were inventive over the antibodies disclosed in document D32.

Claims 1 and 2 of the main request read as follows:

"1. Hybridoma suitable for the production of a monoclonal antibody able to recognize 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3, characterised in that it is selected from the group consisting of the hybridomas deposited in the BCCM/LMBP under deposit numbers LMBP 7011 CB, LMBP 7012CB, LMBP 7013CB, LMBP 7204CB and LMBP 7205CB.

2. Monoclonal antibody able to recognize 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3, characterised in that it is produced from a hybridoma selected from the group consisting of the hybridomas deposited in the BCCM/LMBP under deposit numbers LMBP 7011 CB, LMBP 7012CB, LMBP 7013CB, LMBP 7204CB and LMBP 7205CB."

VIII. In response, the appellant reiterated, *inter alia*, that the antibodies claimed in claim 2 were only defined by their ability to recognise 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D3 and lacked novelty (see letter dated 18 October 2017, points 5.1 to 5.4).

IX. The board appointed oral proceedings, as requested by both the appellant and the respondent and issued a communication pursuant to Article 15(1) RPBA 2007, in which it indicated, *inter alia*, that it was inclined to

hold the appellant's objection as regards lack of sufficient disclosure inadmissible under Article 12(4) RPBA 2007.

X. In response, opponents 1 and 3 informed the board in writing that they would not attend the oral proceedings.

XI. By letter of 12 May 2020 the respondent enquired whether the oral proceedings could be held by video conference (ViCo).

XII. The board issued a communication pursuant to Article 15(1) RPBA 2020 requesting that the appellant, opponent 4 and opponent 5 indicate whether or not they intended to attend the oral proceedings and whether or not they agreed to holding the oral proceedings by ViCo.

XIII. In response, opponents 4 and 5 informed the board in writing that they would not attend the oral proceedings.

XIV. The appellant objected to holding the oral proceedings by ViCo.

XV. With letter of 16 June 2020, the respondent requested a postponement of the oral proceedings.

XVI. With a communication dated 24 June 2020 and sent to the parties by e-mail on 22 June 2020 the board informed the parties that none of the reasons put forward by the respondent qualified as a serious reason within the meaning of Article 15(2)(b) RPBA 2020 which would warrant that the oral proceedings be postponed.

XVII. Oral proceedings took place as scheduled. During the oral proceedings the respondent filed sets of claims of auxiliary requests 1 to 3.

Claim 1 of auxiliary request 1 was identical to claim 1 of the main request, while claim 2 was amended and read as follows (amendments vis-à-vis claim 2 of the main request are indicated):

"2. Monoclonal antibody able to recognize 25-hydroxyvitamin D2 and 25-hydroxyvitamin D3, characterised in that it is produced from a hybridoma selected from the group consisting of the hybridomas deposited in the BCCM/LMBP under deposit numbers LMBP 7011 CB, LMBP 7012CB, LMBP 7013CB, LMBP 7204CB and LMBP 7205CB, wherein said monoclonal antibody has a recognition percentage of 25-hydroxyvitamin D2 and of 25-hydroxyvitamin D3 ranging from 70 and 110%."

Claim 1 of auxiliary request 2 was identical to claim 1 of the main request while claim 2, a new claim, read as follows:

"2. Use of a hybridoma selected from the group consisting of hybridomas deposited in the BCCM/LMBP under deposit numbers LMBP 7011 CB, LMBP 7012CB, LMBP 7013CB, LMBP 7204CB and LMBP 7205CB for production of a monoclonal antibody able to recognize 25-hydroxyvitamin D2 and 25-hydroxyvitamin D3."

Auxiliary request 3 consisted of a sole claim (claim 1) which was identical to claim 1 of the main request.

XVIII. During the oral proceedings the appellant submitted the following questions for referral to the Enlarged Board of Appeal:

"Are non-described or non-relevant differences in a peptide or nucleotide sequence deposited under Rule 31 EPC sufficient for acknowledgement of novelty and inventive step when the objective problem vis-à-vis the prior art and known industrial application is the provision of an alternative solution?

Can a non-described characteristic of a biological material deposited under Rule 31 EPC render an invention novel or inventive (Art. 56 EPC) when it pertains to a known industrial application and when this characteristic is already part of the state of the art?"

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

XX. By a letter dated 6 July 2020, opponent 4 declared that they withdrew their opposition.

XXI. The appellant's arguments submitted in writing and during the oral proceedings as far as relevant to the present decision, are summarised as follows:

Main request - claim 2

The claimed subject-matter - claim construction

The claimed antibodies were solely defined by the functional feature relating to dual recognition of 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3.

The process feature "*produced from a hybridoma* (...)" did not confer any additional technical features on the claimed antibodies.

To be taken into account as a feature of the claimed subject-matter, a characteristic resulting from the process feature had to be disclosed in the application. The amino acid sequences of the antibodies produced by the deposited hybridomas were not disclosed in the application and were not made available to the skilled person by the deposit of the hybridomas producing the antibodies.

The prior art antibodies had an amino acid sequence. No evidence had been provided by the respondent that the amino acid sequence of the claimed antibodies was different. It was not for the appellant to determine the amino acid sequence of the antibodies produced by the hybridomas.

No distinguishing feature resulting from the process "*produced from a hybridoma* (...)" and characterising the antibodies was disclosed in the application.

Novelty (Article 54(2) EPC)

The public prior use of the antibodies disclosed in document D32

Antibodies with the same functional properties as the claimed antibodies were available in the prior art, see decision under appeal, points 4.1 to 4.8.

Respondent's new line of argument based on document D13 should not be admitted into the appeal proceedings. If admitted, more time was needed to react to the argument, e.g. with a further declaration.

Auxiliary requests 1 to 3

Admittance into the appeal proceedings (Article 13(1) RPBA 2007)

Claim 2 of auxiliary request 1 raised new issues under Article 123(2) EPC and was not clearly allowable.

Claim 2 of auxiliary request 2 was a completely new claim which could not be dealt with properly at this late stage of the proceedings.

Auxiliary request 3 - claim 1 (sole claim)

Novelty (Article 54(2) EPC)

A hybridoma-produced monoclonal antibody able to recognise 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3 was available to the public as disclosed in document D32. It was "*obvious that a monoclonal antibody must have been produced by a hybridoma* (...), *thus, rendering also the hybridomas producing such antibodies not novel*" (see statement of grounds of appeal, page 6, fourth paragraph).

Hybridomas with the deposit numbers LMBP 7011CB, LMBP 7012CB, LMBP 7013CB had been deposited before the priority date of the patent. These deposited hybridomas were available to the public and were thus novelty destroying for the subject-matter of claim 1.

The claimed subject-matter was not entitled to the priority date of the first priority document because this document disclosed some, but not all of the claimed hybridomas. The first priority document of the

opposed patent had been published and could be cited against the claimed subject-matter.

Inventive step (Article 56 EPC) - admittance of the objection into the appeal proceedings (Article 13(1) RPBA 2007)

The claimed subject-matter lacked inventive step in the light of the disclosure of documents D2, D3, D8, D10, D47 and D52.

Sufficiency of disclosure (Article 83 EPC) - admittance of the objection into the appeal proceedings (Article 12(4) RPBA 2007)

The lack of sufficiency objection raised in the statement of grounds of appeal was not a fresh argument. The notice of opposition as well as the grounds of appeal both stated that the patent must be revoked for grounds of Article 100(b) EPC and Article 83 EPC. Detailed arguments had been provided in section 3 at pages 8 to 10 of the notice of opposition and in section 5 at pages 3 to 6 of the statement of grounds of appeal.

Clarity (Article 84 EPC)

Claim 1 lacked clarity.

Referral of questions to the Enlarged Board of Appeal

A referral of questions to the Enlarged Board of Appeal was necessary, both in the interest of uniform application of the law and because a point of law of fundamental importance had arisen.

XXII. The respondent's arguments submitted in writing and during the oral proceedings as far as relevant to the present decision, are summarised as follows:

Main request - claim 2

The claimed subject-matter - claim construction

The monoclonal antibodies were produced by specific hybridomas, resulting in antibodies with specific amino acid sequences. The process feature thus imposed structural restrictions on the antibodies.

The antibodies' amino acid sequences and indeed their entire chemical composition were implied features of the claimed subject-matter by virtue of the reference to the deposited hybridoma.

The amino acid sequence of the antibodies produced by the deposited hybridomas could be determined. The burden of proof to show that the prior art antibodies had the same amino acid sequence was on the appellant.

Novelty (Article 54(2) EPC)

The public prior use of the antibodies disclosed in document D32

Antibodies were identical when they had an identical amino acid sequence. The mere allegation that the antibodies described in document D32 were capable of recognising 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3 did not constitute proof that these antibodies were identical to the claimed antibodies.

The claimed antibodies were generated with a different antigen than the antibodies of document D32 and the cross-reactivity profile of the antibodies might be affected by that.

Document D13 casted doubt on the identity of the antibody disclosed in document D32, i.e. whether it was one bispecific antibody or was a mixture of two antibodies.

Auxiliary requests 1 to 3

Admittance into the appeal proceedings (Article 13(1) RPBA 2007)

The board's opinion on lack of novelty of claim 2 of the main request was unexpected. The amendments in these claim requests aimed at addressing the lack of novelty problem of the main request.

Claim 11 as filed provided the basis for the amendment of claim 2 in auxiliary request 1.

The Examples of the application provided an implicit basis for the use-claim of auxiliary request 2.

In auxiliary request 3, claim 2 of the main request had been deleted.

Auxiliary request 3 - claim 1 (sole claim)

Novelty (Article 54(2) EPC)

The mere description of antibodies in the prior art which bind both to 25-hydroxyvitamin D_2 and 25-

hydroxyvitamin D_3 did not take away the novelty of the claimed hybridomas.

The deposits of the claimed hybridomas referred to in the application as filed did not take away the novelty of the claimed hybridomas. Deposits made according to the Budapest Treaty were not publicly available, and hence could not be considered novelty destroying for a subsequent patent filing.

The appellant's novelty objection regarding an alleged "toxic" priority was newly raised in the oral proceedings before the board and should not be admitted into the appeal proceedings. In any case, the objection could not succeed in view of decision G 1/15 of the Enlarged Board of Appeal.

Inventive step (Article 56 EPC) - admittance of the objection into the appeal proceedings
(Article 13(1) RPBA 2007)

The appellant's inventive step attack presented for the first time in the oral proceedings before the board should not be admitted into the appeal proceedings, as this was again a newly raised line of argument relying entirely on documents not mentioned so far in the appeal proceedings.

Sufficiency of disclosure (Article 83 EPC) - admittance of the objection into the appeal proceedings
(Article 12(4) RPBA 2007)

The appellant's objection in the opposition proceedings concerned the process for producing the hybridomas, but not the disclosure of the hybridomas as such.

Referral of questions to the Enlarged Board of Appeal

It was left to the discretion of the board whether or not to refer questions to the Enlarged Board of Appeal.

XXIII. Opponents 1, 3, 4 and 5, parties as of right to the appeal proceedings, did not submit any arguments or requests during the appeal proceedings.

XXIV. The appellant (opponent 2) requested that the decision under appeal be set aside and that the patent be revoked; in case this request was not granted, to refer the questions as filed during the oral proceedings of 2 July 2020 to the Enlarged Board of Appeal.

XXV. The respondent (patent proprietor) requested that the appeal be dismissed (amounting to a request that the patent be maintained in amended form on the basis of the main request considered allowable by the opposition division) or, alternatively, that the patent be maintained on the basis of one of the set of claims of auxiliary requests 1, 2 or 3, all filed during the oral proceedings of 2 July 2020.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

2. An amended version of the Rules of Procedure of the Boards of Appeal (RPBA) came into force on 1 January 2020. The transitional provisions are set out in Article 25 RPBA. In the present case, the statement of grounds of appeal and the reply thereto were filed before 1 January 2020. Therefore, Article 12(4) RPBA 2007 continues to apply

(see Article 25(2) RPBA). The parties were notified of the summons to oral proceedings before 1 January 2020. Therefore, Article 13(1) and (3) RPBA 2007 continue to apply (see Article 25(3) RPBA).

3. The duly summoned opponents 1, 3, 4 and 5, were, as announced in advance, neither present nor represented at the oral proceedings. The board continued the proceedings in their absence, in accordance with Rule 115(2) EPC.

4. After the board's final decision had been announced at oral proceedings, opponent 4 withdrew their opposition. As the final decision became effective immediately on its announcement, the above mentioned withdrawal did not change opponent 4's status as a party to the appeal proceedings.

Main request - claim 2

The claimed subject-matter - claim construction

5. Claim 2 is drafted as a product-by-process claim. It is directed to a monoclonal antibody which is characterised by the functional feature "*able to recognize 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3*" and by the process feature "*produced from a hybridoma selected from the group consisting of the hybridomas deposited in the BCCM/LMBP under deposit numbers LMBP 7011CB, LMBP 7012CB, LMBP 7013CB, LMBP 7204CB and LMBP 7205CB.*"

6. In the decision under appeal the opposition division held that, as a consequence of the process feature, the claimed antibodies were characterised by a unique amino acid sequence because "*deposit numbers allow to*

identify specific hybridomas" and *"each antibody produced by a different hybridoma will have a different sequence (heavy and light chains) which renders the antibody unique."* (see decision under appeal, Reasons, point 4.10).

7. The appellant contested the opposition division's construction of the claim. They argued that the claimed antibodies were only characterised by the functional feature "*able to recognize 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3*" while the process feature did not confer any additional technical features on the claimed antibodies. The respondent disagreed and submitted that as a consequence of the process feature the specific amino acid sequence and indeed the entire chemical composition of the antibodies produced by the deposited hybridomas was a feature of the antibodies of claim 2.

8. According to the case law of the boards of appeal a process feature in a product-by-process claim only contributes to the novelty of a product claim insofar as it gives rise to a distinct and identifiable characteristic of the product (see e.g. decision T 179/03, Reasons, points 3.7 to 3.9). The skilled person following the teaching of the patent must inevitably achieve that characteristic and must be aware of that characteristic so that they can recognise the claimed product and discard any products not having it (see e.g. decision T 412/93, Reasons, point 33 and decision T 1120/00, Reasons, point 7). Furthermore, the Enlarged Board of Appeal held that "[f]*or a product-by-process claim to be allowable it needs to be established that (a) it is impossible to define the claimed product other than in terms of a process of manufacture and (b) the claimed product itself meets the patentability requirements of Article 52(1) EPC.*

Thus, the specific process needed to obtain the claimed product should make it possible to distinguish the inevitable product of the product-by-process claim over the prior-art" (see decision G 2/12, OJ EPO 2016, 27, Reasons, point IV.(5)).

9. At issue in the present case is thus whether or not the process feature in claim 2 *"produced from a hybridoma selected from the group consisting of the hybridomas deposited* (...)" gives rise to the specific amino acid sequence and chemical composition of the claimed antibodies and furthermore, whether the skilled person is made aware of these structural characteristics of the antibodies by the teaching of the patent.

10. The deposit information recited in claim 2, see point 5. above, informs the skilled person (i) about the depositary institution, i.e. "BCCM/LMBP" and (ii) the deposit numbers assigned to the deposited hybridomas by the depositary institution, i.e. "LMBP 7011CB, LMBP 7012CB, LMBP 7013CB, LMBP 7204CB and LMBP 7205CB".

11. From the hybridomas' deposit information the skilled person derives that hybridomas producing the claimed antibodies have been deposited and have been assigned deposit numbers.

12. This deposit information however does not convey any technical information about the chemical composition or molecular structure of the antibodies produced by these hybridomas, such as their amino acid sequence, either explicitly or implicitly.

13. The patent does not provide any information about the chemical composition or amino acid sequence of the

antibodies produced by the deposited hybridomas either, e.g. in the form of a sequence listing (see also Rule 30 EPC).

14. In view of the above considerations it is apparent that the chemical composition and/or the amino acid sequence of the antibodies produced by the deposited hybridomas cannot be inferred by the skilled person from the teaching of the patent in suit.

15. Finally, where a process feature is the only feature allegedly conferring novelty to a product, the burden of proof for showing the fact that the process feature results in a distinct and identifiable characteristic of the product - i.e. in the present case in the chemical composition and/or the specific amino acid sequences of the claimed antibodies - is on the patent proprietor and not on the opponent(s) (see also decision T 179/03, see points 3.9 and 3.14 of the Reasons).

16. The respondent's argument that the appellant could have determined the amino acid sequence of the antibodies produced by the deposited hybridomas can thus not succeed. The respondent has not discharged the burden of proof.

17. The board concludes from the above that the process feature does not impart any identifiable technical feature on the claimed subject-matter. The sole technical feature defining the monoclonal antibodies of claim 2 is thus the functional feature that they are "*able to recognize 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3*".

The public prior use of the antibodies disclosed in document D32

18. Document D32, a sales catalogue, discloses, *inter alia*, an anti-25 Dihydroxy-Vitamin D3 antibody. Two catalogue numbers, A 1025.1 and A1025.2, are given for the antibody, relating to different concentrations, 10 µg and 100 µg, respectively (see page 3, lines 10 and 11).

19. Based on the submissions before it, the opposition division concluded that the antibodies designated as A1025.1 and A1025.2 in document D32 were one and the same antibody (sold at different concentrations), that these antibodies bind to 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3, were available to the public and had been sold before the priority date of the opposed patent (see decision under appeal, Reasons, points 4.1 to 4.8).

20. In other words, the opposition division held that a public prior use of antibodies that fulfil the functional feature characterising the antibodies of claim 2, see point 17. above, had been established by the opponents.

21. Nevertheless, the opposition division acknowledged novelty of claim 2 because they considered that the claimed antibodies were further characterised by their amino acid sequence, see point 6. above, and "*based on the evidence provided by the opponents the Opposition Division cannot conclude that the antibodies referred to in D32 are produced by the same hybridoma and have the same heavy and light chains*" (see decision under appeal, Reasons, point 4.10).

22. However, in view of the claim construction adopted by the board, see point 17. above, the opposition division's reasoning, see previous point, cannot hold.

23. During the written appeal proceedings, the respondent submitted two lines of argument in support of novelty of claim 2, see section XXII. above. In the view of the claim construction set out in point 17. above, both of these lines of argument fail because neither the antibodies' amino acid sequence nor their potentially different cross-reactivity profile is a feature of the claimed antibodies.

24. As a third line of argument, submitted for the first time during the oral proceedings before the board, the respondent argued that is was doubtful that the antibody disclosed in document D32 was indeed bispecific. In support of this new allegation of fact, the respondent relied on document D13.

25. The opposition division's finding that the antibodies designated as A1025.1 and A1025.2 in document D32 were one and the same antibody that bound to 25-hydroxyvitamin D_2 and 25-hydroxyvitamin D_3, see point 19. above, had not been contested, either expressly or implicitly, by the respondent during the appeal proceedings before. The third line of argument thus represented an amendment of the respondent's case at the oral proceedings and its admittance into the appeal proceedings was therefore considered by the board.

26. Admittance of the amendment to the respondent's case was governed by the provisions of Article 13(1) RPBA 2007, see point 2. above.

27. Pursuant to Article 13(1) RPBA 2007, an amendment to a party's case after the filing of the statement of grounds of appeal or reply may be admitted and considered at the board's discretion. That discretion "*shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy*".

28. The board considered that admittance of the new line of argument on the basis of document D13 would have raised issues not previously addressed in the appeal proceedings and thus extended the scope of discussion as determined by the grounds of appeal and the respondent's reply at a very late stage of the proceedings.

29. Such an amendment of the respondent's case would normally make remittal to the opposition division necessary and at the very least, would have meant adjourning the oral proceedings in order to give the appellant an opportunity to respond appropriately. Admittance of the new line of argument would thus also not have served the interest of procedural economy.

30. In view of these considerations, the board, in the exercise of its discretion, decided not to admit the respondent's third line of argument into the appeal proceedings.

Conclusion on novelty of claim 2 of the main request

31. Claim 2 of the main request lacks novelty over the public prior use of the antibodies disclosed in document D32.

Auxiliary requests 1 to 3

Admittance into the appeal proceedings
Article 13(1) RPBA 2007

32. These requests were filed during the oral proceedings, after the board had expressed its opinion that claim 2 of the main request lacked novelty, see section XVII. above.

33. In auxiliary request 1, claim 2 of the main request had been amended while in auxiliary request 2, claim 2 of the main request had been replaced by a new claim, drafted as a "use" claim. In auxiliary request 3, claim 2 of the main request had been deleted.

34. These claim requests represented yet another amendment to the respondent's case and their admittance was again governed by the provisions of Article 13(1) RPBA 2007, see point 2. above.

35. The provisions of Article 13(1) RPBA 2007 have been set out in point 27. above. In the case law of the boards of appeal the following criteria have, *inter alia*, been established for the consideration of the admittance of new requests pursuant to Article 13(1) RPBA 2007: (i) sound reasons exist for filing the request so far into the proceedings, (ii) the request does not extend the scope of discussion as determined by the grounds of appeal and the respondent's reply, (iii) and the request is clearly and obviously allowable in the sense that it is immediately apparent to the board, with little investigative effort on its part, that the amendments made successfully address the issue raised without giving rise to new ones (see Case Law of the

Boards of Appeal, 9th edition 2019, V.A.4.5.1 a)).

36. Auxiliary requests 1 to 3 seek to address an objection, lack of the novelty of claim 2 of the main request, that has been raised in the statement of grounds of appeal of the appellant, see section VI. above and which was maintained by the appellant in the course of the written phase of the appeal proceedings, see section VIII. above. Thus, in light of these procedural circumstances, claim requests aimed at addressing this objection could have been submitted sooner, and no persuasive explanation for not filing auxiliary requests 1 to 3 earlier was provided.

37. Claim 11 as filed was relied on as providing a basis for the feature "*wherein said monoclonal antibody has a recognition percentage of 25-hydroxyvitamin D2 and of 25-hydroxyvitamin D3 ranging from 70 and 110%*" newly introduced into claim 2 of auxiliary request 1.

38. However, claims 9 and 10 as filed, on which claim 11 as filed depends, do not relate to the antibodies produced by the deposited hybridomas but to a generic monoclonal antibody. Thus, it was not directly and unambiguously derivable from claims 9 to 11 as filed that the antibodies produced by the deposited hybridomas also possessed the claimed level of recognition percentage. As a result, amended claim 2 of auxiliary request 1, raised *prima facie* an issue of added subject-matter under Article 123(2) EPC. Therefore, admittance into the appeal proceedings would not have served the interests of procedural economy.

39. In auxiliary request 2, a "use" claim had been introduced. Such a claim has not been pursued in the appeal proceedings before (and also not in the

opposition proceedings). Due to the change in the claim category and thus, in the claimed subject-matter, it was not immediately apparent to the board, with little investigative effort on its part, that the amendment did not give rise to new issues which the board and the appellant could deal with without adjourning the oral proceedings.

40. In view of the above considerations, the board, in the exercise of its discretion under Article 13(1) RPBA 2007, decided not to admit auxiliary requests 1 and 2 into the appeal proceedings.

41. The board considered that the amendment in auxiliary request 3 - deletion of the claim corresponding to claim 2 of the main request - was straightforward and successfully addressed the novelty issue of the main request without giving rise to any new issues. The respondent explicitly did not object to the admittance of this request into the appeal proceedings.

42. The board decided to admit auxiliary request 3 into the appeal proceedings in the exercise of its discretion under Article 13(1) RPBA 2007.

Auxiliary request 3 - claim 1 (sole claim)

Novelty (Article 54(2) EPC)

43. The appellant raised two objections in the statement of grounds of appeal with regard to that claim, namely that: (i) the claimed hybridomas were not novel "*because it was obvious that a monoclonal antibody must have been produced by a hybridoma* (...), *thus, rendering also the hybridomas producing such antibodies not novel*"; (ii) the deposited hybridomas anticipated

the claimed subject-matter, see section XXI. above. These objections are dealt with in point 45. and points 46. to 49. below.

44. During the oral proceedings before the board the appellant raised a third objection, based on an alleged "toxic" priority document. This objection was not admitted into the appeal proceedings, see points 50. to 53. below.

45. With respect to the appellant's first line of argument, see point 43. above, the board notes that the consistent view in the case law is that for an invention to lack novelty, its subject-matter must be directly and unambiguously disclosed in the prior art, while the question of what may be rendered obvious by that disclosure is not relevant (see also Case Law of the Boards of Appeal, 9th edition 2019, I.C.4.3). As the appellant has not referred to any prior art that directly and unambiguously discloses the claimed hybridomas, the appellant's first line of argument fails.

46. The appellant's second line of argument, see point 43. above, hinges on the proposition that deposits of biological material made pursuant to Rule 31 EPC render the deposited material - here hybridomas - available to the public on the date of that deposit.

47. According to Rule 33(1) EPC biological material deposited in accordance with Rule 31 EPC shall be available upon request to any person from the date of publication of the European patent application and to any person having the right to inspect the files under Article 128, paragraph 2, prior to that date.

48. In the present case, the European patent application was published on 4 May 2011, see section II. above. As of this date anyone knew about the existence of the deposited hybridomas and was entitled to obtain a sample of the deposited hybridomas from the BCCM/LMBP. The appellant provided no evidence that any person obtained a sample before that date.

49. On the basis of the evidence on file, the public availability of the deposited hybridomas thus post-dates the filing date of the application. The appellant's second line of argument thus also fails.

50. During the oral proceedings before the board, the appellant argued for the first time in the appeal proceedings that the first priority document of the opposed patent anticipated the claimed subject-matter, see section XXI. above for the full argument.

51. This new objection represented an amendment of the appellant's case and admittance was governed by the provisions of Article 13(1) RPBA 2007, see point 2. above.

52. The board considered that the objection was not only raised at a very late stage of the appeal proceedings but, in view of the Enlarged Board of Appeal's decision G 1/15 (OJ EPO 2017, 82, see Order), was also *prima facie* without any merit.

53. The board, in the exercise of its discretion, decided not to admit the appellant's late objection into the appeal proceedings.

Conclusion on novelty of claim 1 (sole claim) of auxiliary request 3

54. The sole claim of auxiliary request 3 meets the requirements of Article 54 EPC.

Inventive step (Article 56 EPC) - admittance of the objection into the appeal proceedings (Article 13(1) RPBA 2007)

55. The statement of grounds of appeal and the further written submissions of the appellant contained no objection of lack of inventive step of the subject-matter of claim 1.

56. It was only during the oral proceedings before the board that the appellant submitted that the claimed subject-matter lacked inventive step in the light of the disclosure of documents D2, D3, D8, D10, D47 and D52. No explanation for not submitting this objection earlier was provided by the appellant.

57. The new objection represented again an amendment of the appellant's case and its admittance was at the board's discretion pursuant to Article 13(1) RPBA 2007, see point 2. above.

58. The board held that the objection amounted to a new line of argument on the basis of new facts, i.e. the evidence in documents D2, D3, D8, D10, D47 and D52, not relied on earlier during the appeal proceedings, see section VI. above.

59. Admittance of such a "fresh case" would have meant remittal of the case to the opposition division to give the respondent the opportunity to adequately consider the appellant's objection and to respond appropriately.

Admittance of the new objection would thus not have served the interest of procedural economy.

60. The board decided not to admit the appellant's new objection of inventive step into the appeal proceedings.

Sufficiency of disclosure (Article 83 EPC) - admittance of the objection into the appeal proceedings (Article 12(4) RPBA 2007)

61. Claim 1 is directed to hybridomas which are characterised by their deposit numbers, see sections VII. and XVII. above. In the statement of grounds of appeal the appellant submitted that the requirements of Article 83 EPC were not met because the patent did not provide the necessary guidance for the generation of these hybridomas, see section VI. above. This objection amounts to an allegation of fact.

62. Pursuant to Article 12(4) RPBA 2007, the board has discretion to hold inadmissible facts presented with the statement of grounds of appeal (or the reply thereto) if they could have been presented in the proceedings before the opposition division. The admittance hinges, *inter alia*, on the question whether a party was in a position to make its submissions earlier, and whether it could have been expected to do so under the circumstances (see Case Law of the Boards of Appeal, 9th edition 2019, section V.A.4.11.1).

63. Before the opposition division the appellant had argued that the requirements of Article 83 EPC were not met because the patent did not provide the necessary guidance to carry out the claimed process for the production of a hybridoma of claim 1 as granted (see section II. above for the wording of claim 1 as

granted). With respect to the claimed hybridomas, i.e. the subject-matter corresponding to claim 1 under consideration, the appellant had acknowledged in the opposition proceedings "*that the deposition of a hybridoma is an alternative disclosure for the respective hybridoma*" (see notice of opposition, point 3.3.4 on page 10).

64. The objection under Article 83 EPC submitted with the statement of grounds of appeal could thus clearly have been raised in the opposition proceedings. Furthermore, no explanation was offered by the appellant why this objection had not been raised earlier. Finally, the board considered that the objection was *prima facie* without any merit. The disclosure requirement of Article 83 EPC is met by deposit of the hybridomas pursuant to Rule 31 EPC, as was also acknowledged by the appellant during opposition proceedings, see point 63. above.

65. The board decided to hold the objection under Article 83 EPC inadmissible under Article 12(4) RPBA 2007.

Clarity (Article 84 EPC)

66. At the oral proceedings before the board the appellant submitted that claim 1 lacked clarity.

67. The board noted that claim 1 of auxiliary request 3 was a combination of claims 7 and 8 as granted, compare sections II. and VII. above, and thus not open to an objection under Article 84 EPC (see decision G 3/14, OJ EPO 2015, A102).

Referral to the Enlarged Board of Appeal
(Article 112(1) EPC)

68. In written submissions, in the context of discussion of the board's preliminary opinion on novelty, the appellant submitted that the law, in particular Rule 31 EPC (in their letter of 5 June 2020 the appellant inadvertently referred to Rule 28 EPC), had been interpreted by the board in a way which diverged from case law. It was argued that the proposed questions had to be answered (apparently in the negative) because otherwise any biological material deposited under Rule 31 EPC would automatically represent patentable subject-matter. During the oral proceedings the appellant reiterated the request to refer the questions filed during the oral proceedings (see section XVIII. above) to the Enlarged Board of Appeal. These questions concern the interpretation of Rule 31 EPC in the context of novelty as well as inventive step.

69. Pursuant to Article 112(1)(a) EPC, the boards of appeal refer questions to the Enlarged Board, either of their own motion or upon request from a party, in order to ensure uniform application of the law or if a point of law of fundamental importance arises, if they consider that a decision is required for the above purposes and if the answer to that question is not obvious.

70. In the board's assessment of novelty of the subject-matter of claim 1 of auxiliary request 3 "non-described characteristic of a biological material deposited under Rule 31 EPC" played no role; furthermore, the objection concerning absence of an inventive step was not admitted into the appeal proceedings. The requirements for a referral were therefore not fulfilled.

Accordingly, appellant's request was rejected.

Conclusion

71. Auxiliary request 3 is allowable.

Order

For these reasons it is decided that:

1. The request for referral to the Enlarged Board of Appeal is refused.

2. The decision under appeal is set aside.

3. The case is remitted to the opposition division with the order to maintain the patent on the basis of the claim of auxiliary request 3, filed during the oral proceedings of 2 July 2020, and a description to be adapted thereto.

The Registrar: The Chair:

I. Aperribay G. Alt

Decision electronically authenticated