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

Datasheet for the decision of 12 July 2012

Case Number: T 0107/09 - 3.3.04

Application Number: 93102279.2

Publication Number: 555880

IPC: C07K 14/725, C12P 21/08, A61K 39/395

Language of the proceedings: EN

Title of invention:
The CD40CR receptor and ligands therefor

Patentees:
Bristol-Myers Squibb Company

Trustees of Dartmouth College doing bussiness as Dartmouth College

The General Hospital Corporation doing business as Massachusetts General Hospital

Opponent:
Biogen Idec MA Inc.

Headword:
CD40 counter receptor/BMS

Relevant legal provisions (EPC 1973):
EPC Art. 123(2), 54(2), 56, 87
EPC R. 28(1)(2)

Keyword:
"Extension beyond the content of the application as filed (yes)"
"Right to priority (no) - deposit of biological material after the filing date of the earlier application"
"Inventive step (no)"

Decisions and legal literature cited:
G 0002/93, G 0002/98, G 0001/03, T 0542/95, T 0939/92, T 0133/01, T 0512/02, T 0931/04, T 1589/05;

"In re Lundak", 773F.2d 1216, Fed.Cir. 1985

BGH X ZR 89/07 "Olanzapin"

Europäisches Patentübereinkommen: Münchner Gemeinschaftskommentar, eds.: Beier, Haertel, Schricker; 15th edition, April 1991, Art. 53, Moufang, R.

Patentgesetz mit EPÜ, ed.: Schulte, R.; 8th edition, 2008

"Notice of the European Patent Office dated 18 July 1986 concerning European patent applications and European patents in which reference is made to microorganisms", EPO OJ 1986, 269-275

"Notice from the European Patent Office dated 7 July 2010 concerning inventions which involve the use of or concern biological material", EPO OJ 2010, 498-513

Catchword:
See points 6 to 26 of the Reasons

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0107/09 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 12 July 2012

Appellant I: (Patent Proprietor 1)
Bristol-Myers Squibb Company
345 Park Avenue
New York, NY 10154 (US)

Appellant II: (Patent Proprietor 2)
Trustees of Dartmouth College doing business as Dartmouth College
Hanover, New Hampshire 03755 (US)

Appellant III: (Patent Proprietor 3)
The General Hospital Corporation doing business as Massachusetts General Hospital
55 Fruit Street
Boston, MA 02114 (US)

Representative:
Reitstötter - Kinzebach
Patentanwälte
Postfach 86 06 49
D-81633 München (DE)

Respondent: (Opponent)
Biogen Idec MA Inc.
14, Cambridge Center
Cambridge MA 02142 (US)

Representative:
Adams, Harvey Vaughan John
Mathys & Squire LLP
120 Holborn
London EC1N 2SQ (GB)

Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 12 November 2008 concerning maintenance of European patent No. 555880 in amended form.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: G. Alt
B. Claes

Summary of facts and submissions

I. This is the appeal of the patent proprietors against the decision of the opposition division by which it expressed its intention to maintain the European patent no. 0 555 880 in amended form on the basis of the claims of the second auxiliary request.

II. The date of the publication and mention of the grant of the patent was 18 August 2004. The patent has the title "The CD40CR receptor and ligands therefor". It claims priority from the US application No. 835,799 filed on 14 February 1992.

In view of the publication date of the patent, the provisions of the EPC 1973 apply to the present case. For the ease of legibility the indication "1973" is however omitted in the following.

III. The patent had been granted with fifteen claims relating to: soluble ligands to the CD40 counter receptor (CD40CR) molecule, the monoclonal antibody MR1 and a hybridoma producing it deposited with the ATCC under accession number HB 11048, a method of inhibiting B-cell activation by using the soluble ligands and uses of the soluble ligands in treating disorders associated with B-cell activation, for example autoimmune disease or anaphylaxis.

IV. Claims 1 and 5 of the granted patent read:

"1. A soluble ligand which comprises at least a binding portion of an immunoglobulin molecule, in which the immunoglobulin molecule is capable of competitively

inhibiting the binding of monoclonal antibody MR1 as produced by a hybridoma cell line deposited with the ATCC and assigned accession number HB 11048, to CD40CR molecule, which molecule being obtainable from the plasma membrane of activated helper T-cells and having a molecular weight of about 39 kilodaltons as determined by SDS-PAGE.

5. A soluble ligand which comprises (i) an extracellular domain of CD40 that binds to CD40CR and, fused thereto, (ii) an Fc fragment of an immunoglobulin, in which the extracellular domain at the site of the fusion has the amino acid sequence Gly-Pro-Gln-Asp-Pro-Glu, wherein the Fc fragment comprises a hinge, a CH2 and a CH3 region."

V. An opposition was filed against the patent requesting its revocation on the basis of Articles 100(a), 100(b) and 100(c) EPC on the grounds that the claimed subject-matter lacked novelty (Article 54 EPC) and an inventive step (Article 56 EPC), related to subject-matter excluded from patentability (Articles 52(4) EPC and 57 EPC), was insufficiently disclosed (Article 83 EPC) and contained subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

VI. The opposition division dealt with a main request relating to the claims as granted and two auxiliary requests. Claim 1 of the first auxiliary request differed from claim 1 as granted (see section IV above) in that the expression "for CD40CR" was present after the expression at the beginning of the claim "[a] soluble ligand". The claims of the second auxiliary

request were based on claims 5 (see section IV above) to 9 as granted.

VII. From among the various issues raised by the opponent against the subject-matter of the claims of the three requests, the opposition division decided three against the patent proprietors (hereinafter the "appellants"), i.e. the opposition division held (i) that claim 1 of the main request related to subject-matter extending beyond the application as filed, and (ii) that the subject-matter of claim 1 of the first auxiliary request lacked an inventive step in view of the disclosure in document D3, this document belonging to the state of the art in accordance with Article 54(2) EPC because (iii) claim 1 could not validly claim the priority from the US application No. 835,799.

VIII. With regard to the issue of added subject-matter the opposition division reasoned essentially that the skilled person would understand that claim 1 of the main request related to soluble ligands which could comprise as a binding portion either (a) the antigen-binding site of the immunoglobulin defined in claim 1 or (b) the Fc receptor binding portion of this immunoglobulin. Thus, claim 1 related to soluble ligands which bound to the CD40CR via the antigen-binding site but, in view of (b) above also to soluble ligands which bound to an Fc receptor via the Fc receptor binding portion. Those latter ligands - which did not bind to CD40CR - were however not disclosed in the application as filed.

IX. The opposition division held that claim 1 of the first auxiliary request was not entitled to priority from the

US application No. 835,799. The opposition division stated that *"[a] European patent application is only entitled to priority in respect of the "same invention" as disclosed in the earlier application"*. Furthermore, the subject-matter of the claim defining the invention had to be understood as *"the specific combination of features present in the claim". In order to give rise to priority, all the essential elements, ie the features of the invention in the priority document must be either expressly disclosed or directly and unambiguously implied in the text as filed."* The antibody MR1 and thus also the hybridoma cell line was an essential element of the invention. However, this hybridoma cell line had only been deposited after the filing date of the US application which therefore failed to disclose an essential element of the invention and consequently could not be considered as disclosing the *"same invention"* as that according to claim 1 of the European application. Hence, the European application could not enjoy priority from the US application No. 835,799 and therefore document **D3** (PNAS, vol. 89, no. 14, pages 6550-6554, Noelle, R. et al.) constituted prior art pursuant to Article 54(2) EPC.

X. Finally, the opposition division did not acknowledge an inventive step for the subject-matter of claim 1 of the first auxiliary request. The problem to be solved vis-à-vis the closest prior art document D3 was the provision of an alternative ligand which bound to a 39 kD protein (note added by the board: this protein is also termed "CD40CR") isolated from the plasma membranes of activated T-helper cells and which inhibited the activation of B-cells by T-helper cells.

Document D3 disclosed a method which resulted in such a ligand, i.e. the antibody MR1. The skilled person would follow this method and would thus generate alternative ligands without inventive effort.

XI. With the statement of the grounds of appeal the appellants submitted arguments as to why the decision under appeal was not correct. They requested as a main request the maintenance of the patent on the basis of the claims as granted. Furthermore, three auxiliary requests were submitted. These requests were later withdrawn, see the letter of 5 July 2012.

The appellants' arguments were as follows:

Amendments - Extension of subject-matter beyond the content of the application as filed

Granted claim 1 referred to "a soluble ligand [...] to CD40CR molecule" and thus unambiguously defined that the binding target of the soluble ligands was the CD40CR. This was corroborated by the application as filed which only disclosed such ligands.

Inventive step

Right to priority

In order to give rise to a patent and/or a valid priority application the application and/or the priority application had to meet the requirements of Article 83 EPC, i.e. in the case of a priority application it had to contain sufficient information

such as to enable the skilled person to carry the invention claimed in the later application. Rule 28(1) EPC made an exception to that rule and stipulated certain requirements that had to be fulfilled for an invention to comply with Article 83 EPC, even if the invention could not be sufficiently described in a patent or a priority application.

Thus, Rule 28 EPC implemented the general principle of Article 83 EPC, but was a legal framework which was in itself complete. It provided for a fiction of sufficiency of disclosure, if certain requirements were fulfilled and it was the wording of Rule 28 EPC that determined these requirements.

Rule 28(1)(a) EPC stipulated that a deposit had to be made "not later than the date of filing" of the European patent application, whereas Rule 28(2) EPC stipulated that the depositary institution and the file number could be submitted 16 months after the filing date or, if priority was claimed, after the priority date.

Thus, Rule 28 EPC clearly stated when time requirements had to be fulfilled, in particular when the deposit had to be made. In view of the distinction in Rule 28(1) and 28(2) EPC between the filing date and the filing or the priority date, respectively, it could be inferred that, had it been the intention of the legislator that a deposit be made not later than the priority date in case priority was claimed, this would have been certainly explicitly stated in Rule 28(1)(a) EPC.

If it were in fact the requirement that a deposit had to be made at the latest at the priority date, the applicant and depositor would have to consider the requirements of Rule 28 EPC already at the date of filing an earlier application, i.e. an applicant would have had to take into account all national and regional requirements for patent applications for which a deposit was necessary in those countries and regions that were potentially eligible for filing subsequent applications claiming the priority of the earlier application. Given the fact that these requirements differed substantially under national and regional patent law, taking all these requirements into account when filing the earlier application put an undue burden on an applicant and contravened the provisions governing the right of priority.

According to Article 87(2) EPC every filing that was equivalent to a regular national filing under the national law of the state where it was made shall be recognized as giving rise to a right of priority. The present patent claimed priority from a US application and according to US patent law a deposit was not needed at the filing date, see the decision "*In re* Lundak", 773F.2d 1216, Fed.Cir.1985). Thus, the US application 835,799 from which priority was claimed had to be considered as a "regular national filing" and therefore could give rise to a full right to priority.

Since the deposit of the hybridoma cell line producing the antibody MR1 had been made before the filing date of the European patent application, it could claim priority from the US application 835,799. Thus,

document D3 did not belong to the state of the art pursuant to Article 54(2) EPC.

Closest prior art/ Problem and solution/ Obviousness

If document D3 was a prior art document pursuant to Article 54(2) EPC, it could be considered as the closest prior art document. The problem arising in view of it was that, following its teaching, the antibody MR1 could not be produced without undue burden and without needing inventive skill. The present patent solved that problem and actually provided the antibody MR1. Making a non-enabling disclosure enabling involved an inventive step.

XII. The opponent (hereinafter "respondent") did not file a reply to the appellants' statement of grounds of appeal.

XIII. The board informed the parties in a communication of 3 April 2012 annexed to the summons to oral proceedings - to which the appellants, but not the respondent replied - *inter alia* about its preliminary view that the claims of the main request seemed to comply with the requirements of Article 100(c) EPC and that the opposition division had correctly assessed the issue of priority.

XIV. Both parties informed the board that they would not attend the oral proceedings.

XV. Oral proceedings were held on 12 July 2012. The parties did not appear and were not represented.

XVI. The appellants' final request in writing was that the decision under appeal be set aside and that the patent be maintained as granted.

The respondent did not submit any request.

Reasons for the decision

Amendments - Extension of subject-matter beyond the content of the application as filed

1. In the appellants' view claim 1 exclusively relates to soluble ligands that bind to the CD40 counter receptor (CD40CR) because the claim recites *"a soluble ligand [...] to CD40CR molecule"*. The board is not convinced by this view for the following reasons.

2. Claim 1 reads (emphasis added):

"A soluble ligand which comprises at least a **binding portion of an immunoglobulin molecule**, in which **the immunoglobulin molecule** is capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by a hybridoma cell line deposited with the ATCC and assigned accession number HB 11048, **to CD40CR molecule**, which molecule ....."

3. Thus, in fact, claim 1 recites the two terms mentioned by the appellants *"a soluble ligand"* and *"to CD40CR"*, however, not in such a close relationship as suggested by the appellants' submission, i.e. the term *"to CD40CR"* appears only after a definition of the binding

portion (*"binding portion of an immunoglobulin molecule"*) and a definition of a constituent of the soluble ligand (*"the immunoglobulin molecule"*). In the board's view, this has the effect that the skilled person would not consider that the feature in claim 1 *"to CD40CR"* defines a property of the *"soluble ligand"*. Consequently, the position of the words in the claim speaks against the appellants' interpretation.

4. According to claim 1 a mandatory property of the *"soluble ligand"* is that it comprises *"a binding portion of an immunoglobulin molecule"*.

4.1 The skilled person knows that immunoglobulin molecules, i.e. antibodies, have two different regions which mediate the binding to other molecules, i.e. one is the region mediating the binding to antigens and the other is the so-called Fc region by which an antibody attaches to Fc receptors. Hence, the expression *"a binding portion of an immunoglobulin molecule"* refers to two alternatives.

4.2 The board considers that the appellants' view that claim 1 exclusively relates to soluble ligands of which the binding target is the CD40CR could be accepted, if the definition of the binding portion in claim 1 was such that it clearly restricted the meaning of *"binding portion of an immunoglobulin molecule"* to the first alternative mentioned in point 4.1 above, i.e. the binding to the CD40CR.

4.3 The feature "binding portion of an immunoglobulin molecule" is defined in claim 1 as follows: *"in which the immunoglobulin molecule is capable of competitively*

inhibiting the binding of monoclonal antibody MR1 as produced by a hybridoma cell line deposited with the ATCC and assigned accession number HB 11048". The board notes that this definition refers back to the immunoglobulin molecule and not to its the binding portion. Moreover, although the definition *"is capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by a hybridoma cell line deposited with the ATCC and assigned accession number HB 11048"* refers to the antigen-binding capabilities of the antibody, it does not however have a limitative effect, i.e. it is not excluded that immunoglobulin molecules which are *"capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by a hybridoma cell line deposited with the ATCC and assigned accession number HB 11048"* also have the capability of binding to Fc receptors via their Fc binding portion.

Hence, in the context of claim 1 the skilled person would not interpret the definition of the expression *"binding portion of an immunoglobulin molecule"* to mean that the binding portion exclusively binds to the CD40CR. Therefore, the board considers - as did the opposition division (see section VIII above) - that the subject-matter of claim 1 also relates to soluble ligands which bind to Fc receptors.

It is undisputed that the application as filed does not disclose such ligands.

5. The board therefore comes to the conclusion that claim 1 relates to subject-matter which is not disclosed in the application as filed and consequently contravenes the requirements of Article 100(c) EPC.

Inventive step - Article 56 EPC

State of the art - Article 54(2) EPC/
Right to priority - Article 87 EPC

6. The assessment of inventive step hinges on the question whether or not document D3 constitutes prior art pursuant to Article 54(2) EPC. In the decision under appeal it was held that it does, because the subject-matter of claim 1 cannot claim priority from the US application No. 835,799 (see section IX above).

The board also comes to the conclusion that the subject-matter of claim 1 cannot claim priority from the US application No. 835,799, but by a line of reasoning which differs from that of the opposition division.

7. Article 87(1) EPC, inter alia, stipulates that the right to priority for the purpose of filing a European patent application can only be enjoyed insofar as the earlier application and the later European application disclose the *"same invention"*.

8. In its decision G 2/93 (OJ 1995, 275; see point 5 of the Reasons) and particularly in decision G 2/98 (OJ 2001, 413; see point 9 of the Reasons) the Enlarged Board of Appeal held that the expression the *"same invention"* means the *"same subject-matter"*. In point 9

of the Reasons of decision G 2/98 the Enlarged Board of Appeal established further that - in agreement with the standard applied for determining the disclosure content of documents in the context of novelty and amendments in a European patent application or patent - "subject-matter" is considered as "disclosed" in an earlier application if the skilled person can derive it directly and unambiguously, using common general knowledge, from the earlier application as a whole.

9. Furthermore, following the principle that a document must contain an "enabling" disclosure for it to be considered to be detrimental to the novelty of claimed subject-matter, it was also established by the case law that the requirement in Article 87(1) EPC that there be the *"same invention"* implies that the earlier application must disclose the invention claimed in the later European application in such a way that a skilled person can carry it out (see for example Case Law of the Boards of Appeal, 6th edition 2010, V.B.3).

10. It follows from the considerations in points 8 and 9 above that for the purposes of determining the right to priority from an earlier application for a later European application, the assessment of the disclosure content of the earlier application is made in accordance with the EPC and its interpretation by the case law (see for example also Europäisches Patentübereinkommen: Münchner Gemeinschaftskommentar, eds.: Beier, Haertel, Schricker; 15th edition, April 1991, Art. 53, Moufang, R., marginal note 151).

11. Present claim 1 relates to *"[a] soluble ligand which comprises at least a binding portion of an immunoglobulin molecule, in which the immunoglobulin molecule is capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by a hybridoma cell line deposited with the ATCC and assigned accession number HB 11048, to CD40CR molecule, [...]."*

12. The patent at issue discloses that for the generation of the immunoglobulin molecules, the binding portions of which are then to be used for generating the soluble ligands according to claim 1, the immunization is carried out with D1.6 cells, i.e. I-Ad-restricted, rabbit Ig-speific Th1 cells (paragraphs [0076] and [0087]). These cells have embedded in their membrane the CD40CR. Thus, the immunization results in immunoglobulins (antibodies) binding to membrane components of D1.6 cells including any immunoglobulins binding to the CD40CR, i.e. it results not in just those which are *"capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by hybridoma cell line deposited with the ATCC and assigned accession number HB 11048".*

13. Thus, in order to reproduce the invention characterized in claim 1, the antibody MR1 is indispensable for the skilled person to be able to select from all of the produced immunoglobulins those having the property of being *"capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by hybridoma cell line deposited with the ATCC and assigned accession number HB 11048."*

14. As to the question of whether or not the US application No. 835,799 provides an enabling disclosure for the subject-matter of claim 1, the appellants neither argue that this US application discloses itself a process by which a hybridoma cell line with the properties of the hybridoma cell line deposited with the ATCC and assigned accession number HB 11048 could be made, nor that such a process belonged to the common general knowledge, nor that the antibody MR1 or the hybridoma cell line "HB 11048" were publicly available at the date of filing the US application No. 835,799.

Thus, the "written" disclosure in the US application No. 835,799, even if supplemented by common general knowledge, would not enable the skilled person to carry out the invention characterized in claim 1.

15. For inventions which use biological material and where a mere written description is not sufficient to enable a person skilled in the art to carry out the invention, the EPC foresees in Rule 28 that this deficiency can be made good by a valid deposit of the biological material at a recognized depositary institution.

16. However, Rule 28 EPC is concerned with the requirement of sufficiency of disclosure in relation to a **European** patent application.

It is stipulated in Rule 28(1) EPC:

*"If an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in the **European***

patent application *in such a manner as to enable the invention [...]."* (emphasis added).

Thus - and this is also a view taken in the legal literature (see for example Europäisches Patentübereinkommen: Münchner Gemeinschaftskommentar, eds.: Beier, Haertel, Schricker; 15th edition, April 1991, Art. 53, Moufang, R., marginal note 151) - there are no explicit provisions in the EPC as to when a deposit of biological material has to be made in relation to an earlier application in order to ensure that a later European patent application can enjoy the right to priority from that earlier application.

17. However, the Enlarged Board of Appeal has held that the requirement of sufficiency of disclosure must be complied with at the date of filing of the European application or - in relation to an earlier application from which priority is claimed - at the date of filing of that earlier application (see decision G 2/93 point 10 of the reasons and decision G 1/03; OJ 2004, 413; point 2.5.3 of the reasons).

In its decision G 1/03 the Enlarged Board states in point 2.5.3:

"The same must apply if sufficiency of disclosure is at stake. When an application for a patent is filed, the process of making the invention has to be completed. The requirement of sufficiency of disclosure ensures that a patent is only granted if there is a corresponding contribution to the state of the art. Such a contribution is not present as long as the person skilled in the art is not able to carry out the

invention. ***Therefore, the decisive date for fulfilling the requirement has to be the date of filing or priority, as the case may be.*** *Deficiencies in this respect cannot be remedied during the proceedings before the EPO."* (emphasis added).

18. Thus, the board judges that if the deposit of biological material is necessary for the requirement of sufficiency of disclosure to be fulfilled for a "priority application", the deposit of this material must have been made no later than the date of filing of that earlier application.

19. The above cited case law is reflected in the "Notice of the European Patent Office dated 18 July 1986 concerning European patent applications and European patents in which reference is made to microorganisms" (OJ 1986, 269). It is stated in point 8:

"Where a European patent application claims the priority of a previous application in accordance with Articles 87 to 89 EPC, the general conditions covering disclosure of the invention in the previous application apply to the micro-organism. In particular, if an invention, in order to be sufficiently disclosed, requires the deposit of a micro-organism culture to supplement the written description, ***the culture must have been deposited not later than the date of filing of the previous application.*** *The depositary institution and the legal statute under which the micro-organism is deposited must comply with the requirements of the country in which the previous application has been filed. The previous application must also refer to this*

deposit in a manner enabling it to be identified." (emphasis added).

19.1 The position taken in this "Notice" from the year 1986 was later confirmed in relation to the EPC2000 by a "Notice" of 7 July 2010 concerning the same subject ("Notice from the European Patent Office dated 7 July 2010 concerning inventions which involve the use of or concern biological material", (OJ 2010, 498); see point 1.4).

20. The view that, if a later European application claims the right of priority from an earlier application, the deposit of biological material has to have been made not later than the filing date of the earlier application is also endorsed in the legal literature (see for example Europäisches Patentübereinkommen: Münchner Gemeinschaftskommentar, eds.: Beier, Haertel, Schricker; 15th edition, April 1991, Art. 53, Moufang, R., marginal note 150).

21. In the present case - and this is undisputed - the hybridoma cell line producing the antibody MR1 has been deposited with the ATCC on 22 May 1992, i.e. only after the filing date of the US application No. 835,799.

22. The appellants argue that it should be sufficient for ensuring a valid right to priority that the deposit of biological material is made at latest at the date of filing of the later European patent application in view of Rule 28(1) EPC which explicitly refers to the *"date of filing of the application"*.

22.1 However, the appellants' reference to Rule 28 EPC does not convince the board because this Rule lays down the requirements for a valid deposit in relation to **European** patent applications (see point 16 above).

23. In a further line of argument the appellants refer, on the one hand, to Article 87(2) EPC stating that *"every filing that is equivalent to a regular national filing [...] shall be recognized as giving rise to a right of priority"* and, on the other hand, to case law in relation to US patent applications - "*In re* Lundak", 773F.2d 1216 (Fed. Cir. 1985) - according to which *"[t]he enablement requirement of §112, first paragraph does not require such assured access to a microorganism deposit as of the filing date; what is required is assurance of the access (...) prior to or during pendency of the application, so that, upon issuance of a U.S. patent on the application, the public will, in fact, receive something in return for the patent grant"*.

The appellants therefore argue that, since a deposit in relation to a US application is not necessary at its date of filing, but must only be made at the latest before the grant of the corresponding patent, the US application No. 835,799 at issue here complies with the requirements of US patent law. It must therefore be considered as a regular national filing and thus, in accordance with Article 87(2) EPC, must give a right to priority.

23.1 However, what Article 87(2) EPC and the complementing Article 87(3) EPC - which reads *"[b]y a regular national filing is meant any filing that is sufficient to establish the date on which the application was*

filed, whatever may be the outcome of the application" - merely set out is that the date of filing of an application that may give rise to a right to priority under the EPC is accorded in accordance with national law for the purposes of Article 87(1) EPC. It cannot be inferred from these provisions that the standards of national law are applied in relation to other requirements of a potential priority application, for example, in relation to criteria for determining the disclosure content of such an application. As observed in point 10 above, whether an earlier application and a subsequent European application disclose the *"same invention"* is assessed in accordance with the EPC and not, in respect of the earlier application, in accordance with the law of the state in which this earlier application is filed.

Therefore, the reference to Article 87(2) EPC does not convince the board either.

23.2 In the light of the citation from the decision of the Federal Circuit "*In re* Lundak" (see point 22 above) the board accepts that, when it comes to the point in time when a deposit of biological material has to be made in order to fulfil the sufficiency-requirement according to the EPC and the enablement-requirement according to US patent law, the provisions according to the EPC were stricter than those of the US law.

24. It is thus undeniable that in a situation where a deposit of biological material was necessary for a disclosure in an earlier application to be accepted as being "sufficient", this had the consequence depicted by the appellants, namely that an applicant who filed

an application at the US patent office had, already when drafting the US application, to take account of the requirements to be complied with in countries or regions that were eligible for filing subsequent applications claiming the priority of the first application. That may be inconvenient for applicants for European patents claiming priority from US applications, but it is the consequence of the distinct provisions of the two legal regimes.

24.1 The board notes however that it was and is not uncommon when drafting potential priority applications that differences in the patent laws of different countries and/or their interpretation have to be taken into account. Another such example appears to be the different interpretation of the disclosure content of "closed ranges" of numerical parameters according to German and European patent law practice (although this may be harmonised if the principles developed by the German Federal Supreme Court in its decision "Olanzapin" (BGH X ZR 89/07) should be applied to "closed ranges"). While according to the present German jurisprudence the indication of a closed range by a start and an end point is considered as disclosing all intermediate points within this range (see Patentgesetz mit EPÜ, ed.: Schulte, R.; 8th edition, 2008; § 3, marginal note 104 and the decisions referred to therein by reference to foot note 232), this is not necessarily considered to be so according to the case law in relation to the EPC (see for example the decisions cited in the Case Law of the Boards of Appeal of the EPO, 6th edition 2010, I.C.4.2). If this difference is not taken into account when drafting and filing a German application, this may have the consequence that

a later European application claiming only an intermediate point or intermediate part of the complete range disclosed in the earlier German application may not be allowed to rely on that earlier application for claiming priority.

25. To sum up, the board comes to the conclusion that, due to the failure to deposit the hybridoma cell line producing the antibody MR1 no later than the filing date of the US application No. 835,799 (see point 21 above), this US application does not provide a disclosure which is sufficient for the skilled person to carry out the invention claimed in present claim 1. Therefore, the requirement of the "same invention" according to Article 87(1) EPC cannot be considered as being fulfilled (see point 9 above). Hence, claim 1 cannot enjoy the right of priority from the US application No. 835,799.

26. In decision T 542/95 of 2 March 1999 the opponent had objected to the right of priority based on the argument that a deposited hybridoma, that was referred to in the claims and that would be essential for carrying out the invention, had not been deposited at the priority date. The board dealing with that case acknowledged the claim to priority because the remaining features in the claim characterized the subject-matter in a unique manner such that feature relating to the hybridoma could "now be regarded as a mere surplus definition". Thus, the circumstances of that case are different from those in the present one insofar as in the present case the hybridoma is considered as essential for carrying out the invention (see points 11 to 13 above).

27. It follows from the foregoing observations that the relevant date for determining the state of the art pursuant to Article 54(2) EPC is the filing date of the European application. Hence, document D3 constitutes prior art in accordance with Article 54(2) EPC.

Closest prior art

28. Starting from document D3, which the board agrees represents the closest prior art document, the appellants' argumentation with regard to inventive step is in essence that *"while the problem with document D3 was that the monoclonal antibody MR1 could not be produced without undue burden and without needing inventive skill, the present patent solved said problem and provided said monoclonal antibody. [...] making a non-enabling disclosure enabling involves an inventive step"*. The board is not persuaded by this argumentation, essentially because it considers that it relies on an inappropriate application of the problem-and-solution approach in relation to the invention actually claimed in claim 1.

Problem and solution

29. It follows from the appellants' submission summarized above that they appear to formulate the problem to be solved as the actual provision of the monoclonal antibody MR1.

29.1 It has been established by the case law of the Boards of Appeal that, in the framework of the problem-solution-approach, the "objective technical problem" has to be determined by taking into account the

teaching in the closest prior art document, in particular the effects achieved by the subject-matter disclosed therein and the effects achieved by all embodiments of the claimed subject-matter. Hence, the objective technical problem is the problem which can be considered as having actually been solved by all embodiments of a claim (see for example Case Law of the Boards of Appeal, 6th edition 2010, I.D.4.4, 7th paragraph).

29.2 The subject-matter of claim 1 is *"[a] soluble ligand"* and not, as the subject-matter of claim 4, a "[m]onoclonal antibody MR1 produced by a hybridoma cell line as deposited with the ATCC and assigned accession number HB 11048". Therefore, the problem implied by the appellants' argumentation cannot be regarded as the objective technical problem in relation to claim 1.

29.3 Document D3 discloses that a soluble fusion protein comprising the extracellular domains of human CD40 and the Fc domain of human IgG1 inhibit the activation of B-cells by T-helper cells by binding to a 39kDa protein on activated T helper cells (see page 6551, second column, first full paragraph, continued on page 6552). It is common ground that the protein and the "CD40CR" are identical.

The soluble ligands of claim 1 have the same effect.

Thus, the objective technical problem arising in view of the disclosure in document D3 and the effects achieved by the claimed invention is the provision of alternative ligands for inhibiting B-cell activation by virtue of their binding to the CD40CR.

Obviousness

30. Document D3 mentions that the antibody MR1 and the CD40-fusion protein (see 29.3 above) recognize overlapping or identical epitopes on the CD40CR and that they both inhibit B-cell activation (page 6553, second column). It is not derivable from the document whether or not the antibody MR1 was publicly available at the publication date of the document. Yet, it is not unusual that scientific publications disclose experiments with antibodies that are not publicly available. The board has no reason to doubt that the antibody MR1 mentioned in document D3 existed or any reason to assume that the results achieved with the antibody MR1 are erroneous, confidential or hypothetical. Thus, while the document may be considered as failing to provide an enabling disclosure for anything related to the antibody MR1 (see appellants' argument in point 28 above), the document nevertheless teaches that B-cell activation can be inhibited by the binding to the CD40CR receptor of a compound which has the structure of an antibody.

31. In view of this teaching the skilled person would therefore be motivated to provide - as a solution to the problem formulated in point 29.3 above - further antibodies which have this effect and this the more so, since document D3 describes a method to generate such antibodies (see page 6551, first column, third full paragraph).

32. Yet, claim 1 is directed to a subgroup of all the B-cell activity-inhibiting antibodies that the skilled

person would be motivated to provide in view of the disclosure in document D3, namely those which at the same time are *"capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by a hybridoma cell line deposited with the ATCC and assigned accession number HB 11048, to CD40CR molecule"* (see also points 11 to 13 above). However, any technical effect in addition to B-cell-activity-inhibition is not derivable from the patent for the members of this subgroup. Without such an effect, the subgroup, i.e. the subject-matter of claim 1, has to be considered as an arbitrary selection from a larger group which the skilled person would have provided in an obvious way (see point 31 above). Subject-matter which is the result of an arbitrary selection is not considered to involve an inventive step (see for example decisions T 939/92, OJ 1996, 309, point 2.5.3; T 133/01 of 30 September 2003, point 4.6; T 512/02 of 26 October 2006, point 2.5; T 931/04 of 7 September 2007, point 4.11.1; T 1589/05 0f 28 March 2008, point 1.8).

33. Hence, the subject-matter of claim 1 does not fulfil the requirements of Article 56 EPC.

34. It follows from points 5 and 33 above that the only claim request before the board is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Cremona C. Rennie-Smith