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Datasheet for the decision of 12 July 2017

Case Number: T 1681/11 - 3.3.08

Application Number: 96906504.4

Publication Number: 0808367

IPC: C12N15/12, C07K14/705, C12N15/62, C07K19/00, C07K16/28, G01N33/566

Language of the proceedings: EN

Title of invention:
MUCOSAL VASCULAR ADDRESSINS AND USES THEREOF

Patent Proprietor:
MILLENNIUM PHARMACEUTICALS, INC.

Opponents:
Amgen Inc.
PFIZER LIMTED

Headword:
Mucosal endothelial receptor MAdCAM-1/MILLENIUM

Relevant legal provisions:
EPC Art. 83, 113(1), 114(2)
RPBA Art. 12(4), 13(1)

Keyword:
Main request and auxiliary requests 1 to 6 - sufficiency of disclosure (no)
Auxiliary requests 7 to 13 - Admission into the appeal proceedings (no)

Decisions cited:
T 0609/02

Catchword:

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Case Number: T 1681/11 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 12 July 2017

Appellant: (Patent Proprietor)	MILLENNIUM PHARMACEUTICALS, INC. 75 Sidney Street Cambridge, Massachusetts 02139 (US)
Representative:	Dossmann, Gérard Casalonga & Partners Bayerstrasse 71-73 80335 München (DE)
Appellant: (Opponent 2)	PFIZER LIMTED Ramsgate Road Sandwich Kent CT13 9NJ (GB)
Representative:	Ricol, David Pfizer European Patent Department 23-25 avenue du Docteur Lannelongue 75668 Paris Cedex 14 (FR)
Party as of right: (Opponent 1)	Amgen Inc. One Amgen Center Drive Thousand Oaks, CA 91320-1799 (US)
Representative:	Zeman, Steven M. Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on**

27 May 2011 concerning maintenance of the European Patent No. 0808367 in amended form.

Composition of the Board:

Chairman	B. Stolz
Members:	P. Julià
	J. Geschwind

Summary of Facts and Submissions

I. European patent No. 0 808 367 with the title "Mucosal vascular addressins and uses thereof" was granted on European patent application No. 96 906 504.4, filed as international application under the PCT and published as WO 96/24673. The patent was granted with 59 claims.

II. Two oppositions to the grant of the patent were filed relying on the grounds for opposition under Article 100(a) EPC in conjunction with Articles 54 and 56 EPC, and Articles 100(b) and 100(c) EPC.

III. In a decision under Article 101(3)(a) EPC posted on 27 May 2011, an opposition division of the European Patent Office found that the main request (claims as granted) contravened Article 123(2) EPC, and that auxiliary requests 1a and 1b did not fulfil the requirements of Articles 54 and 56 EPC, respectively. Auxiliary request 2 was not admitted into the procedure. The patent was maintained on the basis of an auxiliary request 3 filed on 18 January 2011 at the oral proceedings before the opposition division.

IV. Appeals were lodged by the patent proprietor and opponent 02 (appellants I and II, respectively). With the statement setting out its grounds of appeal, appellant I filed a main request (identical to auxiliary request 1b underlying the decision under appeal), auxiliary requests 1 to 6, and new evidence.

V. Opponent 01 (party as of right) replied to appellant I's grounds of appeal, and appellant I replied to the submissions of the party as of right and to the statement of grounds of appeal of appellant II. With

its reply to appellant II's grounds of appeal, appellant I filed new auxiliary requests 7-13 and new evidence.

VI. As a subsidiary measure, oral proceedings were requested by all parties.

VII. The board summoned the parties to oral proceedings. In a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) attached to the summons, the board expressed a provisional, non-binding opinion on some of the issues of the case.

VIII. In reply thereto, all parties, without making substantive submissions, withdrew their request for oral proceedings and informed the board that they would not attend them if maintained.

IX. Oral proceedings were held on 12 July 2017 in the absence of all parties.

X. Claims 34, 41 and 43 of the main request read as follows:

"34. Use of an antibody or antigen-binding fragment thereof which binds the ß7 chain of α4ß7 integrin and inhibits binding of primate MAdCAM to α4ß7 integrin for the manufacture of a medicament for treating a disease selected from the group consisting of pancreatitis, insulin-dependent diabetes mellitus, mastitis, cholecystitis, cholangitis, pericholangitis, chronic bronchitis, chronic sinusitis, asthma and graft versus host disease, wherein said primate MAdCAM is (a) a naturally occurring primate MAdCAM selected from the group consisting of the protein shown in Figure 1 (SEQ ID NO: 2), the protein shown in Figure 2 (SEQ ID

NO: 4), the protein shown in Figure 3 (SEQ ID NO: 6), and the mature form of any of the foregoing, or (b) a functional variant thereof which binds α4ß7 integrin, and wherein the amino acid sequence of said functional variant is at least 75% similar to the sequence of a protein shown in Figure 1 (SEQ ID NO: 2), Figure 2 (SEQ ID NO: 4) or Figure 3 (SEQ ID NO: 6), and amino acid sequence similarity is determined by the Clustal method with the PAM250 residue weight table, using a gap penalty of 10, a gap length penalty of 10 and pairwise alignment parameters of ktuple = 1, gap penalty = 3, window = 4, and diagonals saved = 5.

41. Use of an antibody or antigen-binding fragment thereof which binds α4ß7 integrin for the manufacture of a medicament for treating a disease selected from the group consisting of pancreatitis, insulin-dependent diabetes mellitus, mastitis, cholecystitis, cholangitis, pericholangitis, chronic bronchitis, chronic sinusitis, asthma and graft versus host disease, wherein said antibody or antigen-binding fragment has the epitopic specificity of the ACT-1 monoclonal antibody.

43. Use of an antibody or antigen-binding fragment thereof which binds α4ß7 integrin for the manufacture of a medicament for treating inflammatory bowel disease in a human, wherein said antibody or antigen-binding fragment has the epitopic specificity of the ACT-1 monoclonal antibody."

XI. Claim 34 of auxiliary request 1 is identical to claim 34 of the main request except for the deletion of the diseases: mastitis, chronic bronchitis, chronic sinusitis and asthma. Claims 41 and 43 are identical to claims 41 and 43 of the main request, respectively,

except for the characterization of the α4ß7 integrin as a primate α4ß7 integrin in both, claims 41 and 43, and the deletion of the diseases mastitis, chronic bronchitis, chronic sinusitis and asthma, in claim 41.

XII. Claims 34, 40 and 42 of auxiliary request 2 are identical to claims 34, 41 and 43 of auxiliary request 1, respectively.

XIII. Claims 34, 40 and 41 of auxiliary request 3 are identical to claims 34, 40 and 42 of auxiliary request 2, respectively, except for the deletion of the diseases pancreatitis and insulin-dependent diabetes mellitus in claims 34 and 40.

XIV. Claim 39 of auxiliary request 4 reads as follows:

"39. Use of an antibody or antigen-binding fragment thereof which binds primate α4ß7 integrin for the manufacture of a medicament for treating inflammatory bowel disease in a human, wherein said antibody binds the same epitope as ACT-1 monoclonal antibody."

XV. Claim 37 of auxiliary request 5 is identical to claim 43 of the main request. Claims 36 and 38 of auxiliary request 6 are identical to claims 41 and 43 of the main request, respectively.

XVI. The following documents are cited in this decision:

D11: D.P. Andrew *et al.*, J. Immunol., 1994, Vol. 153, No. 9, pages 3847 to 3861;

D32: A.I. Lazarovits *et al.*, J. Immunol., 1984, Vol. 133, No. 4, pages 1857 to 1862;

D33: T. Schweighoffer *et al.*, J. Immunol., 1993, Vol. 151, No. 2, pages 717 to 729;

D63: X-d. Yang *et al.*, Diabetes, 1997, Vol. 46, pages 1542 to 1547;

D64: A.J. Grant *et al.*, Hepatology, 2001, Vol. 33, No. 5, pages 1065 to 1072;

D65: A. Petrovic *et al.*, Blood, 2004, Vol. 103, No. 4, pages 1542 to 1547;

D66: D.H. Adams and B. Eksteen, Nature Reviews/ Immunology, 2006, Vol. 6, pages 244 to 251;

D67: US 4,699,880 (publication date: 13 October 1987);

D68: D. Herlyn *et al.*, Science, 1986, Vol. 232, pages 100 to 102;

D69: US 5,223,392 (publication date: 29 June 1993);

D71: B.G. Feagan *et al.*, New England J. Med., 2005, Vol. 352, pages 2499 to 2507;

D72: L. Prasad *et al.*, J. Biol. Chem., 1993, Vol. 268, No. 15, pages 10705 to 10708;

D73: USPTO Office Action in parallel US application 08/386,857, dated 13 June 2001;

D74: ATCC deposit form for ACT-1 monoclonal antibody designation PTA-3663, dated 7 September 2001;

D87: L. Brossay *et al.*, Infection and Immunity, 1994, Vol. 62, No. 2, pages 341 to 347;

D89: J.J. Calvete *et al.*, Biochem. J., 1991, Vol. 273, pages 767 to 775;

D90: J.J. Calvete *et al.*, Biochem. J., 1991, Vol. 274, pages 457 to 463;

D91: J.L. Bednarczyk *et al.*, J. Biol. Chem., 1994, Vol. 269, No. 11, pages 8348 to 8354;

D93: Declaration of Eric Fedyk, signed on 3 October 2011.

XVII. The submissions of appellant I under Article 83 EPC, insofar as they are relevant to the present decision, may be summarised as follows:

Manufacture of a medicament for treating a disease selected from "pancreatitis, insulin-dependent diabetes mellitus, mastitis, cholecystitis, cholangitis, pericholangitis, chronic bronchitis, chronic sinusitis, asthma and graft versus host disease" (claim 34)

All the diseases cited in claim 34 were associated with leukocyte infiltration and inflammation of the organs/ tissues of the gastrointestinal tract (including lung and liver), involving immune cells circulating in all these organs. The patent showed that the claimed antibodies reduced the concentration of these cells in inflamed tissue by blocking their migration, thereby reducing tissue inflammation. The *in vivo* and *in vitro* experiments in the patent demonstrated the therapeutic properties of the claimed antibodies (Figures 7-8, 11-12, 17-21 of the patent). Therefore, the requirements for a second medical use claim as set out in the decision T 609/02 of 27 October 2004 (cf. points

8 and 9 of the Reasons for the decision) were fulfilled. Post-published documents D63 to D66, D71 and D93 confirmed that the diseases mentioned in the claims could be treated by the claimed antibodies.

An antibody having "the epitopic specificity of the ACT-1 monoclonal antibody" (claims 41 and 43)

The ACT-1 monoclonal antibody was first described in 1984 (document D32) and methods for producing, identifying and characterizing this antibody and antibodies having the same epitopic specificity were available to the skilled person (cf. page 14, lines 23 to 26 of the patent citing documents D32 and D33). Methods for identifying epitopes on the α4ß7 heterodimer as well as methods for determining whether an antibody had the epitopic specificity of the ACT-1 monoclonal antibody were common general knowledge (documents D11, D91) (cf. also page 13, lines 42 to 44, and page 14, paragraph [0088] of the patent). Epitopic specificity (documents D33, D91) and methods in general for preparing (monoclonal) antibodies and analyzing their specificity were also known in the prior art (cf. documents D67 to D69, D87, D89 and D90; also page 14, paragraphs [0088] to [0092] of the patent).

XVIII. Appellant II's submissions under Article 83 EPC concerned only a feature in the claims related to sequence similarity comparison ("*the Clustal method*").

XIX. The submissions of the party as of right concerning issues under Article 83 EPC, insofar as they are relevant to the present decision, may be summarized as follows:

Manufacture of a medicament for treating a disease selected from "pancreatitis, insulin-dependent diabetes mellitus, mastitis, cholecystitis, cholangitis, pericholangitis, chronic bronchitis, chronic sinusitis, asthma and graft versus host disease" (claim 34)

The disclosure of the patent was not sufficient for using an anti-ß7 antibody in the treatment of all the diseases mentioned in claim 34. Examples 4 to 6 of the patent provided a basis for the treatment of colitis/ ulcerative colitis in mice/non-human primates and of celiac diseases in non-human primates. There was however no experimental evidence that any of the other diseases cited in claim 34 could be successfully treated. In this context, reference was made to the decision T 609/02 (*supra*).

An antibody having "the epitopic specificity of the ACT-1 monoclonal antibody" (claims 41 and 43)

Although there was prior art referring to the ACT-1 monoclonal antibody (page 31, paragraph [0200], Example 6 of the patent), the ACT-1 monoclonal antibody was deposited only seven years after the relevant date of the patent (documents D73 and D74). Moreover, although a variety of methods were available to the skilled person for measuring the specificity of the ACT-1 monoclonal antibody, the results obtained by these methods could be different (document D72), particularly in view of the complex nature of the α4ß7 heterodimer.

XX. The appellant I (patent proprietor) requested in writing that the decision under appeal be set aside and the patent be maintained on the basis of the main request or, alternatively, auxiliary requests 1 to 6, all filed with its statement of grounds of appeal, or

auxiliary requests 7 to 13 filed with its reply to appellant II's statement of grounds of appeal.

XXI. The appellant II (opponent 02) requested in writing that the decision under appeal be set aside and the patent be revoked in its entirety.

XXII. The party as of right (opponent 01) requested in writing that the appeal be dismissed.

Reasons for the Decision

Main request

1. The subject-matter of the main request relates to the mucosal vascular addressin MAdCAM-1 (Mucosal Addressin Cell Adhesion Molecule-1). According to the patent, MAdCAM-1 is an immunoglobulin superfamily adhesion receptor for lymphocytes (lymphocyte homing endothelial cell receptor) distinct from the vascular cell adhesion molecule-1 (VCAM-1) and the intercellular adhesion molecule-1(ICAM-1). MAdCAM-1 is a selective receptor for the lymphocyte α4ß7 integrin, i.e. it specifically binds the integrin α4ß7 heterodimer (cf. paragraphs [0001] to [0009] of the patent).

2. The claims of the main request are directed to the following subject-matter:

i) Claims 1 to 23, claims 31 to 33 and claims 48 to 57 directed to primate MAdCAM-1 and related subject-matter. In particular, these claims relate to the two forms of human MAdCAM-1 (nucleic acid sequences SEQ ID NO: 1 and 3, and predicted encoded amino acid sequences SEQ ID NO: 2 and 4, respectively; Figures 1 and 2) and

the macaque MAdCAM-1 (nucleic acid sequence SEQ ID NO: 5 and predicted amino acid SEQ ID NO: 6; Figure 3) disclosed in the patent.

ii) Claims 24 to 30, claims 39 and 40, claim 47 and claims 54 to 58 directed to antibodies binding primate MAdCAM-1 (and functional variants/fragments of said MAdCAM-1) and uses thereof.

iii) Claims 34 to 38 and claims 54 to 58 directed to the use of an antibody that binds the ß7 chain of the α4ß7 integrin and inhibits the binding of (primate) MAdCAM-1 to said α4ß7 integrin for the manufacture of a medicament for treating several diseases.

iv) Claims 41 to 46 and claims 54 to 58 directed to the use of an antibody that binds the α4ß7 integrin and has the epitopic specificity of the ACT-1 monoclonal antibody for the manufacture of a medicament for treating several diseases.

3. The main request is identical to auxiliary request 1b underlying the decision under appeal. The opposition division considered this request to fulfil the requirements of Article 54 EPC but claims 34 to 38 and claims 41 to 46, i.e. the subject-matter of the third and fourth groups cited in point 2 above, not to involve an inventive step (Article 56 EPC). The opposition division did however not examine auxiliary request 1b for compliance with the requirements of Article 83 EPC (cf. pages 7 to 11 of the decision under appeal).

4. In the communication pursuant to Article 15(1) RPBA, the board informed the parties of its provisional, non-binding opinion on some of the issues raised by the

parties in the appeal proceedings. These issues were related to Articles 123(2), 83, 54 and 56 EPC and were expected to be discussed at the scheduled oral proceedings. As regards Article 83 EPC, the board referred to four objections raised by appellant II and by the party as of right, in particular to a first objection concerning the treatment of all the diseases mentioned in claim 34, and to a second objection concerning the "*epitopic specificity of the ACT-1 monoclonal antibody*" in claims 41 and 43. These two objections were considered by the board to be highly relevant and, in this context, the question was raised whether the disclosure of the patent was sufficient for a skilled person to carry out the invention without undue burden and/or inventive skills (cf. points 15 to 18 of the board's communication pursuant to Article 15(1) RPBA).

5. None of the parties replied in substance to the board's communication (cf. point VIII *supra*). By neither replying to the board's communication in substance nor attending the oral proceedings, the parties effectively chose not to avail themselves of the opportunity to comment or present their observations on the board's provisional, non-binding opinion (Article 113(1) EPC). In view of this course of action, the board has no reason to change its provisional, non-binding opinion and the present decision is thus based thereupon.

Article 83 EPC

Manufacture of a medicament for treating a disease selected from "pancreatitis, insulin-dependent diabetes mellitus, mastitis, cholecystitis, cholangitis, pericholangitis, chronic bronchitis, chronic sinusitis, asthma and graft versus host disease" (claim 34)

6. According to experimental evidence provided by the patent, human MAdCAM-1 has a restricted tissue expression which is consistent with that known in the art for mouse MAdCAM. MAdCAM-1 is "*highly expressed in the small intestine and ... to a lesser extent in the colon and spleen ... No significant expression was observed in other tissues examined, including heart, brain, placenta,* ***lung****, liver, skeletal muscle, or kidney; however, low levels of expression were detected in pancreas*" (emphasis by the board) (cf. page 21, paragraph [0144] of the patent). In line therewith, Examples 4 to 6 of the patent provide information on the treatment of gut/intestine/colon conditions only.

7. The post-published documents cited by appellant I do not support appellant I's argument that post-published documents confirm that the diseases mentioned in the claims can be treated by the claimed antibodies (cf. point XVII *supra*). Document D63 refers to the treatment of autoimmune-mediated lymphocytic inflammation of pancreatic islets (IDDM, Insulin-Dependent Diabetes Mellitus) emphasizing the tissue specificity of lymphocyte homing, in particular, of the lymphocyte α4ß7 integrin binding to MAdCAM-1 (cf. *inter alia*, page 1542, right-hand column, first and second paragraphs). Document D64 refers to tissue tropism and states that the endothelial ligand MAdCAM-1 of the gut-circulating memory T-cells expressing α4ß7 integrin was "*previously thought to be found almost exclusively in the gut*" (page 1065, right-hand column, second paragraph), and it is only after suggesting "*an enterohepatic T-cell recirculation ... between the liver and gut*" (paragraph bridging pages 1065 and 1066) that the authors are led to the treatment of autoimmune (chronic inflammation) liver disease. Likewise, documents D65,

D66 and D71 refer to tissue-specific distribution of lymphocyte homing with the treatment of inflammatory bowel disease (IBD) and gut-associated lymphoid tissues. Document D65 (published in 2004) does not support the use of the claimed antibodies for the treatment of graft-versus-host disease in general, since it describes only intestinal graft-versus-host disease. Expert declaration D93 describes studies using vedolizumab, an antibody that "*binds to α4ß7 integrin and has the epitopic specificity of the Act-1 monoclonal antibody*" (cf. page 1, point 3). These studies conclude that this antibody "*did not affect organs and tissues outside of the GI* [gastrointestinal] *tract*" (cf. page 9, point 34).

8. In view thereof and in the absence of any further argument or evidence on file, the board concludes that the patent does not disclose the use of an antibody in the manufacture of a medicament for the treatment of several of the diseases cited in claims 34 and 41, such as mastitis, chronic bronchitis, chronic sinusitis, asthma and graft-versus-host disease in general, in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

An antibody having "the epitopic specificity of the ACT-1 monoclonal antibody" (claims 41 and 43)

9. The reference to "*epitopic specificity*" is understood by the board to require that the claimed antibodies bind the same epitopes of the α4ß7 integrin as the ACT-1 monoclonal antibody. It is well-known in the art that different epitopes on an integrin can be involved in distinct functions (cf. *inter alia*, page 3848, left-hand column, last two sentences of first paragraph in document D11). However, none of the epitopes bound by

the ACT-1 monoclonal antibody has been described in the prior art (documents D32, D33 and D91).

10. At the date of filing, the skilled person trying to raise an antibody with the epitopic specificity of the ACT-1 monoclonal antibody was therefore confronted with the problem of first having to identify those epitopes.

11. This situation was further complicated by the fact that the monoclonal antibody ACT-1 was deposited only on 22 August 2001 (document D74), whereas the filing date of the patent is 12 February 1996 (the first and second priority dates of the patent are 10 February 1995 and 1 September 1995, respectively). At the time of filing, it was thus not available to the skilled person for comparative experiments.

12. According to document D33, the ACT-1 monoclonal antibody binds ß7-containing integrins, such as α4ß7, but does not recognize all ß7-containing integrins, i.e. it is not specific for the ß7 chain *per se*. There is however no information on whether the α4ß7 epitopes to which ACT-1 monoclonal antibody binds are conformational epitopes of the α4ß7 integrin or linear epitopes of the ß7 subunit but not accessible in other ß7-containing integrins. Protein based epitope mapping methods used for characterization of conformational epitopes are not as straightforward as the standard peptide-based epitope methods (enzymatic/chemical cleavage of the antigen, peptide (library) synthesis and immunoassay as described in documents D87, D89 and D90), and they depend on the particular conditions used.

The development of anti-idiotypic antibodies specifically binding to an epitope of the hypervariable

region of the ACT-1 monoclonal antibody was also not straightforward in the absence of a deposited ACT-1 monoclonal antibody (documents D67 and D68).

13. Document D33 states that, whilst the interaction of α4ß7 with fibronectin (FN) is inhibited with ACT-1 monoclonal antibody, this antibody augments the cell binding to vascular cell adhesion molecule-1 (VCAM-1). Based on these results, document D33 suggests that the binding of the ACT-1 monoclonal antibody induces a conformational change in the α4ß7 integrin (cf. page 723, left-hand column, second paragraph). In the board's view, the claimed antibodies (required to bind to the same epitopes as the ACT-1 monoclonal antibody, *supra*) must necessarily also have these functional properties. In the absence of a deposited ACT-1 monoclonal antibody, the determination of the functional properties of an antibody and their comparison to those of the ACT-1 monoclonal antibody (same experimental conditions, etc.) amounted however to an undue burden.

14. Document D32 discloses the production of the ACT-1 monoclonal antibody (cf. pages 1857, right-hand column, last paragraph to page 1858, left-hand column third paragraph of document D32). However, it is questionable whether a skilled person would be in a position to achieve a monoclonal antibody with the same epitopic specificity as that of the ACT-1 monoclonal antibody with the information provided by this document. In the light of the starting material used (a human tetanus toxoid-specific T lymphocyte line), the method performed (activation and propagation of antigen-specific T lymphoblasts, immunization of BALB/c mouse, fusion with myeloma line NS-1, etc.), and of the experimental details provided by this document, the

board considers that an undue amount of work would be required.

15. The board concludes that, at the date of filing, the skilled person was not in a position to obtain an antibody with the epitope specificity of the monoclonal ACT-1 antibody readily and without undue burden.

16. It follows from all the above that the subject-matter of claims 34, 41 and 43 of the main request is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC). Therefore, the main request does not fulfil the requirements of the EPC.

Auxiliary requests 1 to 6

17. These auxiliary requests were filed by appellant I at the earliest stage of the appeal proceedings, namely with the statement setting out its grounds of appeal (cf. point IV *supra*), and they intended to address the objections raised by the opposition division in the decision under appeal. None of the parties has challenged their admission into the appeal proceedings. The board, in the exercise of its discretion, decides to admit them into the appeal proceedings (Article 114(2) EPC, Article 12(4) RPBA).

18. Auxiliary requests 1 to 3 and 6 contain claims that refer to some of the diseases mentioned in claims 34 and 41 of the main request. Auxiliary requests 1 to 6 contain claims that refer to a feature concerning "*the epitopic specificity of the ACT-1 monoclonal antibody*" or "*the same epitope as ACT-1 monoclonal antibody*" (cf. points XI to XV supra). Therefore, for the same reasons as those given in points 6 to 8 and points 9 to 16 for

the main request, none of these auxiliary requests fulfils the requirements of Article 83 EPC.

Admission of auxiliary requests 7 to 13

19. Auxiliary requests 7 to 13 are identical to the main request and auxiliary requests 1 to 6, respectively, except for the replacement of the feature concerned with the sequence similarity comparison ("*the Clustal method*") by a feature concerned with hybridization ("*hybridization under high stringency conditions*").

20. Since all these auxiliary requests contain claims with subject-matter identical to that of the main request and auxiliary requests 1 to 6 which the board does not consider to fulfil the requirements of Article 83 EPC (cf. points 6 to 16 *supra*), the board, in the exercise of its discretion, decides not to admit them into the appeal proceedings (Article 114(2) EPC, Articles 12(4) and 13(1) RPBA).

Conclusion

21. In the absence of an allowable request, the patent must be revoked.

Order

For these reasons it is decided that:

The patent is revoked.

The Registrar: The Chairman:

A. Wolinski B. Stolz

Decision electronically authenticated