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Datasheet for the decision of 02 April 2009

Case Number: T 1651/07 - 3.3.08

Application Number: 98903272.7

Publication Number: 0909388

IPC: G01N 33/68

Language of the proceedings: EN

Title of invention:
Immunological assay for spongiform encephalopathies

Patentee:
ENFER TECHNOLOGY LIMITED

Opponents:
PRIONICS AG
IDEXX Laboratories, Inc.

Headword:
Prion immunoassay/ENFER

Relevant legal provisions:
EPC Art. 54, 113(2)

Relevant legal provisions (EPC 1973):
EPC R. 64(b)

Keyword:
"Admissibility of appeal (yes)"
"Main and sole request - novelty (no)"

Decisions cited:
T 0198/84, T 0382/96, T 0446/00

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1651/07 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 02 April 2009

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 23 July 2007 revoking European patent No. 0909388 pursuant to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
B. Günzel

Summary of Facts and Submissions

I. European patent no. 0 909 388, based on European patent application no. 98 903 272 (published as International patent application WO 98/35236), was opposed by two opponents on the grounds as set forth in Articles 100(a),(b) and (c) EPC. The opposition division considered that the main request (claims as granted) and the auxiliary request 1 (filed on 22 June 2007 at the oral proceedings before the opposition division) did not comply with the requirements of Article 56 EPC and revoked the patent.

II. The patentee (appellant) filed a notice of appeal on 24 September 2007 and, in a letter dated 22 November 2007, filed the statement setting out its grounds of appeal.

III. In a letter dated 11 February 2008, the opponent 02 (respondent II) replied to the appellant's grounds of appeal. The respondent considered *inter alia* that the appeal was neither admissible nor substantiated and that the appellant's claim requests were not novel over the disclosure of document D1 (WO 93/11155 with publication date 10 June 1993) and did not fulfil the requirements of Articles 56 and 83 EPC. No submissions were received from the opponent 01 (respondent I).

IV. On 28 October 2008 and, as an annex to the summons to attend oral proceedings, the board sent a communication to the parties pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA). In this communication the board informed the parties of its preliminary, non-binding opinion on both procedural and

substantive issues of the appeal proceedings. In particular, the attention of the parties was drawn *inter alia* to the substantiation and admissibility of the appeal, the novelty of the claim requests in the light of document D1 and of the scope of the claims, and the question as to whether or not the auxiliary request formed part of the appeal proceedings.

V. None of the parties filed any substantive submission in reply to the board's communication. In letters dated 1 December 2008 and 24 March 2009, the appellant and the respondent I, respectively, announced their intention not to attend the oral proceedings.

VI. Oral proceedings took place on 2 April 2009 in the sole presence of respondent II, which withdrew its request made in writing that the appeal be dismissed as being inadmissible. The other grounds submitted in writing for dismissing the appeal were maintained.

VII. The **main request** (granted claims) contained six claims. Independent claims 1 and 6 read as follows:

"1. A method "in vitro" for detecting the putative agent for TSE in animals comprising reacting a body tissue sample taken from an animal in a immunological assay with a labelled antibody which is capable of reacting with PrP^{SC} and determining the amount of labelled antibody bound to the sample, **characterized in that** the antibody is a prion specific antibody raised against one or more of the following sequences:

MVKSHIGSWILVLFVVAMWSDVGLCKKRPKPGGGWNTGGSRYPGQ-44
GSPGGNRYPPQGGGGWGQPHGGGWGQPHGGGWGQPHGGGQGQP-87

GGGGWGQGGSHSQWNKPSKPPKTNMKHVAGAAAGAVVGGLGGY-131
MLGSAMSSPLIHFGNDYEDRYTRENMYRYPNQVYYRPVDRYSNQNN-177 ".

"6. A test kit for the detection of TSE in animals comprising an anti-peptide antibody, wherein the antibody is a prion specific antibody raised against one or more of the following sequences:

MVKSHIGSWILVLFVVAMWSDVGLCKKRPKPGGGWNTGGSRYPGQ-44
GSPGGNRYPPQGGGGWGQPHGGGWGQPHGGGWGQPHGGGQGQP-87
GGGGWGQGGSHSQWNKPSKPPKTNMKHVAGAAAGAVVGGLGGY-131
MLGSAMSSPLIHFGNDYEDRYTRENMYRYPNQVYYRPVDRYSNQNN-177 ".

Claims 2 to 5 were directed to preferred embodiments of claim 1.

VIII. In the decision under appeal (cf. pages 10 to 12, point V.3), the opposition division acknowledged the novelty of the appellant's main request. The procedural issues raised in the appeal proceedings by the board in its communication pursuant to Article 15(1) of the RPBA as regards the appellant's requests (main and auxiliary request, cf. points 7 to 10 and 32 of the board's communication dated 28 October 2008) were not part of the opposition proceedings. Since the appellant did not reply to the submissions made by the respondent II in reply to the statement of grounds of appeal nor to the board's communication pursuant to Article 15(1) of the RPBA, there are no arguments on file from the appellant concerning any of these procedural issues or the novelty objection raised by the respondent II (cf. point IX *infra*). The appellant's statement of grounds of appeal was only concerned with experimental evidence submitted in support of the inventive step.

IX. The arguments put forward by the respondent II in its reply to the appellant's grounds of appeal, as far as relevant to the present decision, may be summarised as follows:

Novelty (Article 54 EPC)

Document D1 related to synthetic polypeptides with at least one antigenic site of a prion protein (PrP), methods for producing and using antibodies raised against these polypeptides, and diagnostic kits containing these polypeptides and/or antibodies. Document D1 identified antigenic PrP regions and found that PrP of the desired type comprised six regions of interest that were labelled A to F. Further sequences disclosed in document D1 represented overlapping parts of those PrP sequences A to F.

The application of the patent in suit as originally filed contained a general formula that formed the basis for the sequence of claims 1 and 6. Although during the examination proceedings of the application, the general formula was deleted and it was thus not present in the patent in suit, the claimed sequences were nevertheless part of this general formula (PrP sequence) originally disclosed in the application. This general formula was identical to Formula 1 of document D1. Further sequences disclosed in document D1 represented overlapping parts of the PrP sequences A to F, in particular Formulas I, II, Va, Vb and Vc were either identical to all or comprised parts of the sequences of claims 1 and 6. Thus, it had to be assumed that, as far as the sequence was concerned, the same antibodies

resulted from using all these sequences. Indeed, document D1 disclosed the use of these sequences for inducing polyclonal antibodies in rabbits, which were then used in immunological assays like ELISA and Western blot and tested both in infected and non-infected animal brains. Good anti-peptide titers and discrimination between PrP^{C} and PrP^{SC} were explicitly indicated, in particular for peptide Vc.

The first underlined sequence of claim 1 comprised a sequence with 100% identity to SEQ ID NO: 23 of document D1. It followed that antibodies raised against these sequences were bound to be identical. The sole difference between SEQ ID NO: 23 and the first underlined sequence was that the former (SEQ ID NO: 23) lacked or missed four terminal amino acids. However, there was evidence on file showing that it was general common knowledge of the skilled person that the four amino acids missing in SEQ ID NO: 23 were always present in prion proteins, as shown in the multiple alignments of the various prion proteins made in document D1. Therefore, its absence in SEQ ID NO: 23 was completely irrelevant.

X. The patentee (appellant) requested that the decision under appeal be set aside and the patent be maintained.

XI. The opponent 02 (respondent II) requested that the appeal be dismissed. There were no requests on file from the opponent 01 (respondent I).

Reasons for the Decision

Admissibility of the appeal and requests to be considered

1. In the appellant's notice of appeal, there is no explicit reference to any claim request and it is only stated that "*the Patentee wishes to appeal this decision of the Opposition Division under Article 106 EPC, in respect of the finding of lack of inventive step for the subject-matter of the patent*". Likewise, in the appellant's grounds of appeal, there is no explicit indication as to whether maintenance of the patent is requested based on the main request (granted claims) and/or on the auxiliary request 1 (filed on 22 June 2007 at the oral proceedings) before the opposition division.

2. Both the appellant's notice of appeal (24 September 2007) and the statement setting out the grounds of appeal (22 November 2007) were filed before the entry into force of the EPC 2000 (13 December 2007). It follows that Rule 64(b) EPC 1973 applies in the present case and thus, the notice of appeal is required to contain "*a statement identifying the decision which is impugned and the extent to which amendment or cancellation of the decision is requested*".

3. According to the case law developed under Rule 64(b) EPC 1973, if the patent is revoked, a statement of the patent proprietor that he is appealing against the decision is invariably tantamount to his stating that he requests the decision to be set aside entirely. And, the objective value of explanation of the notice of appeal has to be considered, i.e. the context of the

case and, more particularly, the requests made during the opposition proceedings (cf. "Case Law of the Boards of Appeal of the EPO", 5th edition 2006, VII.D.7.4.1(b), page 619). In the present case, by the explicit reference made in the notice of appeal to the subject matter of the patent, the appellant's intention can be interpreted as being the maintenance of the patent on the basis of the claims as granted having formed the main request before the opposition division. By contrast, it cannot clearly be derived from the appellant's submissions that it also wishes to defend its patent on the basis of the auxiliary request as filed before the opposition division.

4. On several occasions, the boards of appeal have acknowledged as a basic principle of the European patent law that it is the duty of any party to proceedings, in particular the appellant in appeal proceedings, to make its own case and to formulate its own requests. This responsibility cannot be shifted to the European Patent Office, in this case the board of appeal (cf. *inter alia* T 382/96 of 7 July 1999, points 5.2 and 5.3 of the Reasons, and T 446/00 of 3 July 2003, point 3 of the Headnote).

5. In the present proceedings, the board, in its communication pursuant to Article 15(1) RPBA, had made the appellant aware that it was doubtful whether the auxiliary request formed part of the present appeal proceedings since the appellant's intention was not clearly and unambiguously derivable from the content of its notice of appeal or the statement setting out its grounds of appeal (cf. point IV *supra* and point 32 of the board's communication dated 28 October 2008). The

appellant did not reply to the board's communication and did not attend oral proceedings either (cf. points V and VI *supra*).

6. In the absence of any attempt by the appellant to clarify its requests and, in view of Article 113(2) EPC which states that "*the European Patent Office shall examine, and decide upon, the European patent application or the European patent only in the text submitted to it, or agreed, by the applicant or the proprietor of the patent*", the board considers that the auxiliary request filed on 22 June 2007 at the oral proceedings before the opposition division cannot be regarded as put before this board in the present appeal proceedings and cannot therefore be examined and decided upon by the board since it has not been clearly and unambiguously submitted by the patentee.

7. In conclusion, the appeal is admissible and the main request (claims as granted) is considered to be the sole claim request for the maintenance of the patent.

Main and sole request (Claims as granted)
Article 123(2) EPC

8. The findings of the opposition division on Article 123(2) EPC are not contested by the respondent. Nor does the board see any reason to do so of its own motion either.

Article 54 EPC (Novelty)
The scope of the claims

9. There is, to say the least, a certain degree of ambiguity in claims 1 and 6 caused by the wording "*one or more of the following sequences*" immediately before what appears to be *prima facie* four independent peptide sequences (cf. point VII *supra*). However, by explicit indication of their (misleading) numeration (44, 87, 131, 177), the skilled reader receives the additional information that the four peptide sequences are not independent but a single polypeptide sequence. This information, which is in contradiction with the wording of claims 1 and 6, is nevertheless in line with the description of the patent in suit, which identifies this single sequence as the N-terminal sequence of a synthetic prion (PrP) sequence (cf. page 9, line 26 of the patent in suit). In this context, the description refers to "*rabbit antibodies raised to the following synthetic prior peptides*" disclosing, immediately thereafter, the single N-terminal sequence of claims 1 and 6 and adding that "*both underlined sequences ... are used to raise rabbit anti-PrP antibodies*" (cf. page 9, lines 20 to 25 and lines 42 to 43). Although in claims 1 and 6 the same sequences are underlined, there is no reference to them in any of these claims. It is only in dependent claim 2 that this reference is found.

10. The opposition division accepted the patentee's arguments and interpreted the wording of claims 1 and 6 as being related only to three specific sequences, namely the single sequence (residues 0 to 177) and the two underlined sequences (residues 27 to 59 and residues 88 to 126). Based on this interpretation, the

opposition division considered that SEQ ID No. 23 of document D1 (WO 93/11155, publication date 10 June 1993) lacked the first four residues when compared with the first underlined sequence of the patent in suit and that SEQ ID No. 23 was not used to raise antibodies in document D1. Hence, novelty was acknowledged (cf. page 11 of the decision under appeal).

11. Although it is established case law of the boards of appeal that the skilled person, when considering a claim, should rule out interpretations which are illogical or technically meaningless and should try to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the patent (cf. "Case Law", *supra*, II.B.5.1, page 205), it is also established case law that, when novelty and inventive step are assessed, there is no reason to use the description to interpret an excessively broad claim more narrowly, if it is a question not of understanding concepts that require explanation but rather of examining an excessively broad request in relation to the state of the art (cf. "Case Law", *supra*, I.C.2.9, page 78).

12. In the present case, there is no reason to interpret the wording of claims 1 and 6 as restricting their scope to the use of antibodies raised - only and exclusively - against the three sequences referred to by the appellant and excluding thereby the use of antibodies raised against any other possible sequence comprised within the single sequence shown in these claims, i.e. any fragment of the single sequence (residues 0 to 177). This latter interpretation is not technically meaningless and, in the absence of any

reference to the underlined sequences in claims 1 and 6, it is also supported by dependent claim 2, which relates then to a preferred selection among all these possible sequences (fragments), namely "*antibodies raised against the underlined sequences shown in claim 1*" (cf. granted claim 2).

13. A broad interpretation of claims 1 and 6 is also fully justified in the light of the application of the patent in suit, which referred to the underlined sequences only as those used to raise the "*preferred antibodies*", but explicitly contemplated other antibodies, namely "*suitable antibodies are those directed against the synthetic peptides disclosed in WO 93/1155*" (cf. page 4, lines 25 to 32 of the published application of the patent in suit). In this context, both the application and the patent in suit refer to the use of a (preferred) "*C5 antibody to PrP^{SC}*" which is acknowledged to be commercially available (cf. page 4, lines 28 to 30 of the published application and page 3, paragraph [0018] of the patent in suit). There is no information on the epitopic site(s) recognized by this antibody and, although the issue had been raised in the present appeal proceedings (cf. point 17 of the board's communication dated 28 October 2008), no submissions have been made by the parties and no further information is found on file.

The disclosure of document D1

14. Document D1 shares the same concerns as the patent in suit, namely the possible transmission of spongiform encephalopathies to humans (cf. *inter alia* page 1, lines 26 to 28 and page 2, lines 4 to 7), and refers to

the development of appropriate diagnostics (immunodiagnostics) (cf. *inter alia* page 1, lines 12 to 13, page 2, lines 7 to 9). Document D1 acknowledges that "*the major problem in the search for a specific diagnostic agent ... against the scrapie agent PrP^{SC} is that it is almost identical to the natural form of the protein PrP^{C}* " (cf. page 2, line 30 to page 3, line 7). Six regions, labelled A to F (as well as combinations, sub-fragments and variants thereof), are identified in these prion proteins to be used in the development of diagnostic agents (cf. page 4, lines 13 to 20 et seq.), in particular as immunogens to raise prion specific antibodies (cf. *inter alia* page 20, lines 5 to 14, page 26, lines 33 to 36 and page 27, line 23 to page 28, line 14).

15. Whereas regions D and F do not have any relation to the N-terminus sequence identified in the patent in suit, the other four regions are related thereto. Region A overlaps with the C-terminus sequence of the second underlined sequence of the patent (residues 113 to 140), region B and region C overlap with the C-terminus of the single sequence of the patent (residues 135 to 163 and 156 to 177, respectively) and region E overlaps with the first underlined sequence (residues 31 to 62). Accordingly, most of the sequences of document D1 are related to the single sequence and the two underlined sequences of the patent: SEQ ID Nos. 23, 26, 29 and 49 to the first underlined sequence, SEQ ID Nos. 24, 27, 30 and 46 to the intermediate sequence between the first and second underlined sequences, SEQ ID Nos. 1-3, 5, 25, 28, 31, 38, 47 and 51 to the second underlined sequence and SEQ ID Nos. 4, 6-18 and 41-45 to the C-terminus of the single sequence (residues 132 to 177).

Peptides of the regions A, B and C are explicitly identified in document D1 as preferred for discriminating between PrP^{C} and PrP^{SC} (cf. page 29, lines 2 to 18) and, at least for two of them (SEQ ID Nos. 42 and 47, corresponding, respectively, to residues 135 to 155 and 93 to 115), successful results are reported in document D1 (cf. page 39, last paragraph). Some of the sequences disclosed in document D1 (SEQ ID Nos. 24, 30) are identical to fragments of the single sequence shown in claims 1 and 6.

Novelty in the light of document D1 and the scope of the claims

16. In view of the interpretation of claims 1 and 6 by the board (cf. points 12 and 13 *supra*), namely that their subject-matter relates to antibodies raised against any fragment of the single sequence shown in these claims (residues 0 to 177), and the disclosure of document D1 as summarized in points 14 and 15 above, there can be no doubt that document D1 anticipates the subject-matter of claims 1 and 6 and thus, novelty cannot be acknowledged.

17. For the sake of completeness, the board would also like to add that, even if the scope of the claims 1 and 6 is narrowly interpreted, i.e. related to antibodies raised only and exclusively to the single sequence and to the two underlined sequences shown in these claims, the claimed subject-matter would also be considered as being anticipated by document D1. Contrary to the appellant's arguments put forward in the context of Article 56 EPC, the board does not consider that these three specific sequences fulfil the criteria of a

selection invention as defined in the established case law of the Boards of Appeal (cf. T 198/84, OJ EPO 1985, page 209), namely to be narrow and far away from the polypeptides disclosed in document D1 and representing a purposive selection over these polypeptides (cf. points 21 to 27 of the board's communication dated 28 October 2008). However, in view of the conclusions reached above, there is no need to deal with this issue in more detail.

18. It follows from all the above that the claimed subject-matter does not fulfil the requirements of Article 54 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski L. Galligani