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D E C I S I O N
of 6 August 2004

Case Number: T 0811/01 - 3.3.4

Application Number: 88908512.2

Publication Number: 0341273

IPC: C07K 14/435

Language of the proceedings: EN

Title of invention:
Biological materials, processes for producing biological materials and for using such materials in therapy

Patentee:
BIOGEN, INC.

Opponent:
Amgen Inc.

Headword:
IL-1 inhibitor/BIOGEN

Relevant legal provisions:
EPC Art. 83, 111

Keyword:
"Sufficiency of disclosure - (yes)"
"Remittal to the first instance - (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0811/01 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 6 August 2004

Appellant: (Proprietor of the patent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 25 May 2001 revoking European patent No. 0341273 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: S. C. Perryman
Members: A. L. L. Marie
M. R. J. Wieser

Summary of Facts and Submissions

I. European patent No. 0 341 273 was granted on the basis of a set of 13 claims, claim 1 of which read:

"1. A substantially pure IL-1 INH, migrating as a single band on SDS/PAGE and substantially free of apolipoprotein A1 and retinol binding protein the IL-1 INH being characterized by:

(a) an inhibitory activity to the LAF activity of IL-1,
(b) an inhibitory activity to the MCF activity of IL-1,
(c) an inhibitory activity to IL-1 mediated fibroblast proliferation;
(d) an inhibitory activity to the IL-1 binding to IL-1 receptors;
(e) a non-inhibitory activity to the TNFα mediated production of PGE_2 and collagenase; and
(f) a specific activity of at least $1.2x10^3$ U/mg in an IL-1 mediated IL-2 production assay."

Independent claims 8, 9, 12 and 13 were directed to a method of producing a recombinant DNA sequence coding for interleukin-1 inhibitor (IL-1 INH), a recombinant DNA coding for IL-1 INH, a process for producing IL-1 INH and a pharmaceutical composition comprising IL-1 INH, respectively. Dependent claims 2 to 7, 10 and 11 referred to further embodiments of the IL-1 INH, the method or the recombinant DNA of claims 1, 8 and 9.

II. Notice of opposition was filed and the revocation of the patent was requested on the grounds of Article 100(a)(b) EPC. In particular, besides objections under Article 83 EPC, the opponent also raised objections under Article 56 EPC for lack of inventive step. The patent was revoked by the opposition division pursuant to Article 102(1) EPC which concluded that the subject-matter of claim 1 as granted and of auxiliary request 1 filed during the oral proceedings (which differed from claim 1 as granted by the amendment of feature (f) from "*a specific activity of at least 1.2x10^3 U/mg in an IL-1 mediated IL-2 production assay*" into "*a specific activity of at least 3.5x10^4 U/mg in an EL-4/CTLL assay*") did not meet the requirements of Article 83 EPC, whereas the subject-matter of claim 1 of auxiliary request 2, also filed during the oral proceedings (in which feature (f) of claim 1 as granted was replaced by an "*insert a*" summarizing the different steps of the purification procedure as described in Example 1) did not fulfil the requirements of Article 84 EPC.

In particular, the opposition division, following the argumentation of the opponent, took the view that feature (f) of claim 1 as granted or of the first auxiliary request, which only made sense in the context of a particular assay using a particular cell line, was not enabled, because the EL-4.6.1c10 cell line used was not publicly available and had not been deposited pursuant to Rule 28 EPC. Documents (24) and (25)(cf *infra* section VII) were no evidence of the availability of the EL-4.6.1c10 cell line at the priority date of the patent in suit, because in the former document a

different cell line (EL-4 NOB-1) was used and the latter was published after said priority date.

III. The appellant (the patentee) filed an appeal against the decision of the opposition division and submitted his statement of grounds of appeal.

IV. With his letter of 2 October 2003, the respondent (the opponent) withdrew his opposition and did not answer the statement of grounds of appeal submitted by the appellant. However, during the opposition proceedings, the respondent had raised objections under Article 83 EPC against claims 1 to 7 and 13 as granted because the patent in suit did not provide an enabling disclosure of an IL-1 INH with a specific activity of at least 1250 U/mg, such as the product obtained after Step 6 of the purification process depicted in Figure 9 of the patent in suit, which also exhibited the features mentioned in claim 1 of

(i) being substantially pure.

(ii) migrating as a single band on SDS-PAGE

(iii) being substantially free of apolipoprotein A1

(iv) being substantially free of retinol binding protein.

Document (12) was cited in this context, in particular lanes 6 and 7 of the SDS-PAGE gel depicted in Figure 1. The subject-matter of claim 7 as it depended on claim 1, ie an IL-1 INH with a specific activity of at

least $3.0x10^4$ U/mg in an IL-1/MCF assay, which implied the use of a chromatography on Phenyl-Sepharose as disclosed in Example 1(f) of the patent in suit, was also not enabled, because the obtained IL-1 INH was not substantially pure, since three bands were seen on the corresponding lane 7 of Figure 1 of document (12). A calculation based on Table 1 of document (12) also showed that the product obtained after Step 6 of the purification process, which was identical to that of Figure 9 of the patent in suit, contained at least 91.1% contaminants.

Objections under Article 83 EPC had also been raised against claims 8 to 12 as granted, directed to the preparation of a recombinant DNA molecule for the production of IL-1 INH, which were considered to paraphrase a mere desire rather than to provide any technical teaching. There was no evidence that an extrapolation of the teaching of documents (13) and (14), on the purification and sequencing of IL-1 INH and the expression of a cDNA encoding a human IL-1 receptor antagonist, was possible. In document (13), the IL-1 INH was obtained from another source than urine and purified by another method including ion exchange, gel filtration and HPLC which yielded a protein of a much higher purity and serious difficulties were nevertheless encountered in sequencing the protein. The patent in suit did not provide any information on the preparation and the screening of a cDNA library which did not appear, in view of the teaching of document (14), to have been straightforwardly feasible at the priority date of the patent in suit.

V. The Board issued a communication pursuant to Article 11(1) of the rules of procedure of the Boards of Appeal, in which it indicated that the only issue decided relative to the claims before the Board was that the subject-matter of claim 1 as granted was not enabled for the purposes of Article 83 EPC. The Board further indicated that it was inclined to deviate from the opinion of the opposition division and that, provided the appellant be successful on the issue concerning Article 83 EPC, it would propose to remit the case to the opposition division pursuant to Article 111(1) EPC for the latter to exercise its discretion as to whether other issues raised in the original opposition should be taken up *ex officio* pursuant to Rule 60 EPC.

VI. The appellant in his letter of 5 February 2004 made his request for oral proceedings dependent on the intention of the Board to finally revoke the patent in suit and agreed with the suggestion of the Board to remit the case to the opposition division, in case the requirements of Article 83 EPC were considered as fulfilled.

VII. The following documents are cited in the present decision:

(4) P.L. Seckinger et al., 18th Forum in Immunology, 1987, pages 486 to 488

(8) P.L. Seckinger et al., Journal of Leukocyte Biology, C.C. Stewart editor, Alan Riss Inc., New York, 1987, Vol. 42, page 543

(12) G.J. Mazzei et al., Eur. J. Immunol., 1990, Vol. 20, pages 683 to 689

(13) C.H. Hannum et al., Nature, 1990, Vol. 343, pages 336 to 340

(14) S.P. Eisenberg et al., Nature, 1990, Vol. 343, pages 341 to 346

(17) R.H. Zubler et al., Journal of Immunology, 1985, Vol. 134, No. 6, pages 3662 to 3668

(18) Declaration of Dr Gonzalo Mazzei dated 5 August 1998

(24) A.J.H. Gearing et al., Journal of Immunological Methods, 1987, Vol. 99 pages 7 to 11

(25) D. Urdall et al., Journal of Biological Chemistry, 1988, Vol. 263, pages 2870 to 2877

VIII. The arguments submitted by the appellant in view of Article 83 EPC in favour of his request to maintain the patent in suit on the basis of the claims as granted can be summarized as follows:

Feature (f) of claim 1 as granted was enabled by the priority application, the application as filed and the patent in suit, because the EL-4.6.1c10 cell line had been made publicly available by its description in document (17) and was set at the disposition of the skilled worker in both academic institutions and biotech/pharmaceutical companies, as in the case of document (25) that was submitted for publication before

the priority date of the patent in suit. Document (24) was also evidence that the EL-4.6.1c10 cell line, which was used as a precursor for the preparation of the EL-4 NOB-1 cell line disclosed therein, was available to the public from ECACC, a recognized International Depository Authority under the Budapest Treaty. Furthermore, other similar EL-4 cell lines were known in the prior art, as shown for instance in document (24), which could have been used instead. There was further no necessity to make a deposit of the EL-4.6.1c10 cell line according to Rule 28 EPC, since, contrary to the requirements of this Rule before its amendment on 1 October 1996, the subject-matter of claim 1 was not an invention which both concerned a microbiological process *and* involved the use of a microorganism.

The subject-matter of claim 1, as far as it embraced an IL-1 INH with a specific activity of 1250 U/mg, such as the product obtained after Step 6 of the process depicted in Figure 9 of the patent in suit, was enabled, since in the patent in suit the expression "*substantially pure*" meant "*substantially free of apolipoprotein A1 and retinol binding protein*" and was achieved by a step of negative immunosorption using antibodies against retinol binding protein and apolipoprotein A1, which resulted in a IL-1 INH with a specific activity of at least 1.2×10^3 U/mg in an EL4/CTLL assay. This step could have been repeated several times to obtain an IL-4 INH migrating as a single band on SDS/PAGE and being free of apolipoprotein A1.

In Figure 1 of document (12) a SDS/PAGE of the urinary IL-1 INH was depicted, lanes 1 to 6 of which were stained with coomassie brilliant blue and lane 7 with silver, which was a more sensitive method. In lane 7, two minor contaminants were seen, but there was no evidence that these minor bands corresponded to retinol binding protein and apolipoprotein A1. They were separated from IL-1 INH by a further negative immunosorption on an antibody column raised against urinary proteins. Furthermore, "*substantially free*" did not mean 100% free and the subject-matter of the claims was not directed to an IL-1 INH free from other urinary proteins.

The patent in suit described in detail how to proceed to prepare a recombinant DNA molecule encoding IL-1 INH and the methods therefor were routine at the priority date of the patent in suit.

IX. The appellant requested that the decision under appeal be set aside and the patent maintained on the basis of the claims as granted.

Reasons for the Decision

Claims as granted

Article 83 EPC

1. For the purpose of considering whether a European patent does or does not disclose the invention, the subject-matter of a particular claim, in a manner sufficiently clear and complete to be carried out by a

person skilled in the art (Article 100(b), Article 83 EPC), the Board has to be satisfied firstly that the patent specification certainly puts the skilled person in possession of at least one way of putting the claimed invention into practice, and secondly that the skilled person can put the invention into practice over the whole scope of the claim.

2. In the present case, the opposition division (page 3 of the decision) considered that the indication of a particular value for the specific activity only made sense in the context of a particular assay using a particular cell line, since different assays using different cell lines would lead to different results and alter the definition of the compound of claim 1. The non-availability to the public of the cell line EL-4.6.1c10 used in the assay for determining the specific activity mentioned in feature (f) of claim 1 as granted prevented the skilled person from reproducing the invention.

3. The EL-4/CTLL assay disclosed in Example 4 of the patent in suit (page 10, column 15, lines 18 to 40), which led to the specific activity mentioned in feature (f) of claim 1, determines the inhibition obtained with a given IL-1 inhibitor on the IL-1 mediated interleukin-2 (IL-2) production by the EL-4.6.1c10 cell line. The only significant feature of the EL-4.6.1c10 cell line in the context of the EL-4/CTLL assay used in the patent in suit is its ability to produce IL-2 upon stimulation with IL-1. Thus, even if one concurred with the opposition division that the value of the specific activity given by various assays might be different (this is indeed

shown in the paragraph bridging columns 10 and 11 of the patent in suit), in the context of the EL-4/CTLL assay, the replacement of a cell line having the feature mentioned above, such as the EL-4.6.1c10 cell line, by another one exhibiting the same feature should be without influence on the value obtained, as far as the production of IL-2 upon stimulation by IL-1 is not the limiting factor of the reaction.

4. The question to be answered for determining whether the requirements of Article 83 EPC are met by the subject-matter of claim 1 is, therefore, whether the EL-4.6.1c10 cell line or a cell line having the ability of producing IL-2 upon IL-1 stimulation was publicly available at the priority date of the patent in suit.

5. Whether the EL-4.6.1c10 cell line was, as argued by the appellant, publicly available from the group of scientists having prepared it as disclosed in document (17), is besides the point, because document (17) in fact, contrary to the allegation of the appellant, does not describe the preparation of this cell line. In this document, the preparation of the cell line EL-4.6.1 is described, by sub-cloning of the parental cell NIH EL-4 leading to EL-4-16, then submitting the obtained EL-4-16 cell line to mutagenesis with methane sulfonate and culture in presence of 5-bromo-2-deoxyuridine and ouabain (bridging paragraph between pages 3662 and 3663). The preparation of a further sub-clone, EL-4BU^{r}OU^{r}6.1b, is also described (page 3664, left column, lines 17 to 21 and right column, line 12), but nothing can be retrieved form document (17) concerning the cell line EL-4.6.1c10 used in the patent in suit.

6. In document (24), however, the preparation of NOB-1 cell line (abstract, page 9, left column, last paragraph), which is a sub-clone of the mouse EL-4.6.1 cell line of document (17), is described. This cell line constitutively produces very little IL-2, but in response to IL-1 produces high concentration of IL-2 (abstract) and it is said, on page 10 (heading "*Discussion*"), to meet all the requirements for the determination of IL-1 activity. It was deposited at and available from PHLS tissue culture collection (page 8, left column), the name of which has been changed since then, according to the appellant's indication in his statement of grounds of appeal, into "European Collection of Cell Cultures" (ECACC), an international depository authority under the Budapest Treaty. The respondent has submitted no evidence to the contrary or suggesting that the availability to the public of said NOB-1 cell line was in some way subjected to special restrictions.

7. Therefore, the skilled person, taught by the patent in suit that the only relevant feature of the cell line used in the EL-4/CTLL assay is its ability to produce IL-2 upon IL-1 stimulation, had at the priority date of the patent in suit at least one publicly available functional equivalent to the EL-4.6.1c10 cell line used in the patent and was well able to determine feature (f) of claim 1.

8. The respondent had also objected that the product obtained after Step 6 of the purification process depicted in Figure 9 of the patent in suit and which is embraced by the subject-matter of claim 1, because of

its specific activity of 1250 U/mg, does not exhibit the features of

(i) being substantially pure

(ii) migrating as a single band on SDS-PAGE

(iii) being substantially free of apolipoprotein A1

(iv) being substantially free of retinol binding protein, as requested by claim 1.

This is allegedly shown by the disclosure of document (12), since

(a) the product run on lane 6 of Figure 1 of document (12), which corresponds to the product obtained after Step 6 of the purification process depicted in Figure 9 of the patent in suit, contains, besides IL-1 INH, apolipoprotein A1 as a contaminant,

(b) a comparison of the values of the protein concentration and the specific activity given in Table 1 of document (12) which depicts, as Figure 9 of the patent in suit, the purification process of IL-1 INH, leads to the conclusion that the product of Step 6 of said process still contains 91.1% contaminants and is hence not substantially pure as required by claim 1.

9. Dr Mazzei, one of the inventors of the patent in suit and one of the authors of document (12), has indicated in his declaration (document (18), point 10) that, whereas in document (12) the specific activity reported for the protein preparation in Step 6 of Table 1 has been obtained, as in Figure 9 of the patent in suit, using two negative immunosorption columns (one containing anti-retinol binding protein antibodies and the other anti-apolipoprotein A1 antibodies), the preparation run on SDS-PAGE in lane 6 of Figure 1 of document (12) has been treated by a single immunosorption using only antibodies directed against retinol binding protein. This assertion is corroborated by the legend of Figure 1 of document (12) on page 685. There is thus no difference between Table 1 of document (12) and Figure 9 of the patent in suit, which both depict the various steps of the purification process of IL-1 INH. In contrast to this, the results depicted in Figure 1 of document (12) from lane 6 onwards do not relate to a product similar to that obtained from Step 6 onwards of the process disclosed in Figure 9 of the patent in suit or in Table 1 of document (12). Furthermore, the product of Step 6 of Figure 9 of the patent in suit or of Table 1 of document (12), which has been treated with anti-lipoprotein A1 antibodies, displays a specific activity of only 1250 U/mg, ie a specific activity very close to the lowest limit mentioned in feature (f) of claim 1 (1.2×10^3 U/mg). On the other hand, apolipoprotein A1 is said on page 9 (column 13, lines 1 to 10) of the patent in suit to be one of the two major contaminants representing, before Step 6, 90% of the protein content and in point 13 of document (18) one pass on anti-apolipoprotein A1 antibodies is said the remove 50 to 60% of said

apolipoprotein A1. The specific activity of the product run on lane 6 of Figure 1 of document (12), which has not been submitted to a pass through a column containing anti-apolipoprotein antibodies, can hence be expected to be lower than $1.2x10^3$ U/mg. Therefore, the product run on lane 6 of Figure 1 of document (12) is not encompassed by the subject-matter of claim 1 and the argumentation of the respondent is basically based on an incorrect interpretation of the teaching of document (12).

10. Furthermore, this line of argumentation is in contradiction with Figure 1 of document (12), in which the product run on lane 6, although less pure than the product obtained after Step 6 of the process of the patent in suit or of Table 1 of document (12), migrates as a single band on SDS-PAGE. Indeed, the presence of a single band on SDS-PAGE does not necessarily imply that only a single molecular species is present in the band, as the respondent assumes on page 17 of his statement of facts and arguments supporting the opposition filed on 8 October 1997.

11. The argument mentioned above (point 8) under point (b) is based on a calculation made in the statement of facts and arguments supporting the opposition (pages 10 to 11, point 4.1.1.2 and page 16, point 5.1.1.1) using the values given in Table 1 of document (12) and Figure 9 of the patent in suit for the protein concentration and the total IL-1 INH activity. This calculation leads to the conclusion that the IL-1 INH of Step 6 (ie after the immunosorption on anti-apolipoprotein A1-antibodies and anti-retinol binding protein antibodies) still contains more than 91.1%

contaminants and cannot be considered as "*substantially pure*", this term being characterized in the patent in suit (page 4, column 4, lines 46 to 51) by two attributes:

(a) substantially free of retinol binding protein and apolipoprotein A1

(b) migration as a single band on SDS-PAGE.

12. It has already been shown (*cf* supra point 10) that the attribute (b) is fulfilled by the product run on lane 6 of Figure 1 of document (12) and that the product of Step 6 of the purification process described in the patent in suit and in Table 1 of document (12), being even more pure, should also migrate as a single band.

13. As far as the attribute (a) is concerned, the meaning of the expression "*substantially free of retinol binding protein and apolipoprotein A1*" has to be determined. The patent in suit does not give any numerical value of this expression. However, Example 1(e) shows what is meant by this expression. The product obtained at the end of Step 6 has a specific activity of 1250 U/mg and migrates as a single band (page 9, column 13, lines 29 to 36) and is hence encompassed by the subject-matter of claim 1. It has been subjected to a single pass on immunosorption using anti-retinol binding protein and anti-apolipoprotein antibodies, a treatment which is said in point 13 of document (18) to result in an almost complete absence of retinol binding protein and in the removal of 50 to 60% of the apolipoprotein A1. This is an illustration of what the expression "*substantially free of retinol*

binding protein and apolipoprotein A1" as used in the patent in suit means. Since the product of Step 6 serves to exemplify the meaning of the feature "*substantially free of retinol binding protein and apolipoprotein* A1", the question as to whether this product, which also migrates as a single band in SDS-PAGE (Figure 1 of document (12), lane 6), is "*substantially pure*" in the meaning of the patent in suit is superfluous.

14. Furthermore, this line of argumentation is in contradiction with the teaching of the patent in suit (page 9, column 13, lines 1 to 36) which mentions that the two major contaminants representing at least 90% of the protein content are present in the preparation obtained *after the gel filtration on Ultrogel AcA54* (Step 5 of the purification process) in the form of retinol biding protein and apolipoprotein A1, ie *before* the immunosorption on antibodies raised against apolipoprotein A1 and retinol binding protein. Since in document (18), Dr Mazzei indicates (points 12 and 13 of the declaration) that a single pass on anti-retinol binding protein and anti-apolipoprotein A1 antibodies removes substantially all the retinol binding protein and 50 to 60% of the apolipoprotein A1, the protein preparation of Step 6 can no longer contain 91.1% contaminants, as had been argued by the respondent.

15. The discrepancy between the results obtained from the calculation of the respondent and the logic behind the steps of the purification process (Figure 9 of the patent in suit or Table 1 of document (12)) suggests, as possible explanations, an interference of the remaining contaminants or of the buffers used in

Steps 6 and 7 with the EL-4/CTLL assay. Indeed in Step 6, the column is developed with a phosphate buffer, whereas in Step 7 the elution from the Phenyl-Sepharose column is made using a gradient of NaCl in Tris buffer. Phosphate and Tris ions may have a different influence on the determination of the specific activity. On the other hand, IL-1 INH migrates in SDS-PAGE more slowly on lane 6 than on lane 7 of Figure 1 of document (12). The product run on lane 6 is, however, the same as on lane 7, except for the presence of apolipoprotein A1 as contaminant (because it has not been passed through a column of anti-apolipoprotein A1 antibodies). This suggests some kind of tight interaction between IL-1 INH and apolipoprotein A1 which modifies the migration behaviour of the former. Such a tight interaction modifying the migration behaviour of IL-1 INH can reasonably be expected to also have an impact on the specific activity of IL-1 INH, so that the basis for the calculation made by the respondent is rather hypothetical.

16. The respondent had also objected that even with the step of hydrophobic chromatography on Phenyl-Sepharose (Step 7 of the purification process) no preparation substantially free of retinol binding protein and apolipoprotein A1 can be obtained, since, according to lane 7 of Figure 1 of document (12), a product containing three bands is obtained, the two contaminant bands being assumed to be retinol-binding protein and apolipoprotein A1. The Board does not share the respondent's opinion and considers that the very faint contaminating bands seen on lane 7 of Figure 1 of document (12) are encompassed by the definition of the expression "*substantially free of retinol binding*

protein and apolipoprotein A1" as used in the patent in suit (*cf supra* point 14) which does not imply the total absence of retinol binding protein and apolipoprotein A 1.

17. The respondent had further argued during the opposition procedure that claims 8 to 12 directed to the production of IL-1 INH by recombinant DNA technology are the paraphrase of a mere desire and provide no technical teaching. Documents (13) and (14) were cited to show that the sequencing of the polypeptides and the establishment of a cDNA library caused difficulties. The Board cannot concur with this view. In document (13), three IL-1 receptor antagonists (x, α and β) are disclosed which have the same amino acid sequence (x-form), from which the α- and the β-forms are glycosylation variants (page 340, left column, heading "*Discussion*"). These IL-1 receptor antagonists are said on page 340 (right column, last paragraph) to "*quite likely be the same protein as the IL-1 INH isolated from urine of febrile patients*", ie the IL-1 INH of the patent in suit. On page 338 (left column, first full paragraph), the three forms of the inhibitor are said to be "*directly sequenceable*". This teaching is not in contradiction with the information mentioned on page 337 (right column, last paragraph), according to which of ten samples only two yielded significant sequence information and three preparations of the β-protein yielded no sequence information, because the failure can be explained by the poor yield of the fractions from the reverse-phased HPLC column (the last step of the purification procedure (page 337, left column, last paragraph)) used for the sequence determination. It can be assumed that the failure was

due to an insufficient concentration of the inhibitor in these fractions. Document (14) discloses the expression of a cDNA of a human IL-1 receptor antagonist isolated from monocytes (page 342, right column first paragraph) which is the IL-1 INH described in document (13). A cDNA library has been constructed and screened with mixed oligonucleotide probes, this process leading finally to the isolation of a cDNA coding for the IL-1 INH (page 343, left column, second paragraph and paragraph bridging the left and right columns). The nucleotide sequence of the cDNA and of the corresponding polypeptide are given in Figure 2. There is no indication in document (14) that unexpected difficulties were encountered during the completion of this work. Therefore, the Board considers that the sequencing of the polypeptide in order to prepare hybridisation probes, the preparation of a cDNA library and its screening with the probes were feasible for the skilled person at the priority date of the patent in suit without undue burden of experimentation or the use of inventive skill.

18. In view of the foregoing, the Board is of the opinion that the subject-matter of the claims as granted meets the requirements of Article 83 EPC.

Article 111 EPC

19. The opposition division, having considered that the patent in suit did not fulfil the requirements of Article 83 EPC, has not dealt in its decision with the objections raised by the opponent under Article 56 (*cf supra* section II). Decision G 9/91 (OJ EPO 1993, 408) in point 18 after indicating that "*the purpose of the*

appeal procedure inter partes is to give the losing party the possibility of challenging the decision of the opposition division on its merits", further states that "*it is not in conformity with this purpose to consider grounds for opposition on which the decision of the opposition division has not been based".* Accordingly, the Board remits the case for further prosecution by the opposition division, including exercising its discretion as to whether any other issues raised in the original opposition should be taken up *ex officio* pursuant to Rule 60 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution.

The Registrar: The Chairman:

P. Cremona S. Perryman