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Datasheet for the decision of 8 September 2011

Case Number: T 1069/08 - 3.3.08

Application Number: 98915430.7

Publication Number: 0975766

IPC: C12N 15/53

Language of the proceedings: EN

Title of invention:
Methods and compositions for synthesis of long chain polyunsaturated fatty acids

Patentee:
Calgene LLC, et al

Opponent:
Bayer S.A.S.

Headword:
Desaturase/CALGENE

Relevant legal provisions:
EPC Art. 83, 56
RPBA Art. 12(2), 13(1), 13(3)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Admissibility of appeal (yes)"
"Sufficiency of disclosure (yes)"
"Inventive step (yes)"

Decisions cited:
G 0009/91, T 0220/83, T 0019/90, T 0939/92, T 0207/94, T 0386/94, T 0111/00, T 1120/00, T 0320/01, T 1120/01, T 1064/01, T 0604/04, T 0005/06, T 0250/06, T 0087/08

Catchword:
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Case Number: T 1069/08 **-** 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 8 September 2011

Appellant: (Opponent)
Bayer S.A.S.
16 rue Jean-Marie Leclair
FR-69009 Lyon (FR)

Representative:
Monconduit, Hervé
Bayer S.A.S.
Patents & Licensing Department
14-20 Rue Pierre Baizet
B.P. 9163
F-69263 Lyon Cedex 09 (FR)

Respondents: (Patent Proprietors)
Calgene LLC
1920 Fifth Street
Davies
CA 95616 (US)

ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park
IL 60064 (US)

Representative:
Brasnett, Adrian Hugh
Mewburn Ellis LLP
33 Gutter Lane
London EC2V 8AS (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 18 April 2008 rejecting the opposition filed against European patent No. 0975766 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman: R. Moufang
Members: P. Julià
M. R. Vega Laso

Summary of Facts and Submissions

I. The opposition filed against the European patent No. 0 975 766 on the grounds of Article 100(a), (b) and (c) EPC was rejected by the opposition division under Article 101(2) EPC. The patent had been granted with 22 claims and claim 1 read as follows:

"1. A purified or isolated polypeptide which is capable of desaturating a fatty acid molecule at carbon 6 or 12 from the carboxyl end of said fatty acid, said polypeptide having an amino acid sequence which has at least 60% homology to the 457 amino acid sequence of SEQ ID NO:2 or the 399 amino acid sequence of SEQ ID NO:4."

Claims 2 to 8 were directed to various embodiments of the polypeptide of claim 1. Claims 9 to 10 related to an isolated nucleic acid encoding a polypeptide as defined in any one of claims 1 to 8. Claim 11 was directed to a nucleic acid construct comprising an acid nucleic as defined in claims 9 or 10 operably linked to a promoter. Claims 12 to 14 concerned transformed host cells. Claims 15 and 16 related to methods for the production of the fatty acids gamma linolenic acid and linoleic acid comprising growing a culture of host cells according to claim 12, 13 or 14. Claims 17 to 20 were directed to embodiments of the methods of claims 15 and 16. Claims 21 and 22 related to the use of a microbial host cell of "claim 13, 14 or 15" (*sic*) for the production of a fatty acid.

II. The opponent (appellant) filed a notice of appeal and a statement setting out its grounds of appeal. Oral proceedings were requested, if the board did not intend to revoke the patent.

III. On 24 February 2009, the patent proprietors (respondents) replied to the grounds of appeal and requested that the appeal be dismissed and that the patent be maintained as granted (main request) or, in the alternative, on the basis of one of auxiliary requests 1 to 4 filed therewith. On 6 December 2010, they further contested the admissibility of the appeal and drew the attention of the board to the decisions T 5/06 of 23 January 2009 and T 87/08 of 11 February 2010. As a subsidiary request, oral proceedings were requested.

IV. On 14 April 2011, the parties were summoned to oral proceedings. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, the board informed the parties of its preliminary, non-binding opinion on some of the issues to be discussed at the upcoming oral proceedings.

V. With letters of 8 August 2011 and 19 July 2011, both the appellant and the respondents replied, respectively, to the board's communication and maintained their previous requests. The respondents filed four amended versions of the description, each one adapted to one of the auxiliary requests 1 to 4, and informed the board of their intention not to attend the oral proceedings.

VI. With a letter dated 9 August 2011, the board was informed that the original appellant/opponent (Bayer CropScience S.A.) had merged into the company Bayer S.A.S. on 4 January 2010 and that, as a consequence of this merger, Bayer S.A.S. had become the universal successor of the original appellant as from that date, 4 January 2010. In its letter, the appellant provided a copy of a legal document as evidence of the merger and requested that the change of name be registered.

VII. Oral proceedings were held on 8 September 2011 in the absence of the respondents.

VIII. The following document is referred to in the present decision:

D1: WO 96/21022 (publication date: 11 July 1996)

IX. The submissions of the appellant can be summarized as follows:

Admissibility of the appeal

The objections raised in the statement of grounds of appeal were appropriately supported by arguments and evidence. All grounds of appeal were substantiated.

Main request (claims as granted)
Article 100(b) EPC

According to the case law, the scope of the claims had to be commensurate with the contribution of the patent over the prior art. The patent-in-suit did not open a new technical field because Δ6- and Δ12-desaturases

were already known in the prior art, such as shown by document D1. The polypeptides defined in claim 1 were characterized by a functional feature (desaturase activity) and a structural feature (at least 60% homology to specific SEQ ID NOs). However, among the many possible sequences fulfilling the structural requirement, there were only a few, if at all, having the functional feature. Apart from the disclosed specific SEQ ID NO, there was no disclosure in the patent-in-suit of other sequences having both features and there was no guidance as to how to obtain them. Although reference was made to two different approaches, namely the natural source approach and the mutagenesis approach, none of them could be applied without undue burden.

As for the mutagenesis approach, 60% homology allowed for the introduction of 40% mutations (up to 183 or to 160 residues for SEQ ID NO:2 or 4, respectively). It was known in the art that the introduction of minor changes in the amino acid sequence of an enzyme could have significant effects on its activity. In the absence of any indication in the patent-in-suit on the domains, regions and/or positions on which these mutations could be introduced without affecting the desaturase activity, the skilled person had to try each and every position (457 and 399 residues for SEQ ID NO:2 or 4, respectively) with every possible mutation, which clearly amounted to an undue burden.

As for the natural source approach, it was known in the art that members of the family of the membrane-bound desaturases (which also includes e.g. Δ5-, Δ9- and Δ15-desaturases) shared significant homology, including

three conserved histidine boxes, as acknowledged in the patent-in-suit and in document D1. Thus, it was not straightforward to isolate specific Δ6- and Δ12-desaturases from a mixture of several desaturases, requiring steps that were not disclosed in the patent-in-suit. The patent referred only to general methods and known techniques but did not provide any information for obtaining the claimed Δ6- and Δ12-desaturases. Although some results were shown in Examples 9 to 12 of the patent-in-suit, the putative enzymes obtained therein were not characterized and not shown to have a Δ6- or Δ12-desaturase activity.

Since none of these approaches could be carried out without undue burden, a combination of both approaches did not remedy their deficiencies. Moreover, the subject-matter of claim 1 was not limited to natural or to mutated (synthetic) homologues of the disclosed Δ6- and Δ12-desaturases. Even if the natural source approach were to be considered as sufficiently disclosed, there was no support in the patent-in-suit for the mutagenesis approach.

The degree or level of credibility required to support a claim was in direct relation to the breadth of that claim. For the broad scope of claim 1, the disclosure of the patent-in-suit was insufficient and not credible. The degree of homology of the claimed polypeptides was arbitrarily chosen and not supported by the disclosure of the patent-in-suit.

Article 100(a) EPC in connection with Article 56 EPC
Is the problem solved across the entire scope of the claims?

Document D1, the closest prior art, disclosed the Δ6-desaturase of the plant ***Borago officinalis***. The technical problem to be solved was the provision of alternative Δ6- and Δ12-desaturases. The solution provided by the patent-in-suit was the Δ6- and Δ12-desaturases of the fungus ***Mortierella*** (SEQ ID NO:2 and 4). The enzymatic activity of these enzymes was shown in Example 5 but there was no information in the patent-in-suit on the activity of any other desaturase, such as the putative homologues identified in Examples 9 to 12.

The subject-matter of claim 1 was not limited to SEQ ID NO:2 and 4 but embraced polypeptides with amino acid sequences of at least 60% homology thereto. However, there was no experimental data in the patent-in-suit for these sequences and it was not credible that substantially all polypeptides having this low level of homology possessed a Δ6- or Δ12-desaturase activity. Since the patent-in-suit did not provide sufficient information on how to obtain, among all possible sequences with a low level of homology, those with Δ6- or Δ12-desaturase activity and since this activity was the only and necessary justification for acknowledging an inventive contribution, the reference to the desaturase activity in claim 1 was only a mere recitation of a purported effect supposedly supporting the inventive contribution. The scope of claim 1 was thus arbitrary and encompassed polypeptides which most likely did not possess a Δ6- or Δ12-desaturase activity.

These sequences did not solve the technical problem and did not involve an inventive contribution.

According to the case law, if a known compound was claimed, the addition of a functional limitation (enzymatic activity) not recognized in the art did not make that compound novel. For inventive step, it was the provision of evidence of the claimed effect which justified inventive step, not a mere recitation of that effect in the claim. In the decision T 939/92 (OJ EPO 1996, 309), the board did not suggest the introduction of a functional limitation (herbicidal activity) into the claims but indicated that the only possibility to overcome the rejection of the patent application was to limit the scope of the claims to these compounds for which the herbicidal activity had actually been shown and that the burden to show that substantially all of the claimed compounds possessed the herbicidal activity was on the applicant. This was in line with other decisions, such as T 320/01 of 12 March 2004, T 1064/01 of 25 March 2004 and T 111/00 of 14 February 2002.

Is the solution obvious?

From the beginning of the opposition proceedings and again of the appeal proceedings, document D1 was always identified as the closest prior art. Accordingly, making an argument of lack of inventive step based on this document was not a new ground and it did not contravene the procedural requirements of the EPC. It was only after knowing the board's opinion on Article 83 EPC in the oral proceedings that the relevance of the board's reasoning leading to this

opinion became apparent to the appellant for the purpose of Article 56 EPC.

X. The submissions in writing by the respondents can be summarized as follows:

Admissibility of the appeal

According to the case law (T 5/06 and T 87/08, ***supra***), for an objection pursuant to Article 56 EPC to be reasoned, the closest prior art had to be identified and a logical chain of reasoning regarding the state of the art had to be provided. Since for the objection raised under Article 56 EPC no single document had been identified in the appellant's grounds of appeal, the objection was not reasoned and the appeal was thus inadmissible.

Main request (claims as granted)
Article 100(b) EPC

The objections raised under Article 83 EPC were essentially identical to those raised under Article 56 EPC and they were merely directed to the breadth of the claims. According to the case law, the burden of proof rested on the appellant to submit and produce evidence that the invention could not be carried out over the whole scope of the claims. In absence of this evidence, appellant's objections amounted only to a mere speculation as to what the skilled person was able to perform when following the teachings of the patent-in-suit.

Article 100(a) EPC in connection with Article 56 EPC
Is the problem solved across the entire scope of the claims?

The contribution to the art of the patent-in-suit was the provision of new Δ6- and Δ12-desaturases from *Mortierella alpina*. The scope of the claims was commensurate with this contribution and conventional in the practice of the EPO (T 1120/00 of 22 October 2004, T 604/04 of 16 March 2006, T 250/06 of 11 October 2007 and T 1120/01 of 14 July 2003) which, for a disclosure of a new and inventive (gene) sequence, allowed to claim other sequences defined in terms of a structural sequence similarity (percentage of homology, hybridization, etc.) and of a functional limitation relating to the activity of the encoded protein. The acceptable balance between structural and functional features was generally fact-dependent.

In the light of this contribution, it was reasonable to expect the claims to cover allelic variants of the specific SEQ ID NOs disclosed in the patent-in-suit. Indeed, such variants existed in other isolates of *Mortierella alpina*. The genus *Mortierella* comprised numerous species and it was reasonable to expect them to have Δ6- and Δ12-desaturases with sequences similar to the SEQ ID NOs disclosed in the patent. The genus *Mortierella* belonged to the fungal family of Mucorales which comprised over 300 species. Paragraph [0035] of the patent-in-suit referred to other members of this family and directed the attention of the skilled person thereto as a possible natural source of fungal Δ6- and Δ12-desaturases. Paragraph [0038] referred to methods known in the art for isolating, producing and

manufacturing industrial enzymes. There was no evidence on file showing that these methods were unsuitable to provide further desaturases based on the teaching achieved from the specific SEQ ID NO:2 and 4. Appellant's position to ignore the functional feature of the claimed polypeptides was not correct and went against the rationale shown in the decisions of the boards of appeal.

Is the solution obvious?

In the grounds of appeal and in the notice of opposition, document D1 was cited only to define the technical problem addressed by the patent-in-suit but not to analyze whether the solution was obvious. The whole thrust of appellant's case was based on an alleged failure of the patent-in-suit to solve the technical problem across the whole scope of the claims and not on the argument that the solution was obvious from the prior art.

Document D1 was cited in a first communication of the examining division (as document D2) in relation to Article 56 EPC and, in response thereto, facts and evidence were provided that were found by the examining division to be persuasive in establishing that the present claims met the requirements of Article 56 EPC. Since neither the appellant/opponent nor the opposition division had challenged the findings of the examining division on the question of obviousness, it went beyond the grounds of the present appeal proceedings to do so now.

In the light of decision G 9/91 (OJ EPO 1993, 408), there was no justification to seek now to revisit a ground of opposition that was not raised by the opponent and not introduced by the opposition division. To do so prejudiced the patentees' right to be heard.

XI. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

XII. The respondents (patentees) requested in writing that the appeal be either rejected as inadmissible or dismissed, or, in the alternative, the patent be maintained in amended form on the basis of any of auxiliary requests 1 to 4.

Reasons for the Decision

Change of status of opponent/appellant

1. According to the established case law of the boards of appeal, opponent status can be transferred to an universal successor of the original opponent. In the present case, the appellant made a corresponding request and submitted documentary evidence showing that Bayer S.A.S. had become the universal successor of the original opponent/appellant (Bayer CropScience S.A.) as of 4 January 2010 (see section VI *supra*).

2. The board considers the documentary evidence which has not been contested by the respondents to be sufficient to show that the universal succession took place as

submitted. The transfer of the opponent/appellant status is therefore acknowledged.

Admissibility of the appeal

3. As regards the respondents' request to reject the appeal as inadmissible, the board considers that the appellant's grounds of appeal clearly specified the legal reasons for which, in the appellant's view, the decision under appeal had to be set aside. The arguments presented in the grounds of appeal enabled the board and the respondents to understand why the decision under appeal was allegedly incorrect (cf. T 220/83, OJ EPO 1986, 249).

4. In the appellant's grounds of appeal, document D1 was clearly identified as the closest prior art and both the technical problem and the solution provided by the patent-in-suit were also clearly identified. The opponent's argument of a lack of inventive step was based only on the scope of the claims which, in its view, was too broad and encompassed subject-matter that did not solve the technical problem. This was the sole argument addressed under Article 56 EPC in the decision of the opposition division now under appeal. The reasons given by the opposition division in that decision were contested and fully addressed in appellant's grounds of appeal. In this regard, appellant's grounds of appeal were appropriately reasoned.

5. In the case law cited by the respondents, namely T 5/06 (*supra*) and T 87/08 (*supra*) (cf. section X *supra*), the boards considered that the decisions under appeal -

both dealing with Article 56 EPC - were insufficiently reasoned in violation of Rule 111(2) EPC. None of these decisions, however, dealt with the statement of grounds of appeal and the requirements it must meet in order for an appeal to be admissible. Thus, these decisions are considered not to be relevant by the board.

6. The appeal is thus considered to be admissible.

Scope of the appeal proceedings

7. The opposition division decided that the claims as granted fulfilled the requirements of Article 123(2) EPC. As regards Article 54 EPC, the opponent did not maintain the objections raised in the notice of opposition, and the opposition division did not see any reason to pursue them on its own motion. These findings were not contested in the appellant's grounds of appeal nor have they been contested during the appeal proceedings. Thus, the grounds of opposition set out in Article 100(a) EPC, as regards lack of novelty (Article 54 EPC), and Article 100(c) EPC are not part of the appeal proceedings.

8. The grounds of opposition which remain to be examined in appeal are Article 100(b) EPC and Article 100(a) EPC, as regards inventive step (Article 56 EPC).

Main request (claims as granted)
Article 100(b) EPC

9. Claim 1 as granted is directed to a polypeptide characterized by a functional feature ("***capable of desaturating a fatty acid molecule at carbon 6 or 12***

from the carboxyl end of said fatty acid") and a structural feature ("*having an amino acid sequence which has at least 60% homology to the 457 amino acid sequence of SEQ ID NO:2 or the 399 amino acid sequence of SEQ ID NO:4*") (cf. section I *supra*). The objection under Article 100(b) EPC arises from an insufficiency, in the appellant's view, of the disclosure of the patent-in-suit not allowing the skilled person to obtain - without undue burden or inventive skill - the few polypeptides having a Δ6- or Δ12-desaturase activity within the large number of possible polypeptides having amino acid sequences with a degree of homology as low as of 60% to SEQ ID NO:2 or 4 (cf. section IX *supra*).

10. The examples of the patent-in-suit disclose the construction of a cDNA library from *M. alpina*, the isolation of Δ6- and Δ12-desaturase nucleotide sequences and the putative encoded amino acid sequences SEQ ID NO:2 and 4 (Examples 1, 2 and 4). The three conserved "histidine boxes" known in the prior art to be conserved among membrane-bound desaturases, are identified in the disclosed Δ6- and Δ12-desaturases (cf. paragraphs [0113] and [0147] of the patent-in-suit). The expression and activity of these (recombinant) desaturases in baker's yeast and the optimization of culture conditions are disclosed in Examples 5 to 8.

11. It is suggested in the patent that, based on the disclosure of the specific sequences from *M. alpina*, other polypeptides having a Δ6- or a Δ12-desaturase activity can be isolated and purify. In particular, it is suggested that Δ6- or Δ12-desaturases from other microorganisms (a natural source) can be isolated by

methods known in the prior art as well as by other techniques available to the skilled person, such as screening of sequence databases, "*cassette mutagenesis or total synthesis*" (cf. paragraphs [0035] to [0038] and [0041] to [0043] of the patent-in-suit).

12. Examples 9 and 11 of the patent disclose further nucleotide sequences and the (putative) encoded amino acid sequences (SEQ ID NO:20 and 24 obtained from *Dictyostelium discoideum* and *Schizochytrium*, respectively) with a degree of homology of about 50-55% to SEQ ID NO:2 - although only over a length of about 120 and 60 residues, respectively. For the amino acid sequence SEQ ID NO:22 obtained from *Phaeodactylum tricornutum*, the degree of homology is of about 65-70% over a length of 70 residues (Example 10). All these sequences were isolated by random cDNA cloning, sequencing and comparison of the obtained sequences with SEQ ID NO:2 using informatic means (BLAST, TBLASTN) (cf. paragraphs [0142] to [0146] of the patent-in-suit).

13. The board is persuaded that, in view of the technical information contained in these examples, a skilled person could obtain - without undue burden - desaturases with at least 60% homology to SEQ ID NO:2 or 4 by using the methods indicated in the patent-in-suit, such as by random cDNA cloning and sequencing or by screening a cDNA library from the microorganisms cited therein, such as *Mortierella* or *Mucor* strains, using a probe based on the sequences SEQ ID NO:2 or 4 (cf. paragraphs [0035] and [0041] of the patent-in-suit).

14. The appellant has argued that, in the patent-in-suit, the sequences in Examples 9 to 11 are identified only as encoding putative Δ5- and Δ6-desaturases and that the activity, if any, of these putative desaturases had not been characterized. With reference to the presence of highly conserved homologous regions among members of the membrane-bound desaturase family, the appellant suggested that the putative desaturases shown in Examples 9 to 11 might not be Δ6- or Δ12-desaturases but other members of the same protein family (cf. section IX *supra*). However, this argument has not been backed up or supported by any documentary and/or experimental evidence. In absence of this evidence, appellant's argument, on its face, does not go beyond the mere formulation of possible doubts.

15. Likewise, appellant's argument concerning possible technical problems that a skilled person would encounter when using known methods for cloning Δ6- or Δ12-desaturase genes from natural sources other than *M. alpina*, has not been supported by any documentary and/or experimental evidence. No facts or evidence have been put forward to show that it would not be possible to clone further genes encoding Δ6- or Δ12-desaturases from the microorganisms mentioned in paragraph [0035] of the patent-in-suit and, particularly, those which are identified as being of particular interest such as those of the genus *Mortierella, Porphyridium* or *Mucor*. Nor has it been shown that the nucleotide sequences encoding the amino acid sequences SEQ ID NO:2 or 4, or probes derived therefrom, are not suitable for carrying out said cloning in these microorganisms. Appellant's arguments rely merely on assumptions rather than on facts like the presence of real technical difficulties

(cf. *inter alia* T 386/94, OJ EPO 1996, 658 and T 207/94, OJ EPO 1999, 273; though in the context of inventive step). It is observed that similar cloning methods are described also in document D1, which discloses the cloning of a Δ6-desaturase derived from a plant (borage), with a degree of homology to SEQ ID NO:2 lower (45%) than that required in claim 1 and thus, phylogenically far less related to *M. alpina* than the microorganisms cited in paragraph [0035] of the patent-in-suit.

16. As regards the use of methods other than cloning, in particular the so-called "mutagenesis approach", the board does not share the appellant's view that the skilled person would have to try every possible mutation for each and every position of the amino acid sequence SEQ ID NO:2 or 4 in order to arrive at the homologues encompassed by claim 1 (cf. point IX *supra*). Presented in these terms, the mutagenesis approach might well require undue experimentation and not be a realistic approach for a skilled person. However, a combination of cloning and mutagenesis may represent a more realistic situation in which the skilled person would not necessarily have to start the mutagenesis from scratch. It is worth noting that the claimed polypeptides are not required to have any particular degree or level of activity, and thus homologues with a low desaturase activity also fall within the scope of claim 1. This combined approach may require a fair amount of work, but not an undue burden of experimentation.

17. The board considers that the doubts raised by the appellant are not supported by facts or evidence and

thus, not sufficient to meet the standard applied by the case law of the boards of appeal when deciding on sufficiency of disclosure (cf. T 19/90, OJ EPO 1990, 476). Therefore, the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent as granted.

Article 100(a) EPC in connection with Article 56 EPC
Is the problem solved across the entire scope of the claims?

18. Document D1 is regarded as the closest state of the art for the assessment of inventive step. This document describes the nucleic acid and the encoded amino acid sequences of the Δ6-desaturases from ***Synechocystis*** cyanobacteria (SEQ ID NO:1 and 2) and borage (***Borago officinalis***) (SEQ ID NO:4 and 5), which have approximately 40-45% homology to SEQ ID NO:2 of the patent-in-suit. The use of these sequences for isolating and identifying nucleic acids encoding Δ6-desaturases from other organisms is also suggested in document D1 (cf. ***inter alia*** page 10, lines 6 to 22), In particular, animal cells, bacteria and certain plants as well as certain fungi, including those of the genus ***Mortierella*** (cf. page 5, lines 20 and 21), are cited as possible (natural) sources of desaturases (cf. page 5, lines 17 to 23).

19. In view of document D1, the objective technical problem to be solved can be formulated as the provision of alternative Δ6- and Δ12-desaturase genes and the encoded desaturases. There are no doubts, and it has not been contested by the appellant, that the Δ6- and Δ12-desaturase genes and the encoded desaturases from

M. alpina (SEQ ID NO:2 and 4 of the patent-in-suit) solve this problem.

20. The appellant has however argued that the technical problem is not solved across the entire scope of the claims and, in particular, it is not solved by polypeptides having amino acid sequences with "*at least 60% homology to the 457 amino acid sequence of SEQ ID NO:2 or the 399 amino acid sequence of SEQ ID NO:4*". In the appellant's view, this degree of homology is arbitrary and claim 1 encompasses many polypeptides that do not have a Δ6- or Δ12-desaturase activity, and thus do not solve the technical problem formulated above.

21. As stated in point 9 *supra*, the polypeptides defined in claim 1 are characterized by both a structural and a functional feature. Appellant's argument on inventive step, which totally disregards the presence of the functional feature in the claim, is understood by the board to be inherently linked to the arguments submitted by the appellant under Article 100(b) EPC: if the technical disclosure of the patent-in-suit does not allow a skilled person to obtain the few polypeptides with desaturase activity within the large number of polypeptides having the (arbitrarily) low degree of homology specified in claim 1, the functional feature amounts to nothing more than the formulation of a mere desire and, therefore, it should be disregarded for the purpose of assessing inventive step.

22. However, in view of the above considerations under Article 83 EPC and the conclusions drawn therefrom (cf. points 9 to 17 *supra*), the board cannot endorse

appellant's argument. The functional limitation in claim 1 cannot be disregarded at all. The scope of that claim comprises only polypeptides having both the required structural homology **and** the functional Δ6- or Δ12-desaturase activity. For these polypeptides, there can be no doubts that they solve, in a successful manner, the technical problem formulated above.

Is the solution obvious?

23. The findings of the examining division in examination proceedings regarding the non-obviousness of the claimed subject-matter were not contested in the opponent's notice of opposition, nor did the opposition division consider that there was any reason to examine them of its own motion. Accordingly, the decision under appeal is silent on this issue. This issue was not raised in the appellant's grounds of appeal which, as regards Article 56 EPC, contested, only and exclusively, the broad scope of the claims (cf. point 4 ***supra***).

24. Indeed, it was only in the board's communication pursuant to Article 15(1) RPBA that the board, when discussing the issues under Article 56 EPC, drew the attention of the parties to the examination proceedings and noted that "***none of the parties in the present appeal proceedings has explicitly referred to these specific arguments ... or to the particular documents introduced into the examination proceedings to support them***". The board further pointed out the relationship between sufficiency of disclosure and inventive step and to the fact that the "***same criteria***" had to be applied for assessing both the disclosure content of the patent-in-suit and that of the prior art documents.

25. In reply to this communication, the respondents vehemently protested against a revision of the examination proceedings. With reference to decision G 9/91 (*supra*), they stated that "*none of those facts, evidence and arguments have been put into the present proceedings, since they were, and are, irrelevant to the parameters of the opposition established by the parties to this opposition*" (cf. section X *supra*).

26. In its reply, the appellant argued that "*making an argument of lack of inventive step of the claims based on the teaching of D1 is not a new ground, and this does not contravene the procedural requirements of the EPC*" because document "*D1 has since the beginning of these proceedings always been considered as the closest prior art by the opponent*" (cf. section IX *supra*).

27. Apart from this statement of the appellant, no other submissions were made in appeal and in opposition proceedings on the obviousness - or lack thereof - of the claimed subject-matter. It was only at the oral proceedings that the appellant requested the board to have the opportunity to present its arguments on this issue.

28. This request was not allowed by the board for the following reasons:

28.1 According to Article 12(2) RPBA, the statement of grounds of appeal shall contain a party's **complete** case and specify **expressly** all the facts, **arguments** and evidence relied on. Article 13(1) RPBA states that any amendment to a party's case after it has filed its

grounds of appeal may be admitted and considered at the board's discretion.

In the present case, the appellant's statement of grounds of appeal did not include any argument regarding the obviousness of the claimed subject-matter. Hence, the introduction of this new argument at oral proceedings would represent an amendment to the appellant's case. It is thus at the board's discretion to admit and consider it.

28.2 Article 13(1) RPBA states that this discretion shall be exercised in view of, *inter alia*, the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

In the present case, the appellant failed to submit the new argument at an early stage of the appeal proceedings. Even after the board's communication in which reference was made to the examination proceedings and to the relationship between sufficiency of disclosure and inventive step (cf. point 24 *supra*), the appellant did not consider it necessary to introduce the new argument into the appeal proceedings but only referred, in very general terms, to its right to raise an objection for lack of inventive step based on document D1 (cf. point 26 *supra*). Oral proceedings in appeal are usually, if not always, the latest stage of appeal proceedings and thus, facts, arguments and evidence submitted at that stage are usually considered to be late.

28.3 The appellant argued that the new argument at oral proceedings was a direct reaction to the board's

reasoning when arriving at its opinion on Article 100(b) EPC in the oral proceedings. No other reasons were provided to justify the introduction of this argument at such a late stage of the appeal proceedings (cf. section IX *supra*).

In the light of the content of the board's communication pursuant to Article 15(1) RPBA, the board's reasoning when arriving at its opinion on Article 100(b) EPC in the oral proceedings cannot be considered to have come as a surprise to the appellant. It was in this communication that the board addressed the relationship between sufficiency of disclosure and inventive step and pointed to the use of the "*same criteria*" for both articles (cf. point 24 *supra*). The appellant could, and indeed should, have considered that the board could reach the same conclusion as the opposition division as regards Article 100(b) EPC and, if it wished the board to consider a new argument to establish inventive step based on the use of the "*same criteria*" in both Articles 83 and 56 EPC and/or on the obviousness of the claimed subject-matter, it should have set out this argument, at the very latest, in its reply to the communication of the board.

28.4 This was all the more so in view of the respondents' protest in their reply to the board's communication, in which they also announced their intention not to attend the oral proceedings (cf. sections V and X *supra*). It was in the appellant's interest to submit all new facts, arguments and evidence as soon as possible, and certainly before the oral proceedings, so as to avoid the possible risk of taking aback the respondents and/or the board, and thereby compelling the board to

adjourn the oral proceedings or to disregard these new facts, arguments and/or evidence.

28.5 Indeed, the appellant's failure to submit the new argument in reply to the board's communication deprived the respondents of the opportunity to present their comments thereon and/or of the opportunity to reconsider their intention not to attend the oral proceedings. The introduction of this new argument at oral proceedings - in the absence of the respondents - could well raise the question whether the board could arrive at a decision without violating the respondents' right to be heard (Article 113(1) EPC) or, in order to avoid it, to adjourn the oral proceedings.

28.6 In this regard, Article 13(3) RPBA states that amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the board or the other party cannot reasonably be expected to deal with without adjournment of the oral proceedings. This is in line with the need for procedural economy referred to in Article 13(1) RPBA for the board to exercise its discretion (cf. point 28.2 *supra*).

In view of the submissions made by the parties during the written phase of the appeal proceedings, the board was convinced that the introduction at oral proceedings of the appellant's new argument - with or without reference to all the evidence submitted at the examination proceedings - certainly went against the need for procedural economy and it could well require the adjournment of oral proceedings.

28.7 Thus, the board in the exercise of its discretion did not admit the appellant's request to have an opportunity to present its arguments on the obviousness of the claimed subject-matter at the oral proceedings.

29. Having considered the arguments put forward by the appellant, the board is not persuaded that the subject-matter of the claims as granted lacks inventive step within the meaning of Article 56 EPC. Thus, the ground for opposition under Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski R. Moufang