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D E C I S I O N
of 13 April 1999

Case Number: T 0236/96 - 3.3.4

Application Number: 85309453.0

Publication Number: 0188920

IPC: C12N 15/25

Language of the proceedings: EN

Title of invention:
Interleukin 1 and its derivative

Patentee:
Dainippon Pharmaceutical Co., Ltd.

Opponent:
Otsuka Pharmaceuricals Co. Ltd.

Headword:
Interleukin 1/DAINIPPON

Relevant legal provisions:
EPC Art. 83, 54, 56, 87, 89

Keyword:
"Sufficiency of disclosure - yes"
"Priority -yes"
"Novelty -yes"
"Inventive step - yes"

Decisions cited:
-

Catchword:

-

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Case Number: T 0236/96 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 13 April 1999

Appellant I: (Proprietor of the patent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 18 December 1995 concerning maintenance of European patent No. 0 188 920 in amended form.**

Composition of the Board:

Chairman: U. M. Kinkeldey

Members: F. L. Davison-Brunel
W. Moser

Summary of Facts and Submissions

I. European patent No. 0 188 920 with the title "Interleukin 1 and its derivative" was granted with 24 claims on the basis of European application No. 85 309 453.0 claiming five priorities, the earliest dated from 25 December 1984.

Granted claims 1, 3, 22 and 23 read as follows:

"1. DNA of the IL-1 precursor coding sequence depicted in Table 5 hereof, or an allelic variant of the gene containing this IL-1 precursor coding sequence as obtainable by cloning from human genomic DNA or by cloning cDNA from human macrophage-like cells."

"3. DNA, other than that encoding murine IL-1, and which encodes a modification, by way of amino acid deletion and/or replacement of the polypeptide encoded by the DNA of the precursor coding sequence as defined in claim 1 or 2, and which has IL-1 activity."

"22. A polypeptide having IL-1 activity as obtainable by a process of any one of claims 17 to 19."

"23. A polypeptide having IL-1 activity and having the amino acid sequence 113 to 271 depicted in Table 5 hereof."

Dependent claims 2, 4 to 14 specified further features of the DNA of claim 1. Claims 15 and 16 were addressed to an expression vector and a recombinant host organism containing the DNA of claims 1 to 14. Claims 17 to 21 related to processes for the production of the IL-1

polypeptide encoded by the claimed DNAs comprising or not its use as a medicament. Claim 24 related to a pharmaceutical composition comprising a polypeptide according to claim 22 or 23.

II. A notice of opposition was filed requesting the revocation of the patent in suit under Article 100(a) EPC (lack of novelty and inventive step) and under Article 100(b) EPC (insufficiency of disclosure).

III. The Opposition Division maintained the patent in suit in amended form on the basis of the auxiliary claim request filed with the submission dated 13 February 1995 and an amended description filed during oral proceedings. It was decided that the description did not provide a sufficient disclosure of the invention as claimed in claim 3 of the main request. Furthermore, claim 22 of this request, when dependent on claims 6 to 14, lacked novelty over document (7).

IV. Both Appellants I (Patentees) and Appellants II (Opponents) filed an appeal, paid the appeal fee and submitted written statements setting out the grounds of their appeals.

V. A series of exchanges of submissions followed between both Appellants.

VI. A communication was sent according to Article 11(2) of the Rules of Procedure of the Boards of Appeal, setting out the Board's provisional, non-binding opinion, together with the summons to oral proceedings.

VII. Appellants II informed the Board that they would take

no further part in the appeal proceedings, and, thus, would not attend oral proceedings before the Board.

VIII. Appellants I indicated they would withdraw their request for oral proceedings in case the Board would be prepared to maintain the patent on the basis of either of a number of requests (see par. XIII, below).

IX. Oral proceedings were cancelled.

X. The following documents on file were considered by the Board:

(1): Lomedico et al., Nature, vol. 312, pages 458 to 462, 29 November 1984,

(2): Auron et al., Proc. Natl. Acad.Sci. USA, vol. 81, pages 7907 to 7911, December 1984 (published on 10 January 1985),

(3): March et al., Nature, vol.315, pages 641 to 647, 20 June 1985,

(4): EP-A-0-188 864,

(5): EP-A-0 200 986,

(7): Krakauer, T., Preparative Biochemistry, vol. 14(5), pages 449 to 470, 30 April 1985,

(9): Cameron et al., J.Exp.Med., vol. 164, pages 237 to 250, July 1986,

(12): Old, R. and S. B. Primrose, Principles of

Genetic manipulation, Second Edition, Blackwell Scientific Publications, 1980, Chapter 11, page 164,

(16): Yanovsky, S. and G. Zurawski, The Journal of Biological Chemistry, vol. 265, pages 13000 to 13006, 1990,

(17): Mosley et al., Proc.Natl.Acad.Sci., vol. 84, pages 4572 to 4576, July 1987,

(18): Krakauer, T., Arch. of Biochem. and Biophy., vol. 234, No. 2, pages 371 to 376, November 1984.

(20): Schmidt, J., J.Exp.Med., vol. 160, pages 772 to 787, September 1984.

XI. As regards the main request, Appellants I argued essentially as follows:

Sufficiency of disclosure

Claim 3 and subsequent claims did not relate to DNAs encoding polypeptides which were homologous to human IL-1 such as IL-1 DNAs from other natural sources, but to DNAs encoding modifications of the specified amino acid sequence of human IL-1 which had IL-1 activity. Thus, whether the isolation of natural IL-1 DNAs other than human IL-1 DNA could be achieved starting from the teachings of the patent specification was irrelevant to sufficiency of disclosure. In any case, natural IL-1 DNAs other than human ones were also enabled by the specification by reference to the disclosure of the

rabbit gene made therein.

At the priority date, the skilled person could easily have isolated a DNA encoding a modification by amino acid substitution of the amino acid sequence of human IL-1 without destroying its function. Although some substitutions would destroy the activity, a great many more would not have that effect. In document (16), it was shown that even in the N-terminal one third of the protein, all of the amino acids could be substituted with retention of some activity. So far as document (17) was concerned, nothing was said as to the possibility of introducing substitution in the 140 amino acid long core sequence of human IL-1.

Priority

In the first priority application the possibility of altering IL-1 DNA in such a way that it encoded IL-1 polypeptides carrying amino acid substitution was clearly envisaged. At the priority date, the level of skill necessary to achieve this type of alteration was a matter of common general knowledge. Accordingly, claim 3 was entitled to the earliest priority date for all of its embodiments including the DNAs encoding substituted IL-1 polypeptides.

By the same token, claim 22 was entitled to the earliest priority date, insofar as it referred to claim 3 since the first priority application disclosed the concept of IL-1 gene expression.

Novelty

Claim 3

Document (1) did not disclose modifications of the mature murine sequence. Furthermore, the disclaimer of DNA encoding murine IL-1 inserted in claim 3 excluded allelic variants of murine IL-1 DNA as well as the particular mature sequence. Finally, it was scientifically unrealistic to consider the mouse IL-1 DNA sequence as a modification of the human IL-1 sequence. For all these reasons, claim 3 was novel over document (1).

The same was true in relation to document (2) which disclosed a DNA encoding a polypeptide with 25% homology to IL-1.

Documents (4) and (5) were irrelevant to the novelty of claim 3 as this claim was entitled to the earliest priority date.

Other claims

All other claims were novel over documents (1), (2), (4) or (5) either because they were entitled to the earliest priority date or because they related to DNA fragments/polypeptides with such features as were not found in the human IL-1 DNA/polypeptides disclosed in the state of the art at the relevant dates. The same was true of claim 22 in relation to document (7).

Inventive step

Claim 3 was entitled to priority rights from the first priority application. Thus, the only documents which

could be cited against inventive step were those published before the earliest priority date. At that time, there was a suggestion in the art that more than one form of human IL-1 would exist: for example, document (18) disclosed that IL-1 activity was exhibited by a number of proteins. Starting from the premices that the skilled persons might try to clone and characterize the DNA for such protein as human IL-1, there must be doubt whether they could have achieved it. A murine cDNA clone had been isolated (document (1)) which could have been used as a probe. But there was no basis for a reasonable expectation of success that the screening of human IL-1 DNA could be achieved in this way given the rather low homology between the human and murine species. Claim 3 was, thus inventive.

XII. The submissions by Appellants II with regard to the main request can be summarized as follows:

Sufficiency of disclosure

Claim 3 and subsequent claims comprised two subsets of IL-1 DNA molecules/proteins, the isolation of which could not be achieved without undue burden. These were, firstly, the subset of naturally occurring IL-1 DNA molecules which had some homology to human IL-1 DNA and, thus, could be considered as encoding modified forms of human IL-1, and, secondly, the subset of DNAs encoding human IL-1 polypeptides modified by way of amino acid replacement and which retained IL-1 activity.

With regard to the first subset, the disclosure of the

patent in suit was insufficient in that it provided no information for the cloning and expression of any IL-1 DNAs homologous to human DNA except for rabbit IL-1 DNA.

With regard to the second subset, the production of modified human IL-1 having IL-1 activity by selecting specific positions and amino acids was very difficult and unpredictable, since human IL-1 was very sensitive to mutation as shown in documents (16) and (17). These documents showed that for the protein to exhibit appreciable activity, 15 out of 53 amino terminal acid residues had to be conserved in character and the region between amino acids 128 to 267 had to be left intact.

Priority

Claim 3 was not entitled to the earliest priority date insofar as it related to DNAs which encoded a modification by way of amino acid replacement of the polypeptide encoded by the DNA of the precursor IL-1 coding sequence and which had IL-1 activity. Indeed, whilst the first priority document provided a formal basis for the wording " modification by amino acid replacement", it was not enabling with regard to making such modified DNAs encoding active IL-1.

By the same token, claim 22 as granted was not entitled to the earliest priority date insofar as it was dependent on claim 3 and therefore comprised IL-1 polypeptides carrying amino acid substitutions of the premature IL-1.

Novelty

Claim 3:

Document (1) published before the first priority date explicitly disclosed murine precursor IL-1 DNA, mature murine IL-1 DNA and a range of DNA fragments derived thereof. The three types of DNA molecules could all be considered to be modifications of human IL-1 DNA, taking into consideration that murine IL-1 was 62% homologous to human IL-1.

In claim 3, the disclaimer to murine IL-1 DNA only excluded the DNA encoding mature murine IL-1. Thus, the claim comprised the precursor murine IL-1 DNA or parts of mature IL-1 DNA as disclosed in document (1) and was not novel.

Document (2) disclosed IL-1â which was 25% homologous to IL-1. IL-1â could be considered to be a modification of IL-1. Hence claim 3 also lacked novelty over document (2).

Documents (4) and (5) were relevant to novelty pursuant to Article 54(3)(4) EPC. Both documents disclosed DNAs encoding human IL-1 polypeptides differing from those of the patent in suit in terms of amino acid replacement at positions 67 and 114 and enjoyed earlier rights of priority in respect of this disclosure than the patent in suit in respect of the subject-matter of claim 3. This claim, thus, further lacked novelty over both documents.

Claims 4, 5, 14 to 17, 20, 21, 24:

The same reasoning which led to the conclusion that claim 3 lacked novelty over documents (1), (4) or (5) applied with respect to claims 4, 5, 14 to 17. Furthermore, document (5) was detrimental to the novelty of claims 20, 21 and 24 as it disclosed pharmaceutical compositions comprising IL-1 or variants thereof.

Claim 22

This claim lacked novelty over documents (1), (2), (4) and (5), when dependent on claim 3 relating to DNA encoding IL-1 carrying amino acid alterations, for the same reasons as given in connection with claim 3.

Furthermore, documents (7) and (18) disclosed the purification from human monocytes of an IL-1 which differed by two amino acids from the polypeptide disclosed in the patent in suit (document (9)) and could, thus, be considered to be encoded by a DNA encoding a modified polypeptide within the meaning of claim 3.

They were also detrimental to the novelty of claim 22.

Inventive step

Murine IL-1 DNA sequence was cloned before the earliest priority date (document (1)). It was known from document (18) or (7) that two species of human IL-1 could be purified from human monocytes. Document (2) disclosed the cloning of a cDNA encoding a protein with IL-1 activity (IL-1â). The skilled person would have been motivated to repeat the screening procedure to

isolate the clone encoding the other IL-1 species. By using murine cDNA as a probe, it would have required only routine trial and error experiments. Obtaining therefrom DNAs encoding other natural IL-1 polypeptides could be achieved without inventive step by using the human IL-1 DNA as a probe. In the same manner, any IL-1 human DNAs encoding IL-1 modified by amino acid replacement could be isolated as a matter of routine starting from the murine sequence disclosed in document (1), the IL-1â sequence disclosed in document (2) or the IL-1 sequence disclosed in document (3).

Accordingly, claim 3 lacked inventive step. This was also true of claim 22 which was dependent on claim 3.

XIII. Appellants I requested that the patent be maintained on the basis of any of:

- the main request (description and claims as granted) or

- the first auxiliary description request (description as filed on 19 March 1999) in conjunction with the granted claims or

- the second auxiliary description request (description as amended in opposition proceedings) in conjunction with the granted claims or

- the third auxiliary claim request with claims as allowed by the Opposition Division or

- the fourth auxiliary claim request: with options (i)-(v) for modifying claim 3.

In the event the Board was not prepared to maintain the patent in suit on the basis of any of the main request, or the first and second auxiliary description request in conjunction with the claims as granted, or the fourth auxiliary claim request, options (i)-(iii), oral proceedings were requested.

Appellants II requested in writing that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. The appeals are admissible.

Main request

Sufficiency of disclosure

2. Appellants II raised an objection for lack of sufficient disclosure with respect to DNAs encoding natural IL-1 polypeptides other than human, which DNAs, in their opinion, fell within the scope of claim 3 if they encoded polypeptides homologous to human IL-1.

3. The Board observes that the patent specification describes the isolation of rabbit IL-1 cDNA which encodes an IL-1 which is 65% homologous to human IL-1. Furthermore, by disclosing in an enabling manner human IL-1 cDNA, it provides the tool necessary to isolate homologous DNAs thereto. Finally, Appellants II failed to show that DNAs encoding IL-1s homologous to human

IL-1 could not be obtained by following the teachings of the patent in suit. DNAs encoding IL-1s homologous to human IL-1 are, thus, considered enabled.

4. The possibility of isolating without undue burden modified versions of the human IL-1 polypeptide carrying amino acid substitutions **and** retaining IL-1 activity was also challenged in view of the results obtained in post-published documents (16) and (17), which are studies of the regions of human IL-1 which are important to IL-1 activity. In particular, it was argued that the sensitivity of IL-1 to mutation disclosed in document (16) would make the task difficult and unpredictable.

5. Document (16) discloses that 12 amino acid residues at the N-terminal end of mature IL-1 can be dispensed with, and 20 amino acids in that same region can be substituted by any other amino acids, without affecting biological activity (passage bridging pages 13003 and 13004 and page 13004, 1st paragraph, left hand column). 15 other amino acids also from this region can be replaced by amino acids conserved in character with the protein exhibiting appreciable activity (page 13005, right hand column). In the Board's judgment, this document shows that biologically active IL-1 can be obtained without undue burden by amino acid substitutions in the first third of the molecule. Appellants II failed to provide any evidence that amino-acid substitutions in the rest of the molecule would destroy its activity.

6. Document (17) does not present any data on modification by amino acid substitution and, thus, cannot serve to

sustain the above objection. It shows that the first 128 amino acids of premature IL-1 can be deleted without its biological activity being altered and, thus, provides evidence that DNAs which encode biologically active IL-1 molecules can be isolated without undue burden by deleting parts of DNA encoding premature IL-1.

7. The requirements of Article 83 EPC are fulfilled.

Priority

8. Claim 3 was argued not to be entitled to the earliest priority date with respect to the embodiment: "DNA ... which encodes a modification, by way of amino acid ... replacement of the polypeptide encoded by the DNA of the precursor coding sequence as defined in claim 1 or 2, and which has IL-1 activity" because the first priority document was not enabling in this regard.

9. Modifications of IL-1 by amino acid substitution is clearly contemplated in the first priority document on page 12, second paragraph from the bottom, on page 13, second and last paragraphs and on page 20, middle passage. Admittedly, no examples are provided how to isolate the corresponding DNA molecules. However, at the very end of 1984, altering DNA sequences could be achieved by the skilled person as a matter of routine (see document (12), published in 1980). An assay was available for IL-1 activity. The structure of the protein is such that it can be altered without destroying its biological activity (see point 5, supra). Accordingly, the first priority document is

enabling with regard to the embodiment defined in claim 3 as well as with regard to all other embodiments disclosed in the patent in suit.

10. The first priority document also discloses DNAs encoding biologically active parts of the IL-1 polypeptide, expression vectors, host organisms as well as processes for IL-1 expression and use in the preparation of a medicament, and pharmaceutical compositions thereof. Accordingly, claims 1 to 5, 12 as well as claims 14 to 17, 20 to 22 and 24 are entitled to the first priority date when directly or indirectly dependent on claim 3.

Novelty

Claims 1 to 5, 12 and claims 14 to 17, 20 to 22, 24 when directly or indirectly dependent on claims 3 to 5.

11. As stated above, these claims are entitled to the earliest priority date. Documents (2) and (7), which were published after that date, and documents (4) and (5), which are only entitled to a later priority date than the earliest priority date of the patent in suit, are not relevant to novelty.

12. Document (1) discloses the cloning of premature murine IL-1 DNA and of a subfragment thereof encoding the last 156 amino acids. On page 460, bottom of the right hand column, it is stated that the cloned subfragment encodes a recombinant IL-1 which "possesses the same range of biological activities as the natural IL-1 produced by murine macrophages". In the Board's judgement, this implies that both these cloned DNA

molecules fall within the definition of DNA encoding murine IL-1.

13. It was argued that claim 3 was not novel because it comprised the two murine molecules described in document (1) in spite of the disclaimer of DNA encoding murine IL-1, because this disclaimer was to be understood as directed to DNA encoding mature murine IL-1 DNA. However, there is no restriction in the disclaimer to any specific DNA encoding murine IL-1. Thus, in view of the findings in point 12 above, this argument must fail.

14. Accordingly, claims 1 to 5 and the other above mentioned dependent claims are found novel.

All remaining claims/claimed embodiments

15. In the Board's judgment, the subject-matter of all of these claims or claimed embodiments is novel as well.

16. The decision of the Opposition Division to refuse the main request was based on the opinion that claim 22, insofar as it was indirectly dependent on claims 6 to 14 which were not entitled to the earliest priority date, was also not entitled to this priority date and, thus, lacked novelty over document (7). Their reasoning was as follows: claims 6 to 14 related to DNAs which encoded specific IL-1 polypeptides. Yet, they also comprised DNAs modified therefrom, as they were dependent on claim 3 which was related to modifications of IL-1 DNA. Accordingly, claim 22 by virtue of its dependency on claims 6 to 14 comprised modifications of the specific polypeptides encoded by the DNAs of

claims 6 to 14. Document (7) disclosed the natural human IL-1 polypeptide, which could be considered as a modification of the specific polypeptides encoded by the DNAs of claims 6 to 14. Therefore, it was detrimental for the novelty of claim 22.

17. The Board cannot follow this reasoning. By virtue of their dependency on claim 3, claims 6 to 11, 13 and 14 comprise DNAs which are specific examples of the modifications envisaged in this claim. Any further modifications of the DNAs of claims 6 to 11, 13 and 14 could only be covered by these claims if they were expressly mentioned therein, which they are not. Claims 6 to 14 only comprise the DNAs which they explicitly claim. None of these DNAs encode polypeptides having the same sequence as natural human IL-1. Claim 22, thus, does not comprise the natural IL-1 polypeptide. From this, it follows that document (7) is not detrimental to the novelty of the subject-matter of claim 22.

18. For sake of completeness, it may also be remarked that it would not be possible to isolate, by way of deletion or codon replacement, modified versions of the DNAs of claims 6 to 11 encoding natural human mature IL-1 as disclosed in document (7), because the claimed DNAs encode smaller polypeptides than natural IL-1 which lack the first 112 amino-acids of premature IL-1 (document (3)).

19. Novelty is, thus, acknowledged.

Inventive step

20. Claim 3 is entitled to the first priority date. Thus, documents (1), (18) and (20) are state of the art and are to be taken into consideration.

21. Document (18) is considered the closest prior art. It discloses that human IL-1 is produced by activated macrophages and may have an effect in immunological and inflammatory reactions in addition to its ability to enhance the response of thymocyte proliferation to mitogenic stimulation. The molecule is found to comprise two major species which differ by their pIs.

22. Starting from this prior art, the objective technical problem can be defined as the provision of DNAs encoding human IL-1 and variants thereof with IL-1 activity.

23. The Board is satisfied that this problem is solved by the DNA molecules of claims 1 to 3.

24. Document (1) discloses the cloning of murine IL-1 cDNA. According to Appellants II, the availability of the cloned murine cDNA as a probe would give the skilled person a reasonable expectation of success that human IL-1 cDNA could be isolated.

25. However, documents (18) and (20) emphasize the differences between human and murine IL-1: document (18), page 375: "In this sense (the existence of more than one species of human IL-1), human IL-1 differs from that of the mouse..." (brackets added), document (20), page 773: "There is evidence that human IL-1 differs significantly from murine IL-1 with respect to its biochemical and antigenic properties". In the

Board's judgment, the skilled person aware of these two documents would not have had a reasonable expectation that the DNAs encoding murine and human IL-1 would be so homologous that the earlier could successfully serve as a probe to isolate the latter. The cloning of IL-1 DNAs and production of variants thereof is, thus, considered inventive.

26. Appellants II also presented the following argument in support of lack of inventive step: a cDNA encoding a modified version of murine IL-1 could be considered to be a DNA encoding a modified version of human IL-1 according to claim 3, because the claim did not specify which modifications of human IL-1 were intended. Starting from the cloned murine IL-1 DNA sequence disclosed in document (1), it would have been routine work to obtain DNAs encoding modified versions of murine IL-1 ie of human IL-1. Accordingly, the subject-matter of claim 3 was not inventive.

27. Following this line of argument, the technical problem to be solved could be defined as the provision of DNAs encoding modified versions of human IL-1 starting from the murine IL-1 cDNA of document (1). In the Board's judgment, such a problem can only be formulated if it is possible to identify the DNAs supposedly encoding modified versions of human IL-1 as potentially derivable from human IL-1 DNA. As the sequence of human IL-1 DNA was not known at the priority date, the reasoning must thus fail for being based on hindsight and, this, even before considering the feasibility of isolating mouse modified DNAs which could be considered to be human IL-1 modified DNAs.

28. Those claims which are not entitled to the first priority date were not challenged for lack of inventive step. But, in their submissions with regard to such embodiments of claim 3 as they deemed not to be entitled to the first priority date, Appellants II argued that the same reasoning as starting from document (1) (see point 26 above) could be carried out starting from documents (2), (3) and (7) and led to the conclusion of lack of inventive step for these embodiments. The Board will thus review the content of these documents with regard to the claims which relate to DNA molecules encoding specific modifications of human IL-1 by way of deletions and/or substitutions and are entitled to late priorities.

29. Document (7) is not concerned with cDNA cloning and document (2) discloses a DNA which has less homology to human IL-1 than murine IL-1 DNA. None of them are relevant for the same reasons as given in points 25 and 26 supra. Document (3) discloses the cloning and expression of IL-1 cDNA but does not suggest that DNAs could be isolated with specific modifications such as claimed, which would encode biologically active IL-1. It is also not relevant to inventive step.

30. The findings in points 20 to 29 above lead to the conclusion that the requirements of Article 56 EPC are fulfilled by the claims of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted

The Registry: The Chairperson:

U. Bultmann U. Kinkeldey