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Datasheet for the decision of 22 June 2018

Case Number: T 2090/14 - 3.3.04

Application Number: 04748575.0

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Language of the proceedings: EN

Title of invention:
C1 inhibitor with short half-life for transient treatment

Applicant:
Pharming Intellectual Property B.V.

Headword:
Recombinat human C1 inhibitor/PHARMING

Relevant legal provisions:
EPC Art. 54(2), 83, 84, 111(1), 123(2)

Keyword:
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2090/14 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 22 June 2018

Appellant: (Applicant)	Pharming Intellectual Property B.V. P.O. Box 451 2300 AL Leiden (NL)
Representative:	P. ten Haaft Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 13 May 2014 refusing European patent application No. 04748575.0 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairwoman	G. Alt
Members:	R. Morawetz
	L. Bühler

Summary of Facts and Submissions

I. The appeal of the applicant (hereinafter "appellant") lies against the decision of the examining division refusing European patent application No. 04 748 575.0, entitled "*C1 inhibitor with short half-life for transient treatment*", published as WO 2004/100982 (hereinafter "application as filed").

II. The following documents are referred to in this decision:

D2 WO 01/57079 (2001)

D5 Nobuhisa A. *et al.*, Brain and Nerve (2001), Abstract

D7 Horstick G. *et al.*, Circulation (2001), vol. 104, pages 3125 to 3131

III. The examining division held that the subject-matter of claims 1, 2 and 4 to 7 of the main request before it was anticipated by the disclosure of document D2 (see decision under appeal, Reasons, points 2.3.2 to 2.3.4). It also considered that the subject-matter of claims 1, 2 and 4 to 9 of auxiliary request 1, of claims 1 to 5 of auxiliary request 2, of claims 1 to 9 of auxiliary request 3 and of claims 1 to 5 of auxiliary request 4 did not fulfil the requirements of Article 54 EPC in view of the disclosure of document D2 (*ibid.*, points 2.4.2, 2.5.2, 2.6.2 and 2.7.2).

IV. With its statement of grounds of appeal, the appellant maintained the claim requests underlying the decision

under appeal, i.e. the main request and auxiliary requests 1 to 4, and filed auxiliary request 5.

V. The appellant was summoned to oral proceedings and was subsequently informed of the board's preliminary opinion in a communication under Article 15(1) RPBA.

VI. In response the appellant filed a new main request and auxiliary requests 1 to 3.

VII. In the course of the oral proceedings the appellant replaced all pending claim requests with a new main request.

Claim 1 of the new main request reads as follows:

"1. Use of a recombinant human C1 inhibitor with shorter half-life than plasma-derived C1 inhibitor for the preparation of a medicament for the transient treatment of an individual suffering from or susceptible to any of ischemic reperfusion injury after emergency coronary surgery for failed percutaneous transluminal coronary angioplasty (PCTA), or after any vascular surgery with blood vessel cross clamping; stroke; after hemorrhagic shock; after or during extra corporal circulation; after/during cardio-pulmonary bypass; after/during any transplantation surgery; intestinal ischemia; pancreatitis after manipulation of pancreatic or bile duct (ERCP), wherein the C1 inhibitor is produced in a transgenic rabbit."

The subject-matter of dependent claims 2 and 3 relates to dosages for intravenous administration.

At the end of the oral proceedings the chairwoman announced the board's decision.

VIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of the set of claims of the main request filed during the oral proceedings on 22 June 2018.

Reasons for the Decision

Main and sole request

Amendments (Article 123(2) EPC)

1. The board is satisfied that the subject-matter of claims 1 to 3 finds a basis in the application as filed on page 7, lines 11 to 15, in combination with claims 1, 10, 11 and 12.

As to claim 1 of the main request, claim 1 of the application as filed is a claim in the second medical use format relating to the use of a C1 inhibitor, specifying that it has a shorter half-life than plasma-derived C1 inhibitor and that it is for the transient treatment of an individual, while claim 10, which is dependent on claim 1, recites the disorders the individual is suffering from as now referred to in claim 1 of the main request. The passage on page 7 discloses that the C1 inhibitor used in accordance with the invention may be a human one recombinantly produced in transgenic rabbits.

The dosages according to claims 2 and 3 of the main request are disclosed in claims 11 and 12 of the

application as filed, which are both dependent on claim 1 as filed.

2. The requirements of Article 123(2) EPC are fulfilled.

Clarity (Article 84 EPC)

3. The board considers that the characterisations of the recombinant human C1 inhibitor (rhC1INH) and of the conditions to be treated according to claim 1 are clear for the skilled person, as are the indications for the route of administration and dosage in claims 2 and 3.

Sufficiency of disclosure (Article 83 EPC)

4. The board considers that the application as filed provides sufficient guidance for the skilled person to produce rhC1INH in transgenic rabbits without undue burden, see Example 1.

5. According to established case law, to fulfil the requirements of Article 83 EPC in the context of a claim for a medical use, evidence must be available in the application or as part of the common general knowledge to demonstrate the suitability of the claimed compounds for the claimed therapeutic application (see Case Law of the Boards of Appeal, 8th edition 2016, II.C.6.2). In view of the functional characterisation of rhC1INH produced in transgenic rabbits provided in the application as filed (see Examples 1, 2 and 3), and considering that document D5 (see abstract) and document D7 (see page 3125, under "Conclusions") disclose that C1INH reduces reperfusion damage and protects ischemic tissue from reperfusion damage in animal models, the board is also satisfied that the

skilled person would consider rhC1INH to be suitable for the treatment of the conditions listed in claim 1.

6. The requirements of Article 83 EPC are fulfilled.

Novelty (Article 54(2) EPC)

7. The examining division considered that the disclosure of document D2 was novelty-destroying for the subject-matter of all claim requests before it.

8. Document D2 discloses the recombinant production of C1INH in rabbits (see examples 1 to 6) and its use in the transient treatment of an individual suffering from or susceptible to C1INH deficiency, or to treat other diseases in which classical pathway complement activity and/or contact system activity contributes to undesired immune or inflammatory responses, or to treat disorders in which excess classical route complement and/or contact activation and/or C1 inhibitor consumption has been implicated in the pathophysiology (see page 18, line 14, to page 19, line 28). Specific examples of disorders falling within these indications are listed on page 18, lines 18 to 29, of document D2.

9. The subject-matter of claim 1 of the main request differs from the subject-matter of the claims before the examining division *inter alia* in that the group of diseases to be treated has been restricted to a defined group of indications. None of these indications is disclosed in document D2 (see page 18, line 14, to page 19, line 28). In the board's judgement, the disclosure of document D2 therefore does not anticipate the subject-matter of claim 1 or of claims 2 and 3 dependent on it.

10. The board concludes that the subject-matter of claims 1 to 3 is novel vis-à-vis the disclosure of document D2.

Allowability of the appeal

11. Lack of novelty vis-à-vis the disclosure of document D2 was the sole reason given in the decision under appeal for the refusal of the application. In the board's judgement (see above), the subject-matter of the claims of the main request is not anticipated by the disclosure of document D2.

12. The appeal is thus found to be allowable.

Remittal (Article 111(1) EPC)

13. Pursuant to Article 111(1) EPC, following the examination as to the allowability of the appeal, the board will decide on the appeal, and in that respect it may either exercise any power within the competence of the department which was responsible for the decision or remit the case for further prosecution.

14. Since the examining division has not dealt with inventive step and as the appellant has requested remittal, the board decides to remit the case to the examining division for further prosecution, thereby giving the appellant the opportunity to have its case heard by two instances.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution on the basis of the set of claims of the main request filed during the oral proceedings on 22 June 2018.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated