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Datasheet for the decision of 23 February 2015

Case Number: T 0053/11 - 3.3.07

Application Number: 00948171.4

Publication Number: 1200103

IPC: A61K33/00, A61P25/36

Language of the proceedings: EN

Title of invention:
XENON AS NMDA ANTAGONIST for neuroprotection

Patent Proprietor:
Imperial Innovations Limited

Opponent:
L'AIR LIQUIDE, Société Anonyme
pour L'étude et L'exploitation
des procédés Georges Claude

Headword:

Relevant legal provisions:
EPC Art. 84

Keyword:
Claims - clarity after amendment (no)

Decisions cited:
G 0005/83, T 0830/08

Catchword:

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Case Number: T 0053/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 23 February 2015

Appellant: (Patent Proprietor)	Imperial Innovations Limited 52 Princes Gate South Kensington London, Greater London SW7 2PG (GB)
Representative:	Nachshen, Neil Jacob D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Opponent)	L'AIR LIQUIDE, Société Anonyme pour L'étude et L'exploitation des procédés Georges Claude 75, Quai d'Orsay 75321 Paris Cedex 07 (FR)
Representative:	Pittis, Olivier L'Air Liquide, S.A. Direction de la Propriété Intellectuelle 75, Quai d'Orsay 75321 Paris Cedex 07 (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 November 2010 revoking European patent No. 1200103 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	P. Schmitz

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division to revoke European patent No. 1 200 103.

The patent was granted with 7 claims. Independent claim 1 read as follows:

"1. Use of xenon in the preparation of a pharmaceutical for use in neuroprotection and/or for inhibiting the development of tolerance to opiates."

II. The patent was opposed under Article 100(a) and (b) EPC on the grounds that its subject-matter lacked novelty and inventive step and was not sufficiently disclosed. The following document was among those cited during the opposition proceedings:

D8: EP 1 158 992

III. The opposition division's decision was based on two sets of claims filed as main request and auxiliary request 1 during the oral proceedings held on 26 October 2010.

Claim 1 of the main request read as follows:

"1. Use of xenon in the preparation of a pharmaceutical for use in neuroprotection, wherein the pharmaceutical is for delivery by inhalation, excluding the use of xenon or xenon gas mixtures for preparing a pharmaceutical composition for treating neurointoxications caused by a neurotransmitter excess."

Claim 1 of the auxiliary request differed from claim 1 of the main request in the wording of the disclaimer, which read as follows:

"... excluding the use of xenon or xenon gas mixtures for preparing a pharmaceutical composition for treating neurointoxications by reducing the release of dopamine, glutamate and/or noradrenalin from neurons."

IV. In its decision the opposition division came to the conclusion that the disclaimer introduced in claim 1 of the main request in order to restore novelty over the post-published document D8 did not comply with the requirements set forth in Enlarged Board of Appeal decision G 1/03. In particular, claim 1 was not clear in view of the introduction of the disclaimer, and its subject-matter was still not novel over document D8. Hence, the criteria defined in G 1/03 for the admission of a disclaimer were not fulfilled and the requirements of Articles 123(2), 84 and 54(3)(4) were not met.

The same objections applied to the subject-matter of the first auxiliary request.

V. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal sent on 25 March 2011 he requested that the decision under appeal be set aside and that the patent be maintained on the basis of a main request or alternatively on the basis of auxiliary requests 1 to 4 filed therewith.

The main request and auxiliary request 4 were identical respectively to the main request and to the auxiliary request of the appealed decision.

Claim 1 of auxiliary requests 1 to 3 differed from claim 1 of the main request only in the wording of the disclaimers, which read as follows:

Auxiliary request 1:

"... excluding the use of xenon or xenon gas mixtures for preparing a pharmaceutical composition for treating neurointoxications."

Auxiliary request 2:

"... excluding the use of xenon or xenon gas mixtures for preparing a pharmaceutical composition for treating neurointoxications caused by uncontrolled neurotransmitter release."

Auxiliary request 3:

"... excluding the use of xenon or xenon gas mixtures for preparing a pharmaceutical composition for treating neurointoxications caused by increased neurotransmitter release."

VI. The opponent (respondent) replied to the grounds of appeal with a letter dated 24 August 2011.

VII. By letter dated 10 April 2014, the board summoned the parties to oral proceeding to be held on 9 December 2014.

On 27 August 2014 the respondent communicated his decision not to attend oral proceedings. The appellant did the same by letter dated 3 December 2014. The parties were informed by the board with a fax sent on 5 December 2014 that the oral proceedings were cancelled.

VIII. As far as relevant to the present decision, the appellant's written arguments can be summarised as follows:

The earlier filed application D8 claimed the use of xenon for preparing a pharmaceutical composition for treating neurointoxications caused by a neurotransmitter excess. In contrast, the opposed patent claimed the use of xenon in broader terms, namely in the manufacture of a pharmaceutical for use in neuroprotection in general, but explicitly excluded that portion of the invention overlapping with D8, i.e. treating neurointoxications caused by a neurotransmitter excess. The term "neuroprotection" was not equivalent to "neurointoxications caused by an excess of neurotransmitter", and it was therefore appropriate to exclude the narrower term of D8 from the broader term claimed in the patent. Contrary to D8, the invention of the opposed patent was based on the ability of xenon to act as an antagonist of NMDA receptors. By virtue of this different mechanism of action, the invention opened up the possibility of providing neuroprotection in a broader context, for example in circumstances in which there was no excess of neurotransmitter.

IX. As far as relevant to the present decision, the respondent's written arguments can be summarised as follows:

Claim 1 did not comply with the requirements of clarity, in that it was not possible to make a clear distinction between patients suffering from a neurointoxication caused by a neurotransmitter excess and patients suffering from other forms of neurointoxication. Furthermore, the therapeutic applications covered by

claim 1 were not clearly defined, and also the description of the patent did not provide any example of disease falling within the scope of the claim.

X. The appellant requested that the decision under appeal be set aside and that the patent be maintained according to the main request or auxiliary requests 1 to 4 filed with the statement setting out the grounds of appeal of 25 March 2011.

XI. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Main request

1. Article 84 EPC

Since claim 1 was amended after grant, objections under Article 84 EPC may be raised for any lack of clarity arising out of the amendment.

1.1 Claim 1 of the main request is worded in accordance with the Swiss-type format, which was introduced by decision G 5/83 in order to allow the protection of an invention relating to a new and inventive therapeutic application of a known substance. A claim drafted in this format satisfies the requirements of clarity only if the therapeutic application is clearly defined in it. This implies that the disease to be treated, which is an element of the therapeutic application, must also be clearly defined (see for instance T 830/08, reasons 4).

Claim 1 is furthermore characterised by the presence of a disclaimer which was introduced in order to restore the novelty of the claim over the disclosure of the

post-published document D8. In view of the introduction of this disclaimer, the diseases covered by the claim are defined in a functional manner and can be seen as the result of the exclusion of neurointoxications caused by a neurotransmitter excess from the diseases requiring neuroprotection.

Thus, the question underlying the issue of clarity is whether the skilled person could clearly attribute a disease or group of diseases to the functional definition of claim 1.

1.1.1 As a preliminary remark the board observes that the patent does not disclose any single example of disease unambiguously covered by the definition of claim 1. As examples of conditions requiring neuroprotection, only ischaemic and traumatic injuries are mentioned in the patent (see [0026]). However, according to document D8 craniocerebral trauma (i.e. a traumatic injury) and ischaemia are diseases associated with an excessive release of neurotransmitters (see [0026]). Hence, the two diseases mentioned in the patent fall in the area of the diseases disclaimed from claim 1, or at least overlap with that area. Accordingly, none of these diseases is clearly covered by the scope of claim 1.

1.1.2 In view of the above, it must be investigated whether the skilled person would be able to determine which group of diseases are covered by the functional definition of claim 1, even in the absence of specific examples in the patent, by relying on the general information contained in the description and on the common knowledge.

In this respect it is observed that according to the definition given in the patent, the term

"neuroprotection" means protecting a neural entity, such as a neuron, at a site of injury (see [0026]). It was agreed by the parties that the concept of "neuroprotection" comprises the treatment of neurointoxications caused by a neurotransmitter excess. Hence to establish which diseases are covered by the patent, it is necessary to split up the general group of diseases requiring neuroprotection into two sub-groups, the first one consisting of neurointoxications caused by a neurotransmitter excess and the second one consisting of all the remaining diseases.

However, neither the description of the patent nor document D8, which discloses the subject-matter of the disclaimer, provides objective criteria, such as experimental tests, useful in determining whether a disease requiring neuroprotection is or is not a neurointoxication caused by a neurotransmitter excess. There is also no indication that such criteria form part of the general knowledge in the field of the patent.

Accordingly, in the absence of any general procedure based on objective criteria, the skilled person would have to set up his own method of determining whether a disease requiring neuroprotection is a neurointoxication caused by an excess of neurotransmitter. In the board's opinion such a cumbersome procedure for determining which diseases are covered by the claim is not compatible with the requirement of clarity. Furthermore, it would result in an assessment of the subject-matter of the claim which is not objective, which also goes against the principles underlying Article 84 EPC.

1.2 The appellant argued that the invention of the patent in suit was based on the observation that xenon was able to act as an antagonist of the NMDA receptors. This

property of xenon, which was not mentioned in D8, opened the possibility of providing neuroprotection in a broader context, i.e. also in circumstances in which there was no excess of neurotransmitter.

In the board's opinion, this argument does not address the main issue underlying the problem of clarity, namely the possibility of making a clear distinction between the diseases covered by the claim and the diseases which are excluded by virtue of the disclaimer. It is not disputed that the discovery of a new mechanism of action may potentially result in the use of xenon for the treatment of diseases which are not mentioned in D8. However, as discussed before, the patent neither discloses these diseases nor provides criteria for distinguishing them from the neurointoxication caused by an excess of neurotransmitter.

1.3 In the light of the above, the board concludes that claim 1 does not comply with the requirements of Article 84 EPC.

Auxiliary requests 1 to 4

2. Claim 1 of each auxiliary request differs from claim 1 of the main request in the wording of the disclaimer.

2.1 The considerations set out in respect of the subject-matter of claim 1 of the main request, in particular with regard to the absence of any indication of specific diseases covered by the claim (see point 1.1.1) and with regard to the absence of any objective criteria for distinguishing the diseases falling in the ambit of the disclaimer from the other diseases requiring neuroprotection (see point 1.1.2), also apply to claim 1 of the auxiliary requests. The board notes in this

respect that the appellant did not submit any specific argument regarding the subject-matter of the auxiliary requests.

It follows that claim 1 of the auxiliary requests likewise does not fulfil the requirements of Article 84 EPC.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated