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# Datasheet for the decision of 29 May 2018

**Case Number:** T 0433/14 - 3.3.04

**Application Number:** 03772495.2

**Publication Number:** 1583541

**IPC:** A61K38/26, A61P25/00, A61K38/23, A61K38/27, A61K38/22

**Language of the proceedings:** EN

**Title of invention:**
Compounds and methods for increasing neurogenesis

**Patent Proprietor:**
Newron Sweden AB

**Opponents:**
Novo Nordisk A/S
Amylin Pharmaceuticals, Inc.

**Headword:**
Increasing neurogenesis/NEWRON

**Relevant legal provisions:**
EPC Art. 54
RPBA Art. 12(4), 13(1)

**Keyword:**
Novelty - main request (no) - auxiliary requests 1-9 and 20 (no)
Late-filed auxiliary request 22 - admitted (no)

**Decisions cited:**
G 0005/83, T 0019/86, T 0290/86, T 0893/90, T 0836/01, T 0384/03, T 0406/06, T 1642/06, T 1955/09

**Catchword:**

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**Case Number: T 0433/14 - 3.3.04**

# D E C I S I O N
# of Technical Board of Appeal 3.3.04
# of 29 May 2018

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Newron Sweden AB<br>Södra Fiskartorpsvägen 15 C<br>114 33 Stockholm (SE) |
| **Representative:** | Owen, Deborah Jane<br>Dehns<br>St Bride's House<br>10 Salisbury Square<br>London, EC4Y 8JD (GB) |
| **Respondent:** (Opponent 1) | Novo Nordisk A/S<br>Novo Allé<br>2880 Bagsvaerd (DK) |
| **Representative:** | Potter Clarkson LLP<br>The Belgrave Centre<br>Talbot Street<br>Nottingham NG1 5GG (GB) |
| **Respondent:** (Opponent 2) | Amylin Pharmaceuticals, Inc.<br>9360 Towne Centre Drive<br>San Diego, CA 92121 (US) |
| **Representative:** | Hoffmann Eitle<br>Patent- und Rechtsanwälte PartmbB<br>Arabellastraße 30<br>81925 München (DE) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 10 December 2013 revoking European patent No. 1583541 pursuant to Article 101(3)(b) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chair** | G. Alt |
| **Members:** | A. Chakravarty |
| | M. Blasi |

## Summary of Facts and Submissions

I. An appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke European patent No. EP 1 583 541. The patent has the title "*Compounds and Methods for Increasing Neurogenesis*". The application from which the patent originated was filed on 20 November 2003, claiming priority from US application 427912P filed on 20 November 2002.

II. Two oppositions were filed against the patent on the grounds of Article 100(a) EPC (lack of novelty, Article 54 EPC and lack of inventive step, Article 56 EPC), Article 100(b) EPC and Article 100(c) EPC. The opponents are respondents (I and II, respectively) to the appeal of the patent proprietor.

III. In the decision under appeal, the opposition division considered a main and nine auxiliary requests. It held that the subject-matter of claims 1 and 13 of the main request lacked novelty and that this conclusion also applied to the subject-matter of auxiliary requests 1 to 9.

IV. With the statement of grounds of appeal, the appellant re-submitted the main and auxiliary requests 1 to 9 considered by the opposition division and submitted auxiliary requests 10 to 21, not considered by the opposition division. The statement of grounds of appeal was also accompanied by documents D34 to D37.

V. Claim 1 of the main request reads:

"1. At least one agent that elevates intracellular cAMP levels in neural tissue, wherein said agent is selected

from the group consisting of Thyrocalcitonin, Calcitonin, Glucagon-Like Peptide-1 (7-37), Exendin-3 and Exendin-4, and analogs of Glucagon-Like Peptide-1 (7-37), Exendin-3 or Exendin-4, wherein said Glucagon-Like Peptide-1 (7-37), Exendin-3 or Exendin-4 analog interacts with a G-protein coupled receptor (GPCR) which is the Glucagon-like peptide 1 receptor, for use in increasing neurogenesis in neural tissue of a patient exhibiting a central nervous system disorder selected from the group consisting of neurodegenerative disorders, ischemic disorders, neurological traumas, and learning and memory disorders, wherein the agent increases neurogenesis in the patient, thereby increasing neurogenesis in the neural tissue of the patient, and wherein increasing neurogenesis is increasing proliferation, differentiation, migration or survival of an adult neural stem cell in said neural tissue".

Claim 1 of auxiliary request 1 is the same as claim 1 of the main request.

Claim 1 of auxiliary request 2 is the same as claim 1 of the main request except that thyrocalcitonin, calcitonin have been deleted from the agents listed.

Claim 1 of auxiliary request 3 is the same as claim 1 of the main request except that the group of agents consists of only glucagon-Like Peptide-1 (7-37), Exendin-3 and Exendin-4, while in auxiliary request 4, Exendin-4 is the only agent mentioned.

Claim 1 of auxiliary request 5 is the same as claim 1 of the main request except that the phrase "and wherein increasing neurogenesis is increasing proliferation, differentiation, migration or survival of an adult

neural stem cell in said neural tissue" is replaced by the phrase "and wherein increasing neurogenesis is increasing proliferation of an adult neural stem cell in said neural tissue".

Claim 1 of auxiliary requests 6 to 9 combines the amendments made in auxiliary requests 1 to 4 with those made in auxiliary request 5.

Claim 1 of auxiliary request 20 is the same as claim 1 of the main request with the addition of the phrase "to replace neural cells that have been lost or destroyed" at the end of the claim.

Finally, claim 1 of auxiliary request 22 is the same as claim 1 of the main request with the deletion of "neurodegenerative disorders and learning and memory disorders" from the list of disorders.

VI. Respondents I and II filed replies to the statement of the grounds of appeal. Respondent II also filed document D38.

VII. In preparation of the oral proceedings, the board had issued a communication on 10 November 2017 in which the board gave a preliminary opinion on the issue of novelty and *inter alia* drew attention to decision T 406/06.

VIII. Oral proceedings before the board were held on 29 May 2018. The appellant attended the oral proceedings, while the respondents were absent, having informed the board in writing that they would not attend. During the oral proceedings, the appellant withdrew auxiliary requests 10 to 19 and 21 and filed auxiliary request 22. At the end of the oral

proceedings, the chair announced the decision of the board.

IX. The following document is referred to in this decision:

D12: WO 03/011892, published on 13 February 2003

Documents D34 to D38 are also mentioned but it is not necessary to provide their bibliographic details for the purposes of this decision (see point 2. of the reasons).

X. The appellant's arguments made in writing and at the oral proceedings can be summarised as follows.

*Priority - Article 87 EPC*
*All requests*

The appellant made no submissions on the right to priority of any of the claimed subject-matter.

*Novelty - Article 54 EPC*
*Main request and auxiliary requests 1 to 9 - claim 1*

The invention lay in the use of the agents recited in the claim for increasing neurogenesis in neural tissue of a patient exhibiting a central nervous system disorder selected from the group mentioned in the claim, wherein the agent increased neurogenesis in the neural tissue of the patient, wherein increasing neurogenesis was increasing proliferation, differentiation, migration or survival of an adult neural stem cell in said neural tissue.

The subject matter of the independent medical use claims of the main request and of auxiliary requests 1

to 9 had been incorrectly found by the opposition division to lack novelty in view of the disclosure of document D12. However, document D12 did not disclose the use of any agent for the proliferation of adult neural stem cells (NSCs). Instead, it disclosed "*a method of promoting neuronal differentiation or proliferation, comprising contacting one or more neurons or neuronal precursor cells with a polypeptide comprising GLP-1, exendin-4, or a differentiation-inducing or proliferation-inducing GLP-1 or exendin-4 analogue*" (see page 21, line 22 to page 22, line 6). "*[N]euronal precursor cells*" were neuronal, i.e. they developed into neurons, and were not NSCs. These latter were undifferentiated and could still become any of neurons, astrocytes or oligodendrocytes (see paragraph 5 of the patent). Thus, the invention described in document D12 was at most a disclosure of using Exendin-4 or GLP-1 or analogues thereof to affect neurons or neuronal precursor cells, but not adult NSCs.

In fact, no proliferative effect of the claimed agents on any cell type was demonstrated in document D12. Instead, that document disclosed only a neuroprotective effect, i.e. a mechanism through which neurons are protected from damage. This effect occurred directly at the neuron level and could not result in the generation of new neurons or any other progeny of neural stem cells. In contrast, the neurogenesis effect disclosed in the patent occurred at the NSC level and allowed regenerative therapy which could replace lost or damaged neurons. This was a clinical effect that was distinct and independent from that disclosed in document D12 and was reflected in the wording of the claim.

Thus, the claimed agents were for use in a new clinical situation, i.e. in the treatment of a group of subjects (patients) distinguishable from those treated according to document D12. The new patient group consisted of those patients for whom neuroprotective treatments would be ineffective, i.e. those who were at a disease stage where neurons had already been destroyed. The treatment defined in the claim involved stimulating adult NSCs to divide. These subsequently migrated to the site of the damage, replacing the lost neural cells. Examples of patients who could benefit were those suffering from ischemic disorders such as stroke or neurological trauma, where there was sudden and essentially complete loss of neurons.

Decisions T 290/86, T 836/01, T 1642/06, and T 1955/09 dealt with situations similar to the present one in which subject-matter defined in a claim by a technical effect was novel over the prior art due to that effect defining a new clinical situation (new patient group).

*Auxiliary request 20*
*Admission - Article 12(4) RPBA*

Auxiliary request 20, filed together with the statement of grounds of appeal, was a direct reaction to section 6.13 of the decision of the opposition division. The amendments made in claim 1 of auxiliary request 20 were done to emphasise the fact that the claimed agents were for a new clinical situation and hence for a new patient group. They made explicit a feature that had been implicit in the preceding requests and therefore did not change the case being made. The request was therefore admissible.

*Novelty - Article 54 EPC*
*Claim 1*

The claim included the phrase "to replace neural cells that have been lost or destroyed" which emphasised the fact that the claimed agents were for a new clinical situation and hence for a new patient group. The claimed subject-matter was novel in the light of the disclosure in document D12 because of this new clinical situation and new patient group.

*Auxiliary request 22*
*Admission - Article 13(1) RPBA*

Auxiliary request 22 was filed to take into account the board's finding at oral proceedings and could therefore not have been filed earlier. It focused the claim on diseases in which there was a need to replace lost or destroyed neural cells, i.e. ischemic disorders and neurological traumas. Since the amendments were merely deletions, the subject-matter now claimed had been present since the grant of the patent, thus no one could be taken by surprise by the subject-matter of the amended claims. In view of the above, the request should be admitted into the proceedings.

XI. The respondents' arguments made in writing and relevant to the decision can be summarised as follows:

*Priority - Article 87 EPC*
*All requests*

It was noted that the appellant had not disagreed with the conclusion reached in the decision under appeal that the claimed priority of the patent was invalid. This view was agreed with.

*Novelty - Article 54 EPC*
*Main and auxiliary requests 1 to 9 - claim 1*

In view of the lack of a valid right to priority, document D12 was prior art for the subject-matter of all these claim requests. The opposition division had been right to revoke the patent due to a lack of novelty of the claimed subject-matter over the disclosure in document D12 of the same agents for the treatment of the same patients having the same disorders as recited in the claim.

Document D12 disclosed GLP-1 and Exendin-4 peptides and analogues thereof, as well as their uses, in particular their use in the treatment of subjects with a neurodegenerative condition and their use in reducing one or more symptoms of a neurodegenerative condition (see page 22, line 30 to page 23, line 3). Such conditions were for example Parkinson's disease or Alzheimer's disease (see page 24, line 27).

Contrary to the view of the appellant, document D12 disclosed not only neuroprotection, but also the actual creation of new neurons: page 22, line 30 to page 23 line 7 read: "*The present invention also relates to a method of treating a subject with a neurodegenerative condition or of reducing one or more symptoms of a neurodegenerative condition in a subject, comprising administering to the subject a therapeutically effective amount of a polypeptide comprising GLP-1, exendin-4, or a therapeutically effective GLP-1 or exendin-4 analogue. More specifically, the treatment could be directed to neurodegenerative conditions selected from the group consisting of Alzheimer's disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, stroke, multiple*

*sclerosis, brain injury, spinal cord injury, and peripheral neuropathy*".

Some of the claims of document D12 explicitly referred to the identical invention claimed in the opposed patent, while others mentioned the treatment of specific diseases. For example, claim 78 read: "*A method of promoting neuronal differentiation or proliferation, comprising contacting one or more neurons or neuronal precursor cells with a polypeptide comprising GLP-1, exendin-4, or a differentiation-inducing or proliferation-inducing GLP-1 or exendin-4 analogue*" and claim 88 read: "*A method of treating a subject with a neurodegenerative condition or of reducing one or more symptoms of a neurodegenerative condition in a subject, comprising administering to the subject a therapeutically effective amount of a polypeptide comprising GLP-1, exendin-4, or a therapeutically effective GLP-1 or exendin-4 analogue*".

Thus, these claims specifically disclosed a method of promoting neuronal differentiation or proliferation comprising contacting neuronal precursor cells with GLP-1, Exendin-4 or an analogue thereof and also a method of treating a patient with a disease such as Alzheimer's or Parkinson's with GLP-1 or Exendin-4 or an analogue thereof.

The appellant argued that the claimed subject-matter related to a neurogenic effect not disclosed in document D12. However, the claim referred to the increase of proliferation, differentiation, migration, or survival and was not limited to subject-matter relating to neurogenesis, even if this effect were indeed new. Moreover, the claimed subject-matter was not directed to treatment of patients in a new clinical

situation. Document D12 already disclosed the administration of GLP-1, Exendin-4 and analogues to the CNS to treat patients having central nervous system disorders, such as Alzheimer's disease and Parkinson's disease.

Some of the appellant's arguments on novelty were based on the treatment of specific patient groups having "*severe physical trauma*", "*intrauterine damage*", "*hypoxic-ischemic encephalopathy*" and other specific conditions. However, the claims of the requests on file were not limited to these specific situations.

It was true that two different mechanisms of action of a drug might split a group of patients being treated into two distinct subgroups, as in the cases considered in decisions T 19/86 and T 893/90. However, this was clearly not the case here because the patent did not disclose any new sub-groups of patients to be treated.

Even if the physiological effects mentioned in the claim were not known in the state of the art, these could only be regarded as the discovery of additional items of knowledge about further mechanisms of action underlying the known therapeutic application.

*Auxiliary request 20*
*Admission - Article 12(4) RPBA*

Claim 1 and 13 of this request contained the entirely new feature "*to replace neural cells that have been lost or destroyed*". The request thus dealt with issues that had been part of the proceedings before the opposition division all along and should therefore have been filed during these proceedings. Furthermore, the

added feature was taken from the description and did not simplify the issues, but rather introduced further problems. Finally, the amended subject-matter was not *prima facie* allowable. Hence, the request should not be admitted into the proceedings.

*Novelty - Article 54 EPC*
*Claim 1*

The arguments presented for the main request applied equally to the subject-matter of this request. The claim included the additional feature "to replace neural cells that have been lost or destroyed". This additional feature did not restore novelty because most clinical situations disclosed in document D12 were the same as those claimed and also comprised the loss or destruction of neural cells, e.g. stroke or brain injury, peripheral nerve injury or injury of the central nervous system, neurodegenerative conditions such as Alzheimer's or Parkinson's disease and they were also treated by the replacement of the missing neural cells through the regenerative capacity of the administered compounds.

XII. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the one of the sets of claims of the main request or auxiliary requests 1 to 9 or 20, all filed with the statement of grounds of appeal, or further alternatively, on the basis of the claims of auxiliary request 22 filed during the oral proceedings before the board.

XIII. Both respondents requested that the appellant's appeal be dismissed. In addition, respondent I requested to not remit the case to the opposition division and

respondent II requested that auxiliary requests 10 to 21 and documents D34 to D37 be held inadmissible and that document D38 be admitted into the proceedings.

## Reasons for the Decision

1. Neither of the duly summoned respondents attended the oral proceedings before the board, which were then held in their absence (Rule 115(2) EPC). In accordance with Article 15(3) RPBA both respondents are treated as relying on their written case.

*Admission of documents D34 to D38*

2. This issue was not decided by the board. None of the parties relied on any of these documents in their submissions relevant to the present decision and the board has not relied on them to reach the decision.

*Main and auxiliary requests 1 to 9 and 20 - claim 1*
*Priority - Article 87 EPC*

3. The opposition division held that the subject-matter of the patent and of the main and auxiliary requests was not entitled to the priority claimed from US application 427912P filed on 20 November 2002 (see decision under appeal, section 4). This finding was not disputed by the appellant.

4. In view of the above, the board sees no reason to depart from the conclusion reached in the decision under appeal. Thus, the relevant date for the assessment of novelty is the filing date of the patent, 20 November 2003. Consequently, document D12, published on 13 February 2003 is comprised in the state of the art pursuant to Article 54(2) EPC.

*Main and auxiliary requests 1 to 9 - claim 1*
*Novelty - Article 54 EPC*

5. Article 54(5) EPC provides that the general rules of law relating to novelty do not exclude the patentability of any substance or composition, comprised in the state of the art, for any specific use in a method referred to in Article 53(c) EPC, provided that such use is not comprised in the state of the art.

6. Claim 1 of each of the requests considered here is such a "purpose-limited product claim", wherein the product is selected from the group consisting of thyrocalcitonin, calcitonin, glucagon-like peptide-1 (7-37), Exendin-3 and Exendin-4, and analogs of glucagon-like peptide-1 (7-37), Exendin-3 or Exendin-4 and the specific use (the medical purpose) is the therapeutic treatment of a patient exhibiting a central nervous system disorder selected from the group consisting of neurodegenerative disorders, ischemic disorders, neurological traumas, and learning and memory disorders.

7. Claim 1 of the each of the main and auxiliary requests 1 to 4 further specifies the mechanism by which the therapeutic treatment is achieved, i.e "wherein the agent increases neurogenesis in the patient, thereby increasing neurogenesis in the neural tissue of the patient, and wherein increasing neurogenesis is increasing proliferation, differentiation, migration or survival of an adult neural stem cell in said neural tissue."

8. Claim 1 of each of auxiliary requests 5 to 9 specifies the mechanism by which the therapeutic treatment is achieved in the same way, except that "increasing

neurogenesis" is defined only as "increasing proliferation of an adult neural stem cell in said neural tissue".

9. Thus, the feature "wherein the agent increases neurogenesis in the patient, thereby increasing neurogenesis in the neural tissue of the patient, and wherein increasing neurogenesis is increasing proliferation of an adult neural stem cell in said neural tissue" is common to claim 1 of all claim requests and is the feature dealt with in considering the main and auxiliary requests 1 to 9.

10. The respondents argue that the disclosure in document D12 anticipates the claimed subject-matter. Given that the appellant did not contest that document D12 discloses the claimed product for a medical use, the question to be answered in deciding on the novelty of the claimed subject-matter is whether or not there is a disclosure in document D12 of any of Thyrocalcitonin, Calcitonin, Glucagon-Like Peptide-1 (7-37), Exendin-3 and Exendin-4, and analogs of Glucagon-Like Peptide-1 (7-37), Exendin-3 or Exendin-4 for any of the specific uses mentioned in claim 1.

11. Claim 88 of document D12 reads *"A method of treating a subject with a neurodegenerative condition or of reducing one or more symptoms of a neurodegenerative condition in a subject, comprising administering to the subject a therapeutically effective amount of a polypeptide comprising GLP-1, exendin-4, or a therapeutically effective GLP-1 or exendin-4 analogue".*

Furthermore, document D12 at page 21, line 6 to page 22, line 6 discloses an agent as presently claimed, i.e. "*GLP-1, exendin-4, or a differentiation-inducing*

*or proliferation-inducing GLP-1 or exendin-4 analogue*", for the specific medical uses disclosed on page 21, lines 16 to 21, in particular, therapeutically treating a "*neurodegenerative condition or* [...] *diseases, including, for example, Alzheimer's disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, multiple sclerosis, and peripheral neuropathy*", ischemic disorders ("*stroke*"), neurological traumas ("*brain or spinal cord injury*"), and learning and memory disorders (cf. *Alzheimer's disease*). This subject-matter falls within the ambit of the present claims.

12. As set out in point 9. above, claim 1 of each request includes the feature according to which the treatment is achieved by "*increasing neurogenesis in the neural tissue of the patient*" by "*increasing proliferation of an adult neural stem cell in said neural tissue*". The board is of the view that the above mentioned physiological effects inherently occur when treating subjects in accordance with the relevant disclosure of document D12. In other words they describe a mechanism for the treatment disclosed in document D12. These features therefore cannot serve to differentiate the claimed subject-matter from that disclosed in document D12.

13. The appellant argued that document D12 did not disclose the use of any of the agents recited in claim 1 (of each the main and auxiliary requests 1 to 9) for the proliferation of any type of cells, in particular not of adult neural stem cells. Instead, the document was said to disclose the protection of neural cells/neural precursor cells from damage. This difference, which was established by the wording of the claim, was said to allow the treatment of a distinct clinical situation

and of a different patient group from the one disclosed as treated in document D12. Thus the therapeutic use (i.e. the specific use of Article 54(5) EPC) of the claimed subject-matter differed from that disclosed in document D12.

14. Although the respondents disputed the appellant's interpretation of the disclosure of document D12 as not disclosing a neuroproliferative effect for GLP-1, Exendin-4 and analogues thereof, the board is of the view that this issue need not be decided because, even if it were accepted that document D12 does not disclose a neuroproliferative effect of the claimed agents, it does disclose the presently claimed agents, i.e. Exendin-4 and GLP-1, for use in treating a patient suffering from a neurodegenerative disease or neurological trauma (see point 11., above) and thus discloses subject-matter identical to that presently claimed.

15. The board's view, based on the evidence before it, is that the physiological effects referred to in the claim describe a mechanism underlying the therapeutic use known from document D12. Thus, these effects cannot serve to define a new clinical situation or a new (sub)group of patients to be treated. It is therefore of no consequence to the novelty of the claimed subject-matter that there may exist a patient group that could benefit from the claimed invention but not from the therapeutic treatment disclosed in document D12, because the claimed subject-matter is not directed to such a group. The appellant's arguments that the claimed subject-matter is novel because it relates to a new patient group and thus a new clinical situation therefore fail.

16. The appellant further argued that "*new groups of patients can be identified and treated with the presently claimed invention, which cannot be treated by the therapies discussed in D12 and D10. [...] said new clinical situations (new sub groups of patients) [are] sufficient for establishing novelty over the prior art, in line with decisions T1642/06, T836/01, T384/03 and T290/86*".

17. The board notes however that the presently claimed subject-matter is not limited to a new clinical situation or to a new patient group but is for a clinical situation and patient group that is either identical or overlapping with that known from document D12.

18. Such a situation also underlay the considerations in decision T 406/06. Here the board, in a different composition, noted that "*it is not stated in G 5/83 that novelty of a therapeutic use can be established merely on the basis of a new technical effect*" and that "*in interpreting decision G 5/83, the boards of appeal have [...] ruled that a new technical effect alone is not sufficient to establish novelty of a second medical use, but that a therapeutic use may only be considered as novel if the new technical effect also leads to a truly new industrial/commercial application or activity*" (see reasons 12.3).

19. As set out in point 15. above, the board considers that the presently claimed subject-matter does not relate to a new clinical situation or to a new (sub)group of patients to be treated, and therefore differs from the circumstances of the cases underlying the decisions cited by the appellant.

20. For the above reasons the board concludes that the subject-matter of claim 1 of the main and auxiliary requests 1 to 9 lacks novelty.

*Auxiliary request 20*
*Admission - Article 12(4) RPBA*

21. Article 12(4) RPBA provides that everything presented in the statement of grounds of appeal or in the reply in accordance with Article 12(2) RPBA shall be taken into account, subject to the power of the board to hold inadmissible, *inter alia* requests which could have been presented or were not admitted in the first instance proceedings.

22. Auxiliary request 20 was filed with the statement of grounds of appeal and addresses aspects of novelty mentioned in the decision under appeal. It is considered by the board as a legitimate reaction to these. Thus the board decided not to exclude it from the appeal proceedings.

*Novelty - Article 54 EPC - Claim 1*

23. The claim includes the phrase "to replace neural cells that lost or destroyed". This feature is considered as further describing a mechanism inherent in the treatment disclosed in document D12. The finding of lack of novelty set out above for claim 1 of the main request therefore applies to the subject-matter of the claim, *mutatis mutandis*.

*Auxiliary request 22*
*Admission - Article 13(1) RPBA*

24. The request, filed after the statement of grounds of appeal, represents an amendment to the appellant's case. Hence, pursuant to Article 13(1) RPBA, it may be admitted and considered at the board's discretion.

25. The claim request was filed during the oral proceedings before the board, i.e. at a very late stage of the appeal proceedings. Considering that the board had issued a communication setting out its preliminary opinion and that at oral proceedings the case did not develop in an unforeseeable manner, the board can see no reason why the claim request could not have been filed at an earlier stage of the appeal proceedings, thus allowing it to be duly considered by the board before the oral proceedings. The appellant's argument that the board's opinion only became clear after it had given its opinion at the oral proceedings, was not convincing in view of the fact that the finding of lack of novelty was based on objections raised in the respondents' replies to the statement of grounds of appeal.

26. A further criterion that the boards may also apply when exercising their discretion to admit or not such late-filed requests is whether or not the claims of such a request are clearly allowable. A claim is clearly allowable if, ideally, the board can quickly ascertain that it does not give rise to new objections and overcomes all outstanding objections under the EPC and its patentability can be assessed without giving rise to any difficulty or delay. There must be no doubt that the late-filed requests meet the formal requirements and that they constitute a promising attempt to counter

all the outstanding objections, at least the ones so far addressed (see Case Law of the Boards of Appeal, 8th edition 2016, IV.E.4.4.2(a)).

27. Claim 1 of auxiliary request 22 is amended compared to that of the main request to limit the disease to be treated to ischemic disorders and neurological traumas. Document D12 on page 21, lines 16 to 18, mentions Exendin-4 for use in the "*treatment [...] to rescue neurons and reduce neuronal death following a stroke, brain or spinal cord injury*". Thus, it is not immediately apparent that the subject-matter of the claim is novel in the light of the disclosure of document D12.

28. The board, exercising its discretion under Article 13(1) RPBA, decided not to admit auxiliary request 22 into the proceedings.

29. In conclusion, no claim request considered by the board meets the requirements of Article 54 EPC.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar: The Chair:

P. Cremona G. Alt

Decision electronically authenticated