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**Datasheet for the decision  
of 3 April 2007**

**Case Number:** W 0020/06 - 3.3.04

**Application Number:** PCT/DK 2005/000694

**Publication Number:** WO 2006/045319

**IPC:** A61K 38/22

**Language of the proceedings:** EN

**Title of invention:**

Uses of growth hormone secretagogues in the treatment of individuals suffering from renal and/or liver failure

**Applicant:**

Gastrotech Pharma A/S

**Opponent:**

-

**Headword:**

Growth hormone secretagogues/GASTROTECH

**Relevant legal provisions:**

PCT Art. 17(3)(a)  
PCT R. 13.1, 40.1, 40.2(c)(e)  
EPC Art. 150(2), 154(3)  
EPC R. 105(3)

**Keyword:**

"Competence of the Boards of Appeal for examining the protest (yes)"

"Protest fee duly paid (yes)"

"Admissibility of the protest (yes)"

"Invitation to pay additional fees sufficiently reasoned (yes)"

"Unity of invention (yes)"

"Refund of additional search fee (yes)"

"Refund of protest fee (yes)"

**Decisions cited:**

G 0001/89, W 0013/87, W 0026/06

**Headnote:**

There is no conflict between Rule 40.2(c) PCT as in force from 1 April 2005 and Article 154(3) EPC; Article 150(2), third sentence, EPC does not apply (see points 7 to 9, deviating from decision W 0026/06 of 28 February 2007).



Case Number: W 0020/06 - 3.3.04

International Application No. PCT/DK 2005/000694

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.04  
of 3 April 2007

**Applicant:** Gastrotech Pharma A/S  
Nyhavn 43B  
DK-1051 Copenhagen K (DK)

**Representative:** Pernille Winding Gojkovic  
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**Decision under appeal:** Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicant against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 7 June 2006 .

**Composition of the Board:**

**Chair:** U. Kinkeldey  
**Members:** B. Claes  
T. Bokor

## Summary of Facts and Submissions

- I. International patent application no. PCT/DK2005/000694 published as WO 2006/045319 and having the title "Uses of growth hormone secretagogues in the treatment of individuals suffering from renal and/or liver failure" was filed on 27 October 2005 with 67 claims.

Claims 1 and 49 read as follows:

"1. Use of a secretagogue compound or pharmaceutically acceptable salt thereof for the preparation of a medicament for the stimulation of appetite, food intake and/or weight gain in an individual suffering from liver failure.

49. Use of a secretagogue compound for the preparation of a medicament for the stimulation of appetite, food intake and/or weight gain in an individual suffering from renal failure."

- II. On 7 June 2006, the European Patent Office (EPO), acting in its capacity as International Searching Authority (ISA) under Article 16 PCT and Article 154 EPC, informed the applicant that the application did not comply with the requirement of unity of invention (Rule 13.1 PCT) and invited the applicant to pay within a time limit of one month one additional search fee, in accordance with Article 17(3)(a) PCT and Rule 40.1. PCT.
- III. In the invitation to pay additional fees, the ISA defined the two inventions to which the application related as follows:

"1. claims: 1-5 complete and 6-48 all partially

Use of a secretagogue compound or a pharmaceutically acceptable salt thereof for the preparation of a medicament for the stimulation of appetite, food intake and/or weight gain in an individual suffering from liver failure.

2. claims: 49-52, 53-67 completely and 6-48 all partially

Use of a secretagogue compound or a pharmaceutically acceptable salt thereof for the preparation of a medicament for the stimulation of appetite, food intake and/or weight gain in an individual suffering from renal failure."

IV. The reasons for the finding of non-unity by the ISA were that the general common concept of the application was the use of a secretagogue for the stimulation of appetite, food intake and/or weight gain in an individual suffering from liver or renal failure. This common concept was not novel in view of document US2002111461 (D1) which disclosed synthetic peptidomimetics having growth hormone releasing activity in mammals. According to document D1, the administration of the described secretagogues for purposes of stimulating the release of endogenous growth hormone could have the same effects or uses as growth hormone or the somatomedins themselves, such as reducing cachexia and protein loss due to chronic illness such as cancer or AIDS; treatment of

hyperinsulinemia including Type II diabetes; treatment of renal failure and renal insufficiency. Reference was made to the abstract, page 2, left-hand column, paragraph 9 to page 9, right-hand column, paragraph 107, page 15, paragraph 171 to page 16, left-hand column, paragraph 176, page 68, left-hand column, paragraph 313 to right-hand column, paragraph 318, of document D1.

In view of document D1, the problem underlying the application was to be redefined as the provision of further pharmaceutical compositions comprising a secretagogue for the stimulation of appetite, food intake and/or weight gain in an individual suffering from further diseases accompanied by loss of appetite or weight loss. Since the general common concept was not novel, there was lack of unity. Neither the description, not the claims revealed any further features that could be considered special in the sense of Rule 13(1) PCT. In consequence, inventions 1 and 2 were not so linked as to form a single general inventive concept.

- V. The communication of 7 June 2006 also contained the results of the partial international search, wherein document D1 was cited.
  
- VI. With letter dated 21 June 2006, the applicant requested the debiting of one additional search fee from its deposit account. The payment was made under protest according to Rule 68.3(c) PCT.

Amended claims 1 to 63 were submitted, which should replace previously filed claims 1 to 67.

The applicant argued that the invitation by the ISA to pay additional fees was unjustified because the reasons were not adequately substantiated as required by Rule 68.2 PCT. In view of the decision G 1/89 and several W decisions of the Boards of Appeal, an "a posteriori" objection should only be raised in situations where the independent claims clearly lacked novelty or inventive step. The cited document D1 was stated in the Search Report as being an "A" document, thus a document of only general relevance to describing the background of the invention, and could thus by definition not form the basis of an *a posteriori* unity objection. Furthermore, in contrast to the compounds described in document D1, the present invention related to uses of the peptide hormone ghrelin and related analogues thereof. The subject-matter of the invention was thus linked by the common concept of "the use of a ghrelin-like compound for the stimulation of appetite, food intake and/or weight gain in an individual suffering from liver or renal failure". The subject-matter now claimed was both novel and inventive over the prior art.

The applicant requested the reimbursement of the additional search fee, and that the ISA withdraws the objection for lack of unity and searches both inventions 1 and 2 as claimed in the amended set of claims.

- VII. On 23 June 2006, the ISA informed the applicant that Article 19 PCT foresaw amendment of claims only after the receipt of the international search report (ISR), and that the communication sent on 7 June 2006 was not the ISR, but an invitation to pay additional fees. Any

further search would be conducted on the basis of the claims as originally filed.

The applicant was requested to inform the ISA within a time limit of 15 days whether it still wished to pay the additional fees.

VIII. With letter of 29 June 2006, the applicant confirmed to pay the extra search fee under protest. The examination of the protest should be based on the argumentation sent with letter dated 21 June 2006. Even if the originally filed claims were to be taken as starting point, the arguments would still stand, as it was believed that the unity objection raised by the ISA was not adequately substantiated as required by Rule 68.2 PCT.

IX. On 10 August 2006, the ISA invited the applicant to pay a protest fee and informed the applicant that a prior review had confirmed that the invitation to pay additional search fees was justified.

In the Annex to the communication, the review panel decided that the additionally paid search fee would not be refunded.

X. With letter of 30 August 2006, the applicant requested debiting the protest fee from its deposit account.



## Reasons for the Decision

### *Procedural issues*

1. Given that the international application under consideration has an international filing date of 27 October 2005, the protest is subject to the provisions of the PCT as in force from 1 April 2005.

### *Competence of the Boards of Appeal for examining the protest*

2. Concerning non-unity findings in the international search, the applicable version of Rule 40.1 PCT requires that the "Invitation to pay additional fees provided for in Article 17(3)(a) shall:
  - (i) specify the reasons for which the international application is not considered as complying with the requirement of unity of invention;
  - (ii) invite the applicant to pay the additional fees within one month from the date of the invitation and indicate the amount of those fees to be paid; and
  - (iii) invite the applicant to pay, where applicable, the protest fee referred to in Rule 40.2(e) within one month from the date of the invitation, and indicate the amount to be paid".
3. Pursuant to the applicable version of Rule 40.2(c) PCT, "Any applicant may pay the additional fees under protest, (...). Such protest shall be examined by a review body constituted in the framework of the

- International Search Authority, which to the extent that it finds the protest justified, shall order the total or partial reimbursement to the applicant of the additional fees."
4. Compared to Rule 40 PCT as in force before 1 April 2005, the amendments to Rule 40.1 and 40.2 PCT have the effect that the former requirement to carry out a review of the justification for the invitation to pay additional search fees under Article 17(3)(a) PCT prior to requiring payment of a protest fee (Rule 40.2(e) PCT) has been deleted, and that the new rule now requires that the applicant is simultaneously invited to pay the additional search fee and the protest fee within a time limit of one month.
  5. It is the understanding of the board that these amendments of the PCT, which aim to make the protest procedure before the respective ISA more concise and simple, were made in view of the amendment of Article 154(3) and Rule 105(3) EPC by the EPC 2000 revision. These amendments of the EPC are, however, not yet in force.
  6. The question may arise whether or not there may be a conflict between the amended Regulations under the PCT and Article 154(3) and Rule 105(3) EPC still in force. Should there be a conflict, then Article 150(2), third sentence, EPC applied, which states: "In the case of conflict, the provisions of the Cooperation Treaty shall prevail". Therefore, the board will examine whether the amended Rule 40.1 and 40.2 PCT provide for requirements which could be in conflict with Article 154(3) EPC as still in force.

7. Rule 40.2(c) PCT as in force before 1 April 2005 provided for a "three-member board or other special instance of the International Searching Authority or any competent higher authority" to examine the protest, whereas under the PCT as in force from 1 April 2005, Rule 40.2(c) provides that a "review body constituted in the framework of the International Searching Authority" shall judge on the protest.

The board does not see any differences in these former and actual requirements which could in any respect result in a conflict with Article 154(3) EPC still in force because each Board of Appeal, being an organisational part of the European Patent Office (EPO), constitutes a review body within the framework of the EPO as ISA in compliance with Rule 40.2(c), second sentence, PCT, having the competence to decide fully on the protest, i.e. not only on a possible refund of additional fees paid after invitation but also on the final refusal of the requested refund.

8. The competence for a final refusal was not given to the unspecified body performing the "prior review", which was referred to in the formerly valid Rule 40.2(e), first sentence, PCT. The Decision of the President of the EPO dated 25 August 1992 (OJ EPO 1992, 547), implementing Rule 105(3) EPC (previously Rule 104a(3) EPC) specified this body as a "review panel", and thereby also made it clear that this body is not to be considered a "three-member board" in the sense of the formerly valid Rule 40.2 PCT. The detailed procedure of the review panel is described in the Notice from the EPO dated 26 August 1992 (OJ EPO 1992, 547). Points 2(b)

and 2(c) of this latter Notice make it clear that the review panel is not competent to finally reject the protest. The "prior review" is thus akin to an interlocutory revision, similar to that foreseen by Article 109(1) EPC. Thus, despite the use of the seemingly identical terms "review" in Rule 105(3) EPC and the now valid Rule 40.2(c), second sentence, PCT, according to Article 154(3) EPC, only the Boards of Appeal are given the powers required for the review body in the presently valid Rule 40.2(c), second sentence, PCT.

9. Accordingly, since there is no conflict between the PCT and the EPC, Article 150(2), third sentence, EPC does not apply (deviating from decision W 26/06 of 28 February 2007).

*Time limit for paying the protest fee*

10. The board notes that, irrespective of the amended regulations referred to above in detail, the ISA carried out for the present application a prior "internal review" according to the procedure set out in the "Notice from the European Patent Office dated 1 March 2005 concerning the protest procedure under the PCT (lack of unity)" (OJ, EPO 3/2005, 226 - hereinafter: Notice).
11. Following the procedure described in the Notice, the applicant had not been invited to pay the protest fee in the invitation to pay additional fees (PCT Article 17(3)(a) and Rule 41.1) as required in Rule 40.1(iii) PCT, but was first invited to in a later communication dated 10 August 2006, informing the

- applicant of the results of the "internal review" by the "internal review body".
12. The Notice states that this review is in the nature of a service from the EPO and the previous procedure described in Rule 105(3) EPC "is no longer applicable". In order to allow the applicant to consider the result of the review the EPO will, by way of concession, not require payment of the protest fee until one month after the date of notification of the review to the applicant (see point 3 of the Notice).
13. It must be noted that the formulation "no longer applicable" is quite misleading, when considering the fact that the Notice actually confirms that the previous procedure in fact will be further applied. However, the main purpose of Rule 105(3) EPC is to express the choice of the EPO to require a protest fee pursuant to Rule 40.2(e) PCT, and at the same time to implement this latter. Accordingly, the Notice should be understood as saying that the present version of Rule 40.2(e) PCT does not explicitly foresee an interlocutory revision before the final decision on the protest. In this sense the procedure according to Rule 105(3) EPC is indeed no longer considered as a **mandatory provision** which finds its legal basis in the PCT, see also point 1 of the Notice.
14. Thus, the EPO acting as ISA does not strictly follow all of the provisions of Rule 40.1 PCT. This may raise the question whether or not the protest fee was timely paid. According to Rule 40.2(e) PCT a protest shall be considered not to have been made, where an applicant

has not, within the time limit under Rule 40.1(iii) PCT, paid the required protest fee.

15. However, it has to be noted that Rule 40.1(iii) PCT not only lays down the time limit for the payment of the protest fee, but also the obligation of the ISA to call the applicant's attention to its liability to pay this fee and to prescribe the time limit. Thus, the term "... from the date of the invitation ..." in Rule 40.1(iii) PCT refers not only to the date of the invitation according to Article 17(3)(a) PCT and Rule 40.1(ii) PCT, but also to the invitation to pay the protest fee itself (see Rule 40.1(iii) PCT, first sentence: "invite the applicant to pay, ..."). Therefore, the legal effect foreseen in Rule 40.2(e) PCT (protest shall be considered not to have been made), cannot occur without a preceding, explicit invitation for payment of the protest fee and the setting of a time limit by the ISA.
16. The procedure according to the Notice corresponds with the provisions of Rule 40.1(iii) PCT in so far as the applicant is invited to pay the protest fee within a time limit of one month. However, it does not correspond with the provisions of Rule 40.1 PCT with regard to the point in time at which the invitation has to be made, as explained in point 11 above.
17. In effect, the discrepancy outlined above only arises from the fact that the EPO continues to perform the interlocutory revision even when it is no longer mandatory. Otherwise the two cornerstones of the procedure, namely the invitation to pay further search fees and the review of the invitation by at least one further instance remains unchanged. The board notes

that these two instances were the pillars of the protest procedure already in the previous version of the PCT Regulations, when considering that the intermediate level of the interlocutory revision (the "prior review" in Rule 40.2(e) PCT, version in force before 1 April 2005) was only required if the ISA availed itself of the possibility to require a protest fee from the applicant. Thus the present practice does not appear to be contrary to the basic principles underlying the protest procedure. The legislative intent behind the latter is to permit the ISA to make a further search, if necessary, within the tight time limits available for the ISA in the so-called PCT Chapter I procedure, while at the same time protecting the applicant from having to pay the required further search fees without good reason. None of these goals is affected by the delayed invitation to pay the protest fee, as also testified by the earlier practice. It is true that the purpose of the new rules, as explained in point 5 above, may not be immediately fulfilled with the implementation according to the Notice. However, as also explained above, the legislative intent was to attain this purpose only when EPC 2000 comes into force.

18. Furthermore, to what extent the implementation of the protest-procedure according to the Notice corresponds to the legal obligations on an ISA under the procedure laid down in the Regulations under the PCT need not to be answered. This board as a review body according to Rule 40.2(c) PCT (see also Article 154(3) EPC) does not consider itself to be competent to approve or prohibit this practice of the EPO acting as ISA. Rather the responsibility of this board, when examining the admissibility of the protest, is restricted to the

examination of the formal requirements for filing a protest. The board, in the absence of competence and of a directly applicable legal basis in the PCT itself, cannot deduce any further legal effect from this unilateral amendment of the protest-procedure by the EPO acting as ISA.

19. The board takes it that the applicant, in view of the Notice, could proceed from the assumption that the procedure of the ISA in the present case would lead to the entrustment of the board with the examination of the protest, provided that the protest fee had been duly paid.
20. Therefore, considering the generally established principle of protection of legitimate expectations, the board takes the view that it has only to be examined if the payment of the protest fee was made on time within the framework of the procedure according to the Notice.
21. In the present case the applicant was invited with the communication of 7 June 2006 ("Form PCT/ISA/228 (April 2005)") to pay the protest fee within one month. In a letter dated 21 June 2006 the applicant requested the debiting of the protest fee from his Deposit Account. Thus, the payment was made in time, and the protest is considered to have been made (Rule 40.2(e) PCT, second sentence).

*Protest sufficiently reasoned*

22. According to Rule 40.2(c) PCT, the applicant may pay the additional fees under protest, "that is, accompanied by a reasoned statement to the effect that



the international application complies with the requirement of unity of invention ...".

23. In the present case, the applicant's protest as filed with letter of 21 June 2006 was accompanied by amended claims and contained arguments as to why these amended claims were novel and inventive over the prior art document D1. However, the amended claims cannot be considered by the board, as the examination of the protest has to be based on the documents available when the ISA issued its invitation to pay the additional search fees; there is no provision for amendments during proceedings before the ISA.

24. However, having regard to those parts of applicant's letter of 21 June 2006 preceding the comments relating to the amended claims, notably page 2, paragraphs 1 to 4, it can be taken that it is the applicant's submission that document D1 only described the background of the invention and that the common general concept as defined by the ISA was not known from this document. Therefore, the board concludes that the applicant has filed a reasoned statement in accordance with Rule 40.2(c) PCT.

25. Consequently, the protest is considered admissible.

*Invitation to pay additional fees sufficiently reasoned*

26. Rule 40.1 PCT stipulates that the invitation under Article 17(3)(a) PCT to pay additional fees must specify the reasons why the international application is not considered to comply with the requirement of unity of invention.

27. The applicant submits in its letter dated 21 June 2006 that the invitation to pay additional fees issued by the ISA was unjustified because the reasons were not adequately substantiated.
28. The purpose of the provision under Rule 40.1 PCT is to enable the applicant (and the board in case of a protest) to examine whether the invitation is justified. This requires that the invitation must be drafted in a form that it is suited to fulfil this purpose, i.e. the reasoning must be comprehensible.
29. Given the fact that the ISA states in its invitation to pay additional fees that the common concept of the invention was "the use of a secretagogue for the stimulation of appetite, food intake and/or weight gain in an individual suffering from liver or renal failure", and that this common concept was not novel in view of specified passages of document D1, the board is convinced that the addressee of the ISA's invitation should have had no difficulty in understanding the reasoning.
30. Hence, the ISA has fulfilled its obligation to substantiate its finding of non-unity.

*Examination of the protest*

31. According to Rule 13.1 PCT, the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. If the ISA considers that the claims lack unity of invention, it is empowered, under

Article 17(3)(a) PCT, to invite the applicant to pay additional fees.

32. Lack of unity may be directly evident *a priori*, i.e. before the examination of the merits of the claims in comparison with the state of the art revealed by the search (cf., for example, decision W 13/87 of 9 August 1988). Alternatively, having regard to decision G 1/89 of the Enlarged Board of Appeal (OJ EPO 1991, 155), the ISA may also raise an objection *a posteriori*, i.e. after having taken the prior art revealed by the search into closer consideration. The Enlarged Board of Appeal indicated that such consideration represents only a provisional opinion on novelty and inventive step which is in no way binding upon the authorities subsequently responsible for the substantive examination of the application (point 8.1. of the Reasons for the decision). In point 8.2 of the Reasons, the Enlarged Board mentioned that such invitation to pay additional fees should always be made "with a view to giving the applicant fair treatment" and should only be made in clear cases.
33. In the invitation to pay additional fees, the ISA argued that the application lacked unity of invention because the general common concept, which was seen as the use of a secretagogue compound or pharmaceutically acceptable salt thereof for the preparation of a medicament for the stimulation of appetite, food intake and/or weight gain in an individual suffering from liver or renal failure, was not novel in view of document D1.

34. This conclusion cannot be accepted by the board for the following reasons:

34.1 Whereas both independent claims 1 and 49 are directed to the use of a secretagogue compound for the preparation of a medicament for the stimulation of appetite, food intake and/or weight gain, the two claims differ in the group of subjects to which the secretagogue compound is applied, i.e. the use according to claim 1 is in an individual suffering from liver failure, and the use according to claim 49 is in an individual suffering from renal failure.

34.2 Document D1 describes secretagogue compounds which promote the release of endogenous growth hormone and IGF-1 in mammals. It is stated in paragraph 175 (bridging pages 15 and 16) that the administration of the disclosed compounds for purposes of stimulating the release of endogenous growth hormone or IGF-1 can have the same effects or uses as growth hormone or the somatomedins themselves. In column 1 of page 16, lines 2 to 38, a detailed list of such uses is given, including treating renal failure or insufficiency resulting in growth retardation (lines 7 to 8), reducing cachexia and protein loss due to chronic illness such as cancer or AIDS (lines 24 to 25), treatment of hyperinsulinemia including Type II diabetes (lines 25 to 26), and enhancing renal function and homeostasis including acute and chronic renal failure (lines 33 to 34).

34.3 The board considers that while paragraph 175 of document D1 suggests the use of the secretagogue compounds in patients with renal failure, there is no

disclosure in the document of stimulating appetite, food intake and/or weight gain in this patient group. In order to assess the novelty of the claimed subject-matter, it is not permissible to combine separate uses belonging to different embodiments. In particular, the described use of the secretagogue compounds for reducing cachexia due to chronic illness such as cancer or AIDS may not be combined with the use of the secretagogue compounds in patients with renal failure in order to arrive at the conclusion that reducing cachexia in patients with renal failure is also disclosed, as this combination is not directly and unambiguously derivable from the document.

- 34.4 Consequently, the board considers that the use of a secretagogue compound or pharmaceutically acceptable salt thereof for the preparation of a medicament for the stimulation of appetite, food intake and/or weight gain in an individual suffering from liver or renal failure, as claimed in claims 1 and 49, respectively, is novel over document D1.
- 34.5 In order to examine whether there is unity of invention, it would in principle be necessary as the next step to assess whether or not the claimed subject-matter involves an inventive step. However, according to decision G 1/89 (supra), restraint should be exercised in the assessment of novelty and inventive step and in borderline cases it should be refrained from considering an application as not complying with the requirement of unity of invention on the ground of lack of novelty or inventive step.

In the present case, the board considers that the assessment of an inventive step of the claimed subject-matter over document D1 would involve complex considerations, which, in order to give the applicant fair treatment, would require a detailed discussion with the applicant. The present case is therefore not a case in which an assessment of inventive step should be made in the context of unity of invention.

35. Consequently, the application is considered to comply with the requirement of unity of invention under Rule 13.1 PCT.

## **Order**

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

1. Refund of the additional search fee paid by the applicant is ordered.
2. The protest fee shall be refunded.

The Registrar:

The Chair:

P. Cremona

U. Kinkeldey