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**Datasheet for the decision
of 16 November 2007**

Case Number: T 1497/06 - 3.3.08

Application Number: 05005946.8

Publication Number: 1580271

IPC: C12N 15/12

Language of the proceedings: EN

Title of invention:

Human Orphan G Protein-Coupled Receptors

Applicant:

Arena Pharmaceuticals, Inc.

Opponent:

-

Headword:

GPCR/ARENA

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

"Extension beyond the content of the application as filed -
yes"

Decisions cited:

G 0001/05, G 0001/06, T 0006/84, T 0260/85, T 0689/90,
T 0737/90, T 0770/90, T 0686/99, T 0872/01

Catchword:

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Case Number: T 1497/06 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 16 November 2007

Appellant: Arena Pharmaceuticals, Inc.
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San Diego, CA 92121 (US)

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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 31 May 2006
refusing European application No. 05005946.8
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
C. Heath

Summary of Facts and Submissions

I. European patent application No. 05 005 946.8 published under No. 1 580 271 (referred to in the present decision as "the application as filed") was filed on 13 October 1999 as a divisional application to European patent application No. 99 972 682.1 published as WO 00/31258 (referred to in the present decision as "the earlier application"). In a decision dated 31 May 2006, the examining division refused the application for not complying with the requirements of Article 123(2) EPC.

II. Claim 1 of the request refused by the examining division reads as follows:

"1. Use of a G-protein coupled receptor to screen candidate compounds as pharmaceutical agents for diabetes, wherein the G-protein coupled receptor comprises a ligand-independent active version of a receptor having SEQ ID NO. 8."

III. The reasons for the refusal were as follows:

- according to the case law (T 260/85, OJ EPO 1989, 105), a priority document was not part of the content of the application as filed and, as stated in the Guidelines for Examination at the EPO C-VI, 5.3.1, it was impermissible to add subject-matter present only in the priority document into the application as filed;

- a priority document did not belong to the public knowledge but merely served the acquisition of a priority date. Therefore, the present situation which

relied on subject-matter derived from a priority document, was different from that of decision T 6/84 (OJ EPO 1985, 238), where the introduced subject-matter was derived from a published patent specification;

- the claimed subject-matter, which was directed to a specific use that was disclosed only in a priority document but not in the application as filed, did not fulfil the conditions listed in the Guidelines for Examination at the EPO C-II, 4.18. These conditions defined the requirements for the incorporation of essential matter from a referenced document and were derived from decision T 689/90 (OJ EPO 1993, 616).

- IV. With letter dated 22 June 2006, the appellant (applicant) filed a notice of appeal and paid the appeal fee. The statement setting out the grounds of appeal was filed with letter dated 23 August 2006, together with a set of claims identical to that underlying the decision under appeal.
- V. The decision under appeal was not rectified by the examining division and the case was remitted to the board of appeal (Article 109(2) EPC).
- VI. On 1 February 2007, the board sent a communication pursuant to Article 110(2) EPC stating its preliminary non-binding opinion. The appellant's attention was also drawn to the referrals to the Enlarged Board of Appeal G 1/05 of 16 September 2005 and G 1/06 of 4 April 2006 (consolidated with G 3/06 of 15 May 2006), which were considered of relevance for the assessment of Articles 76(1) and 123(2) EPC for divisional applications to earlier European patent applications.

- VII. With letter dated 3 April 2007, the appellant replied to the board's communication and requested that, if the board felt these referrals to be critical for the case, oral proceedings be deferred until the Enlarged Board of Appeal had decided.
- VIII. With a communication dated 19 April 2007, the appellant was informed that the board did not intend to proceed with the case before the decision of the Enlarged Board of Appeal was issued.
- IX. After the decisions G 1/05 and G 1/06 of the Enlarged Board of Appeal were issued on 28 June 2007, the appellant was summoned to oral proceedings.
- X. Oral proceedings took place on 16 November 2007.
- XI. The appellant's arguments, insofar as relevant to the present decision, may be summarised as follows:

- The earlier application and the application as filed related to 19 different orphan G protein-coupled receptors (GPCRs). In order to overcome an objection of lack of unity raised in the International phase, it was chosen to pursue, both in the earlier application and in the application as filed, subject-matter related only to the GPCR of SEQ ID No. 8 (Rup3). Each of the (priority) documents - US serial and provisional applications - referred to in the first paragraph of the description of the earlier application and of the application as filed related to **one specific GPCR**. The document USSN 60/141,448, which related in its entirety to Rup3, was clearly identified as being "*incorporated*

by reference in its entirety" both in the earlier application and in the application as filed. The disclosure of this document was closely equivalent to the one of the application as filed, the latter being written more generally so as to be applicable to all 19 GPCRs referred to therein. Document USSN 60/141,448 provided only more details relating to Rup3. Therefore, it was immediately evident to the skilled person that both the application as filed (as regards Rup3) and document USSN 60/141,448 related to the same invention and that their teaching was intended to be considered as a whole. Both documents had to be read together, i.e. as a sole document including everything.

- This was all the more true since, in order to overcome an objection of lack of unity, the subject-matter claimed in the request at issue had been narrowed in comparison with the subject-matter of the application as filed. This limitation directed the attention of the skilled person to the cross-referenced document USSN 60/141,448 and informed the skilled person that the whole content of this document was incorporated thereby, since the whole content of this document was relevant to the limited subject-matter. There was thus a clear indication to the skilled person to incorporate the whole content of document USSN 60/141,448 into the application.

- Both the earlier application and the application as filed referred to the expression of Rup3 only in pancreas out of all other tissues tested. The skilled person was well aware that a significant disorder related to the pancreas was diabetes. The link between the pancreas and diabetes certainly formed part of the

general common knowledge of the person skilled in the art. This link between selective pancreatic expression and diabetes was also expressly made in document USSN 60/141,448. Thus, there was a clear connection between the teaching of the application as filed and that of document USSN 60/141,448, supporting the incorporation of this subject-matter by reference.

- In fact, since the claimed subject-matter had been limited to the use of Rup3, which was disclosed within a specific context of the application as filed, it was evident that the skilled person would immediately have looked for (and easily found) the very same context in document USSN 60/141,448. The skilled person would have been led thereby to diabetes in a straightforward manner, since document USSN 60/141,448 gave no other choices within this particular context. This document referred, only and exclusively, to diabetes and therefore, no selection had to be made in order to incorporate this specific use into the application. Since diabetes had already been included into the application through the incorporation of the whole content of document USSN 60/141,448, there was no need to duplicate its incorporation in the context of the examples of the application as filed when reference was made to the uses of Rup3.

- According to the decision of the Enlarged Board of Appeal G 1/05 of 28 June 2007, there were no limitations in respect of the amendments that could be made or the subject-matter that could be included in a divisional application based on the subject-matter of the earlier application. In the case at issue, there could be no doubts that the whole technical content of

the earlier application and of the application as filed comprised the complete disclosure of document USSN 60/141,448, since this document was incorporated by reference in its entirety in both applications and it was concerned with the same invention (Rup3).

- As established in the case law, the purpose of Article 123(2) EPC was to prevent an applicant to improve its position by adding subject-matter not disclosed in the application as filed. Such improvement would give the applicant an unwarranted advantage and damage the legal certainty of third parties that relied on the content of the original application. In the present case, however, the claimed subject-matter was not an improvement of appellant's position nor was it unexpected to third parties. Firstly, third parties knew from the filing date that the content of document USSN 60/141,448 was incorporated in its entirety (with all technical details) and that this content was frozen, i.e. it could not change during the proceedings. Secondly, from the filing date it was evident to third parties that the whole content of document USSN 60/141,448 was part of the technical content of the application as filed regarding Rup3. Thirdly, the attention of third parties was directly drawn by the context of the application as filed to the corresponding context in the cross-referenced document USSN 60/141,448 and thereby to the specific feature introduced into the claims.

- The case law referred to in the decision under appeal did not exclude that subject-matter of a priority document could be part of the description by virtue of incorporation by reference. There was no restriction

placed on the nature of the document to be incorporated by reference as long as the content of this document was frozen, i.e. unchangeable. This was the case for a priority document. In line with decision T 260/85 (*supra*), it was not the appellant's intention to rely on the priority document as such for the subject-matter introduced into the claims. The priority document was part of the content of the description as filed only because it had been incorporated by reference thereto.

- The Guidelines for the Examination at the EPO referred to the conditions that had to be fulfilled by features disclosed in a cross-referenced document. These conditions could be divided in substantive and temporal conditions and they were derived from the case law of the Boards of Appeal, in particular, from the decisions T 689/90 (*supra*) and T 737/90 of 9 September 1993, respectively. All these requirements were fulfilled by the feature introduced into the claimed subject-matter.

XII. The appellant requested that the decision under appeal be set aside and that the patent be granted on the basis of claims 1 to 8 filed with the statement of grounds of appeal.

Reasons for the Decision

Article 123(2) EPC

1. Claim 1 is directed to the use of a ligand-independent active version of the G-protein coupled receptor Rup3 (SEQ ID NO. 8) to screen candidate compounds as

pharmaceutical agents for diabetes (cf. Section II, *supra*). There is, however, no reference to diabetes in the application as filed and therefore, there is *prima facie* no formal basis for this use in the sense of Article 123(2) EPC.

2. Nevertheless, on page 15, lines 15 to 17 of the cross-referenced document USSN 60/141,448, it is stated that "*candidate compounds identified using a constitutively activated form of RUP3 may be useful for understanding the role of RUP3 in diabetes and/or as therapeutics for diabetes*". It is the appellant's position that this passage of the cross-referenced document provides a formal basis for diabetes (cf. Section XI, *supra*).
3. The question before the board is whether or not the mention of "diabetes" in the cross-referenced document is an appropriate basis for amendment of the application as filed.

General considerations on Article 123(2) EPC

4. According to Article 123(2) EPC, a European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. It is therefore of relevance to establish the content of the application as filed for the assessment of Article 123(2) EPC.
5. This is also acknowledged in explicit form in decision T 689/90 (*supra*), which states that "*the skilled reader should be able to know, by reading the published*

application, the extent of the subject-matter which is within "the content of the application as filed", and thus the extent of the subject-matter for which protection is or may be sought ... in normal circumstances a reader of a published European patent application is entitled to expect that the "description of the invention" ... will itself identify all the features of the described invention for which protection is or may be sought" (cf. point 1.4 of the Reasons). Thus, the limits and extent of the content of the description as filed have to be clear to the skilled reader from the description of the invention.

6. The Boards of Appeal have developed in their case law some criteria for establishing the content of an application, mostly in relation to the requirement set out in Article 83 EPC to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. It is obvious that, for reasons of consistency of approach, these criteria are of value *mutatis mutandis* also when determining the content of an application for formal purposes (Article 123(2) EPC).

7. According to this case law, the content of the application may be seen as reservoir upon which the applicant may draw to amend the description. This reservoir cannot however be expanded after the date of filing (cf. "Case Law of the Boards of Appeal of the EPO", 5th edition 2006, III.A.1.1, page 235, *inter alia* T 770/90 of 17 April 1991, point 2.1 of the Reasons), which is in line with the concept that for a sufficient disclosure the reservoir must be **complete** at the filing date.

8. It is also established that it is not permissible to pick and choose individually disclosed features from this reservoir in order to create particular combinations if there is no hint or pointer to such combinations. For the skilled person, a selection or combination of features must therefore emerge clearly and unambiguously from the content of the application as filed (cf. "Case Law", *supra*, III.A.2.1, page 259, *inter alia* T 686/99 of 22 January 2003 and T 872/01 of 14 July 2004, points 4.3.3 and 2.2.3 of the Reasons, respectively), which is in line with the requirement that the content of the reservoir must be **clear** to the skilled person.

9. Thus, subject-matter that does not form part of the content of the original reservoir or which is arbitrarily selected or drawn from this reservoir without any pointer thereto in the application as filed, contravenes the requirements of Article 123(2) EPC.

Article 123(2) EPC and cross-referenced documents

10. Although, as pointed out in decision T 689/90 (*supra*) with reference to the Guidelines of Examination of the EPO, "*the patent specification should, regarding the essential features of the invention, be self-contained, i.e. capable of being understood without reference to any other document*" (cf. point 1.2 of the Reasons), the case law acknowledges that, under particular conditions and in order to provide a **complete** disclosure, another document may be "incorporated by reference" into the original application.

11. However, in the board's judgement, the reasons for incorporating this document (why it is taken) as well as the purpose thereof (what subject-matter is incorporated) must already be **clear** from the original application. The skilled reader should be able to derive directly and unambiguously which subject-matter of the incorporated document is part of the original application. It would be inconsistent with the above principles as developed under Article 83 EPC to treat cross-referenced documents as a reservoir from which the applicant in the absence of any pointer could arbitrarily draw subject-matter (including combinations). This subject-matter would contravene Article 123(2) EPC.

12. This view is supported by the decisions of the Boards of Appeal referred to above. In particular, in the case of decision T 6/84 (*supra*), the text of the original description stated that "*the synthetic offretite useful in the present invention (as a catalyst for dewaxing a waxy hydrocarbon oil) and its method of preparation are disclosed in Canadian patent 934130*" (cf. T 689/90, *supra*, point 2.1 of the Reasons). Thus, both the reason and purpose for incorporating the cross-referenced document were clearly indicated in the application as filed.

13. Similarly, in the case of decision T 689/90 (*supra*), the description of the application drew the reader's attention to the fact that "*for further details of suitable locating, source, and return members, reference should be made to the application corresponding to US Serial No. 509 897*" (cf. Section III of the Summary), thus indicating the reason and

purpose for incorporating the said document. It is noted that in this decision the appellant acknowledged that the original application concerned "*a mirror picture of the apparatus described in (the) reference document*" and that it could "*therefore be regarded as an additional application in respect of a closely related invention. The words "further details" were chosen as a shortened form of reference in order to avoid a potential objection by the EPO that the entire content of (the) document (was) comprised in the present application*" (cf. Section VIII of the Summary).

The cross-referenced document in the application as filed

14. The application as filed refers to the cross-referenced document USSN 60/141,448 only once at the very beginning of the description and together with other 17 documents identified by their US provisional or serial numbers and 8 documents partially identified by an internal Arena Pharmaceuticals, Inc. docket number (cf. page 2, line 10 of the application as filed). At the end of this passage, it is stated that "*each of the foregoing applications are incorporated herein by reference in their entirety*" (cf. page 2, lines 25 to 26). There is, however, no further information indicating the reasons for their incorporation, let alone the purpose thereof. In this respect, the situation for the present application is very different from that of decisions T 689/90 and T 6/84 (*supra*).
15. According to the appellant (cf. Section XI, *supra*), the reasons for the incorporation of the cross-referenced document USSN 60/141,448 are self-evident to the skilled reader, since the cross-referenced document and

the claimed subject-matter - and part of the application as filed - concern the same invention, namely the G-protein coupled receptor Rup3. In its view, the purpose follows plainly therefrom and is explicitly stated in the application as filed by the wording "*incorporated herein by reference in (its) entirety*", i.e. the whole content of the cross-referenced document is intended to be part of the application as filed. The original reservoir represented by the application as filed also comprises the complete disclosure of the cross-referenced document USSN 60/141,448.

16. The board cannot agree with this argumentation. Although the application as filed and the cross-referenced document USSN 60/141,448 concern the same product (Rup3), they differ to a great extent with regard to the level of detail of their disclosure and they comprise different subject-matter that might be the basis of very different inventions, as shown in particular by the specific subject-matter now claimed. At the filing date of the application and, in the absence of any pointer for the skilled reader towards any specific subject-matter, the reference in the application as filed to document USSN 60/141,448 is understood as a generic reference. In the board's view, to take specific subject-matter from this generic disclosure not only changes the nature and character of the reference itself - from a generic to a specific one - but amounts to a selection of specific subject-matter that, as such, has not been disclosed at the filing date. The skilled person is thus presented with new information that is not directly and unambiguously derivable from the application as filed.

17. It is worth mentioning that the specific disclosure of the application as filed concerned with Rup3, which states that "*a single hRUP3 band is evident only from the pancreas*" out of 16 human tissues studied (cf. paragraph [0062] of the application as filed), cannot help the appellant's case. This reference neither explicitly nor implicitly discloses diabetes as such, and the appellant has not argued that it does. This disclosure cannot thus serve as a valid basis for the claimed subject-matter to comply with Article 123(2) EPC (cf. "Case Law", *supra*, II.A.2, page 259). Moreover, in line with the case law (cf. T 260/85, *supra*), document USSN 60/141,448 cannot be relied on as priority document for the incorporated subject-matter, as acknowledged by the appellant itself.

18. The decision of the Enlarged Board of Appeal G 1/05 (*supra*) concerns amendments of divisional applications and it does not help the appellant's case further. According to this decision, there is no legal basis for limiting amendments on divisional applications and, while any divisional application is still pending, any of its content as filed - interpreted as the whole technical content of the earlier application (insofar as the application as filed and the earlier application are exactly the same except for the claims) - may yet be the subject of patent claims either in the divisional application itself, or in further divisional applications (cf. point 9 of the Reasons). The decision also refers to both Article 123(2) EPC and 76(1) EPC as enshrining the principle that before grant the legal certainty of third parties is sufficiently protected by the prohibition of extending the content of the application by amendment beyond what was originally

disclosed. It is only and exclusively within these limits that the applicant might fully and adequately claim the disclosed invention (cf. point 5.3 of the Reasons). Thus, as stated in point 4 *supra*, for the purpose of Article 123(2) EPC, it is of relevance to establish the **content** of the application as filed. For the reasons given above, the board considers that the subject-matter claimed in the request at issue, in particular the term "diabetes", is not found within the content of the application as filed.

Conclusion

19. The board concludes that claim 1, and thus the request at issue which comprises that claim, does not fulfil the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar:

The Chairman:

A. Wolinski

L. Galligani