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Datasheet for the decision of 20 October 2015

Case Number: T 1673/11 - 3.3.02

Application Number: 99965162.3

Publication Number: 1137762

IPC: C12N9/24, A01N37/18, A61K38/43, A61P3/00

Language of the proceedings: EN

Title of invention:
TREATMENT OF POMPE'S DISEASE

Patent Proprietor:
Genzyme Corporation

Opponents:
ZyStor Therapeutics , Inc.
Lingner, Margrit

Headword:
Treatment of Pompe's disease/GENZYME

Relevant legal provisions:
EPC Art. 123(3), 64(2), 54(5), 112(1)(a)

Keyword:
Article 123(3) EPC: Change from a claim under the provisions of the EPC 1973 invoking the legal fiction according to G 5/83 to a claim under the provisions of Article 54(5) EPC 2000 (not allowable)

Decisions cited:
G 0005/83, G 0002/88, G 0002/08, T 0402/89, T 0250/05, T 0795/06, T 0547/08, T 1635/09, T 0879/12, T 1780/12

Catchword:

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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1673/11 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 20 October 2015

Appellant: (Opponent 2)	Lingner, Margrit Michael-Huber-Weg 26 81667 München (DE)
Representative:	Sharples, Andrew John EIP Fairfax House 15 Fulwood Place London WC1V 6HU (GB)
Respondent: (Patent Proprietor)	Genzyme Corporation 500 Kendall Street Cambridge, MA 02142 (US)
Representative:	Adams, Harvey Vaughan John Mathys & Squire LLP The Shard 32 London Bridge Street London SE1 9SG (GB)
Party as of right: (Opponent 1)	ZyStor Therapeutics , Inc. 10437 Innovation Drive, Suite 100 Milwaukee, WI 53226-4838 (US)
Representative:	Lock, Graham James Fry Heath & Spence LLP The Gables Massetts Road Horley Surrey RH6 7DQ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on**

10 May 2011 concerning maintenance of the European Patent No. 1137762 in amended form.

Composition of the Board:

Chairman	U. Oswald
Members:	K. Giebeler
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 137 762, based on European patent application No. 99965162.3, published as WO 00/34451 and entitled "Treatment of Pompe's disease", was granted with 9 claims.

II. Claim 1 as granted reads:

"The use of human acid alpha glucosidase in the manufacture of a medicament for the treatment of infantile Pompe's disease, wherein the human acid alpha glucosidase is in the 100 to 110 kD form, wherein the medicament is to be administered intravenously, and wherein the treatment is to be continued for at least 4 weeks."

Claims 2 to 9 as granted are dependent on claim 1.

III. Two oppositions were filed against the granted patent, on the grounds of lack of novelty and inventive step (Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

IV. In its interlocutory decision, the opposition division decided that the amended claims of the main request met the requirements of the EPC.

V. Claim 1 of the main request held allowable by the opposition division reads:

"Human acid alpha glucosidase in the 100 to 110 kD form, for use in the treatment of infantile Pompe's disease, wherein the human acid alpha glucosidase is to be

administered intravenously, and wherein the treatment is to be continued for at least 4 weeks."

VI. Opponent 2 (hereafter appellant) filed an appeal against the decision of the opposition division.

VII. The proprietor (hereafter respondent) responded to the appeal with letter of 30 March 2012. It requested that the appeal be dismissed (main request) and filed auxiliary requests as well as questions to be referred to the Enlarged Board of Appeal (EBA).

Claim 1 of **auxiliary request 1** reads:

"Human acid alpha glucosidase in the 100 to 110 kD form, for use in the treatment of infantile Pompe's disease, wherein the human acid alpha glucosidase is to be administered intravenously, and wherein the treatment is to be continued for at least 24 weeks."

Claim 1 of **auxiliary request 2** reads:

"Human acid alpha glucosidase in the 100 to 110 kD form, for use in the treatment of infantile Pompe's disease by reducing the concentration of accumulated lysosomal glycogen in heart and skeletal muscle, wherein the human acid alpha glucosidase is to be administered intravenously, and wherein the treatment is to be continued for at least 4 weeks."

Claim 1 of **auxiliary request 3** reads:

"Human acid alpha glucosidase in the 100 to 110 kD form, for use in the treatment of infantile Pompe's disease by reducing the concentration of accumulated lysosomal glycogen in heart and skeletal muscle, wherein the human

acid alpha glucosidase is to be administered intravenously, and wherein the treatment is to be continued for at least 24 weeks."

Claim 1 of **auxiliary request 4** reads:

"Human acid alpha glucosidase in the 100 to 110 kD form, for use in the treatment of infantile Pompe's disease and the accompanying hypertrophic cardiomyopathy, wherein the human acid alpha glucosidase is to be administered intravenously, and wherein the treatment is to be continued for at least 4 weeks."

Claim 1 of **auxiliary request 5** reads:

"Human acid alpha glucosidase in the 100 to 110 kD form, for use in the treatment of infantile Pompe's disease and the accompanying hypertrophic cardiomyopathy, wherein the human acid alpha glucosidase is to be administered intravenously, and wherein the treatment is to be continued for at least 24 weeks."

The **questions to be referred to the EBA** read as follows:

"1. What criteria should be used when making an assessment, under Article 123(3) EPC, as to whether an amendment to a granted patent extends the protection conferred? In particular, what is the correct interpretation of the term "protection conferred" under the provisions of Article 123(3) EPC, vis-à-vis the meaning of the term "rights conferred" under the provisions of Article 64(1) EPC?

2. In particular, is there any extension of the protection conferred by a patent, under the provisions of Article 123(3) EPC, where an amendment only concerns

a change in the format of a claim from a Swiss-type use claim pursuant to Enlarged Board of Appeal decision G 5/83 to an EPC 2000 medical use claim pursuant to Article 54(5) EPC?"

VIII. On 13 February 2015, the board issued a communication as an annex to the summons to oral proceedings, expressing its preliminary opinion that the claims of the main request did not comply with Article 123(3) EPC and that the referral of questions relating to this issue to the Enlarged Board of Appeal did not appear to be appropriate.

IX. Opponent 1, party as of right, did not file any written submissions.

X. Oral proceedings were held on 20 October 2015 in the absence of the duly summoned opponent 1.

XI. The appellant's arguments, insofar as they are relevant for the present decision, can be summarised as follows:

The patent according to the main request held allowable by the opposition division contravened Article 123(3) EPC, because the change in claim category from Swiss-type process claim in the patent as granted to purpose-limited product claim in the main request extended the protection conferred. It had been stated in decision G 2/08, point 6.5, that the rights conferred by the claim category under Article 54(5) EPC were likely to be broader than those conferred by Swiss-type claims.

The respondent's request for referral to the EBA should be refused, because having regard to decisions G 2/08, point 6.5, and T 250/05, points 3.4 to 3.6, there was no

contradictory case law with respect to the questions at issue.

XII. The respondent's arguments, insofar as they are relevant for the present decision, can be summarised as follows:

With respect to the main request and the auxiliary requests, the requirements of Article 123(3) EPC were fulfilled, because by virtue of Article 64(2) EPC the protection conferred by the claims as granted extended to the product of the manufacturing process referred to in said claims. The claims as granted were formulated broadly, without specifying any single step of the manufacturing process, and the protection conferred under Article 64(2) EPC thus extended to the product as such; the situation corresponded to that of decision T 795/06, point 6.3.3. The claims of the main request and the claims as granted were directed to the same product and had the same use limitations, and their scope of protection was thus identical. When considering the question of novelty, there were no potential embodiments which anticipated the purpose-limited product claims of the main request but not the "Swiss-type" claims as granted.

The statement in decision G 2/08 that the rights conferred by the claim category under Article 54(5) EPC were likely to be broader than those conferred by a "Swiss-type" claim did not apply to the assessment under Article 123(3) EPC, which concerned only the protection conferred. According to decision G 2/88, the question of infringement should not be taken into account when assessing the protection conferred under Article 123(3) EPC. By contrast, in decision T 1898/07, the question of infringement was considered in the context of Article 123(3) EPC. There was thus uncertainty in the case law

with respect to the interpretation of the term "protection conferred" under Article 123(3) EPC vis-a-vis the interpretation of the term "rights conferred" according to Article 64(1) EPC. This uncertainty was expressed in decision T 402/89. In view of this lack of guidance and uniformity within the case law, the referral of questions to the EBA was appropriate.

XIII. The final requests of the parties were:

The appellant requested that the decision under appeal be set aside, that the patent be revoked and that the request for referral to the EBA be refused.

The respondent requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained on the basis of auxiliary requests 1 to 5, all filed with the reply to the statement of grounds of appeal of 30 March 2012. The respondent furthermore requested that the questions set out in the letter of 30 March 2012 be referred to the EBA.

Reasons for the Decision

1. The appeal is admissible.

Main request - Article 123(3) EPC

2. Claim 1 of the main request is drafted in the format of a purpose-limited product claim as provided for by Article 54(5) EPC ("Human acid alpha glucosidase in the 100 to 110 kD form, for use in the treatment of infantile Pompe's disease, wherein..."), whereas all claims as granted are in the so called "Swiss-type" form

("The use of human acid alpha glucosidase in the manufacture of a medicament for the treatment of infantile Pompe's disease, wherein the human acid alpha glucosidase is in the 100 to 110 kD form, wherein...").

3. Under the EPC 1973, it was established practice that a patent relating to a further medical application of a known medicament could only be granted for a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified therapeutic application (so-called "Swiss-type claim"). This practice was based on decision G 5/83 of the EBA (OJ EPO 1985, 64) which had filled a gap in the legal provisions and extended the notional novelty provided for in Article 54(5) EPC 1973 for the first medical use to further medical use claims when drafted in the above format. The law itself (EPC 1973) did not contain any notional acknowledgement of novelty of a claim directed to a further medical use.

The provisions of Article 54(5) EPC now fill this gap in the former provisions. Article 54(5) EPC provides for purpose-limited product protection for 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 (see decision G 2/08 of the EBA, OJ EPO 2010, 456, points 5.9, 5.10.2, 6.4 and 6.5).

4. Article 123(3) EPC provides that during opposition proceedings the claims of the European patent may not be amended in such a way as to extend the protection conferred upon grant.

5. In decision G 2/88 (OJ EPO 1990, 93, point 3.3) the Enlarged Board of Appeal noted that there is a clear distinction between the protection which is conferred

and the rights which are conferred by a European patent: "The protection conferred by a patent is determined by the terms of the claims (Article 69(1) EPC), and in particular by the categories of such claims and their technical features. (...) In contrast, the rights conferred on the proprietor of a European patent (Article 64(1) EPC) are the legal rights which the law of a designated Contracting State may confer upon the proprietor, for example, as regards what acts of third parties constitute infringement of the patent, and as regards the remedies which are available in respect of any infringement. In other words, in general terms, determination of the 'extent of the protection conferred' by a patent under Article 69(1) EPC is a determination of what is protected, in terms of category plus technical features; whereas the 'rights conferred' by a patent are a matter solely for the designated Contracting States, and are related to how such subject-matter is protected."

It is therefore not appropriate for the board to consider the national laws of the Contracting States in relation to infringement (e.g. the rights of the patent proprietor to sue for indirect or contributory infringement); such national provisions are not relevant when deciding upon the admissibility of an amendment under Article 123(3) EPC. With respect to the question of extension of scope of protection under Article 123(3) EPC, it is instead appropriate to take into account that the protection conferred by a patent is determined by the terms of the claims, and in particular by the categories of the claims and their technical features (T 1780/12 of 30 January 2014, point 13; T 547/08 of 10 March 2011, point 3.2).

6. According to decision G 2/88 (point 4.1) the test to be applied under Article 123(3) EPC is whether the subject-matter defined by the claims is more or less narrowly defined as a result of the amendment. In the case of a change of category of claims, the protection conferred by the categories of claims in the patent as granted must be compared with the protection conferred by the new category of claim introduced by the amendment. This comparison necessarily involves considerations on the extent of protection conferred by a given category of claim. As is evident from decision G 2/88, such considerations are independent of the rights conferred under national law and of infringement.

7. The amendment of the patent as granted according to the main request consists in a change of category of claim 1 from a purpose-limited process claim in the format of a Swiss-type claim in accordance with decision G 5/83 to a purpose-limited product claim in accordance with Article 54(5) EPC. It follows from decision G 2/88 (point 5.1) that it is generally accepted as a principle underlying the EPC that a claim to a particular physical activity (e.g. method, process, use) confers less protection than a claim to the physical entity *per se*. As a consequence, a purpose-limited process claim confers less protection than a purpose-limited product claim (T 1780/12, *supra*, point 22, albeit in the context of double patenting; followed by decision T 879/12 of 27 August 2014, point 14; see also T 250/05 of 4 March 2008, point 3.6). Therefore, the change in category of claim 1 of the patent contravenes Article 123(3) EPC.

8. The respondent disagreed with the approach taken in decision T 1780/12 in as far as it was based on a comparison of the claim categories and the principle that a process claim was inherently narrower than a

product claim. In the respondent's opinion, such an approach did not take into account the extension of protection by virtue of Article 64(2) EPC and the delimitation of the subject-matter claimed by the technical features. A purpose-limited process claim in the format of a Swiss-type claim was directed to a process of manufacture of a product. According to Article 64(2) EPC the protection conferred by such a process extended to the products directly obtained. Because the manufacturing process in a Swiss-type claim was not limited by any technical feature, the manufacture could not be limiting on the product obtained by it. The medical use as limiting feature was the same whether the claim was drafted in the format of a Swiss-type claim or as a purpose-limited product claim in accordance with Article 54(5) EPC. As a consequence, the protection conferred by both types of claims was the same.

9. The board does not agree. First, the comparison of the the protection conferred by the categories of claims in the patent before amendment with the protection conferred by the new category of claims introduced by amendment is in line with the test set out in decision G 2/88 (see point 5 above). Second, the protection conferred by a Swiss-type claim in accordance with decision G 5/83 and a purpose-limited product claim in accordance with Article 54(5) EPC is not the same even if, for the sake of argument, it is accepted that Article 64(2) EPC is to be taken into account when assessing the extent of protection conferred by a Swiss-type claim (see decision T 1635/09 of 27 October 2010, point 14.2).

9.1 Claim 1 as granted is directed to the use of human acid alpha glucosidase in the 100 to 110 kD form in the

manufacture of a medicament for the treatment of infantile Pompe's disease. Inasmuch as this use may be regarded as a manufacturing process, the claim would, pursuant to Article 64(2) EPC, confer protection on the product directly obtained thereby. The board judges that the product directly obtained is the manufactured medicament which contains as an active substance human acid alpha glucosidase in the 100 to 110 kD form and which is packaged and/or provided with instructions for use in the treatment of infantile Pompe's disease. Indeed, in a Swiss-type claim, the medicament is characterised by the functional feature of the specified therapeutic application. Contrary to the respondent's opinion, this implies limitations to the product directly obtained, although the manufacturing steps are characterised by the use of a defined compound only.

9.2 Claim 1 of the main request being drafted as a purpose-limited product claim, on the other hand, confers protection on the human acid alpha glucosidase in the 100 to 110 kD form, whenever it is being used for the treatment of infantile Pompe's disease. Since the claim does not refer to a step of manufacture of a medicament, the product claimed, i.e. the human acid alpha glucosidase in the 100 to 110 kD form, is not limited to a manufactured medicament, packaged and/or with instructions for use in the treatment of infantile Pompe's disease.

9.3 It follows from the above that even if, by virtue of Article 64(2) EPC, the protection conferred by granted claim 1 extended to the product directly obtained by the manufacturing process referred to in said claim, the protection conferred by claim 1 of the main request is broader.

9.4 Nor can the board follow the appellant's argument that since the use limitation of the claims of the main request and of the granted claims was the same, their scope of protection was identical.

The board takes the position that, for example, a medicament containing human acid alpha glucosidase in the 100 to 110 kD form packaged and provided with instructions for the use in a treatment other than that of infantile Pompe's disease is encompassed by the scope of claim 1 of the main request when said medicament is being used for the treatment of infantile Pompe's disease. The protection conferred by granted claim 1 does not encompass such use.

9.5 Consequently, claim 1 of the main request would amend the contested patent in such a way as to extend the protection it confers, contrary to Article 123(3) EPC.

10. Decision T 402/89 of 12 August 1991, on which the respondent relied, concerned the question whether an amendment of a granted product claim to one for a particular, described process for making that product was allowable under Article 123(3) EPC. In the context of this particular type of amendment, which differed from the one considered in G 2/88 (*supra*), the board elaborated on difficulties in separating the concepts of "protection conferred" on the one hand and "rights conferred" on the other (see point 2 of the decision).

The present board takes the position that the findings in said decision apply to the particular case considered and are not relevant for this decision which concerns the amendment of "Swiss-type" claims as granted to purpose-limited product claims. In view of points 2 to 9 above, the distinction between the terms "protection

conferred" and "rights conferred" is not critical for the case at issue and moreover is in line with the distinction made in decision T 402/89.

11. In decision T 795/06 of 18 March 2010, also relied upon by the respondent, the board decided that the amendment of a granted claim directed to the use of botulinum neurotoxins for the preparation of a pharmaceutical for cosmetic treatment to a claim directed to the use of a pharmaceutical comprising botulinum neurotoxins for cosmetic treatment was allowable under Article 123(3) EPC, because by virtue of Article 64(2) EPC and given that the process of manufacture in claim 1 as granted was defined in a broad way, the protection conferred by the granted claim extended to any pharmaceuticals that were the direct products of a manufacturing process using the botulinum neurotoxins; consequently, the protection conferred by the granted claim also extended to the use of said pharmaceuticals.

The situation underlying said decision differs from that of the present one *inter alia* in that the amended claim under consideration in decision T 795/06 concerned the use of a pharmaceutical comprising certain substances, whereas claim 1 of the present main request is directed to a substance for use. Therefore, decision T 795/06 is not in contradiction to the present decision.

12. In view of the above, the main request is not allowable under Article 123(3) EPC.

Auxiliary requests 1 to 5 - Article 123(3) EPC

13. Claims 1 of auxiliary requests 1 to 5 are formulated as purpose-limited product claims and differ from claim 1 of the main request in that the treatment is to be

continued for at least 24 weeks instead of 4 weeks, and/ or in that the disease to be treated is further specified.

In view of the fact that the claims as granted are solely "Swiss-type" claims, the above findings with respect to Article 123(3) EPC concerning claim 1 of the main request apply equally to the auxiliary requests.

Consequently, auxiliary requests 1 to 5 do not fulfil the requirements of Article 123(3) EPC.

Referral of questions to the EBA (Article 112(1)(a) EPC)

14. Article 112(1) EPC provides that in order to ensure uniform application of the law, or if a point of law of fundamental importance arises, the board of appeal may, following a request from a party, refer any question to the Enlarged Board of Appeal for opinion. However, the board shall do so only if it considers that a decision is required for the above-mentioned purposes.

15. The respondent requested that two questions be referred to the EBA under Article 112(1)(a) EPC (see section VII above).

16. However, the board has found no inconsistency in the case law pertinent to the case at issue, nor do the board's conclusions deviate from this case law (see points 5 to 11 above).

Consequently, the board sees no need for a decision by the EBA with respect to the questions formulated by the respondent.

17. The board furthermore observes that according to the findings of decision G 2/08 (*supra*), where the subject-matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so-called "Swiss-type" claim as instituted by decision G 5/83, if the patent application has a date of filing or, if priority has been claimed, a priority date after 28 January 2011.

In view of this ruling, the board considers that the second question formulated by the respondent does not concern an important point of law whose resolution would be of general interest for the future.

18. Consequently, the appellant's request for the referral of questions to the EBA is refused.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

3. The request for the referral of questions to the Enlarged Board of Appeal is refused.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated