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**Datasheet for the decision
of 8 September 2020**

Case Number: T 0478/17 - 3.3.02

Application Number: 10785289.9

Publication Number: 2504332

IPC: C07D405/06, A61K31/4025,
A61P35/00

Language of the proceedings: EN

Title of invention:

AN AMORPHOUS AND A CRYSTALLINE FORM OF GENZ 112638
HEMITARTRATE AS INHIBITOR OF GLUCOSYLCERAMIDE SYNTHASE

Patent Proprietor:

Genzyme Corporation

Opponent:

SANDOZ AG

Headword:

Relevant legal provisions:

EPC Art. 56
RPBA Art. 12(4)

Keyword:

Inventive step

Amendments - admittance of the objection

Decisions cited:

T 0777/08, T 2397/12, T 0377/14, T 1684/16, T 0041/17

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0478/17 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 8 September 2020

Appellant:

(Opponent)

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
12 December 2016 concerning maintenance of the
European Patent No. 2504332 in amended form.**

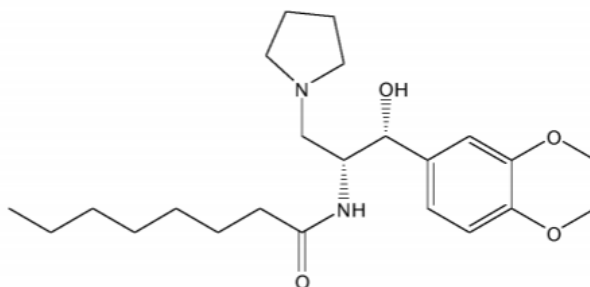
Composition of the Board:

Chairman M. O. Müller
Members: S. Bertrand
R. Romandini

Summary of Facts and Submissions

- I. The appeal by the opponent ("appellant") lies from the interlocutory decision of the opposition division that European patent n°2 504 332 in amended form according to the main request filed in electronic form on 25 February 2016 met the requirements of the EPC.
- II. The main request held allowable by the opposition division contained a set of 24 claims, the independent claims of which read as follows:

"1. A pharmaceutical composition comprising the hemitartrate salt of a compound represented by the following structural formula:



and a pharmaceutically acceptable carrier or diluent, wherein at least 70% by weight of the salt is crystalline."

"11. A pharmaceutical composition comprising:

a hemitartrate salt as defined in any one of Claims 1 to 10;

at least one water-soluble filler; at least one water-insoluble filler; at least one binder; and at least one lubricant."

"19. A hemitartrate salt as defined in any one of claims 1 to 10."

III. The following documents are referred to in the present decision:

- D1 EMEA; Committee for Orphan Medicinal Products; public summary of positive opinion for orphan designation; 1 July 2008
- D11 EMEA, ICH Topic C 6 A, Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances; May 2000; published 2006
- D12 Byrn et al., 1995, *Pharmaceutical Research*, 12 (7), p. 945-954
- D13 Bavin, 1989, *Chemistry and Industry*, p. 527-529
- D19 US 6,855,830 B2
- A001 Genzyme pub. 2008 on genetic diseases disclosing trials of Genz-112638 for Gaucher type 1
- A002 Clinical Trials.gov studies of Genzyme before 26 November 2009 on Gaucher disease
- A003 Clinical Trials.gov updated 30 July 2009 NCT00358150
- A004 Clinical Trials.gov updated 3 November 2009 NCT00891202
- A005 Clinical Trials.gov updated 5 November 2009 NCT00943111

IV. In its decision, the opposition division came to the conclusions, *inter alia*, that claim 12 of the main request fulfilled the requirements of

Article 123(2) EPC and that the subject-matter of the claims according to the main request involved an inventive step in view of D1 as the closest prior art.

- V. In its statement setting out the grounds of appeal, the appellant contested the reasoning of the opposition division and submitted that claims 2-4 of the main request did not meet the requirements of Article 123(2) EPC and that the subject-matter of the claims of this request did not involve an inventive step. They submitted documents A001 to A005.
- VI. In its reply to the grounds of appeal, the patent proprietor ("respondent") provided counter-arguments regarding added subject-matter and inventive step. They requested dismissal of the appeal implying maintenance of the patent on the basis of the main request found allowable by the opposition division and submitted auxiliary requests 1 to 20.
- VII. The appellant submitted in a first further letter comments on auxiliary requests 10 to 20.
- VIII. In a second further letter, the appellant filed further submissions on admittance and inventive step.
- IX. In reply to the board's preliminary opinion, the appellant submitted that A001 to A005 should be considered in view of their *prima facie* relevance.
- X. On 8 September 2020, oral proceedings were held before the board.
- XI. The appellant's case, where relevant to the present decision, may be summarised as follows.

Admittance of the objection according to
Article 123(2) EPC:

- Articles 100(c)/123(2) EPC were raised as a ground of opposition. The decision discussed this ground. The appellant was therefore entitled to address the issue of added matter in claims 2 to 4 of the main request in its statement of grounds of appeal.

Inventive step in view of D1 as the closest prior art:

- D1 was a document discussing the pharmaceutical designation of eliglustat for the treatment of Gaucher disease. It was directed to the L-tartaric acid/L-tartrate salt and a commercially viable pharmaceutical formulation of the same drug for the treatment of Gaucher disease, i.e. the same indication as set out in the patent. D1 was the closest prior art.
- Claim 19, relating to the salt of any one of claims 1 to 10, was the broadest claim of the main request and it differed from the disclosure of D1 in the ratio of tartaric acid to eliglustat (1:2) and the percentage of crystallinity of the salt (at least 70% by weight of the salt is crystalline).
- The effect referred to in the evidence filed on 7 September 2016 by the respondent, namely the chemical stability of crystalline eliglustat hemitartrate versus the corresponding amorphous form, was not mentioned in the application as filed. It was not possible to rely on this effect for formulating the objective technical problem.
- It was not credible that the effect shown in the examples of the patent occurred over the whole scope of claim 19. The results in example 1 of the

patent only gave data for 100% crystalline eliglustat hemitartrate. These results could not be extrapolated for a sample comprising 70% crystalline and 30% amorphous eliglustat hemitartrate, as covered by claim 19 of the main request. Thus, there was no evidence on file that the effect shown in example 1 of the patent would occur with a composition comprising 70% crystalline eliglustat hemitartrate. The burden of proof was on the respondent to show that the effect was achieved over the whole scope of claim 19. In the absence of complete data, no advantages had been shown to be associated with the distinguishing feature.

- The objective technical problem in view of D1 was the provision of an alternative.
- The alternative would have been obvious in view of D1 alone, or in view of the common general knowledge represented by D11, D12 and D13, in line with decisions T 777/08 and T 41/17. D11, D12 and D13 taught a screening procedure to find suitable polymorphs. The solution proposed by claim 19 of the main request corresponded to a "one-way street" situation in view of D1 and thus did not involve an inventive step.

XII. The respondent's case, where relevant to the present decision, may be summarised as follows.

Admittance of the objection according to Article 123(2) EPC:

- The claim dependencies of claims 2 to 4 on which the appellant's objection was based were present in the granted claims, and the appellant could, therefore, have raised this objection as early as in its notice of opposition. There was nothing

preventing the appellant from raising the objection during oral proceedings before the opposition division when they were given the opportunity to comment on the basis indicated for the claims of the main request. No such objection was, however, raised before the opposition division.

Inventive step in view of D1 as the closest prior art:

- Claim 19 differed from the disclosure of D1 in the ratio of tartaric acid to eliglustat (1:2) and the percentage of crystallinity of the salt (at least 70% by weight of the salt is crystalline).
- The examples of the patent showed that eliglustat hemitartrate had no hygroscopicity (example 1, paragraph [0081]), unlike the amorphous eliglustat monotartrate. The experimental evidence filed on 7 September 2016 before the opposition division and re-filed with the reply to grounds of appeal showed that the crystalline eliglustat hemitartrate had a higher chemical stability when compared to the corresponding amorphous form.
- It was credible that the effect shown in the examples (hygroscopicity) was shown over the whole scope of claim 1 of the main request, the crystalline form presenting, over the amorphous form, advantages which would still be present in a mixture in which at least 70% by weight of the salt was crystalline. The burden of proof was on the appellant to provide evidence to the contrary.
- The passages on page 2, lines 11-13, of the application as filed referred to the stability of the eliglustat salt of the invention. The skilled person could thus have derived from this passage the higher chemical stability of the eliglustat

hemitartrate demonstrated in the test filed on 7 September 2016 as a plausible effect. The evidence filed on 7 September 2016 could be thus relied on in the formulation of the objective technical problem.

- The objective technical problem was the provision of an eliglustat tartrate salt with improved hygroscopicity and improved chemical stability.
- There was nothing in D1 or any of the other cited documents which would have given the skilled person a reasonable expectation that the objective technical problem set out above would have been solved by providing a tartaric acid salt form of eliglustat according to the claims of the main request. This case was in line with decisions T 2397/12 and T 1684/16.
- The claims of the main request involved an inventive step.

XIII. The parties' requests were the following:

- The appellant requested that the decision under appeal be set aside, that the patent be revoked in its entirety and that A001 to A005 be admitted into the appeal proceedings.
- The respondent requested that the patent be maintained on the basis of the main request filed in electronic form on 25 February 2016 and considered allowable by the opposition division in its decision (in other words that the appeal be dismissed) or that the decision under appeal be set aside, the patent be maintained on the basis of any of auxiliary requests 1 to 9 filed with the reply

to the statement of grounds of appeal and A001-A005 not be admitted into the proceedings.

Reasons for the Decision

Main request (claims filed in electronic form on 25 February 2016).

1. Admittance of the objection under Article 123(2) EPC
 - 1.1 The appellant has raised an objection of added subject-matter in claims 2 to 4 of the main request in the statement setting the grounds of appeal. The objection concerned the combination of features in dependent claims 2 to 4 which was not disclosed in dependent claims of the application as filed since the claims dependencies were different. The objection was extended to claims 5-11 and 13-24 of the main request in view of their dependency on claims 2 to 4. The respondent requested that the objection under Article 123(2) EPC raised by the appellant in its statement of grounds of appeal not be admitted.
 - 1.2 Pursuant to Article 12(4) RPBA 2007, the board has the power to hold inadmissible, *inter alia*, facts and evidence which could have been presented or were not admitted in the first-instance proceedings even if they were presented with the statement of grounds of appeal and the requirements of Article 12(2) RPBA 2007 are met.

According to this board the objection at issue could and should have been filed during the proceedings before the opposition division for the following reasons.

An objection against claims 2 to 4 of the main request was not raised during the written opposition proceedings. Accordingly, in the impugned decision (see paragraph IV), no objection of added matter against claims 2-4 of the main request was discussed. According to the minutes of the oral proceedings before the opposition division (point 5), the only objection under Article 123(2) EPC was raised in the oral proceedings against dependent claims 12-18 of the main request. Claims 12-18 of the main request are dependent on claim 11. The latter relates to a pharmaceutical composition comprising a hemitartrate salt as defined in any one of claims 1 to 10 of the main request and further ingredients of pharmaceutical compositions, namely fillers, binder and a lubricant. Dependent claims 12-18 of the main request define the further ingredients and their amounts. Claims 2-4 of the main request, on the other hand, concern crystalline properties of the hemitartrate salt of claim 1 of the main request. Thus, the objection of added subject-matter against claims 2-4 of the main request is based on facts different from the ones presented in the context of claims 12-18 of the main request before the opposition division. Thus, the objection under Article 123(2) EPC against claims 2-4 of the main request is neither based on nor derivable from the objection raised before the opposition division. It constitutes a new allegation of fact raised for the first time in the statement of grounds of appeal (paragraph 2).

Since the main request corresponds to the request held allowable by the opposition division, the appellant could and should have objected to added subject-matter of claims 2-4 in the proceedings before the opposition division, i.e. at the very latest during the oral proceedings before the opposition division. For the

sake of completeness, claims 2-4 of the main request correspond to claims 3-5 as granted and thus the objection could have been raised in the notice of opposition.

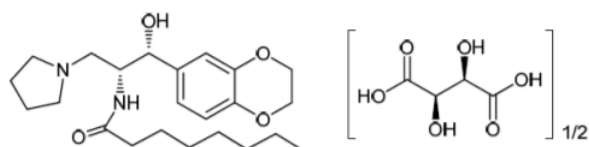
Consequently, since the objection could and should have been presented in the first-instance proceedings, the board, by exercising its discretion under Article 12(4) RPBA, decided not to admit the objection into the appeal proceedings.

2. Admittance of A001-A005
 - 2.1 With its statement of grounds of appeal, the appellant submitted A001 to A005. These documents are publications from 2008 disclosing an intention to launch phase 3 clinical trials using "Genz-112638" (A001), as well as four documents which are extracts from the ClinicalTrials.gov website that concern studies with "Genz-112638" (A002, A003, A004 and A005). The appellant resorted to these documents essentially as evidence in support of the alleged physical form of the salt disclosed in D1.
 - 2.2 The respondent requested that these documents not be admitted.
 - 2.3 During the oral proceedings, the appellant stated that they were not relying on A001-A005. The documents essentially disclose the solid state of the compound disclosed in D1. Since this feature is not relevant in the assessment of inventive step (see below), there is no need to decide on the admittance of A001-A005.

3. Article 56 EPC

3.1 Claim 19 of the main request relates to a hemitartrate salt of eliglustat in which at least 70% by weight of the salt is crystalline.

The above salt may be represented by the following formula:



Hence, the claimed compound eliglustat hemitartrate is a salt in which the cation and anion forming the salt are present in a specific stoichiometry. More specifically, the salt has a tartrate:eliglustat stoichiometry of 1:2.

3.2 Both D1 (disclosing eliglustat tartrate) and D19 (disclosing eliglustat freebase, i.e. a compound not in the form of a salt) were considered by the appellant in its written submissions as the closest prior art. During the oral proceedings, the appellant only maintained the attack based on D1 as the closest prior art.

3.3 D1 discloses a compound which is an eliglustat L-tartaric acid salt for the treatment of Gaucher disease. D1 does not explicitly disclose the physical state of the compound. In the following, it will be assumed in the appellant's favour that the compound, being a salt, is in the form of a solid.

Furthermore, it cannot be determined from the name referred to in D1 ("(1R,2R)-octanoic acid...**tartaric**

acid salt") what the eliglustat:tartrate stoichiometry is.

Lastly, D1 does not state the crystallinity of the tartaric acid salt it discloses.

3.4 Distinguishing features

It was common ground between the parties that the distinguishing features of the subject-matter of claim 19 in view of D1 are the eliglustat:tartrate stoichiometry (claim 19: ratio of tartaric acid to eliglustat of 1:2) and the percentage of crystallinity of the salt (claim 19: at least 70% by weight of the salt is crystalline).

3.5 Technical problem

3.5.1 The examples of the patent show that eliglustat hemitartrate has no hygroscopicity (example 1, paragraph [0081]). In contrast, solid eliglustat monotartrate (i.e. a 1:1 salt of eliglustat with tartaric acid) was obtained in a form which was non-crystalline and hygroscopic (example 1, paragraph [0081]).

Furthermore, the experimental evidence filed on 7 September 2016 by the respondent before the opposition division in response to the summons to attend oral proceedings and re-filed with the reply to grounds of appeal shows that the crystalline eliglustat hemitartrate has a lower chemical reactivity than amorphous eliglustat hemitartrate. The crystalline form exhibits a 0% increase of N-oxide degradation under storage at room temperature after 1 month, while the amorphous form has an 87% increase under the same conditions.

3.5.2 The appellant objected that the effect was not achieved over the whole scope of claim 19 of the main request. It argued that there was no evidence on file that the effect shown with 100% crystalline eliglustat hemitartrate would occur with a composition comprising 70% crystalline eliglustat hemitartrate. The burden of proof was on the respondent.

The board considers that if a sample comprising 100% crystalline eliglustat hemitartrate is better than a sample comprising 0% crystalline eliglustat hemitartrate (and thus 100% amorphous eliglustat hemitartrate), it is credible that a composition comprising 70% crystalline (and thus 30% amorphous eliglustat hemitartrate) is still better than a sample comprising 0% crystalline eliglustat hemitartrate. With the credibility that the technical problem is solved over the whole scope of claim 19 of the main request established, the burden of proof to the contrary lies with the appellant. Since no evidence to the contrary has been filed by the appellant, it has to be assumed that the effect is achieved over the whole scope of claim 19 of the main request.

3.5.3 The appellant also argued that the effect referred to in the evidence filed on 7 September 2016 was not derivable from the application as filed. As a consequence, according to the appellant, it was not possible to rely on this effect for formulating the objective technical problem. Example 15 of the application as filed referred to the "forced-degradation" and "stability" of formulations of the crystalline eliglustat hemitartrate and not of the salt per se (paragraphs [0146] and [0148]). The passages of page 2, lines 11-13, and of page 3, lines 3-5, also

referred to stable pharmaceutical formulations and stable granules for capsules formulations.

The board disagrees for the following reasons. The passage on page 2, lines 11-13, of the application as filed reads "*There is also a need for pharmaceutical compositions in which **this drug candidate is stable** and*" (emphasis added by the board). When this passage is read with the previous sentence, it is clear that the "drug candidate" is understood as the salt form of eliglustat, which encompasses the compounds of the invention. Thus, this passage refers to the stability of eliglustat salt of the invention. The skilled person would derive from this passage the lower chemical reactivity (i.e. the higher chemical stability) of the eliglustat hemitartrate as demonstrated in the test filed on 7 September 2016. As set out in e.g. T 377/14 (point 2.1.5), for a proprietor to be able to rely on a certain problem, the problem does not have to be explicitly disclosed in the application as filed; it being foreshadowed is sufficient.

3.5.4 In view of the above, the technical problem may be seen as the provision of an eliglustat tartrate salt with improved (reduced) hygroscopicity and improved chemical stability.

3.6 Non-obviousness

It remains to be investigated whether the proposed solution would have been obvious to the skilled person in the light of the prior art and the relevant common general knowledge.

D1 only discloses an eliglustat tartrate salt for the treatment of Gaucher disease. It does not teach how to improve hygroscopicity and chemical stability. The

subject-matter of claim 19 of the main request is therefore inventive in view of D1 taken alone.

The appellant, in arguing that the claimed solution would have been obvious, referred to D11, D12 and D13. Documents D11, D12 and D13 reflect common general knowledge in the field of pharmaceutical drug preparation.

As regards the preparation of pharmaceutical products, D11 (section 3.3.1.c) states that "*Some new drug substances exist in different crystalline forms which differ in their physical properties. Polymorphism may also include solvation and hydration products (also known as pseudopolymorphs) and amorphous forms. Differences in these forms could, in some cases, affect the quality or performance of the new drug products. In cases where differences exist which has been shown to affect drug product performance, bioavailability or stability, then the appropriate solid state should be specified*".

D12 (sections A and B under the heading "Polymorphs") refers, *inter alia*, to a flow chart outlining the investigations of the formation of polymorphs, the analytical tests available for identifying polymorphs and studies of the physical properties of polymorphs.

D13 (page 528, left-hand column, first paragraph) relates to the preparation and identification of polymorphs. It focuses on the motivation for searching for different polymorphs to give each candidate the best chance of progressing and to avoid eventual disruption later in their development.

Each of D11, D12 and D13 thus teaches the need for polymorph screening but does not focus on hygroscopicity and improved chemical stability.

Furthermore, D11, D12 and D13 are silent about the influence of a different stoichiometry on the properties of salts of an active ingredient like in this case (hemitartrate versus tartrate).

In view of their disclosure, D11 to D13 do not teach that eliglustat **hemitartrate** being at least 70% by weight crystalline would exhibit an improved (reduced) hygroscopicity and improved chemical stability and would, for this reason, solve the technical problem.

The board concludes that, having regard to the cited prior art, it would not have been obvious to the skilled person to isolate eliglustat hemitartrate in which at least 70% by weight of the salt was crystalline and arrive at the compound as defined in claim 19 of the main request.

- 3.6.1 The appellant submitted that the claimed solution would have been obvious since D12 (page 952, right column, first paragraph) taught that "*Amorphous forms are sometimes less chemically stable*". Thus, the skilled person would have considered a crystalline form of the salt of D1. D1 proposed only two choices (tartrate and hemitartrate), and it was standard to test 2 options, thus leading to a "one-way street situation".

The board does not agree. First, the passage referred to in D12 by the appellant uses the term "sometimes" and, thus, does not imply that every crystalline form is more chemically stable than the corresponding amorphous form. Second, the question to be answered is whether D1 in combination with D12 renders obvious the solution proposed by claim 19 of the main request, i.e. whether it teaches that eliglustat hemitartrate being at least 70% by weight crystalline would have an improved hygroscopicity and an improved chemical

stability. However, D12, like D1, is silent about hygroscopicity. For this reason, D1 in combination with D12 would not have led the skilled person, faced with the technical problem to be solved, to the specific salt of claim 19 of the main request.

The board can also not see any "one-way street situation" in view of D1. The skilled person starting from D1 would have had various choices in terms of stoichiometry and degree of crystallinity. As set out above, none of the cited prior art documents suggests the claimed choice as a solution to the objective technical problem, let alone do any of the cited prior art documents offer this choice as the only possible "one-way street" solution.

- 3.6.2 This finding is in line with decisions T 777/08 (OJ EPO 2011, 633), T 41/17, T 1684/16 and T 2397/12, discussed by the parties.

The board distinguishes the present case from the situation at issue in decision T 777/08. This decision dealt with an arbitrary selection of any crystalline form and considered it obvious that any arbitrary crystalline form had **better filterability and drying characteristics** than the corresponding amorphous form. This is entirely different from the present case. The present case is not about the selection of any crystalline form but about the selection of one specific salt, namely eliglustat **hemitartrate**, in which at least 70% by weight of the salt is crystalline. Furthermore, the selection of this specific salt is not arbitrary. Rather, this salt has unexpected properties, namely an improved (reduced) hygroscopicity and an improved chemical stability.

Decision T 41/17 was concerned with the selection of a specific crystalline form of sorafenib tosylate (polymorph I), which was subjected to mechanical stress. By using a stable form of the active ingredient, the risk that it was converted to another form was reduced and helped to ensure the manufacture of a pharmaceutical product with consistent properties. There was a teaching in the prior art to select the thermodynamically stable polymorph for avoiding changes during the manufacture of the pharmaceutical preparation. Thus, the claimed subject-matter, being the thermodynamically most stable polymorph, was considered obvious by the board in that case. The present case differs from T 41/17 where inventive step was denied since it is not about the selection of a crystalline form of a compound disclosed in an amorphous form in the closest prior art but about the selection of one specific **salt**, namely eliglustat **hemitartrate**. Furthermore, unlike the case in T 41/17, in the present case, no teaching is available in the prior art to select the claimed salt to solve the objective technical problem.

In the case underlying T 1684/16, the distinguishing feature was the specific crystalline form of bosutinib monohydrate ("Form I"). The technical effect associated with the distinguishing feature was a stable crystalline form; hence, the objective technical problem was to provide a form of bosutinib that was more stable.

The appellant in that case submitted that the claimed solution would have been obvious since screening of polymorphs was a routine task as demonstrated by D4, D5 and D7. It submitted that there would have been a reasonable expectation of success for the skilled person as regards whether Form I of bosutinib

monohydrate would maintain its stability in terms of appearance, purity, water content and crystallinity after being exposed to 70°C and 75% relative humidity for two weeks. The board in that case did not agree. It held that the fact that the skilled person would have been taught in the prior art to investigate polymorphs in order to isolate the crystalline form having the most desirable properties was in itself not necessarily sufficient to consider a specific polymorphic form having a certain desired property obvious and deny inventive step. Only if the prior art contained a clear pointer that it was the claimed subject-matter that solved this problem or where it at least created a reasonable expectation that a suggested investigation would be successful, could inventive step be denied. So, in the present case, in line with T 1684/16, the fact that D11, D12 and D13 teach the need of polymorph screening in itself is not a sufficient reason to consider the claimed subject-matter obvious. Again, in line with the above-mentioned decision, the claimed solution in the present case has to be considered non-obvious since there is in none of the documents cited by the appellant a pointer that eliglustat hemitartrate being at least 70% by weight crystalline would solve the objective technical problem, namely the provision of a eliglustat tartrate salt with improved (reduced) hygroscopicity and improved chemical stability.

Lastly, T 2397/12 relates to squalamine dilactate. In the context of inventive step, it was found that it was not known which form of salt (mono- or dilactate) was present in the closest prior art. Squalamine dilactate was not disclosed in any of the documents of the prior art and was not a compound that the skilled person would inevitably have selected when carrying out their routine tests for finding suitable crystallisation

conditions. On this basis, the board acknowledged inventive step.

In the present case, like in T 2397/12, D1 does not disclose in which form the eliglustat tartrate is present, and the prior art cited does not teach the compound. Consequently, in the same way as in T 2397/12, eliglustat hemitartrate would not inevitably have been selected by the skilled person when considering the objective technical problem to be solved.

- 3.7 Therefore, the subject-matter of claim 19, and by the same token dependent claims 20 to 24 of the main request, involves an inventive step pursuant to Article 56 EPC. The same applies to the compositions of claims 1 to 18, which all contain a salt as defined in claim 19.

4. In the absence of any further objections, the main request is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



N. Maslin

M. O. Müller

Decision electronically authenticated