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Datasheet for the decision of 28 April 2021

Case Number: T 2430/17 - 3.3.07

Application Number: 11710202.0

Publication Number: 2549983

IPC: A61K9/20, A61K31/517

Language of the proceedings: EN

Title of invention:
NOVEL COMPOSITION FOR TREATMENT OF ESSENTIAL THROMBOCYTHEMIA

Patent Proprietor:
AOP Orphan Pharmaceuticals AG

Opponent:
Galenicum Health S.L.

Headword:
Thrombocythemia/GALENICUM HEALTH

Relevant legal provisions:
EPC Art. 83, 56, 123(3)
RPBA 2020 Art. 12(1)(a), 12(2)

Keyword:
Sufficiency of disclosure - main request (no)
Inventive step - main request (no)
Amendments - broadening of claim (yes)
Basis of proceedings - decision under appeal

Decisions cited:
T 2017/07, T 0287/11

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Case Number: T 2430/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 28 April 2021

Appellant: (Patent Proprietor)	AOP Orphan Pharmaceuticals AG Wilhelminenstrasse 91/II f/B 4 1160 Wien (AT)
Representative:	Loidl, Manuela Bettina REDL Life Science Patent Attorneys Donau-City-Straße 11 1220 Wien (AT)
Appellant: (Opponent)	Galenicum Health S.L. Avenida Diagonal 123 floor 11 08005 Barcelona (ES)
Representative:	Galenicum Health S.L. Avinguda de Cornellà 144, 7th floor 08950 Esplugues de Llobregat (ES)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 5 September 2017 concerning maintenance of the European Patent No. 2549983 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	Y. Podbielski

Summary of Facts and Submissions

I. European patent 2 549 983 was granted on the basis of thirteen claims.

Claim 1 as granted related to:

"A pharmaceutical composition free of gastric coating comprising anagrelide HCl, a non-pH dependent polymer and a pharmaceutically acceptable water soluble acid, wherein the non-pH dependent polymer is selected from the group polyacrylacids, cellulose derivatives or polyacrylamids, preferably it is Carbopol™ and wherein the amount of the non pH dependent polymer is 1.5 to 2.5 fold of anagrelide (w/w)."

II. The patent was opposed on the grounds that the claimed invention was not sufficiently disclosed and lacked an inventive step. Appeals were filed by the patent proprietor (hereinafter appellant-patent proprietor) and the opponent (hereinafter appellant-opponent) against the interlocutory decision of the opposition division that the patent as amended in accordance with auxiliary request 1 was found to meet the requirements of the EPC.

The decision was based on the main request filed on 4 July 2017 and on auxiliary request 1 submitted during the oral proceedings held on 10 July 2017. The claims of the main request corresponded to the claims as granted except for the deletion of claim 10. The claims of the auxiliary request 1 corresponded to the claims of the main request except that in claim 1 the non-pH dependent polymer is defined as "selected from the

group of polyacrylic acids, preferably it is Carbopol™" with the deletion of cellulose derivatives and polyacrylamides.

III. The following documents are cited herein:

D2: Expert opinion by Dr. Johannes Bartholomäus
D6: Letter filed on 10-03-2014 by the Applicant
D7: US 2004/0062800 A1
D8: Formulating Controlled Released Tablets and Capsules with Carbopol®* Polymers, Pharmaceutical Bulletin, Lubrizol, 29th October 2008
D9: Extract from Handbook of Pharmaceutical Excipients, Raymond C. Rowe, Paul J. Sheskey, Marian E. Quinn, Pharmaceutical Press, 2009
D10: Pharmaceutical Polymers for Oral Solid Dosage Forms, Lubrizol, 2007

D11: US20040028729
D12: Lubrizol: Carbopol® polymers for controlled release tablets
D13: Evonik, Eudragit® L 100-55

D14: Carbohydrate Polymers 86 (2001) 85-93, Asare-Addo et al.

Documents D2 and D6-D10 were cited in the decision under appeal. Documents D11-D13 were cited by the appellant-opponent in its statement of grounds of appeal. Document D14 was cited by the appellant-patent proprietor in its statement of grounds of appeal.

IV. According to the decision under appeal:

(a) Documents D8, D9 and D10 were admitted because these documents were filed within the Rule 116 EPC

time limit and were relevant for disclosing characteristics of Carbopol, which was the preferred type of polyacrylacid according to the patent.

(b) The term "non-pH dependent polymer" in claim 1 of the main request did not represent a limiting feature, because it was in contradiction with the definition of polyacrylacids as suitable polymers.

(c) The subject-matter of claim 1 of the main request met the requirement of sufficient disclosure. The opponent had not substantiated that it required undue burden for the skilled person to reproduce the claimed invention. The objections regarding the definition of the pH dependent polymer concerned the requirements of Article 84 EPC rather than the requirement of sufficiency.

(d) The subject-matter of claim 1 of the main request did not involve an inventive step. Document D7, in particular formulation I from Table 4, represented the closest prior art describing a sustained release formulation of anagrelide with the non-pH dependent polymer Polyox, the sustained release polymer Eudragit and fumaric acid. The subject-matter of the patent differed from this prior art in the presence of cellulose derivatives, polyacrylamides and/or polyacrylacid and the definition of the ratio 1.5-2.5 for the sum of the amounts of these polymers with respect to anagrelide. The only experimental data on file concerned compositions comprising polyacrylacid showing a sustained release profile. It was not credible that every cellulose derivative or polyacrylamide would allow for a similar effect as

polyacrylacids. The problem solved over the whole scope of the claim was therefore seen in the provision of a mere alternative anagrelide formulation irrespective of its release properties. As solution to such a problem the use of any of the polymers of document D7, including cellulose derivatives or polyacrylamides, in any amount given, was obvious to the skilled person.

(e) The subject-matter of claim 1 of auxiliary request 1 was not broader than claim 1 as granted, because both claims required the presence of a non-pH sensitive polymer in a defined ratio to anagrelide, whilst in claim 1 of auxiliary request 1 cellulose derivatives and polyacrylamides were merely deleted from the list of non-pH dependent polymers.

(f) The subject-matter of claim 1 of auxiliary request 1 involved an inventive step. The problem solved with respect to the closest prior art represented by document D7 was seen in the provision of an alternative anagrelide formulation with sustained release characteristics. No prior art suggested that the use of polyacrylacid in the defined low ratio would still allow for obtaining an anagrelide formulation showing sustained release characteristics.

V. In the statement setting out the grounds of appeal the appellant-patent proprietor relied on a main request and auxiliary request 1, which correspond to the main and auxiliary requests on which the appealed decision was based. Document D14 was additionally filed.

With the statement setting out the grounds of appeal the appellant-opponent submitted the additional documents D11-D13.

VI. With its reply the appellant-patent proprietor filed auxiliary requests 2 and 3. Claim 1 of auxiliary request 2 additionally defines with respect to claim 1 of auxiliary request 1 the feature: "wherein anagrelide HCl is in an amount between 2 and 3 mg." Claim 1 of auxiliary request 3 additionally defines with respect to claim 1 of auxiliary request 2 the feature: "and wherein the non-pH dependent polymer is present in an amount between 2.5 and 5 mg."

In its reply the appellant-opponent explained its objections against the requests submitted by the appellant-patent proprietor.

VII. In a communication pursuant to Article 15(1) RPBA 2020 issued on 14 October 2020 the Board expressed *inter alia* doubts whether the subject-matter as defined in the claims of the requests submitted by the appellant-patent-proprietor met the requirements of sufficiency of disclosure and inventive step. Moreover the Board indicated that the subject-matter of auxiliary requests 1-3 did not seem to meet the requirement of Article 123(3) EPC.

VIII. With the letter of 23 March 2021 the appellant-patent proprietor announced that it would not attend the oral proceedings scheduled for 30 April 2021.

With the communication of 31 March 2021 the oral proceedings were cancelled.

IX. The appellant-patent proprietor's arguments relevant to the present decision are summerized as follows:

(a) Documents D8, D9 and D10 had been filed without justification just prior to the limit set under Rule 116 EPC by the opposition division and well after expiry of the opposition period. The documents, which did not mention anagrelide, lacked prima facie relevance.

The late filed documents D11, D12 and D13 did not present information of additional relevance.

(b) The description of the patent provided in paragraphs [0041] and [0067] guidance regarding the non-pH dependent polymers to be used and in paragraphs [0068]-[0069] instructions with respect to the amounts of the components to be used. As confirmed by the declaration in document D2 this information was sufficient for the skilled person to carry out the invention. No serious doubts based on verifiable facts had been raised against the sufficiency of the disclosure of the claimed invention.

(c) The difference with the closest prior art represented by document D7 concerned the definition of the non-pH dependent polymer used in a 1.5-2.5 fold amount with respect to anagrelide. As shown in figures 1 and 2 of the patent as well as in document D6 compositions comprising a polyacrylic acid allowed for sustained release of anagrelide. The defined cellulose derivatives and polyacrylamides allowed for the same effect. Document D14 confirmed in this context that the cellulose derivate hydroxypropyl methylcellulose

(HPMC) allows for pH-independent drug release profiles. The problem to be solved was the provision of an improved formulation allowing sustained release of anagrelide. No prior art suggested that sustained release could be achieved using the defined low ratio of the non-pH dependent polymer.

(d) The amendment in claim 1 of auxiliary request 1 merely concerned the deletion of two alternatives from a list of three families of polymers. The considerations of T 2017/07 did not apply.

X. The appellant-opponent's arguments relevant to the present decision are summerized as follows:

(a) The opposition division correctly recognized that Documents D8, D9 and D10 were filed within the time limit set under Rule 116 and were relevant to its decision.

The late filed documents D12 and D13 related to the properties of polyacrylic acids, including the Carbopol-type polymers preferred according to the patent, and were therefore prima facie relevant.

Document D11 related to anagrelide sustained release formulations with non-pH dependent polymers and was therefore also prima facie relevant.

(b) As evidenced by documents D8-D10 and D12 polyacrylic acids cover a wide number of polymers with varying properties. The single example of the patent did not specify the type of polyacrylic acid used and it would require undue burden to establish

which polyacrylic acid was suitable for use in accordance with the patent.

(c) Document D7 already described anagrelide formulations free of gastric coating comprising a non-pH dependent polymer and a water-soluble acid. The defined subject-matter differed only in the definition of the amount of the non-pH dependent polymer. No comparison with the closest prior art could be established and the problem solved could consequently only be seen in the provision of an alternative composition. As solution to such problem the defined subject-matter would be obvious to the person skilled in the art.

(d) The restriction of the definition of the non-pH dependent polymers in accordance with auxiliary request 1-3 resulted in a broadening of the scope of protection, because this definition was linked with the limitation of the amounts of these polymers defined in the claims as granted. The considerations from decisions T 2017/07 and T 287/11 as outlined in the Guidelines for the Examination in the EPO, H-IV 3.5 applied.

XI. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or auxiliary request 1, both filed with its statement of grounds of appeal of 15 January 2018, or on the basis of auxiliary request 2 or 3, both filed with its reply of 19 July 2018.

The appellant-patent proprietor further requested that documents D8, D9 and D10 as well as documents D11, D12 and D13 not be admitted.

XII. The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

Reasons for the Decision

1. Admittance of late filed documents

1.1 The opposition division admitted documents D8, D9 and D10 in view of their relevance and the fact that they were filed within the time limit set under Rule 116 EPC. It considered the documents when deciding whether the invention according to the claims of the main request complied with the requirements of Article 83 EPC. Accordingly, these documents are part of the appeal proceedings (Article 12(1) a) and 12(2) RPBA 2020).

1.2 Document D11 was cited by the appellant-opponent in its statement of grounds of appeal without apparent justification other than that it was already considered during examination. The Board notes that the appellant-opponent has not relied on this document in any of its arguments submitted with its statement of grounds of appeal and its reply to the proprietor's appeal. The Board thus finds no reason why this document should be considered during the appeal procedure.

1.3 Documents D12 and D13 were cited by the appellant-opponent in its statement of grounds of appeal in support of the argument that contrary to the decision under appeal the terms Carbopol and polyacrylacid comprise a variety of products with quite different

types of properties, that certain types of Carbopol were known for use in concentrations between 3-10% and that Eurdragit qualifies as polyacrylicacid.

Document D14 was cited by the appellant-patent proprietor in its grounds of appeal in support of the argument that contrary to the decision under appeal cellulose derivatives and polyacrylamides show non-pH dependent swelling allowing for the desired pH independent drug release profiles.

The Board thus concludes that documents D12-D14 were filed in legitimate response to the grounds for the decision under appeal and therefore sees no reason to exercise its discretion not to admit these documents into the appeal proceedings.

2. Main request

2.1 Sufficiency of disclosure

The Board observes that claim 1 of the main request relies on the one hand on a generic structural definition of the polymers as polyacrylacids, cellulose derivatives or polyacrylamides and on the other hand on the functional requirement that these polymers are non-pH dependent. The patent refers in paragraph [0036] to the polymers as having pH independent swelling and defines in paragraph [0041] the term "non-pH dependent" specifically as meaning that "colloidal dispersion of said polymer is not pH dependent, i.e. is dispersed not only under high and low pH conditions, specifically at a pH $\leq$4 and $\geq$9, but also between pH 4 and 9."

In view of this explicit teaching in the patent the Board does not agree with the decision under appeal,

that the feature "non-pH dependent polymer" does not represent a limiting feature.

For the requirement of Article 83 EPC to be met, the skilled person should therefore on the basis of the teaching in the patent and the common general knowledge be able to determine without undue burden, which polyacrylacids, cellulose derivatives and polyacrylamides meet the functional requirement of being non-pH dependent within the meaning of the patent.

In this context the Board further notes that claim 1 of the main request defines that the non-pH dependent polymer is preferably Carbopol and that the patent mentions in paragraph [0042] Polyacrylacid 971P (Carbopol^{TM}) as an example of such Carbopol polymer. The actual example of a formulation presented in the patent does not further specify the polyacrylacid used (see paragraph [0085]). Documents D8, D9, D10 and D12 indicate, however, that swelling and gel formation of Carbopols are generally pH dependent (see D8 page 8, final paragraph; see D9 page 112, left column, second and third paragraphs; see D10 page 3, second paragraph and page 4 right column fifth paragraph; see D12, page 5, section 11).

In view of this information from documents D8, D9, D10 and D12, according to which Carbopols will generally not meet the functional requirement defined in claim 1 of the main request, and in the absence of further guidance in the patent as to the polyacrylacids, in particular the preferred Carbopols, which could nevertheless qualify as non-pH dependent, the Board concludes that the patent does not enable the skilled person to determine without undue burden the

polyacrylic acid polymers to be used in accordance with claim 1 of the main request.

The appellant-patent proprietor has argued that the patent provides instructions regarding suitable polymers in paragraphs [0041] and [0067]-[0069] and that according to the expert opinion in document D2 the information in the patent was sufficient for the skilled person to carry out the invention. The Board observes, however, that the cited passages in the patent and the opinion in document D2 do not identify any example of a non-pH dependent polyacrylacid nor otherwise indicate how the skilled person could, notwithstanding the information from documents D8, D9, D10 and D12, carry out the claimed invention using non-pH dependent polyacrylacids.

Accordingly the patent does not disclose the invention defined in claim 1 of the main request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The main request does therefore not meet the requirement of Article 83 EPC.

2.2 Inventive step

The identification of document D7, in particular formulation I from Table 4, in the decision under appeal as closest prior art is not in dispute.

The Board takes the view that the claimed subject-matter differs from this prior art in the presence of the non-pH dependent polymer being selected from polyacrylacids, cellulose derivatives or polyacrylamides and the definition of the ratio of 1.5-2.5 for the sum of the amounts of these polymers

with respect to anagrelide. In this context the Board agrees with the decision under appeal, that the term polyacrylacids relates to products obtained from polymerization of specifically acrylic acid and not of any acrylic monomer. This term is therefore not considered to cover the Eudragit L100-55 mentioned in document D7 for formulation I of Table 4, as such Eudragit is a copolymer of methacrylic acid and ethylacrylate (see D13).

The description of the patent mentions that the purpose of the defined composition is the provision of a formulation for sustained release of anagrelide (see paragraphs [0024],[0040] and [0070]).

The Board observes that document D7 describes sustained release pharmaceutical dosage forms having a pH-independent or minimized pH-dependent release profile (see paragraph [0001]), wherein the active agent, which may be anagrelide HCL, is preferably present in an amount of 1-40 wt% (see paragraph [0006]) and wherein a non-pH dependent sustained release agent, which may for instance be a cellulose derivative, is preferably present in an amount of 10-30 wt% (see paragraph [0007]). In addition to these ingredients document D7 requires the presence of a pH dependent release agent and/or an solubilizing agent such as an organic acid (see paragraph [0008]). Accordingly, in as far as the main request relates to compositions comprising available non-pH dependent polymers such as cellulose derivatives, the subject-matter of claim 1 of the main request represents a mere selection with respect to the teaching of document D7.

No advantage with respect to the prior art has been shown for the claimed subject-matter and the problem to

be solved is therefore seen in the provision of an alternative anagrelide composition. As solution to such problem the mere selection of subject-matter which the prior art already indicated generally as suitable would be obvious to the skilled person.

Accordingly, the subject-matter of claim 1 relating to compositions comprising available non-pH dependent polymers such as cellulose derivatives does not involve an inventive step and therefore does not meet the requirement of Article 56 EPC.

3. Auxiliary requests

3.1 Auxiliary request 1

Claim 1 of auxiliary request 1 differs from claim 1 as granted in that the defined group of non-pH dependent polymers is limited to polyacrylacids following the deletion of cellulose derivatives and polyacrylamides. As a result of this deletion the restriction in claim 1 as granted regarding the ratio of the non-pH dependent polyacrylacids, cellulose derivatives or polyacrylamides to the anagrelide applies according to claim 1 of auxiliary request 1 only with respect to polyacrylacids.

Consequently, claim 1 of auxiliary request 1 covers compositions that include non-pH dependent cellulose derivatives or polyacrylamides in amounts in excess of the 2.5 ratio permitted in claim 1 as granted. In line with the considerations in T 2017/07 (see reasons 2.2.1-2.2.3) and T 287/11 (see reasons 2.3.1) the amendment in accordance with claim 1 of auxiliary request 1 thereby results in an extension of the scope

of protection with respect to the claims of the patent as granted.

The appellant-patent proprietor argued that the considerations of T 2017/17 do not apply to the present case, in which merely a list of three families of polymers as defined in claim 1 as granted is limited by deletion of two alternatives. The Board observes, however, that in a similar manner as in the case underlying T 2017/07 (see reasons 2.2.3) claim 1 of auxiliary request 1 defines the composition in an open manner allowing inclusion of any further component, unless otherwise specified, and like in the case of T 2017/07 (see reasons 2.2.1-2.2.2) the amendment removes the implied proviso regarding the amounts of the compounds deleted from the claims as granted.

In its communication pursuant to Article 15(1) RPBA the Board already expressed the opinion that claim 1 of auxiliary request 1 could be considered to cover compositions that were not included in claim 1 as granted in the light of the above indicated interpretation of these claims. The appellant-patent proprietor did not file a response contesting this interpretation.

The Board is therefore of the opinion that claim 1 of auxiliary request 1 does not meet the requirement of Article 123(3) EPC.

3.2 Auxiliary requests 2 and 3

Claim 1 of auxiliary request 2 additionally defines with respect to claim 1 of auxiliary request 1 the amount of anagrelide HCl to be between 2 and 3 mg. Claim 1 of auxiliary request 3 additionally defines

with respect to claim 1 of auxiliary request 2 the amount of the non-pH dependent polymer to be between 2,5 and 5 mg.

These further amendments with respect to auxiliary request 1 leave the objection under Article 123(3) EPC unaffected, as the resulting claims still cover compositions that include non-pH dependent cellulose derivatives or polyacrylamides in amounts in excess of the 2.5 ratio permitted in claim 1 as granted.

Accordingly, auxiliary requests 2 and 3 are also not acceptable under Article 123(3) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

Decision electronically authenticated