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**Datasheet for the decision  
of 24 March 2014**

**Case Number:** T 1839/09 - 3.3.07

**Application Number:** 00918833.5

**Publication Number:** 1169024

**IPC:** A61K9/20, A61K47/36, A61K47/48,  
A61K31/445, A61K31/505

**Language of the proceedings:** EN

**Title of invention:**  
PREGELATINIZED STARCH IN A CONTROLLED RELEASE FORMULATION

**Patent Proprietor:**  
Janssen Pharmaceutica NV

**Opponent:**  
Colorcon Inc

**Headword:**

**Relevant legal provisions:**  
EPC Art. 113(2), 111(1)  
EPC R. 103(1)(a)

**Keyword:**  
Basis of decision - text submitted or agreed by patent  
proprietor (no)  
Appeal decision - remittal to the department of first instance  
(yes)  
Reimbursement of appeal fee - (yes)

**Decisions cited:**

G 0006/88, T 0666/90, T 0647/93, T 0425/97

**Catchword:**



**Beschwerdekammern  
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Case Number: T 1839/09 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 24 March 2014**

**Appellant:** Janssen Pharmaceutica NV  
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**Representative:** Metten, Karl-Heinz  
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**Respondent:** Colorcon Inc  
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**Representative:** Ferreccio, Rinaldo  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 16 July 2009  
revoking European patent No. 1169024 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman:** J. Riolo  
**Members:** A. Usuelli  
W. Ungler

## Summary of Facts and Submissions

- I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division announced at the oral proceedings on 29 April 2009 to revoke European patent No. 1 169 024.

The patent was granted with 25 claims. Independent claim 1 read as follows:

"1. Use of pregelatinized starch in a hydrophilic controlled release formulation comprising one or more active ingredients and one or more viscous hydrophilic polymers to counter the impairing effect of ionic strength of the release medium on the controlled release of said active ingredient(s) from said formulation."

The patent contained two additional independent claims (claims 2 and 7) concerning other non-medical uses of pregelatinised starch.

- II. An opposition was filed against the patent as a whole requesting its revocation on the grounds of lack of novelty and lack of inventive step, in accordance with Article 100(a) EPC. The opponent relied *inter alia* on the following document:

D1: US 4,806,359

- III. Oral proceedings were held before the first instance on 29 April 2009. The final requests of the patent proprietor were the maintenance of the patent as granted, as main request, or the maintenance of the patent in accordance with 15 auxiliary requests filed during oral proceedings.

IV. The decision of the opposition division was based on a wording of claim 1 of a main request defining a product claim for a hydrophilic controlled release formulation characterised *inter alia* in that it comprised pregelatinised starch that made it possible to maintain a controlled release of the active ingredient. The decision was furthermore based on the 15 auxiliary requests filed during oral proceedings. The independent claims of all these requests were worded in the form of the use of a pregelatinised starch for the preparation of a medicament.

V. The decision under appeal can be summarised as follows:

- a) Claim 1 of the main request related to a product claim concerning a hydrophilic controlled release formulation comprising pregelatinised starch. This formulation was not novel because it was implicitly disclosed in D1.
- b) Auxiliary requests 1 to 3 and 5 to 15 were considered to lack of clarity because although worded in accordance with the Swiss-type format they defined neither a therapeutic application nor an active ingredient.
- c) The subject-matter of claim 1 of auxiliary request 4 was regarded as obvious in view of the teaching of D1.

VI. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal it submitted a new main request and 24 auxiliary requests, the last auxiliary request being the patent as granted. In the same letter the appellant underlined that its main request before the first instance was the maintenance of the patent as granted and remarked that the decision of the opposition division was based on a

wording of claim 1 of the main request which was different from the actual wording of claim 1 of the granted patent and therefore requested the remittal of the case to the first instance.

VII. In a communication sent on 21 January 2014 the Board informed the parties about its intention to remit the case to the first instance in view of the deficiency in the appealed decision underlined by the appellant. In the same communication the Board stated that the discussion at the oral proceedings scheduled for 24 March 2014 should be limited to the issue of remittal to the opposition division.

VIII. Oral proceedings were held on 24 March 2014. As announced by letter sent on 23 December 2013, neither the opponent (respondent) nor its representative was present. The appellant requested that the maintenance of the patent as granted (previous auxiliary request 24) be considered the main request.

IX. As far as relevant for the present decision, the appellant's arguments can be summarised as follows:

In its reasoning with respect to claim 1 of the main request, the opposition division referred to a product claim whereas claim 1 of the main request actually was a use claim. Thus, the subject-matter addressed in the decision did not correspond to the subject-matter covered by the main request. The decision should therefore be set aside and the case be remitted to the first instance so that it could provide appropriate reasons for the decision.

X. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent

be maintained as granted or according to auxiliary request 1, corresponding to the former main request as filed with letter dated 26 November 2009, or according to auxiliary requests 2 to 24 corresponding to the requests filed on 26 November 2009 as auxiliary requests 1 to 23. As an alternative the appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division.

The respondent (opponent) did not file a request during the appeal proceedings.

### **Reasons for the Decision**

1. The main request of the appellant before the opposition division was the maintenance of the patent as granted. This fact is clearly acknowledged in the minutes (see paragraph 15.1) and in the decision itself (paragraph IX of the "Facts and submissions"). The same request is pending before the Board as main request.

#### *The impugned decision*

2. Paragraph 3 of the reasons for the decision deals with the requirement of novelty of claim 1 of the main request. The first part of this paragraph reads as follows:

"Main request, lack of novelty

Claim 1 of the granted patent reads:

"A hydrophilic controlled release formulation comprising pregelatinised starch, one or more active ingredients, one or more viscous hydrophilic polymers and optionally pharmaceutically acceptable formulating agents characterized in that the pregelatinised starch

enables the formulation to maintain a controlled release of the incorporated active ingredient(s) in release media with changing ionic strength".

The second part of paragraph 3 relates to the assessment of novelty of this claim over the disclosure of D1. The conclusion is that this document is implicitly novelty-destroying.

3. The statement of the previous paragraph quoted from the decision of the first instance is factually incorrect because claim 1 of the granted patent is actually a different claim. Indeed, as indicated in paragraph I of the "Summary of facts and submissions", claim 1 of the granted patent is a non-medical use claim. Besides the change of category, the claim considered by the opposition division differs from claim 1 of the granted patent also with regard to the feature "to maintain a controlled release of the incorporated active ingredient(s)", which is not part of granted claim 1 but is included in granted claim 2. Conversely, the feature of granted claim 1 "to counter the impairing effect of ionic strength of the release medium on the controlled release of said active ingredient(s)..." is not included in the version of the claim considered by the opposition division.

The claim analysed by the opposition division is also different from the remaining 24 claims of the granted patent, which are all non-medical use claims. Thus, the conclusion of lack of novelty of the main request is based on the analysis of a claim which is not part of this request.

In this respect the Board notes also that the decision of the opposition division is completely silent as to



the reasons for having considered a version of claim 1 which is different from all the claims of the granted patent.

4. The impugned decision also contains conclusions on the lack of clarity of auxiliary requests 1 to 3 and 5 to 15 and on the lack of inventive step of auxiliary request 4. However, none of these requests relates to the same non-medical use claims of the main request, not even partially. From the above it follows that the decision of the opposition division does not deal at all with the main request of the appellant.

Hence, the decision involves an infringement of Article 113(2) EPC, according to which the European Patent Office shall consider and decide upon a European patent application or a European patent only in the text submitted to it, or agreed, by the applicant or the proprietor of the patent. This is a fundamental procedural principle, being part of the right to be heard, and is of such prime importance that any infringement of it must, in principle, be considered as a substantial procedural violation (see T 666/90 of 28 February 1994; T 647/93 OJ EPO 1995, 132; T 425/97 of 8 May 1998).

*Remittal to the department of first instance (Article 111(1) EPC*

5. Due to the aforementioned deficiencies the Board cannot properly examine the reasons why the opposition division came to its conclusion of lack of novelty of claim 1 of the main request. According to Article 11 of the Rules of Procedure of the Boards of Appeal, the Board shall remit the case to the first instance if fundamental deficiencies are apparent in the first-

instance proceedings. The Board thus considers it appropriate to make use of its powers under Article 111(1) EPC to remit the case to the department of first instance for further prosecution.

*Additional remark*

6. The Board observes that at least in its letter of 27 February 2007 the appellant referred to Enlarged Board of Appeal decision G 6/88 (OJ 1990, 114) to indicate the relevant criteria to be followed in the assessment of novelty of a claim relating to the use of a compound for a particular purpose. Without entering in the merit of the appellant's arguments, the Board agrees that the novelty of a non-medical use claim should be assessed following the principles established in G 6/88 (*supra*).

*Reimbursement of appeal fees*

7. As pointed out above, the opposition division based its written decision on a version of the claims of the main request which was neither submitted nor agreed by the proprietor of the patent. This was an infringement of Article 113(2) EPC and must be considered as a substantial procedural violation (see point 4 above). Thus, the Board considers it equitable to refund the appeal fee under Rule 103(1)(a) EPC.

**Order**

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

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

3. Reimbursement of the appeal fee is ordered.

The Registrar:

The Chairman:



L. Fernández Gómez

J. Riolo

Decision electronically authenticated