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**Datasheet for the decision
of 4 March 2008**

Case Number: T 0905/04 - 3.3.02

Application Number: 00974061.4

Publication Number: 1212046

IPC: A61K 9/70

Language of the proceedings: EN

Title of invention:

Flushable disposable polymeric products

Applicant:

Tepha, Inc.

Opponent:

-

Headword:

Flushable disposable products/TEPHA, INC.

Relevant legal provisions:

EPC Art. 111, 113(1)

EPC R. 103

Relevant legal provisions (EPC 1973):

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Keyword:

"Remittal (yes): undecided issues"

"Substantial procedural violation (no): no concrete evidence submitted"

Decisions cited:

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Catchword:

-



Case Number: T 0905/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 4 March 2008

Appellant: Tepha, Inc.
840 Memorial Drive
Cambridge MA 02139 (US)

Representative: Bassett, Richard Simon
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 20 February 2004
refusing European application No. 00974061.4
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: J. Riolo
Members: A. Lindner
P. Mühlens

Summary of Facts and Submissions

I. European patent application No. 00 974 061.4 (publication No. WO 01/15671) was refused by a decision of the examining division of 13 January 2004 on the basis of Article 97 EPC on the grounds of lack of novelty under Article 54 EPC.

II. The following documents were *inter alia* cited during the proceedings before the examining division and the board of appeal:

- (1) CA-A-2 259 098
- (2) GB-A-2 166 354
- (3) C.W. Pouton and S. Akhtar, "Biosynthetic polyhydroxyalkanoates and their potential in drug delivery", *Advanced Drug Delivery Reviews* 18 (1996), 133-162
- (4) US-A-5 502 116
- (5) WO 98/51812
- (6) WO 99/32536

III. The decision was based on claims 1-16 of the main request filed during the oral proceedings of 13 January 2004.

Independent claim 1 of the main request before the examining division reads as follows:

"1. A flushable drug delivery device which degrades after exposure to environmental conditions including water and air, wherein the device comprises as a structural or adhesive component a polyhydroxyalkanoate, produced by a biosynthetic pathway."

Furthermore, the examining division decided not to admit the auxiliary request filed during the oral proceedings of 13 January 2004, because it *prima facie* did not comply with the requirements of Article 123(2) EPC.

Independent claim 1 of the auxiliary request reads as follows:

"1. A flushable drug delivery device which degrades after exposure to environmental conditions including water and air, wherein the device comprises as a structural or adhesive component a polyhydroxyalkanoate produced by a biosynthetic pathway, wherein the polyhydroxyalkanoate forms a laminate or barrier in the device which breaks down within six to twelve months in an aqueous environment, the polyhydroxyalkanoate forms a drug permeable membrane, and the membrane can control the rate of drug release from the device."

IV. The arguments in the decision may be summarised as follows:

In connection with the main request it was held that devices as claimed in claim 1 were already disclosed in any of documents (1) to (6).

With regard to the auxiliary request, the examining division came to the conclusion that claim 1 contained features from claims 3, 11 and 12 as originally filed, which as such was allowable under Article 123(2) EPC. However, the combination of the thus amended claim 1 with dependent claims 3-7 led to new specific

combinations of features that had not been specifically disclosed in the application as originally filed.

- V. The appellant (applicant) lodged an appeal against said decision.

With the statement of the grounds of appeal dated 21 June 2004, the appellant filed a new main request as well as eight auxiliary requests.

- VI. After a communication of the board dated 8 January 2008, in which problems under Articles 54 and 123(2) EPC were addressed, the appellant, with a letter dated 16 January 2008, filed a new main request and a new auxiliary request 1 and auxiliary requests 6-8 as filed with the statement of the grounds of appeal of 21 June 2004 renumbered as new auxiliary requests 2-4.

Independent claim 1 of the new main request is identical to claim 1 of the auxiliary request filed during the oral proceedings before the examining division of 13 January 2004 (see point III above), except for the deletion of the word "wherein" after the passage "produced by a biosynthetic pathway".

- VII. With the official communication dated 24 January 2008, the oral proceedings scheduled for 6 February 2008 were cancelled and the procedure was continued in writing.

- VIII. The appellant's submissions can essentially be summarised as follows:

As regards the admissibility of the newly filed main request and auxiliary request 1, the appellant argued

that the amendments had been made in direct response to objections raised by the board; moreover, they only involve deletion of sub-claims and do not raise any new issues.

In connection with the procedural violation, it was held that new objections had been raised for the first time at the oral proceedings before the examining division and that the applicant had been given no opportunity to amend the claims in response to these new objections.

- IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, of any of auxiliary requests 1 to 4. Furthermore, refund of the appeal fee for substantial procedural violation according to Rule 103 EPC was requested. Finally, oral proceedings were requested, unless the case was remitted to the examining division for further prosecution on the basis of the main request or auxiliary requests 1 or 2.

Reasons for the decision

1. The appeal is admissible.
2. *Admissibility of the new main request:*

The new main request is in principle identical to the auxiliary request filed during the oral proceedings before the examining division and to auxiliary request 4 as filed with the statement of the grounds of appeal,

except that claims 3 to 7 of the former requests have been deleted. By deleting these claims, the appellant reacted to an objection raised by the board in its communication of 8 January 2008 (see point 4). As a consequence, the new main request is admissible.

3. By filing a new main request, the appellant did not maintain the former main request, which had been refused by the examining division for lack of novelty.

The auxiliary request filed at the oral proceedings before the examining division had not been admitted because of objections raised under Article 123(2) EPC on a *prima facie* basis in connection with the combination of claim 1 with dependent claims 3-7. By deleting said claims 3-7 in the present main request, this objection has also been overcome.

As a consequence, the decision of the examining division no longer holds good, as none of the objections raised therein is still applicable to the present main request.

4. *Remittal to the first instance:*
 - 4.1. Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should where appropriate be given the opportunity to have two readings of the important elements of the case. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not

yet been examined and decided by the department of first instance.

4.2. Thus, the Board has reached the conclusion that, in the circumstances of the present case, the case should be remitted to the examining division for further prosecution on the basis of the main request filed with letter dated 16 January 2008.

5. *Substantial procedural violation:*

5.1. It appears from the file that objections raised under Article 123(2) EPC in connection with the auxiliary request filed during the oral proceedings before the examining division and concerning a new specific combination of features as a result of the combination of amended claim 1 plus dependent claims 3 to 7 were formulated for the first time during the oral proceedings. It also appears from the file (see point 1 of the minutes) that the chairman declared at the beginning of the oral proceedings that "one further request would be consented" and that this possibility had been used up by the appellant by the filing of a new main request and the auxiliary request (see point 6 of the minutes) against which the objections under Article 123(2) EPC mentioned above were then raised for the first time.

5.2. However, there is no evidence for the examining division refusing an additional request which would overcome the objections raised under Article 123(2) EPC, as the appellant did not formally submit such a request. Reference is made to the statement of the grounds of

appeal (see page 4, first complete paragraph), where it is stated that

"the undersigned **offered** to delete the allegedly offending dependent claims but was told that he had used up his opportunity of filing further requests and none would now be admitted".

[emphasis by the board]

This passage is in contradiction to a statement on page 7 of the decision under appeal which relates to the same issue and which reads:

"The applicant did not offer to meet this objection but contested this by arguing... "

Although contradictory as far as the question as to whether or not the appellant offered to file a further request is concerned, both citations show that he factually did not file a further request.

- 5.3. In view of these circumstances and in the absence of concrete evidence which would prove that the appellant was denied the right to be heard, the board concludes that it has not been established that the examining division had committed a substantial procedural violation. As a consequence, the appeal fee will not be refunded (Rule 103 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of the main request as filed with the letter of 16 January 2008.

The Registrar:

The Chairman

A. Townend

J. Riolo