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**Datasheet for the decision  
of 26 April 2017**

**Case Number:** T 0195/12 - 3.3.01

**Application Number:** 01949158.8

**Publication Number:** 1294379

**IPC:** A61K31/44, A61K31/16, A61P9/00

**Language of the proceedings:** EN

**Title of invention:**  
A NEW USE FOR DEFERIPRONE

**Patent Proprietor:**  
APOTEX INC.

**Opponent:**  
Lipomed AG

**Headword:**  
Deferiprone against cardiac iron overload/APOTEX

**Relevant legal provisions:**  
RPBA Art. 12(2), 12(4), 13(1), 13(3)  
EPC Art. 54, 111(1)

**Keyword:**

Admission of main request (yes)  
Admission of late-filed documents (yes)  
Novelty (yes), new group of patients  
Remittal (yes)

**Decisions cited:**

T 0872/09, T 0023/10, T 1165/10, T 0301/11, G 0009/91,  
G 0010/91

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 0195/12 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 26 April 2017**

**Appellant:** APOTEX INC.  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 22 November  
2011 revoking European patent No. 1294379  
pursuant to Article 101(2) EPC.**

**Composition of the Board:**

**Chairman** A. Lindner  
**Members:** J. Molina de Alba  
M. Blasi

## Summary of Facts and Submissions

I. European patent No. 1 294 379, based on European patent application No. 01 949 158.8, was granted with thirty-four claims. Granted independent claims 1 and 18 read as follows (emphasis added):

"1. Use of a therapeutically effective amount of deferiprone or a physiologically acceptable salt thereof for manufacture of a medicament containing said therapeutically effective amount sufficient to chelate iron accumulation in the heart and prevent further iron accumulation in the heart **for cardio-selective prevention, treatment, stabilization or reversal of cardiac disease in a transfusion dependent patient.**

...

18. A therapeutically effective amount of deferiprone or a physiologically acceptable salt thereof sufficient to chelate iron accumulation in the heart and prevent further iron accumulation in the heart **for use in cardio-selective prevention, treatment, stabilization or reversal of cardiac disease in a transfusion dependent patient."**

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

(4) Orna D.C. et al., Pediatric Clinics of North America, 44(1), February 1977, 235-247

(6) Tricta F. et al., The New England Journal of Medicine, 339, December 1998, 1710-1714

- (8) Aydinok Y. et al., *Acta Haematologica*, 102, 1999, 17-21
- (9) Agarwal M.B. et al., 10th International Conference on Oral Chelators in the Treatment of Thalassaemia and Other Diseases and Biomed Meeting, Cyprus, March 2000
- (11) Töndury P. et al., 6th International Conference on Thalassaemia and the Haemoglobinopathies, Malta, April 1997
- (41) Alduri, M.A., *Acta Haematologica*, 84, 1990, 113-117
- (42) Olivieri N.F. et al., *Blood* 86 (10 Suppl. 1), 249a, 1995
- (43) Matsui D. et al., 94th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Hawaii, March 1993, Paper PI-43

- III. Notice of opposition was filed, in which revocation of the patent in suit pursuant to Articles 100(b) and 100(a) EPC (Articles 52(2) and 53(c) EPC and lack of novelty and inventive step) was requested.
- IV. The appeal lies from the decision of the opposition division revoking the patent. The decision was based on the patent as granted as main and sole request. The opposition division concluded that the provisions of Articles 52(2), 53(c) and 100(b) EPC did not prejudice the maintenance of the patent. However, the subject-matter of the independent claims was found to lack novelty over documents (4), (6), (8), (9) and (11),

based on the premise that the feature "cardio-selective" was not limiting.

- V. The appellant (patentee) filed notice of appeal against this decision. With the statement of grounds of appeal, it filed auxiliary requests 1 and 2.

Claim 1 of auxiliary request 1 differed from claim 1 as granted in that the definition appearing in bold in point I above had been modified to read as follows (emphasis added):

"for cardio-selective prevention, treatment, or reversal of cardiac disease in a transfusion dependent patient **having iron induced cardiac disease said therapeutic amount being sufficient to reduce the iron stores in the heart and in preference to less critical organs/tissues in the body.**"

Claim 16 of auxiliary request 1 contained an equivalent amendment in relation to claim 18 as granted.

Claim 1 of auxiliary request 2 differed from claim 1 as granted in the deletion of the features "**prevention**", "**stabilization**" and "**reversal**".

Claim 14 of auxiliary request 2 contained the same deletions in relation to claim 18 of the main request.

- VI. In its response to the statement of grounds of appeal, the respondent (opponent) argued against the admission of the auxiliary requests and the novelty of the subject-matter of claim 1 of each of the requests on file over documents (4), (6), (8), (9) and (11).

VII. With letter dated 9 July 2013, the appellant filed auxiliary request 3.

Claim 1 of auxiliary request 3 differed from claim 1 as granted in that it further specified that the transfusion-dependent patient was **"in need of such cardio-selective prevention, treatment, stabilization or reversal of cardiac disease"**.

Claim 18 of auxiliary request 3 contained the same addition in relation to granted claim 18.

VIII. In its preliminary opinion, sent as annex to the summons to oral proceedings, the board concurred with the opposition division that the subject-matter of claims 1 and 18 of the main request was not novel. By contrast, the subject-matter of claims 1 and 16 of auxiliary request 1 was considered to be novel.

IX. In response to the board's preliminary opinion, the appellant filed document (41), and the respondent filed documents (42) and (43).

In addition, the respondent argued against the admission of auxiliary requests 1 to 3 and document (41) into the proceedings, and raised a new objection against auxiliary request 1 under Article 83 EPC.

X. Oral proceedings were held before the board on 26 April 2017, in the course of which the appellant made auxiliary request 1 its main request.

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

Concerning the admission of the main request and auxiliary request 2, the appellant argued that they should be admitted into the appeal proceedings under Article 12(4) RPBA because they had been filed with the statement of grounds of appeal in response to reasons that were explained for the first time in the decision under appeal. In particular, the appellant asserted that the reasons why the opposition division considered the feature "cardio-selective" to be non-limiting were set out for the first time in the appealed decision. Further, in connection with the decisions of the boards of appeal cited by the respondent against the admission into the appeal proceedings of requests that could have been filed in opposition (i.e. T 23/10, T 872/09, T 1165/10 and T 301/11), the appellant submitted that, contrary to the present case, the cited decisions dealt with cases in which the patent proprietor had had the opportunity to respond to the objections during the opposition proceedings. Moreover, the decisions concerned issues of added subject-matter or the deletion of dependent claims rather than an objection of lack of novelty directed to the subject-matter of the independent claims.

On the admission of documents (42) and (43), the appellant contended that these documents had been filed to contest the novelty of the subject-matter claimed in the requests filed with the statement of grounds of appeal and should therefore have been filed with the respondent's reply to the statement of grounds of appeal (Articles 12(2) and 13(1) RPBA). Moreover, the documents were *prima facie* not relevant to the novelty of the use of claim 1 of the main request, because document (42) did not mention any cardiac disease, and the cardiac disease in one patient referred to in document (43) was not disclosed as being iron-induced.



With regard to the novelty of the subject-matter of claim 1 of the main request, the appellant noted in the statement of grounds of appeal (see point 5.2 therein) that none of the cited prior art disclosed or suggested that deferiprone might be effective in treating a patient having iron-induced cardiac disease by reducing the iron stores in the heart in preference to less critical organs/tissues in the body. The disclosure of documents (9), (42) and (43) was discussed in more detail during oral proceedings before the board. In particular, the appellant submitted that none of these documents disclosed a clinical treatment with the purpose of claim 1 because they lacked a baseline to assess changes in cardiac status. In addition, the cardiac deficiencies in the patients of documents (9) and (43) were not specified as being iron-induced, and the patients considered in document (42) to have cardiac iron amounts higher than normal were not regarded as having a cardiac disease. Furthermore, document (9) did not make clear whether the mild diastolic dysfunction identified in two patients had been observed at the beginning or at the end of the trial.

In the context of the admission of the new objection under Article 83 EPC, the appellant maintained that it should have been raised with the reply to the statement of grounds of appeal (Articles 12(2) and 13(1) RPBA), rather than one month before oral proceedings and that, if the objection were admitted by the board, the case would have to be remitted to the opposition division.

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

The respondent asserted (see letter of 24 March 2017, point 1) that the main request and auxiliary request 2 should not be admitted under Article 12(4) RPBA because the appellant had had the opportunity to file them on several occasions during the opposition proceedings and had nevertheless decided not to do so. A decision of the opposition division on said requests had thereby been precluded, and the procedure had been delayed in an abusive manner, as established in decisions T 23/10, T 872/09, T 1165/10 and T 301/11 (see Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, IV.E.4.3.2 c)).

With respect to the admission of documents (42) and (43), the respondent argued that these documents had been filed in reaction to the communication annexed to the summons to oral proceedings, in which the board had not restricted itself to a revision of the appealed decision but, to the respondent's surprise, had expressed its opinion on the main request (i.e. auxiliary request 1 filed with the statement of grounds of appeal). Furthermore, the documents were very short, entailed no complexity, and were *prima facie* relevant to the novelty of the use of claim 1 of the main request, because the patient treated with deferiprone to reduce cardiac iron in document (42) had an initial TRT value which amounted to a cardiac disease, and because one of the patients in document (43) had an established cardiac disease.

The respondent's objection of lack of novelty in the subject-matter of claim 1 of the main request was initially based on documents (4), (6), (8), (9), (11), (42) and (43), which disclosed the treatment of transfusion-dependent patients with deferiprone to

reduce cardiac iron. At the oral proceedings before the board, however, the respondent based its arguments as to lack of novelty only on documents (9), (42) and (43) and confirmed that these remained its sole requests on the issue of novelty. In relation to documents (9) and (43), the respondent drew attention to the patients with diastolic dysfunction and cardiac disease in these documents, respectively, and noted that, because transfusion-dependent patients generally suffered from high cardiac iron concentrations that needed to be reduced, the cardiac diseases mentioned in these documents were implicitly iron-induced. In relation to document (42), the respondent contended that the abnormal cardiac iron concentrations before treatment with deferiprone had to be seen as being pathological and, therefore, amounted to an iron-induced cardiac disease.

Turning to the issue of the admission of the objection under Article 83 EPC against the main request, the respondent argued that the objection had not been raised before the board's communication was issued because the new main request had not been considered to be in the proceedings. In addition, sufficiency of disclosure was a ground for opposition under Article 100(b) EPC, and the main request had to be fully examined for its compliance with the EPC because it had been filed for the first time in the appeal proceedings.

XIII. The final requests of the parties were as follows:

- The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the claims of the main request filed as

auxiliary request 1 with the statement of grounds of appeal, or alternatively on the basis of auxiliary request 1, corresponding to the patent as granted, or further alternatively on the basis of the claims filed as auxiliary request 2 with the statement of grounds of appeal or as auxiliary request 3 filed with letter dated 9 July 2013.

- The respondent requested that the appeal be dismissed and that auxiliary request 3 not be admitted into the proceedings.

XIV. At the end of the oral proceedings, the decision of the board was announced.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Admission of the main request (i.e. auxiliary request 1 filed with the statement of grounds of appeal) and of auxiliary request 2 - Article 12(4) RPBA*
  - 2.1 Under Article 12(4) RPBA, the board has the power to hold inadmissible facts, evidence or requests that could have been presented in the opposition proceedings.
  - 2.2 The claim requests under consideration were filed by the appellant with the statement of grounds of appeal and in the board's view they constitute a proper reaction to the opposition division's decision, which considered the subject-matter of the granted independent claims to lack novelty, following the conclusion that the feature "cardio-selective" was not limiting. In addition, the requests essentially result

from the incorporation of dependent claims into the granted independent claims (claim 1 of the main request results from the combination of granted claims 1 and 7, and claim 1 of auxiliary request 2 essentially results from the combination of granted claims 1 and 2). Moreover they cannot be seen as introducing complexity into the appeal proceedings or hampering procedural economy.

- 2.3 The respondent argued against the admission of these requests on the basis that, in accordance with decisions T 23/10, T 872/09, T 1165/10 and T 301/11, they could and should have been filed during the opposition proceedings. As to this argument, the board notes that the circumstances that led to those decisions differ substantially from those of the present case, and that their conclusions cannot be extended to the appeal at issue.

In the cases underlying decisions T 23/10 and T 301/11, the patentee had to deal with an objection of added subject-matter during oral proceedings before the opposition division. The objection, however, was directed to a dependent claim, so that a way of overcoming it without affecting the independent claims, namely by deleting the dependent claim, was straightforward and did not require much further consideration. For this reason, withholding such an amended claim request in the proceedings before the opposition division precluded the patentee from having such a request subsequently considered by the board (see T 23/10, reasons 2.1 and 2.6, last paragraph; and T 301/11, reasons 2.2 and 2.5.1). By contrast, in the present case, the appellant had to overcome an objection of lack of novelty directed to the subject-matter of the independent claims, based on the question

of how the feature "cardio-selective" was to be interpreted. Hence, an amendment to this objection in opposition proceedings was not straightforward and required careful consideration by the appellant.

In the case underlying decision T 872/09 (see reasons 2.1), the patentee withdrew an auxiliary request in opposition which undisputedly overcame the novelty objection of the opposition division that had led to the revocation of the patent, but filed the request once again in the appeal proceedings. This course of action prevented the opposition division from taking a reasoned and sufficiently comprehensive decision on the further objections concerning novelty and inventive step. In the case underlying decision T 1165/10 (see reasons 1.2), the patentee was informed by the opposition division with its summons to oral proceedings that the requests on file lacked novelty or added subject-matter. The patentee, however, neither reacted in writing nor attended oral proceedings. In the subsequent appeal proceedings, the patentee then filed amended requests which had no clear relationship with the requests in opposition proceedings and failed once more to attend oral proceedings, this time before the board of appeal. In the present case, the main request and auxiliary request 2 were not presented and withdrawn in opposition and subsequently re-filed in appeal, nor had the opposition division given a preliminary opinion on the issue of novelty of the patent as granted (i.e. the then main request) in advance of the oral proceedings.

The board therefore cannot conclude that the present case is similar to any of the situations underlying decisions T 23/10, T 301/11, T 872/09 or T 1165/10.

2.4 In view of the above considerations, the board decided not to hold the main request and auxiliary request 2 inadmissible and so decided to take them into account in these appeal proceedings.

3. *Admission of documents (42) and (43) - Article 13(1), (3) RPBA*

The filing of documents (42) and (43) may be seen as the respondent's reaction to the board's preliminary opinion, which considered the subject-matter of claim 1 of the present main request to be novel by virtue of its restriction to a group of patients having an iron-induced cardiac disease. The documents are very short, their content may be quickly analysed, and they appear to be *prima facie* relevant to the question of novelty of the use of claim 1 of the main request because they disclose the use of deferiprone as chelating agent for reducing cardiac iron in thalassaemia major patients, where the patients of document (42) might have a cardiac disease and one patient in document (43) had an established cardiac disease. That documents (42) and (43) were filed only one month before oral proceedings did not render the case unduly complex, nor did it require postponement of the oral proceedings. Accordingly, the board, exercising its discretion, decided to admit documents (42) and (43) into the proceedings.

4. *Novelty (main request) - Article 54 EPC*

4.1 The following analysis of the novelty of the subject-matter of claim 1, formulated as a "Swiss-type" claim, applies *mutatis mutandis* to the subject-matter of independent claim 16, formulated as a purpose-related product claim under Article 54(5) EPC, since both

claims are directed to essentially the same subject-matter.

4.2 In the novelty assessment of the appealed decision, the decisive issue was to establish the extent to which the feature "cardio-selective" was limiting. Claim 1 of the main request under consideration by the board, however, contains an additional restriction compared to the claims on which the appealed decision was based, namely that the transfusion-dependent patient has an iron-induced cardiac disease. For this reason, the discussion of novelty before the board, especially in the oral proceedings, focused primarily on the analysis of whether or not the use of deferiprone as iron chelator disclosed in the cited documents had been carried out on patients having an iron-induced cardiac disease.

4.3 The novelty of the subject-matter of claim 1 was contested by the respondent in the light of documents (9), (42) and (43).

Regarding the disclosure of documents (9) and (43), the board agrees with the appellant that the cardiac deficiencies identified in the patients prior to their treatment with deferiprone were not explicitly disclosed to be caused by iron storage. Nor can any implicit disclosure be derived from these documents, since cardiac deficiencies may have an origin other than iron storage. Moreover, it is not clear from the teaching of document (9) whether the cardiac disease was identified before or after deferiprone treatment. Consequently, neither of documents (9) and (43) disclosed the treatment of a patient having an iron-induced cardiac disease with deferiprone.



In relation to document (42), the board notes that a patient having cardiac iron amounts higher than what the author of the document considers normal does not inevitably imply that the patient suffered from a cardiac disease. It is also noted that the document does not establish any relationship between iron levels outside the normal range and a pathological condition. Accordingly, in the board's view, document (42) likewise does not disclose patients having an iron-induced cardiac disease.

In conclusion, the subject-matter of independent claims 1 and 16 of the main request is novel over the prior art cited by the respondent.

5. *Admission of the objection under Article 83 EPC - Article 13(1), (3) RPBA*

With letter dated 24 March 2017, the respondent raised an objection under Article 83 EPC against the present main request, based on an alleged contradiction in claim 1 between the expression "prevention" and the fact that the treated patient already had a cardiac disease. This objection was raised in reaction to the board's communication accompanying the summons to oral proceedings, in which the board discussed several substantive issues.

The objection could already have been raised by the respondent in its reply to the statement of grounds of appeal because auxiliary request 1 had, in compliance with Article 12(2) RPBA, already been presented by the appellant with the statement of grounds of appeal. However, as indicated in the board's communication accompanying the summons to oral proceedings, the board intended to remit the case for further prosecution in

the event that novelty could be acknowledged. Hence, once the conclusion on novelty was reached, it became clear that the admission of the objection under Article 83 EPC neither delayed the appeal proceedings nor was unfair to the appellant, since it would be able to argue on this aspect before the opposition division. Therefore, the board decided to admit the objection into the proceedings under Article 13(1), (3) RPBA.

6. *Remittal - Article 111(1) EPC*

In view of the conclusions on the issue of novelty, the appeal was allowable and the decision under appeal was to be set aside pursuant to Article 111(1), first sentence, EPC.

Under Article 111(1), second sentence, EPC the board had discretion over whether to decide the case on its own or remit the case to the department whose decision had been appealed.

In accordance with Enlarged Board of Appeal decisions G 9/91 and G 10/91 (see OJ EPO 1993, 408 and 420, reasons 18), the purpose of the appeal proceedings *inter partes* is mainly to give the losing party the possibility of challenging the decision of the opposition division.

In the present case, the decision under appeal did not address the issue of inventive step and, during the appeal proceedings, the respondent raised a new line of argument with respect to sufficiency of disclosure in relation to the main request. Therefore, essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the opposition division.

Consequently, the board finds it appropriate to remit the case to the opposition division for further prosecution on the basis of the claims of the present main request.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution on the basis of the claims of the main request filed as auxiliary request 1 together with the statement of grounds of appeal.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated