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**Datasheet for the decision
of 8 December 2010**

Case Number: T 2033/08 - 3.3.01

Application Number: 04770646.0

Publication Number: 1618111

IPC: C07D 495/00

Language of the proceedings: EN

Title of invention:

Salts of Clopidogrel and process for preparation

Patentee:

CADILA HEALTHCARE LIMITED

Opponent:

-

Headword:

Crystalline Clopidogrel besylate/CADILA

Relevant legal provisions:

EPC Art. 113(1), 94(3), 53(c)

RPBA Art. 11

EPC R. 103(1)(a)

Relevant legal provisions (EPC 1973):

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Keyword:

"Substantial procedural violation - (yes) - no opportunity to
comment on the reasons of the refusal"

"Remittal - (yes)"

"Reimbursement of appeal fee - (yes)"

Decisions cited:

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Catchword:

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Case Number: T 2033/08 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 8 December 2010

Appellant:

CADILA HEALTHCARE LIMITED
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Satellite Cross Roads
Ahmedabad 380 015
Gujarat (IN)

Representative:

Spencer, Michael David
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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 8 May 2008
refusing European patent application
No. 04770646.0 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: C. M. Radke
Members: J.-B. Ousset
L. Bühler

Summary of Facts and Submissions

- I. The appellant lodged an appeal against the decision of the examining division to refuse European patent application 04 770 646.0.
- II. The following documents were considered relevant by the examining division:
- (4) WO-A-2004/072084
 - (5) WO-A-2004/072085.
- III. Claims 1 and 12 of the main request on which the decision of the examining division was based read as follows:
- "1. Crystalline Clopidogrel besylate"
 - "12. A method of inhibiting platelet aggregation comprising administering to a patient in need thereof a Clopidogrel salt according to any of Claims 1 to 4 or Claim 11 or pharmaceutical compositions containing them."
- IV. In its decision, the examining division took the view that claim 12 contravened the requirements of Article 53(c) EPC and that examples 1 and 2 of documents (4) and (5) were prejudicial to the novelty of claims 1-5, 7 and 9-13.
- V. The appellant's arguments relevant for the present decision can be summarised as follows:

- The appeal fee should be refunded. The refusal of the present application was the first time that certain issues were raised, so that the applicant was not given the opportunity to overcome the deficiencies of the application.

- VI. Oral proceedings before the board took place on 8 December 2010.
- VII. The appellant requested that the decision under appeal be set aside, the appeal fee be reimbursed and the case be remitted to the examining division for further prosecution. In the alternative, the appellant requested that the application should proceed to grant on the basis of the main request or of one of the auxiliary requests 1 to 7 filed with the appellant's letter of 8 November 2010. The appellant further requested that pages 13 to 16 of Annex 2 submitted with letter of 8 November 2010 be removed from the public part of the file and not taken into consideration for the oral proceedings.
- VIII. At the end of the oral proceedings, the decision of the board was announced.

Reasons for the Decision

- 1. The appeal is admissible.

Availability of pages 13 to 16 of annex 2

- 2. The board decided that, pursuant to Article 1 No. 2 of the decision of the President of the European Patent

Office dated 12 July 2007 concerning documents excluded from file inspection (OJ EPO special edition No. 3/2007, p. 125), pages 13 to 16 of Annex 2 filed with the appellant's letter of 8 November 2010 will neither be available for public inspection nor be used for the purpose of these proceedings.

Procedural matters - Reimbursement of the appeal fee

3. Article 113(1) EPC stipulates that a decision may only be based on grounds or evidence on which the parties have had the opportunity to present their comments.

3.1.1 In its first official communication according to Article 94(3) EPC, the examining division indicated that the deficiencies mentioned in the International Preliminary Examination Report (IPER) gave rise to objections under the corresponding provisions of the EPC. Furthermore, the examining division also mentioned that the documents cited under category "E" in the search report were relevant at least for the assessment of novelty. In the said IPER, novelty was only questioned on the basis of the disclosure of document (1) (US-A-4 847 265) and it was only mentioned that documents (4) and (5) disclosed salts of Clopidogrel in amorphous or crystalline form and might become relevant for the issue of novelty in the regional phase before the EPO.

3.1.2 The above paragraph shows that the communication of the examining division did not explicitly raise a novelty objection based on document (4) or (5). Moreover, the logical chain of reasoning, namely the identification of the relevant passages of the prior art (here

example 2 of document (4) or (5)) and the final conclusion (absence of a distinguishing feature between the compound of claim 1 of the main request and that of example 2) was not made available to the appellant in the first and only official communication but only in the decision under appeal. The absence of an explicit novelty objection, let alone of a logical chain based on the disclosures of documents (4) and (5) in the official communication of the examining division did not permit the appellant to deal, either by amendment or counter-argument, with the novelty objection on which the decision under appeal is based.

3.1.3 Therefore, the board considers that the appellant was not given the possibility of knowing on which legal and factual reasons the decision would be taken and to comment on them or amend his case accordingly. This contravenes the requirements of Article 113(1) EPC and thus constitutes a substantial procedural violation.

3.2 Similarly, the first official communication did not mention any objection based on Article 53(c) EPC. The IPER, referred to in the said first official communication, only mentions that no opinion with respect to the subject-matter of claim 29 as filed would be formulated. Although claim 12 of the set of claims, which the decision under appeal is based on, corresponds to claim 29 as filed, it remains the case that no clear objection as to the patentability of said claim was raised by the department of first instance in its first and only official communication. Therefore, using the lack of patentability of claim 12 as ground for the refusal of the present application represents a substantial procedural violation, since the appellant

did not have the opportunity to comment on or overcome this objection (Article 113(1) EPC).

- 3.3 The appeal is thus deemed to be allowable and the board considers it to be equitable, in view of that substantial procedural violation, to reimburse the appeal fee (Rule 103(1)(a) EPC).

Remittal

4. The appellant has requested remittal under Article 111(1) EPC. Moreover, Article 11 RPBA stipulates that the board will remit the case to the department of first instance if a fundamental deficiency is apparent in the first instance proceedings, unless there are special reasons not to do so. In view thereof, the board finds it appropriate to remit the case to the department of first instance.

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. The request for exclusion from file inspection is allowed.
4. The appeal fee is reimbursed.

The Registrar

The Chairman

M. Schalow

C. M. Radke