

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 14 December 2011**

Case Number: T 0703/08 - 3.3.02

Application Number: 99935949.0

Publication Number: 1098641

IPC: A61K 31/06

Language of the proceedings: EN

Title of invention:

Chemically induced intracellular hyperthermia

Applicant:

St. Jude Pharmaceuticals, Inc.

Opponent:

-

Headword:

Chemically induced intracellular hyperthermia/ST. JUDE
PHARMACEUTICALS

Relevant legal provisions:

EPC Art. 123(2), 111

Keyword:

"Art. 123(2) - (yes): basis in the original application for
the amendments"

"Remittal - (yes): undecided issues"

Decisions cited:

-

Catchword:

-



Case Number: T 0703/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 14 December 2011

Appellant: St. Jude Pharmaceuticals, Inc.
(Applicant) 701 West 14th Street
Texarkana, TX 75501 (US)

Representative: Woods, Geoffrey Corlett
J.A. Kemp & Co.
14 South Square
Gray's Inn
London WC1R 5JJ (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 18 October 2007
refusing European application No. 99935949.0
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
R. Cramer

Summary of Facts and Submissions

- I. European patent application No. 99 935 949.0 was refused by a decision of the examining division pronounced on 10 July 2007 on the basis of Article 97(1) EPC 1973 on the grounds that the subject-matter claimed in the main request and in auxiliary requests 1 to 5 did not meet the requirements of Article 123(2) EPC. Moreover, the subject-matter according to auxiliary request 5 lacked clarity.
- II. The applicant (appellant) lodged an appeal against this decision.
- III. With the statement of the grounds of appeal dated 14 February 2008, the appellant filed a new main request and auxiliary requests 1 to 5.
- IV. In the annex to the summons to oral proceedings issued by the board pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the board in its preliminary opinion raised objections under Article 123(2) EPC in connection with all requests on file.
- V. With a letter dated 14 November 2011, the appellant filed auxiliary requests 6 and 7.
- VI. With a letter dated 13 December 2011, the appellant withdrew the main request and auxiliary requests 1 to 6 and filed auxiliary request 7 as new main and sole request. The independent claims read as follows:

"1. 2,4-dinitrophenol for use in a method of treating an infection of *Borrelia burgdorferi*, *Mycobacterium*

leprae, Treponema pallidum, HIV, hepatitis C, or herpes virus in a subject by inducing intracellular hyperthermia comprising the step of administering to the subject having an infection of Borrelia burgdorferi, Mycobacterium leprae, Treponema pallidum, HIV, hepatitis C, or herpes virus, an amount of 2,4-dinitrophenol sufficient to induce whole body intracellular hyperthermia in the subject, wherein the whole body intracellular hyperthermia is sufficient to treat the Borrelia burgdorferi, Mycobacterium leprae, Treponema pallidum, HIV, hepatitis C, or herpes virus infection in the subject.

6. 2,4-dinitrophenol for use in a method of treating an infestation of Sporothrix schenkii, Histoplasma, paracoccidioides, Aspergillus, Leishmania, malaria, acanthamoeba, or cestodes in a subject by inducing intracellular hyperthermia comprising the step of administering to the subject having an infestation of Sporothrix schenkii, Histoplasma, paracoccidioides, Aspergillus, Leishmania, malaria, acanthamoeba, or cestodes, an amount of 2,4-dinitrophenol sufficient to induce whole body intracellular hyperthermia in the subject, wherein the whole body intracellular hyperthermia is sufficient to treat the Sporothrix schenkli, Histoplasma, Paracoccidioides, Aspergillus, Leishmania, malaria, acanthamoeba or cestodes infestation in the subject."

VII. Oral proceedings were held on 14 December 2011, in the absence of the duly summoned appellant, in accordance with Rule 115 EPC and Article 15(3) RPBA.

VIII. The appellant requested in writing that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of the main request filed with a letter dated 13 December 2011.

Reasons for the decision

1. The appeal is admissible.
2. Article 123(2) EPC
- 2.1 Claim 1

Claim 1 is directed to 2,4-dinitrophenol for use in a method of treating specific infections by inducing hyperthermia. As regards the selection of the active agent out of the list of uncouplers, the board notes that 2,4-dinitrophenol is most preferred embodiment. Reference is made to page 23, lines 4-7 of the original application and to examples 1 to 12 in all of which 2,4-dinitrophenol is used as uncoupler. The induction of hyperthermia as well as the list of specific infections is disclosed in the paragraph bridging pages 14 and 15 of the original application. In connection the specific infections, the board notes that the list was shortened by the deletion of papillomavirus (see page 15, line 2), which does, however, not lead to new specific combinations.

The feature "an amount of 2,4-dinitrophenol sufficient to induce whole body intracellular hyperthermia in the subject" is disclosed on page 14, lines 26-29. In this

context, it is important to note that the induction of whole body intracellular hyperthermia is for technical reasons closely linked to the specific infections to be treated. A treatment of infections involving only local hyperthermia would not be reasonable in view of the fact that the microorganisms causing said infections are normally distributed over the whole body. As a consequence, the selection of the induction of the whole body intracellular hyperthermia on the one hand and the selection of treatment of infections on the other hand does not constitute an unallowable selection from several lists but forms a logical technical unit. Finally, the feature "wherein the whole body intracellular hyperthermia is sufficient to treat ..." is based on the statement on page 14, lines 31 to page 15, line 5, according to which mitochondrial heat is generated by the use of DNP ... for the treatment of ... bacteria ... viruses ... parasites ...". As a consequence, the subject-matter of claim 1 meets the requirements of Article 123(2) EPC.

2.2 Claim 5

The reasoning according to point 2.1 above applies *mutatis mutandis* to the subject-matter of claim 5. Again, the list of pathogens was shortened by the deletion of the fungus *Candida* (see page 15, line 2-4), again, the board came to the conclusion that this deletion does not lead to new specific combinations. As a consequence, the subject-matter of claim 5 meets the requirements of Article 123(2) EPC.

3. Remittal to the examining division

Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of the case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. 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.

In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party based upon certain issues only which are decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issues is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111 EPC).

The observations made above apply fully to the present case, where the examining division issued a decision which is solely based on Articles 123(2) and 84 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.

The Registrar:

The Chairman

N. Maslin

U. Oswald