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D E C I S I O N
of 25 July 2006

Case Number: T 1246/05 - 3.3.01

Application Number: 02005248.6

Publication Number: 1211243

IPC: C07D 211/32

Language of the proceedings: EN

Title of invention:
Polymorphs of donepezil hydrochloride and process for production

Applicant:
EISAI CO., LTD.

Opponent:
-

Headword:
Donepezil hydrochloride/EISAI

Relevant legal provisions:
EPC R. 88

Keyword:
"Rule 88 EPC - need for a request for a correction in order to be a valid ground for refusing the application"

Decisions cited:
G 0010/93

Catchword:
-

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Case Number: T 1246/05 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 25 July 2006

Appellant: Eisai Co., Ltd.
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Representative: HOFFMANN EITLE
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 21 April 2005 refusing European application No. 02005248.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: A. J. Nuss
Members: P. P. Bracke
D. S. Rogers

Summary of Facts and Submissions

I. The appeal lies from the Examining Division's decision refusing European patent application No. 02 005 248.6, which is a divisional application of European patent application No. 97 924 337.5, since the requirement of Rule 88 EPC was not fulfilled.

II. In particular, the Examining Division was of the opinion that the selection of one out of the two sets of data from the description, each set consisting of peaks in the powder X-ray diffraction pattern and wave numbers of infrared absorption spectra, in order to characterise the polymorph (IV) of donepezil hydrochloride in the then pending Claim 1, was a correction which was not immediately evident.

III. At the oral proceedings, which took place at 25 July 2006, the Appellant filed sets of claims according to a Main Request and two Auxiliary Requests.

The claims according to the main request read:

"1. Donepezil hydrochloride, 1-benzyl-4-[(5,6-dimethoxy-1-indanon)-2-yl]methylpiperidine hydrochloride, in the form of polymorph (IV), the polymorph being specified by peaks at below shown diffraction degrees with the below shown intensity in terms of I/I_o in powder X-ray diffraction pattern and the below shown absorption peaks in infrared absorption spectra in potassium bromide in terms of reciprocal centimeters:

Polymorphs (IV)

Peaks in the powder X-ray diffraction pattern are:

Diffraction angles (2θ,°)	Intensity (I/I_0)
6.24	15
9.66	12
11.04	22
12.12	24
12.54	67
12.76	61
13.98	27
14.42	15
14.88	11
16.34	12
17.46	100
18.12	25
18.60	32
19.06	15
19.98	74
20.42	41
20.62	34
21.30	48
21.80	63
22.58	78
23.04	46
24.00	32
24.54	49
25.14	90
25.36	99
26.06	34

28.10	41
28.58	39
29.30	31
29.44	28

Wave numbers (cm^{-1}) of infrared absorption spectra in potassium bromide are:

401, 431, 459, 467, 490, 506, 518, 561, 586, 606, 631, 651, 709, 758, 766, 857, 944, 1009, 1041, 1106, 1119, 1132, 1213, 1225, 1265, 1304, 1318, 1429, 1458, 1470, 1500, 1589, 1605, 1630, 1647, 1683, 2562, 2577, 2608, 2634, 2689, 2717, 2836, 2924, 2949, 2989, 3007, 3032, 3061, 3322, 3376, 3422 cm^{-1}."

"2. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the step of humidifying the polymorph (II) as defined below:

Polymorph (II)

Peaks in the powder X-ray diffraction pattern are:

Diffraction angles (2θ,°)	Intensity (I/I_0)
7.40	8
9.88	100
12.36	13
15.54	40
16.10	38
16.22	38
16.48	35
17.30	17

18.04	20
18.44	17
18.84	19
19.34	19
19.84	47
21.16	24
22.40	19
23.18	33
24.02	22
24.92	25
25.72	27
26.40	18
27.22	14.

Wave numbers (cm^{-1}) of infrared absorption spectra in potassium bromide are:

699, 748, 762, 845, 947, 1009, 1035, 1067, 1103, 1118, 1129, 1174, 1193, 1206, 1222, 1247, 1267, 1317, 1365, 1422, 1436, 1456, 1465, 1502, 1592, 1607, 1688, 2412, 2489, 2627, 2846, 2868, 2913, 2928, 3435 cm^{-1}."

"3. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the steps of dissolving Donepezil in water with or without tetrahydrofuran and adding hydrochloric acid or hydrogen chloride to the solution."

"4. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the steps of dissolving Donepezil in hydrochloric acid and adding tetrahydrofuran to the solution."

"5. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the steps of dissolving Donepezil in toluene and adding hydrochloric acid to the solution."

"6. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the steps of dissolving Donepezil in n-hexane and adding hydrochloric acid to the solution."

"7. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the step of crystallizing Donepezil in a mixture of methanol and hydrochloric acid."

"8. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the step of crystallizing Donepezil hydrochloride from water."

"9. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the step of humidifying the amorphous form of Donepezil hydrochloride."

"10. A process for producing the polymorph (IV) of Donepezil hydrochloride as defined in claim 1, which comprises the step of humidifying the polymorph (II) of Donepezil hydrochloride."

"11. Use of a pharmaceutically effective amount of the Donepezil hydrochloride in the form of polymorph as defined in claim 1 for the preparation of a medicament

for the treatment of a disease accompanied by acetylcholinesterase activity."

"12. Use as claimed in claim 11 in which the disease is senile dementia."

"13. Use as claimed in claim 11 in which the disease is senile dementia of the Alzheimer type."

"14. A therapeutical composition which comprises a pharmacologically effective amount of Donepezil hydrochloride in the form of polymorph as defined in claim 1 and a pharmacologically acceptable carrier."

"15. The Donepezil hydrochloride as claimed in Claim 1, which is in the form of polymorph (IV)."

IV. The Appellant essentially argued that the selection of one out of the two sets of data from the description, each set consisting of peaks in the powder X-ray diffraction pattern and wave numbers of infrared absorption spectra, in order to characterise the polymorph (IV) of donepezil hydrochloride could not be considered as a correction pursuant to Rule 88 EPC. In support of those arguments, the Appellant filed with letter of 23 June 2006 an expert opinion by Dr. C. Lehmann. Furthermore, with telefax of 21 July 2006 he filed schematic representations illustrating the meaning and relevance of measurement errors and a declaration signed by Takashi Kajima.

V. The Appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution on

the basis of claims 1 - 15 of the Main Request; or claims 1 - 15 of the first or second Auxiliary Requests.

Reasons for the Decision

1. The appeal is admissible.

2. *Scope of the appeal*

Whilst Articles 111(1) and 114(1) EPC give the Boards of Appeal the power to raise new grounds in ex-parte proceedings where the application has been refused on other grounds, proceedings before the Boards of Appeal in ex-parte cases are primarily concerned with examining the contested decision (see decision G 10/93, OJ EPO 1995, 172, points 4 and 5 of the reasons), other objections normally being left to the Examining Division to consider after a referral back, so that the Appellant has the opportunity for these to be considered without loss of an instance.

In the present case, the Board restricts itself to examining the basis for the sole ground for refusal of the application, namely whether or not the selection of one out of the two sets of data (see point II above) in order to characterise the polymorph (IV) of donepezil hydrochloride is an objectionable correction pursuant to Rule 88 EPC.

3. *Main Request*

3.1 Articles 76(1) and 123(2) EPC

Claim 1 finds support in Claim 1 of the parent application as filed and Claim 1 of the divisional application as filed with however the restriction to one particular polymorphic form, namely polymorph (IV). Such restriction, resulting from a selection of one polymorph out of several disclosed distinct polymorphs clearly does not result in subject-matter extending beyond the content of the application as filed.

Claim 2 results from the combination of the process feature (4-1) described on page 21 of the parent and divisional applications as filed with the X-ray diffraction pattern data and IR absorption wave numbers on pages 8 to 10 of the parent and divisional applications as filed.

Claims 3 to 10 correspond to Claims 24 to 31 of the divisional application as filed respectively Claims 70 to 77 of the parent application as filed.

Claims 11 to 13 correspond to Claims 9 to 11 of the divisional application as filed respectively Claims 79 to 81 of the parent application as filed.

Claims 14 and 15 correspond to Claims 12 and 14 of the divisional application as filed respectively Claims 25 and 86 of the parent application as filed.

Thus the requirements of Articles 76(1) and 123(2) EPC are fulfilled.

3.2 Rule 88 EPC

3.2.1 Pursuant to Rule 88 EPC, linguistic errors, errors of transcription and mistakes in any document filed with the European Patent Office may be corrected on request. Furthermore, Rule 88 EPC requires that, if the request for such correction concerns a description, claims or drawings, the correction must be obvious in the sense that it is immediately evident to a skilled person that nothing else would have been intended than what is offered as the correction.

From the examination file, however, it is clear that the Applicant, now Appellant, never requested a correction of an error, but that the Examining Division itself interpreted the selection of one out of the two distinct sets of data from the description in order to characterise the polymorph (IV) of donepezil hydrochloride as a request for a correction.

The Applicant, however, has never indicated that one set of data would be correct and/or that the other set of data would be incorrect. On the contrary, although the Appellant admitted that the two sets of data differed from each other, throughout the examination and appeal proceedings he maintained that the differences could be explained by measurement errors and, consequently, that both sets of data were correct.

Since the Appellant, thus, never requested a correction, Rule 88 EPC does not apply. For this reason alone, Rule 88 EPC is not a valid ground for refusing the application in the present case.

3.2.2 Moreover, drafting and amending patent claims which meet the requirements of the EPC is the sole responsibility of the applicant or its representative. The selection of one set of data, out of the two distinct sets disclosed, for the purpose of defining the claimed subject-matter cannot be considered as a request by the Applicant for a correction under Rule 88 EPC.

4. *Auxiliary requests*

In the light of the above findings, there is no need for the Board to consider the first and second auxiliary requests filed at the oral proceedings on 25 July 2005.

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 upon the basis of claims 1 - 15 of the Main Request.

The Registrar: The Chairman:

N. Maslin A. Nuss