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**Datasheet for the decision  
of 24 June 2014**

**Case Number:** T 1005/10 - 3.3.07

**Application Number:** 99960513.2

**Publication Number:** 1133230

**IPC:** A61K9/22, A61K31/55

**Language of the proceedings:** EN

**Title of invention:**

DOSAGE FORMULATIONS FOR ACETYLCHOLINESTERASE INHIBITORS

**Applicant:**

Davis, Bonnie M.

**Relevant legal provisions:**

EPC Art. 123(2)

**Keyword:**

Amendments - added subject-matter (yes)



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Case Number: T 1005/10 - 3.3.07

**D E C I S I O N  
of Technical Board of Appeal 3.3.07  
of 24 June 2014**

**Appellant:** Davis, Bonnie M.  
(Applicant) 160 Cold Spring Road  
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**Representative:** Richards, John  
Ladas & Parry LLP  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 30 December  
2009 refusing European patent application No.  
99960513.2 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** D. Boulois  
**Members:** R. Hauss  
D. T. Keeling

## Summary of Facts and Submissions

I. The appeal by the applicant (appellant) lies from the decision of the examining division, pronounced on 27 November 2009 and posted on 30 December 2009, refusing European patent application No. 99 960 513.2.

II. The impugned decision was based on a main request and eight auxiliary requests numbered 1, 1A, and 2 to 7.

The examining division found that the subject-matter of certain claims of the main request and of auxiliary requests 1A and 2 to 7 extended beyond the content of the application as filed (Article 123(2) EPC) with regard to the feature "acetylcholinesterase inhibition is avoided during normal sleep periods", or with regard to the combination of drug formulations other than galanthamine pills with the feature "allowing/ so as to allow the central nervous system to become relatively hypocholinergic at the time of desired sleep".

Furthermore, the subject-matter of various claims of the main request and of all auxiliary requests then pending did not meet the requirements of Articles 83 and 84 EPC. *Inter alia*, the definition of the acetylcholinesterase inhibitor in terms of its half life in claims 1, 19 and 36 of the main request did not allow the scope of the claims to be ascertained without undue burden, in contravention of Article 84 EPC.

III. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal the appellant submitted a new main request and eight new auxiliary requests to replace all requests hitherto on file.

Independent claims 1 and 19 of the main request read as follows:

"1. A dosage form of a pharmaceutical composition which comprises an effective amount of a centrally-acting acetylcholinesterase inhibitor selected from galanthamine, lycoramine, rivastigmine, analogs of said compounds wherein the methoxy group thereof is replaced by another alkoxy group of from one to six carbon atoms, a hydroxy group, hydrogen, an alkanoyloxy group, a benzoyloxy or substituted benzoyloxy group, a carbonate group or a carbamate group, analogs of galanthamine or lycoramine wherein the hydroxy group of galanthamine or lycoramine is replaced by an alkoxy group of from one to six carbon atoms, hydrogen, an alkanoyloxy group, a benzoyloxy or substituted benzoyloxy group, a carbonate group or a carbamate group and analogs and analogs of galanthamine and lycoramine wherein the N-methyl group of galanthamine or lycoramine is replaced by hydrogen, alkyl, benzyl or a cyclopropylmethyl group or a substituted or unsubstituted benzoyloxy group and wherein acetylcholinesterase inhibitor is formulated so as to delay its activity for a predetermined period of from four to twelve hours.

19. Use of a centrally acting acetylcholinesterase inhibitor selected from galanthamine, lycoramine, rivastigmine, analogs of said compounds wherein the methoxy group thereof is replaced by another alkoxy group of from one to six carbon atoms, a hydroxy group, hydrogen, an alkanoyloxy group, a benzoyloxy or substituted benzoyloxy group, a carbonate group or a carbamate group, analogs of galanthamine or lycoramine wherein the hydroxy group of galanthamine or lycoramine is replaced by an alkoxy group of from one to six carbon atoms, hydrogen, an alkanoyloxy group, a

*benzoyloxy or substituted benzoyloxy group, a carbonate group or a carbamate group and analogs and analogs of galanthamine and lycoramine wherein the N-methyl group of galanthamine or lycoramine is replaced by hydrogen, alkyl, benzyl or a cyclopropylmethyl group or a substituted or unsubstituted benzoyloxy group and wherein acetylcholinesterase inhibitor formulated so as to delay its activity for a predetermined period of from four to twelve hours for preparation of a medicament wherein acetylcholinesterase inhibitor is formulated so as to delay its activity for a specified period such that a dose may be administered to the patient in the evening and allow a night's sleep before the acetylcholinesterase becomes active in the morning."*

Claim 1 of the first auxiliary request corresponds to claim 1 of the main request but is restricted to an **"oral dosage form"**. (The difference in comparison with claim 1 of the main request is marked in bold).

Claim 19 of the first auxiliary request corresponds to claim 19 of the main request but is restricted to the use **"for preparation of an orally administered medicament"**. (The difference in comparison with claim 19 of the main request is marked in bold).

Claim 1 of the second auxiliary request corresponds to claim 1 of the main request but specifies that the **"acetylcholinesterase inhibitor is coated or contained in a matrix** so as to delay its activity for a predetermined period of from four to twelve hours". (The difference in comparison with claim 1 of the main request is marked in bold).

Claim 19 of the second auxiliary request corresponds to claim 19 of the main request but is restricted to the use **"for preparation of a medicament wherein**

*acetylcholinesterase inhibitor is **coated or incorporated into a matrix** so as to delay its activity for a specified period such that a dose may be administered to the patient in the evening and allow a night's sleep before the acetylcholinesterase becomes active in the morning."* (The difference in comparison with claim 19 of the main request is marked in bold).

Claims 1 and 19 of the third auxiliary request are identical to claims 1 and 19 of the main request.

Claims 1 and 19 of the fourth auxiliary request are identical to claims 1 and 19 of the first auxiliary request.

Claims 1 and 19 of the fifth auxiliary request are identical to claims 1 and 19 of the second auxiliary request.

Claim 1 of the sixth auxiliary request is identical to claim 19 of the main request.

Claim 1 of the seventh auxiliary request is identical to claim 19 of the first auxiliary request.

Claim 1 of the eighth auxiliary request is identical to claim 19 of the second auxiliary request.

The appellant argued that the definition of the acetylcholinesterase inhibitors by their structure, as employed in the claims of all current requests, overcame the examining division's objection to the definition of those compounds by their half life, as employed in the former main request and auxiliary request 1 on which the decision under appeal was based.

IV. In a communication issued in preparation for oral proceedings and advising the appellant of the board's

preliminary opinion, the board mentioned the following points:

- Claim 36 of each of the main request and the first and second auxiliary requests related to a method of treatment excluded from patentability pursuant to Article 53(c) EPC.

- Various objections under Articles 84 and 123(2) EPC could be raised against the wording of claims 1 and 19 of the third auxiliary request and the corresponding claims of the fourth to eighth auxiliary requests. The board observed *inter alia* that said claims referred to analogs of rivastigmine, not disclosed in the text of the application as filed.

- As a consequence it appeared that none of the requests on file was allowable.

- V. The appellant did not reply to that communication.
- VI. Oral proceedings were held on 24 June 2014, in the absence of the appellant.
- VII. The appellant had requested in writing that the decision under appeal be set aside and that a patent be granted in accordance with the main request or one of the first to eighth auxiliary requests, all filed with the grounds of appeal dated 30 April 2010.

### **Reasons for the Decision**

- 1. Main request- added subject-matter (Article 123(2) EPC)
  - 1.1 Both claim 1 and independent claim 19 of the main request specify that the acetylcholinesterase inhibitor is "*selected from galanthamine, lycoramine, rivastigmine, analogs of said compounds wherein the*

*methoxy group thereof is replaced by another alkoxy group of from one to six carbon atoms, a hydroxy group, hydrogen, an alkanoyloxy group, a benzoyloxy or substituted benzoyloxy group, a carbonate group or a carbamate group,...*".

- 1.2 The text of the application as filed does not mention any analogs of rivastigmine, whereas amended claims 1 and 19 of the present main request explicitly refer to "analogs of said compounds", i.e. analogs of galanthamine, lycoramine or rivastigmine.

Due to that explicit reference, it cannot simply be assumed that analogs of rivastigmine are excluded by the wording of the claims, even taking into account that rivastigmine does not, in fact, contain a methoxy group. That contradictory information merely has the effect of rendering the definition of said analogs unclear.

- 1.3 Hence the subject-matter of claims 1 and 19 of the main request extends beyond the content of the application as filed and therefore does not meet the requirement of Article 123(2) EPC.

## 2. Auxiliary requests

- 2.1 The objection explained above in the context of claims 1 and 19 of the main request equally applies to the corresponding claims of all auxiliary requests, since those claims contain the same reference to analogs of rivastigmine.
- 2.2 As a consequence, the subject-matter of claims 1 and 19 of each of the first to fifth auxiliary requests and of claim 1 of each of the sixth to eighth auxiliary



requests extends beyond the content of the application as filed, in contravention of Article 123(2) EPC.

3. In view of these findings, a decision on the further issues which were raised under Articles 53(c) and 84 EPC (see point IV supra) is not necessary.

### **Order**

#### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



V. Commare

D. Boulois

Decision electronically authenticated