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Datasheet for the decision of 30 December 2010

Case Number: T 1319/04 - 3.3.02

Application Number: 94306847.8

Publication Number: 0643965

IPC: A61K 31/445

Language of the proceedings: EN

Title of invention:
Nicotinic acid compositions for treating hyperlipidemia

Applicant:
Kos Life Sciences, Inc.

Opponent:
-

Headword:
Hyperlipidemia/KOS LIFE SCIENCES, INC.

Relevant legal provisions:
EPC Art. 54(5)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Articles 54(5) does not excluded that a known medicament be patented for use in a different treatment by therapy of the same illness, also where a dosage requirement is the only feature not comprised in the prior art"

Decisions cited:
G 0005/83, G 0002/08

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1319/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 30 December 2010

Appellant: Kos Life Science, Inc.
2100 N. Commerce Drive
Weston
FL 33326 (US)

Representative: Wallace, Sheila Jane
Marks & Clerk
90 Long Acre
London WC2E 9RA (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 16 June 2004 refusing European application No. 94306847.8 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
S. Perryman
A. Lindner
P. Mühlens

Summary of Facts and Submissions

I. European patent application No. 94 306 847.8 published as No. EP 643 965 was refused by a decision of the Examining Division of 25 September 2003 on the grounds of lack of novelty under Article 54(1) and (2) EPC 1973 and because it did not meet the requirements of Article 52(4) 1973 EPC.

II. The decision was based on the set of 7 claims filed on 25 September 2003 during the oral proceedings before the Examining Division. Independent claim 1 reads as follows:

1. The use of nicotinic acid or a compound metabolized to nicotinic acid by the body selected from a group consisting of d-glucitol hexanicotinate, aluminium nicotinate, niceritrol, d,1-alpha-tocopheryl nicotinate and nicotinyl alcohol tartrate, for the manufacture of a sustained release medicament for use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia characterised in that the medicament does not comprise in admixture, 5-30% hydroxypropyl methylcellulose, 2-15% of a water soluble pharmaceutical binder, 2-20% of a hydrophobic component and 30-90% nicotinic acid.

III. The following documents were cited *inter alia* during the proceedings before the Examining Division in the reason for the decision and during the written proceedings before the Board of Appeal:

(1) EP-A-577504
(2) US-A-5126145

(3) JP-A-6331 0827 (cited as WPI abstract; English translation filed by the applicant)
(4) JP-A-5221 854 (cited as WPI abstract)
(5) J.Clin.Invest., 2(3), 1973, 732-740
(6) EP-A-349235

(11) The American Journal of Medicine, 93 1992, 102-104
(12) The Journal of Family Practice, 34, 1992, 313-31 9
(13) Southern Medical Journal, 84, 1991, 496-497
(14) Metabolism, 34, 1985, 642-650
(15) J. Cardiovasc. Pharmacol. Therapeut., 1, 1996, 195-202
(16) Arch. Biochem. Biophys., 54, 1955, 558-559
(17) JAMA, 261(24), 23/30 June 1989, 3582-3587
(18) Am. J. Med., 91, September 1991, 239-246
(19) JAMA, Zi(9), 2 March 1994, 672-677
(20) American Journal of Medicine, 9, January 1 992, 77-81
(21) Presentation by Dr Eugenio Cefali filed with the appellant's grounds of appeal

Document (15) does not belong to the prior art, and was cited only for references to prior art.

Document (19) was post-published, and is not taken into account in this decision.

Document (21) does not belong to the prior art. It contains experimental data which are relevant for the assessment of inventive step.

IV. As set out in the decision under appeal, the Examining Division was of the opinion that the subject-matter of independent claim 1 and of its dependent claims 2 to 7

was anticipated by the disclosure in documents (2) to (4), which contemplated the use of nicotinic acid for the manufacture of a sustained release medicament for use in the treatment of hyperlipidaemia by oral administration (point 33).

In that respect, the Examining Division, referring in particular to decision T 317/95 and T 584/97, argued that the feature of claim 1 relating to a specific drug regimen, i.e. once per day prior to sleep, reflected a medical activity excluded from patentability under Article 52(4) EPC 1973, which could not therefore be considered to represent a further medical indication from which novelty can be derived (points 27 and 28).

As to the disclaimer in claim 1 vis-à-vis the interfering European patent application (1), which disclosed a medicament comprising, in admixture, 5-30% hydroxypropyl methylcellulose, 2-15% of a water soluble pharmaceutical binder, 2-20% of a hydrophobic component and 30-90% nicotinic acid for the manufacture of a sustained-release medicament for use in the treatment of hyperlipidaemia by oral administration after the evening meal and before bedtime, the Examining Division found that it was in line with the decisions of the Enlarged Board of Appeal G 1/03 and G 2/03 (point 15).

V. The appellant (applicant) lodged an appeal against this decision.

It filed a main and an auxiliary request with its grounds of appeal.

The set of claims of the main request is identical to the set of claims before the Examining Division with the deletion of dependent claims 6 and 7.

VI. The appellant argued in writing that the disclosure in documents (2) to (4) were not novelty-destroying because none of these documents disclosed the specific regimen of claim 1, namely "once per day prior to sleep".

It further held that this feature not only imparted novelty but it was also not excluded by Article 52(4) EPC 1973.

In that respect, it referred in particular to decision T 1020/03 stating that the wording of Article 52(4)EPC 1973 and the Enlarged Board of Appeal decision G 5/83 required broad allowability of claims in second medical use format, which did not require any restriction of the area where novelty can be looked for.

As to inventive step, it submitted that the reduction or elimination of well-known side effects was the result of the timing of niacin administration, once a day prior to sleep.

Having regard to the available prior art, which did not suggest that timing had any effects at all, the appellant considered that the claimed subject-matter was not obvious.

All the more so because the only solution put forward in terms of regimen variation to avoid severe side

effects was to reduce the dosage or stop taking niacin altogether.

VII. In its letter dated 9 November 2004, the appellant requested accelerated appeal proceedings.

VIII. The appellant requested in writing:

1. Reversal of the decision and grant of the application with the main request claims.

2. As an alternative to this request, grant of the application with the auxiliary request claims.

3. If the Board were minded not to grant the request under 1 or 2, referral of the following questions to the Enlarged Board:

1. Can the absence of side effects be considered a technical contribution to the art, or alternatively a technical effect such that it can render the known treatment of a specified pathological condition novel?
2. Are all drug dosage regimens excluded from patentability by Article 52(4) EPC 1973?

Oral proceedings were only requested if the Board contemplated a decision adverse to the appellant.

IX. On 22 March 2008 the Board delivered an interlocutory decision ruling the appeal admissible.

In the decision the Board also established that the feature in claim 1 - "once per day prior to sleep" – was not anticipated by the available prior art

documents (see III.), that this feature, which had an effect on hepatotoxicity, was not obvious vis-à-vis said prior art and that at least the feature in claim 1 relating to the manufacture of a sustained-release medicament containing nicotinic acid for use by oral administration fulfilled the requirements of Article 57 EPC.

The Board accordingly referred the following questions to the Enlarged Board of Appeal

1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness ?
2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime ?
3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000 ?

X. The Enlarged Board ruled as follows in its decision G 2/08 of 16 February 2010:

Question 1:
Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.

Question 2:
Such Patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.

Question 3:
Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83.

XI. With its letter dated 22 October 2009, the appellant filed a new main request and two auxiliary requests as auxiliary request 1 and auxiliary request 2.

The main request contains 14 claims. Claims 1 to 7 of this request correspond to the set of claims before the Examining Division and claim 8 to 14 to claims 1 to 7 but converted to product for use format.

Claim 8 of this request reads:

1. A sustained release medicament comprising nicotinic acid or a compound metabolized to nicotinic acid by the body selected from a group consisting of d-glucitol hexanicotinate, aluminium nicotinate, niceritrol, d,1 -alpha-tocopheryl nicotinate and nicotinyl alcohol tartrate, for use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia characterised in that the medicament does not comprise in admixture 5-30% hydroxypropyl methylcellulose, 2-15% of a water soluble pharmaceutical binder, 2-20% of a hydrophobic component and 30- 90% nicotinic acid.

Claims 1 to 7 of auxiliary request 1 are identical to claims 1 to 7 of the main request.

Claims 1 to 7 of auxiliary request 2 are identical to, respectively, claims 8 to 14 of the main request.

XII. The appellant requested in writing that the appeal be set aside and that a patent be granted on the basis of the main request, or alternatively, on the basis of auxiliary requests 1 or 2, all filed with letter dated 22 October 2009.

Reasons for the Decision

Main request

1. As stated already in the Referral Decision, The appeal is admissible and the claimed subject-matter drafted according to the so called Swiss-type claims complies with Articles 123(2), 84, 54, 56 and 57 EPC (points 2.1 to 2.5). These conclusions also applies *mutatis mutandis* to the product for use format.

2. The Decision of the Enlarged Board of Appeal has fundamentally clarified the legal position that Article 54(5) EPC does not exclude that a medicament be patented for use in a different treatment by therapy of the same illness and that such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.

3. Therefore the present claims of the main request are patentable under the EPC.

4. Moreover, having regard to the time-limit set in the Enlarged Board of Appeal decision G 2/08, it appears that the appellant is still entitled in the present case to so called Swiss-type claim as instituted by decision G 5/83 (see Question 3.).

Order

For these reasons it is decided that:

1. The Examining Division's decision of 25 September 2003 is set aside.

2. The matter is remitted to the department of first instance with the order that a patent be granted on the basis of the main request and a description to be adapted.

The Registrar The Chairman

N. Maslin U. Oswald