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D E C I S I O N
of 27 January 2005

Case Number: T 0134/01 - 3.3.1

Application Number: 91913236.5

Publication Number: 0537269

IPC: C07D 211/60

Language of the proceedings: EN

Title of invention:
Immunosuppressive compounds

Patentee:
VERTEX PHARMACEUTICALS INCORPORATED

Opponent:
Guilford Pharmaceuticals Inc.

Headword:
Immunosuppressives/VERTEX

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
"Amendments (not allowable) - disclaimer - not accidental anticipation"

Decisions cited:
G 0001/03, G 0002/03

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0134/01 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 27 January 2005

Appellant: (Proprietor of the patent)	VERTEX PHARMACEUTICALS INCORPORATED 130 Waverly Street Cambridge, MA 02139-4242 (US)
Representative:	VOSSIUS & PARTNER Postfach 86 07 67 D-81634 München (DE)
Respondent: (Opponent)	Guilford Pharmaceuticals Inc. 6611 Tributary Street Baltimore, MD 21224 (US)
Representative:	Hansen, Bernd, Dr. Dipl.-Chem. Hoffman Eitle, Patent- und Rechtsanwälte Arabellastrasse 4 D-81925 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 17 November 2000 revoking European patent No. 0537269 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: A. J. Nuss
Members: R. Freimuth
R. T. Menapace

Summary of Facts and Submissions

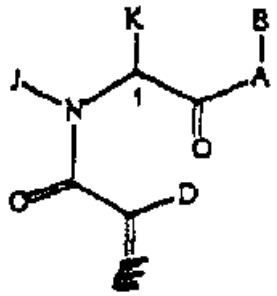
I. The Appellant (Proprietor of the patent) lodged an appeal on 26 January 2001 against the decision of the Opposition Division posted on 17 November 2000 revoking European patent No. 537 269 and filed a written statement setting out the grounds of appeal on 27 March 2001.

II. Notice of Opposition had been filed by the Respondent (Opponent) requesting revocation of the patent in suit in its entirety on the grounds of Article 100(a), (b) and (c) citing *inter alia* document

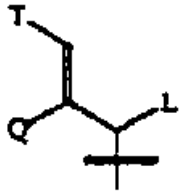
(5) US-A-2 447 587.

III. The decision under appeal was based on an amended set of twenty claims for all the designated Contracting States except ES submitted on 22 September 2000, claim 1 reading as follows:

"1. A compound for use as a medicament, wherein the compound:
i.) is represented by the formula:



and pharmaceutically acceptable salts thereof,
wherein A is O, NH, or N-(C1-C4 alkyl);
wherein B is hydrogen, CHL-Ar, (C1-C6)-straight or branched alkyl, straight or branched alkenyl of up to six carbon atoms, (C5-C7)-cycloalkyl, (C5-C7)-cycloalkenyl or Ar substituted (C1-C6)-alkyl or alkenyl, or



wherein L and Q are independently hydrogen, (C1-C6)-straight or branched alkyl or straight or branched alkenyl of up to six carbon atoms;
wherein T is Ar or substituted cyclohexyl with substituents at positions 3 and 4 which are independently selected from the group consisting of hydrogen, hydroxyl, O-(C1-C4)-alkyl or O-(alkenyl of up to four carbon atoms) and carbonyl;
wherein Ar is selected from the group consisting of 1-naphthyl, 2-naphthyl, 2-furyl, 3-furyl, 2-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl and phenyl having one to three substituents which are independently selected from the group consisting of hydrogen, halo, hydroxyl, nitro, CF_3, (C1-C6)-straight or branched alkyl or straight or branched alkenyl of up to six carbon atoms, O-(C1-C4)-straight or branched alkyl or O-(straight or branched alkenyl of up to four carbon atoms), O-benzyl, O-phenyl, amino and phenyl;

wherein D is U; E is either oxygen or CH-U, provided that if D is hydrogen, then E is CH-U or if E is oxygen then D is not hydrogen;

wherein U is independently selected from hydrogen, O-(C1-C4)-straight or branched alkyl or O-(straight or branched alkenyl of up to four carbon atoms), (C1-C6)-straight or branched alkyl or straight or branched alkenyl of up to six carbon atoms, (C5-C7)-cycloalkyl or (C5-C7)-cycloalkenyl substituted with (C1-C4)-straight or branched alkyl, straight or branched alkenyl of up to four carbon atoms, 2-indolyl, 3-indolyl, [(C1-C4)-alkyl or alkenyl of up to four carbon atoms]-Ar or Ar; and

wherein J is hydrogen or C1 or C2 alkyl; K is (C1-C4)-straight or branched alkyl, benzyl or cyclohexylmethyl; or wherein J and K may be taken together to form a 5-7 membered heterocyclic ring which may contain an O, S, SO or SO_2 substituent therein;

wherein the stereochemistry at carbon position 1 is R or S; and

provided that when E and A are oxygen and J and K together form a 5 to 7 membered ring which does not contain an O, S, SO or SO_2 substituent therein, then:

when D is (C1-C6) lower alkyl, B is not benzyl or (C1-C6) lower alkyl;

further provided that when E and A are oxygen and J and K together form a five membered ring which does not contain an O, S, SO or SO_2 substituent therein, then:

when D is phenyl, B is not hydrogen, methyl, ethyl, isopropyl or benzyl;

further provided that when E and A are oxygen and J and K together form a six membered ring which does not contain an O, S, SO or SO_2 substituent therein, then:

when D is methoxy, B is not tert-butyl or methyl;

further provided that when A is oxygen, D is hydrogen and J and K together form a five membered ring which does not contain an O, S, SO or SO_2 substituent therein, then:

when E is methylene, B is not hydrogen, ethyl, methyl, benzyl, propyl, cyclohexyl or 2,2-dimethylpropyl; and

when E is (3,4,5-trimethoxy)benzyl diradical, B is not hydrogen;

further provided that when A is oxygen, B, D and J are hydrogen, and E is (3,4,5-trimethoxy)benzyl diradical, then:

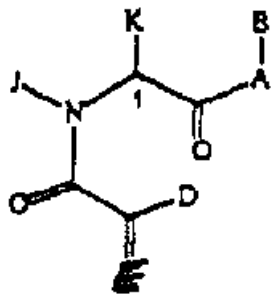
K is not isobutyl or benzyl:

further provided that when A is oxygen, D and J are hydrogen, and E is methylene, then:

when B is hydrogen, K is not methyl; and

when B is ethyl, K is not methyl, isobutyl or benzyl,

and further excluding the following compounds represented by the formula:



wherein the substituents J, K, A, B, E and D are defined as follows:

J	K	A	B	E	D
ethyl	ethyl	N-ethyl	ethyl	CH-1-propene	hydrogen
ethyl	methyl	N-methyl	ethyl	CH-methyl	hydrogen
ethyl	methyl	N-ethyl	ethyl	CH-methyl	hydrogen
ethyl	methyl	N-methyl	methyl	CH-1-propene	hydrogen
ethyl	methyl	N-ethyl	ethyl	CH-1-propene	hydrogen
ethyl	methyl	N-ethyl	methyl	CH-3,4-dimethoxyphenyl	hydrogen
methyl	ethyl	N-methyl	methyl	CH-methyl	hydrogen
methyl	ethyl	N-methyl	ethyl	CH-methyl	hydrogen
methyl	ethyl	N-ethyl	ethyl	CH-methyl	hydrogen
ethyl	ethyl	N-methyl	methyl	CH-methyl	hydrogen
ethyl	ethyl	N-methyl	methyl	CH-1-propene	hydrogen
ethyl	ethyl	N-methyl	ethyl	CH-methyl	hydrogen
ethyl	ethyl	N-ethyl	ethyl	CH-methyl	hydrogen
ethyl	ethyl	N-propyl	propyl	CH-methyl	hydrogen
ethyl	propyl	N-methyl	methyl	CH-methyl	hydrogen

ii.) and is immunosuppressive."

IV. The Opposition Division held that the claimed invention did not involve an inventive step.

V. The Appellant submitted that claim 1 as amended before the Opposition Division was supplemented with a disclaimer excluding specific compounds disclosed in document (5). In accordance with the jurisprudence of the Boards of Appeal, where there is an overlap between the prior art and the claimed subject-matter defined in generic terms, a specific prior art could be excluded even in the absence of literal support for the excluded subject-matter by way of a disclaimer.

VI. In a communication according to Article 12 of the Rules of Procedure of the Boards of Appeal, the Board drew the attention of the parties to the fresh decisions of the Enlarged Board of Appeal G 1/03 and G 2/03 (OJ EPO 2004, 413) relating to the matter of allowability of disclaimers. Both Parties were given the opportunity to modify their requests in view of those decisions, if they so wished.

VII. While the Appellant did not reply to the communication, the Respondent objected to the amendment made to claim 1 in the opposition proceedings which consisted in introducing a disclaimer in table form. This disclaimer did not restore novelty by delimiting the claim against an accidental anticipation as required by the above decisions of the Enlarged Board of Appeal. According to present claim 1, the compounds of the patent in suit were broadly used "as medicament"; the compounds of document (5) were used in the same field since they were pharmaceutically useful. Thus, document (5) was no longer an accidental anticipation and the disclaimer in present claim 1 based thereon did not satisfy the requirement of the decision G 1/03, thereby violating Article 123(2) EPC.

VIII. The Appellant requested in writing that the decision under appeal be set aside and the patent be maintained on the basis of the request submitted on 22 September 2000 before the Opposition Division.

The Respondent requested that the appeal be dismissed.

IX. Oral proceedings before the Board were held on 27 January 2005 in the absence of the Appellant who, after having been duly summoned, had informed the Board in his letter dated 10 January 2005 that he would not attend. At the end of the oral proceedings the decision of the Board was given orally.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments (Article 123(2) EPC)*

2.1 Claim 1 as amended is directed to compounds for use as a medicament as defined in the general formula given therein. One of the amendments made to that claim in opposition proceedings consists in incorporating a fresh disclaimer in table form at the end of the claim excluding individual compounds from the subject-matter claimed. The Appellant and the Respondent concur on the fact that this disclaimer has no basis in the application as filed, but that it is an attempt to delimit the claimed subject-matter from document (5). Nor is there dispute between the parties that this document is prepublished state of the art according to Article 54(2) EPC.

2.2 Following the decisions G 1/03 and G 2/03 of the Enlarged Board of Appeal (*loc. cit.*) a disclaimer vis-à-vis a prepublished state of the art is allowable without changing the subject-matter of the application as filed, within the meaning of Article 123(2) EPC, when it restores novelty by delimiting a claim from an accidental anticipation. An anticipation is considered accidental when the disclosure of the document in question is "so unrelated and remote that the person skilled in the art would never have taken it into consideration when working on the invention". When an anticipation is taken as accidental, this means that it appears from the outset that the anticipation has

nothing to do with the invention (*loc. cit.* points 2.2.2 and 2.3.4 of the reasons of the decisions).

2.3 Therefore, in the present case, the issue arises whether or not document (5) is an accidental anticipation in the sense of the decisions G 1/03 and G 2/03.

The compounds of document (5) have "valuable therapeutic properties" (column 1, line 17) and are "good therapeutics" (column 2, line 49). The compounds claimed are "for use as a medicament" and "pharmaceutical acceptable salts thereof" are covered (see present claim 1, lines 6 and 17). Thus, document (5) belongs to the same technical field, namely to the field of pharmaceuticals, as does the claimed invention. Since this document has not "nothing to do with the invention" and is not "so unrelated and remote" from the invention that it would never have been taken into consideration, it is not an accidental anticipation within the meaning of the decisions G 1/03 and G 2/03.

Document (5) not being an accidental anticipation, it is not allowable to incorporate a disclaimer into claim 1 to delimit the subject-matter claimed from that document. However, the Appellant has done so by incorporating into this claim the fresh disclaimer in table form at the end of the claim.

2.4 For these reasons, the incorporation of that disclaimer into claim 1 is an amendment contravening the provisions of Article 123(2) EPC with the consequence that the Appellant's request must be rejected.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin A. Nuss