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D E C I S I O N
of 30 June 1995

Case Number: T 0531/93 - 3.3.2

Application Number: 88870191.9

Publication Number: 0324328

IPC: A61K 31/445

Language of the proceedings: EN

Title of invention:
Use of the N-n-butyl derivative of desoxynojirimycin in the manufacture of a medicament

Applicant:
Monsanto Company

Opponent:
-

Headword:
BuDNJ/Monsanto

Relevant legal provisions:
EPC Art. 54(3) and (4), 123(2)

Keyword:
"Novelty (yes) - equivalence"

Decisions cited:
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Catchword:
-

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Case Number: T 0531/93 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 30 June 1995

Appellant: Monsanto Company
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Decision under appeal: **Decision of the Examining Division of the European Patent Office dated 4 December 1992 refusing European patent application No. 88 870 191.9 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: U. Oswald
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 88 870 191.9, filed on 20 December 1988 for the contracting states AT, BE, CH, DE, ES, FR, GB, GR, IT, LI, LU, NL, SE and published on 19 July 1989 with publication number 0 324 328, claiming priority of the United States applications on 21 December 1987 US 136 224, 9 March 1988 US 166 065 and 23 September 1988 US 248 461, was refused by the decision of the Examining Division of the European Patent Office dated 4 December 1992. The decision was based on Claims 1 to 5 filed with letter of 23 September 1992. Claim 1 was worded as follows:

> "1.Use of the N-butyl derivative of deoxynojirimicin (BuDNJ) or a pharmaceutically acceptable salt derivative thereof for the manufacture of a medicament with activity human immunodeficiency virus (HIV-virus) inhibitory activity."

II. The stated ground for the refusal was that, except for the contracting state LU, the use of the N-butyl derivative according to Claim 1 lacked novelty under Articles 52 (1) and 54 (3) EPC in the light of the disclosure of document (1) EP-A-0315017. The Examining Division considered that this document unambiguously described on page 11 the use of BuDNJ for the treatment or prophylaxis of HIV induced diseases (AIDS) and that, therefore, the skilled person was not prevented to associate BuDNJ with anti-AIDS activity. The disclosure of document (1) was not limited to the specific examples and the treatment of HIV-infection could be regarded as an obvious rewording for the treatment of AIDS. It was irrelevant for the outcome of the decision whether or not different theories existed as to the cause of AIDS.

III. The Appellant lodged an appeal against this decision and argued as follows:

The relevant content of document (1) on page 11 which reads "for the treatment or prophylaxis of HIV caused diseases" was literally and functionally different from the feature of present Claim 1 which reads "human immunodeficiency virus (HIV-virus) inhibitory activity". Furthermore, the experimental data disclosed in document (1) only were related to studies on anti-retroviral activity against Visna virus in sheep cells.

IV. A new Claim 1, filed with letter of 29 June 1995 differs from Claim 1 under point I. above in that the compounds in question are used for the manufacture of a medicament "for the inhibition of the human immunodeficiency virus (HIV-virus)".

V. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of Claims 1 and 2 filed with the letter of 29 June 1995.

Reasons for the Decision

1. The appeal is admissible.

2. The functional limitation which was not present in the originally filed Claim 1, i.e. the "inhibition of the human immunodeficiency virus" by the medicament finds support on page 4, lines 12 to 17 of the original disclosure. Dependent Claim 2 is based on page 19, lines 1 to 8 of the original disclosure. Claims 3 and 4 are supported by Example 1 of the original disclosure. Claim 5 is based on page 19, lines 9 to 12 of the original disclosure.

The requirement of Article 123(2) is accordingly satisfied.

3. Document (1) designated for the contracting states AT, BE, CH, DE, ES, FR, GB, GR, IT, LI, NL and SE derives priority from the German application DE 3 737 523 filed on 5 November 1987 and was published on 10 May 1989. The question to be investigated is therefore whether the use of the N-butyl derivative of deoxynojirimicin according to present Claim 1 is new with respect to the disclosure of this document under Article 54(3) and (4) EPC for the designated contracting states except LU.

3.1 Document (1) describes the use of 2-Hydroxymethylene-3,4,5-trihydroxypiperidines as antiviral agents in the field of veterinary and human medicine (page 2, lines 1 and 2). A listing of particular preferred compounds on page 7, line 10 up to page 10, line 7 mentions on page 8, line 27, N-butyl-1-desoxynojirimycin. With reference to this listing, it is stated that for example the anti-retroviral efficacy of the compounds was tested in cell cultures on the Visna virus, a virus which, as the HIV virus, belongs to the same retrovirus subfamily of lentiviruses, and that both viruses exhibit a similar genome organisation and a complex transcription pattern compared to the other retroviruses (page 10, lines 8 to 15). As a result of the worked examples on page 10, lines 16 to 38, showing that the compounds according to document (1) are actually active against Visna virus, it is inter alia concluded that the compounds according to this state of the art represent valuable active agents in the field of human and veterinary medicine for the treatment or prophylaxis of diseases (AIDS) caused by HIV (human immunodeficiency virus) and the stages associated therewith (cf. page 11, lines 43 to 50).

There is no further mention of HIV **virus** in document (1).

3.2 In the Board's opinion document (1) unquestionably discloses on page 10, lines 8 to 15 that the Visna virus and the HIV virus both belong to the retrovirus subfamily of leutiviruses and both viruses exhibit a similar genome organization. However, this does not automatically mean that both viruses show **identical** test results in cell cultures. Accordingly, the experimental data given for the compounds of document (1) demonstrating antiviral activity on Visna virus in cell culture are in no way novelty destroying for the presently claimed inhibition of the human immunodeficiency **virus** (HIV-virus) by the N-butyl derivative of deoxynojirimicin.

3.3 Moreover, the Board agrees with the Appellant's submission that the relevant passage on page 11, lines 47 to 50, in particular paragraph "2.)" unambiguously refers to the treatment of diseases **caused** by the HIV-virus and, therefore, cannot be regarded as describing an inhibition effect of the medicament on the virus as such.

3.4 Finally, it is to be noted that the human T cell leukaemia viruses type I and type II (HTLV-I and II) mentioned under paragraph "3.)" of said relevant passage on page 11, belong to the subfamily of Oncovirinae and clearly do not belong to the subfamily of Lentivirinae as the HIV-1 and 2 (formerly named HTLV-III/LAV, see also the description of the european patent application 0 324 328 A2, page 1, lines 4 to 14).

4. It follows from the preceding paragraphs that the subject-matter of Claim 1 would not have been known in the light of the prior art according to document (1). Thus, novelty is not lacking and the requirements of Article 54 are satisfied.

5. According to point 2.4 on page 6 of the decision of the Examining Division inventive step was not discussed and "the search was stopped immediately after the complete subject-matter was shown to lack novelty". Therefore, the Board considered appropriate to remit the case to the first instance for further prosecution.

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 on the basis of Claims 1 to 5 filed with letter of 29 June 1995.

The Registrar: The Chairman:

P. Martorana P. A. M. Lançon