Datasheet for the decision
of 27 March 2014

Case Number: T 1049/10 - 3.3.01
Application Number: 00902887.9
Publication Number: 1152009
IPC: C07H19/067, C07H19/10, C07H19/167, C07H19/20, C07H21/02
Language of the proceedings: EN

Title of invention:
NOVEL NUCLEOSIDES AND OLIGONUCLEOTIDE ANALOGUES

Patent Proprietor:
Daiichi Sankyo Company, Limited

Opponents:
Exigon A/S
Santaris Pharma A/S

Headword:
Nucleosides/DAIICHI SANKYO

Relevant legal provisions:
EPC Art. 54, 84, 123(3)
EPC R. 80
RPBA Art. 13(1)
Keyword:
Amendments - main request: occasioned by a ground of appeal (yes); extension of protection (no)
Claims - clarity - main request (yes)
Novelty - main request (yes)
Remittal to the department of first instance

Decisions cited:
T 0012/90, T 0124/87, T 0666/89

Catchword:
Case Number: T 1049/10 - 3.3.01

DECISION
of Technical Board of Appeal 3.3.01
of 27 March 2014

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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted on 10 March 2010 revoking European patent No. 1152009 pursuant to Article 101(3)(b) EPC.
**Composition of the Board:**

**Chairman:** A. Lindner  
**Members:**  
C. M. Radke  
L. Bühler
Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the decision of the opposition division to revoke European patent No. 1 152 009.

II. The oppositions sought revocation of the patent in its entirety and were based on grounds under Article 100(a) (alleged lack of novelty and inventive step) and (c) EPC.

III. The documents cited during the opposition proceedings include the following:

(D2) WO-A-99/14 226
(D6) P. Nielsen et al., Chem. Comm. (1997), 825-826
(D7) K. Morita et al., Bioorganic & Medicinal Chemistry, vol. 11 (2003), 2211-2226
(D8) S. Obika et al., Bioorganic & Medicinal Chemistry, vol. 9 (2001), 1001-1011
(D9) M. Koizumi et al., Nucleic Acids Research, vol 31 no. 12 (2003), 3267-3273
(D11) D. Braasch and D. R. Corey, Chemistry & Biology, vol 8 (2001), 1-7
(D12) B. Verbeure et al., Nucleic Acids Research, vol 29 no. 24 (2001), 4941-4947
(D13) J. B. Hansen et al., Mol. Cancer Ther., vol 7 no. 9 (2008), 2736-2745
(D14) C. G. Janson and M. J. During (eds.), Peptide Nucleic Acids, Morpholinos and Related Antisense


IV. The decision under appeal was based on the claims as granted (main request) and on the claims of auxiliary request 1.

Claims 1, 4 and 10 as granted read as follows:

"1. A compound of the formula (1):

\[ \begin{align*}
R^1 O & - \text{H} - \text{C} - \text{H} - \text{B} \\
& \text{A} - \text{O} - \text{R}^2 O \\
\end{align*} \]

(1)

wherein

$R^1$ and $R^2$ are the same or different and represent a hydrogen atom, a hydroxyl protecting group, a phosphoric acid group, a protected phosphoric acid group or $-P(R^3)R^4$ [wherein $R^3$ and $R^4$ are the same or different and represent a hydroxyl group, a protected hydroxyl group, a mercapto group, a protected mercapto group, an amino group, an alkoxy group having from 1 to 4 carbon atoms, an alkylthio group having from 1 to 4 carbon atoms, a cyanoalkoxy group having from 1 to 5
carbon atoms or an amino group substituted by an alkyl group having from 1 to 4 carbon atoms];
A represents an alkylene group having from 1 to 4 carbon atoms; and
B represents a purin-9-yl group, a 2-oxo-pyrimidin-1-yl group or a substituted purin-9-yl group or a substituted 2-oxo-pyrimidin-1-yl group having at least one substituent selected from the following α group; or a salt thereof;
α group
  a hydroxyl group,
  a protected hydroxyl group,
  an alkoxy group having from 1 to 4 carbon atoms,
  a mercapto group,
  a protected mercapto group,
  an alkylthio group having from 1 to 4 carbon atoms,
  an amino group,
  a protected amino group,
  an amino group substituted by an alkyl group having from 1 to 4 carbon atoms,
  an alkyl group having from 1 to 4 carbon atoms, and
  a halogen atom."

"4. The compound according to any one of Claims 1 to 3 or a salt thereof, wherein R² is a hydrogen atom, an aliphatic acyl group, an aromatic acyl group, a methyl group substituted by from 1 to 3 aryl groups, a methyl group substituted by from 1 to 3 aryl groups the aryl ring of which is substituted by an alkyl group having from 1 to 6 carbon atoms, an alkoxy group having from 1 to 4 carbon atoms, halogen or cyano group, a silyl group, a phosphoramidite group, a phosphonyl group, a phosphoric acid group or a protected phosphoric acid group."
"10. An oligonucleotide analogue having one or two or more structures of formula (2):

![Chemical Structure](image)

wherein:
A represents an alkylene group having from 1 to 4 carbon atoms; and
B represents a purin-9-yl group, a 2-oxo-pyrimidin-1-yl group or a substituted purin-9-yl group or a substituted 2-oxo-pyrimidin-1-yl group having at least one substituent selected from the following α group;
or a pharmacologically acceptable salt thereof;

α group

a hydroxyl group,
a protected hydroxyl group,
an alkoxy group having from 1 to 4 carbon atoms,
a mercapto group,
a protected mercapto group,
an alkylthio group having from 1 to 4 carbon atoms,
an amino group,
a protected amino group,
an amino group substituted by an alkyl group having from 1 to 4 carbon atoms,
an alkyl group having from 1 to 4 carbon atoms, and
a halogen atom."
V. The opposition division decided
- that documents (D7)-(D9) and the experimental results (C2)-(C6) were admitted into the proceedings, but not (D5), (D6) and (D10)-(D17);
- that the main request contravened the requirements of Article 123(2) EPC (due to the replacement of the terms "lower alkyl" and "lower alkoxy" in granted claim 4); and
- that the subject-matter of claim 1 of auxiliary request 1 was not novel in view of document (D2).

VI. The present decision is based on the following claims:

claims 1-19 of the main request;
claims 1-19 of auxiliary request 1;
claims 1-19 of auxiliary request 2;
claims 1-19 of auxiliary request 3;
claims 1-19 of auxiliary request 4;
claims 1-19 of auxiliary request 5;
claims 1-17 of auxiliary request 6;
claims 1-17 of auxiliary request 7;
claims 1-17 of auxiliary request 8;
claims 1-17 of auxiliary request 9;
claims 1-17 of auxiliary request 10;
claims 1-17 of auxiliary request 11;
claims 1-10 of auxiliary request 12;
claims 1-9 of auxiliary request 13;
claims 1-10 of auxiliary request 14;
claims 1-9 of auxiliary request 15;
all submitted during the oral proceedings before the board on 27 March 2014.

The claims of the main request differ from those as granted in that in claims 1 and 10 the expression
"having at least one substituent" in the definition of the radical B has been replaced by "having a substituent" and in that claim 4 has been amended to read as follows:

"4. The compound according to any one of Claims 1 to 3 or a salt thereof, wherein R² is a hydrogen atom, an aliphatic acyl group, an aromatic acyl group, a methyl group substituted by from 1 to 3 aryl groups, a methylbenzyl, 2,4,6-trimethylbenzyl, 3,4,5-trimethylbenzyl, 4-methoxy-benzyl, 4-methoxy-phenyldiphenylmethy1, 4,4'-dimethoxytriphenylmethyl, 2-nitrobenzyl, 4-nitrobenzyl, 4-chlorobenzyl, 4-bromobenzyl or 4-cyanobenzyl group, a silyl group, a phosphoramidite group, a phosphonyl group, a phosphoric acid group or a protected phosphoric acid group." (emphasis added by the board in order to denote amendments with respect to claim 4 as granted).

VII. The arguments of the respondents, as far as relevant for this decision, may be summarised as follows:

Admission of late-filed requests

The main request and auxiliary requests 1 to 15 were late-filed, should have been filed in immediate response to the board's preliminary opinion and were not prima facie allowable. The number of auxiliary requests was excessive, so that their filing was an abuse of the proceedings. Hence, the main and the auxiliary requests should not be admitted into the proceedings. As the admissibility of the requests was important for the further prosecution of the case by the department of first instance, the board should decide thereon.
Article 123(3) and Rule 80 EPC

The respondents objected to the amendment in claim 4 of the main request.

They argued that this amendment contravened the requirements of Article 123(3) EPC
- as claim 4 as granted did not comprise "2-nitrobenzyl, 4-nitrobenzyl" as substituents and
- as radicals R^2 with such substituents were not clearly covered by claim 1 as granted.

Nor was the insertion of these two substituents occasioned by a ground for appeal, contrary to the requirements of Rule 80 EPC.

Clarity of the claims (Article 84 EPC)

The replacement of the expression "having at least one substituent" in the definition of radical B in claims 1 and 10 as granted by "having a substituent" in claims 1 and 10 of the main request rendered the claims unclear as
- "having a substituent" was inconsistent with claim 7, which listed radicals B, including ones having more than one substituent; and as
- it was not clear from the wording of claim 1 as such whether or not the substituted pyrimidin or purin bases might contain substituents other than a group α.

Novelty

The subject-matter of the claims lacks novelty in view of document (D2), as the person skilled in the art would have seriously considered compounds of formula
IIa where $R^2$ and $R^4$ together designate a biradical of the formula $-O-(CH_2)_2-$ or $-O-(CH_2)_3-$.

VIII. The arguments of the appellant, as far as relevant for this decision, may be summarised as follows:

Admission of late-filed documents

The appellant considered documents (D16) and (D17) to be relevant for assessing the validity of the priority claimed in the patent in suit. Therefore, the decision of the opposition division not to admit these documents should be reversed.

Admission of the main request

The claims of the main request differed from those of auxiliary request 1 filed with the statement setting out the grounds of appeal only by a minor amendment, i.e. in that "having at least one substituent" was replaced by "having a substituent" in the definition of the radical B in claims 1 and 10. This amendment was occasioned by the communication of the board. Therefore the main request should be admitted into the proceedings.

Article 123(3) and Rule 80 EPC

The amendment in claim 4 of the main request was based on the list of substituents disclosed on page 5, lines 16-20, of the application as filed, which also mentions the 2-nitrobenzyl and 4-nitrobenzyl groups. The fact that amended claim 4 now included these two groups could not justify an objection under Rule 80 EPC, as the deletion of these groups from the list could have given rise to an objection under Article 123(2) EPC. It
was evident that all the groups $R^2$ defined in claim 4 were hydroxyl protecting groups as defined in claim 1 as granted. Hence, the protection was not extended by this amendment.

**Novelty**

The subject-matter of the claims was novel as document (D2) did not disclose directly a compound of formula IIa in which $R^{2*}$ and $R^{4*}$ together designate a biradical of the formula $-O-(CH_2)_2- \text{ or } -O-(CH_2)_3-$ (where the oxygen is linked to the carbon in position 4 of the furanose ring).

**Clarity of the claims**

There was no inconsistency between claims 1 and 7 as the expression "having a substituent" encompassed the possibility to have several such substituents, such as in several examples of the group B listed in claim 7. The alleged lack of clarity in claim 1 as such was not caused by an amendment with respect to the claims as granted. Hence, this objection was not admissible in opposition appeal proceedings.

**IX.** During the oral proceedings before the board the appellant withdrew the requests to remit the case to the department of first instance and to reimburse the appeal fee due to a substantial procedural violation in the opposition proceedings.

The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for consideration of inventive step on the basis of the main request or,
alternatively, of any of auxiliary requests 1 to 15 submitted during oral proceedings.

The respondents requested that the appeal be dismissed or, alternatively, that the case be remitted to the department of first instance for consideration of inventive step. Furthermore they requested that auxiliary requests 1 to 15 filed during oral proceedings not be admitted into the appeal proceedings.

X. The chairman announced the decision of the board at the end of the oral proceedings.

Reasons for the Decision

1. The appeal is admissible

Main request

2. Admission of this request

2.1 According to Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the admission of any amendments of the appellant's case after it has filed its grounds for appeal is within the discretion of the board. This discretion "shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy" (see OJ EPO Supplementary publication 1/2014, pages 44-53).

2.2 The claims of the main request differ from those of auxiliary request 1 submitted with the grounds of appeal only in that "having at least one substituent"
was replaced by "having a substituent" in the definition of the radical B in claim 1 and 10. The respondents have not argued that this amendment was complex, nor does the board have reason to consider it to be so.

2.3 This amendment is a reaction to the communication dated 10 January 2014 in which the board raised for the first time the preliminary objection that the replacement of "having a substituent" in the application as filed by "having at least one substituent" might add subject-matter extending beyond the content of the application as filed (see points 5.2 and 5.3 of said communication). So, the amended request could reasonably be expected to be filed only at a late stage of the proceedings. Even if the appellant could have filed the request prior to the oral proceedings of 27 March 2014, the respondents could deduce from said communication that the feature "having at least one substituent ..." might be amended, most probably by way of reverting to the wording of the application as filed, i.e. to "having a substituent ...", which was indeed the case. Hence, the respondents should have been prepared to discuss the claims of the main request and were not disadvantaged by the time of filing of the main request. Moreover, consideration of the main request did not delay the proceedings.

2.4 For these reasons the board decided to admit the claims of the main request into the proceedings.

3. Article 123(3) and Rule 80 EPC

3.1 The appellant has amended claim 4 by replacing the expression
"a methyl group substituted by from 1 to 3 aryl groups
the aryl ring of which is substituted by an alkyl group
having from 1 to 6 carbon atoms, an alkoxy group having
from 1 to 4 carbon atoms, halogen or cyano group"

in claim 4 as granted by

"a methylbenzyl, 2,4,6-trimethylbenzyl, 3,4,5-
trimethylbenzyl, 4-methoxy-benzyl, 4-methoxy-
phenyldiphenylmethy1, 4,4'-dimethoxytriphenylmethyl, 2-
nitrobenzyl, 4-nitrobenzyl, 4-chlorobenzyl, 4-
bromobenzyl, 4-cyanobenzyl group".

3.2 The objections of the respondents were directed against
the introduction of "2-nitrobenzyl, 4-nitrobenzyl" as
possible meanings of the substituent R².

3.3 Rule 80 EPC

In the decision under appeal, the then pending main
request (based on the claims as granted) was rejected
as claim 4 contravened the requirements of Article
123(2) EPC, i.e. because grounds under Article 100(c)
EPC prejudiced the maintenance of the patent as granted
(see point 5 of the reasons). The replacement of the
objected amendment by the definition set out on page 5,
lines 16-20, of the application as filed in claim 4 of
the present main request sought to overcome this
objection. Hence, this amendment as a whole was
occasioned by a ground for opposition.

The fact that amended claim 1 now lists "2-nitrobenzyl,
4-nitrobenzyl" among the meanings of the substituent R²
is not relevant in this respect. Rule 80 EPC requires
that the amendment is occasioned by a ground for
opposition, not that this amendment is necessary to
overcome a respective objection. Moreover, the appellant's argument makes sense in that the insertion of only those substituents listed on page 5, lines 16-20, of the application as filed which are not 2- or 4-nitrobenzyl into the claim might have given rise to an objection under Article 123(2) EPC.

3.4 Article 123(3) EPC

Each of the parties to the proceedings bears separately the burden of proof for the facts it alleges. The respondents alleged that the 2-nitrobenzyl and 4-nitrobenzyl groups could not be considered as hydroxyl protecting groups R² as defined in claim 1 as granted. The respondents did not provide any evidence in support of this fact, nor does the board see any reasons why these nitrobenzyl groups should not act as hydroxyl protecting groups.

3.5 For these reasons, the board decided that claim 4 does not contravene the requirements of Article 123(3) and Rule 80 EPC.

4. Novelty

4.1 The respondents' objection as to novelty was based solely on document (D2). It was disputed whether this document disclosed directly and unambiguously compounds of formula (1) of present claim 1 in which the radical A means "an alkyl group having from 1 to 4 carbon atoms" (see point IV above).

The respondents relied on page 41, lines 10-29, of document (D2), where the following general formula IIa is depicted:
where

B designates a nucleobase, preferably a nucleobase selected from thymine, cytosine, uracil, adenine and guanine (in particular adenine and guanine),

X is -O-,

R^{2*} and R^{4*} together designate a biradical selected from

-(CH_{2})_{0-1}-O-(CH_{2})_{1-3}^{-}, -(CH_{2})_{0-1}-S-(CH_{2})_{1-3}^{-}, and

-(CH_{2})_{0-1}-N(R^{N})-(CH_{2})_{1-3}^{-}, in particular -O-CH_{2}^{-}, -S-CH_{2}^{-} and -R^{N}-CH_{2}^{-}, where R^{N} is selected from hydrogen and C_{1-4}-alkyl.

The respondents argued that the general formula

-(CH_{2})_{0-1}-O-(CH_{2})_{1-3}^{-}

covered six individual biradicals, including those of the formulae

-O-(CH_{2})_{2}^{-} and -O-(CH_{2})_{3}^{-}, i.e. compounds of present claim 1 wherein A is -(CH_{2})^{-} or -(CH_{2})_{2}^{-}. Hence, the compounds of the formula of present claim 1 overlapped with those of formula IIa disclosed in document (D2).

4.2 The respondents deduced from decisions T 12/90, T 666/89 and T 124/87 that such an overlap deprived the claimed subject-matter of novelty; the person skilled in the art would have seriously contemplated working in the region of overlap as document (D2) generally discloses in Figures 2 and 24 the bridging of two carbon atoms of the furanose ring by a group of the formula -O-(CH_{2})_{2}^{-}.
4.3 The board agrees with the respondents in that the disclosure of a prior-art document is not limited to what is disclosed in the examples. On the other hand, there is no reason to disregard the examples when determining the information the skilled person extracts from such a document. This is in accordance with

- T 12/90 (where compounds 23 and 24 were taken into account; see the second paragraph of point 2.5 of the reasons); and
- T 666/89 (which considered experiments 1 and 4 to 9, see OJ EPO 8/1993, the second paragraph on page 500).

Document (D2) discloses in Figures 2 and 24 the bridging of the carbon atoms at positions 3 and 4 of the furanose ring (counting from the oxygen atom in the ring as position 1) by a group of the formula -O-(CH₂)₂-(see the general formulae V and X on page 3/44 and compounds 6 to 8 on page 27/44 of the drawings).

However, document (D2) discloses the bridging of positions 3 and 5 of the furanose ring only with biradicals of the formulae -O-(CH₂)-, -S-(CH₂)- and -N(R⁵)-(CH₂)- (see the following formulae depicted in the pages of the drawings:

- formula Q on page 2/44,
- formulae 2 on page 3/44,
- formulae 36-39 on page 30/44,
- formulae 43-46 on page 31/44,
- formulae 50-53 on page 32/44,
- formulae 57-57D on page 33/44,
- formulae 61-61C on page 34/44,
- formula 44 on page 35/44,
- formulae 64-66 on page 36/44,
- formulae 71 and 61b on page 37/44,
- formulae 73-74A and Monomer $Z_{TNH}^*$ on page 38/44,
- the formulae on page 39/44,
- formulae 76, 76C-76F and Monomer $Z_{US}^*$ on page 40/44,
- formula 36 on page 41/44,
- formulae 202 and 203 on page 42/44,
- the formulae on page 43/44 and
- formulae 212-214, 36 and 37 on page 44/44).

This gives the overall impression that document (D2) discloses compounds having a group of the formula
- $\text{O-} \left( \text{CH}_2 \right)_2 -$ bridging positions 3 and 4, but only those of the formulae $\text{O-} \left( \text{CH}_2 \right)_-, \text{S-} \left( \text{CH}_2 \right)_-$ and
- $\text{N(}$R$^N$)$\text{-(CH}_2\text{)}-$ bridging positions 3 and 5 at the furanose ring. Moreover, it makes sense to have different bridging groups at these positions as the chemical environments and reactivities at positions 4 and 5 on the furanose ring are quite different.

Decision T 124/87 cited by the respondents deals with quite a different situation, namely with the lack of novelty due to the overlap of the values of numerical ranges for two parameters (i.e. the density and the melt index of a copolymer). Hence, T 124/87 is not relevant for the present decision.

Therefore, the person skilled in the art would not have considered the subject-matter of the present claims as a direct and unambiguous disclosure of document (D2). The parties did not consider any other cited document to be relevant as to novelty, nor has the board reason to do so.

Hence, the subject-matter of the present claims is novel.
5. Clarity of the claims

5.1 The respondent saw an inconsistency between claims 1 and 7. Claim 7 lists radicals B which have one or more substituents on the purine ring system or on the pyrimidine ring; claim 1 refers to substituted purine or pyrimidine radicals B "having a substituent" selected from a certain group.

Whereas the respondents argued that the term "having a substituent" limited the number of substituents to one, the appellant was of the opinion that it permitted the radical B to have more than one substituent.

5.2 When assessing whether the term "having a substituent" renders the claim unclear, said term has to be interpreted in the context of the wording of the claims.

Said term forms part of the definition of the radical B in claims 1 and 10, which reads as follows:

"B represents a purin-9-yl group, a 2-oxo-pyrimidin-1-yl group or a substituted purin-9-yl group or a substituted 2-oxo-pyrimidin-1-yl group having a substituent selected from the following α group; or a salt thereof; ...").

Hence, the term "having a substituent" refers "a substituted purin-9-yl group or a substituted 2-oxo-pyrimidin-1-yl group". The expressions "substituted purin-9-yl group" and "substituted 2-oxo-pyrimidin-1-yl group" clearly include such groups having more than one substituent. In this context, the term "having a substituent" cannot mean "having only one substituent"
but allows for more substituents, as the board outlined during the oral proceedings.

Consequently, the alleged inconsistency of claim 1 with claim 7 (which mentioned such groups having more than one substituent) and within claim 1 does not exist.

5.3 A lack of clarity is no ground for opposition under Article 100 EPC. In opposition appeal proceedings, clarity is therefore assessed only to the extent that it is caused by amendments to the claims as granted.

Whether claims 1 and 10 permit other substituents to be present in the radical B than those of the group α does not have to be decided by the board; this alleged lack of clarity was already present in the claims as granted.

5.4 Hence, no lack of clarity prejudices the maintenance of the patent on the basis of the main request.

6. Request to decide on the admission of the auxiliary requests into the appeal proceedings

Subsequent to the finding that the main request was in conformity with Articles 123 and 84 EPC, the board dealt with the request of both parties to remit the case to the department of first instance for consideration of the ground for opposition pursuant to Article 100(a) EPC together with Article 56 EPC. The board exercised its discretion under Article 111(1) EPC in favour of the parties and ordered remittal. As a consequence, there was no further substantive or procedural request with respect to the main request that required a decision by the board. The appellant's auxiliary requests filed during the appeal proceedings
were no longer of relevance for the board's decision, since the appeal could be allowed and the decision under appeal be set aside on the basis of the higher-ranking main request. A decision of this board on the admission of the auxiliary requests was not required and would even have prejudiced the discussion of inventive step by the opposition division and would have run counter the rationale for the remittal. Moreover, a discussion of the admission of the auxiliary requests would have required the parties to engage in a *prima facie* assessment of the state of the art relevant for the issue of inventive step in order to ascertain the relevance of the requests. Therefore, the board rejected the request of the respondents to decide on the admission of the auxiliary requests.

7. In view of the remittal of the case to the department of first instance for consideration of the ground for opposition pursuant to Article 100(a) EPC together with Article 56 EPC, the board also had no power to review the decision of the department of first instance not to admit certain documents as late-filed (see point 3 of the board's communication dated 10 January 2014), as these documents are relevant only when assessing inventive step.
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 on the basis of the main request filed during oral proceedings before the board.

The Registrar: The Chairman:

G. Nachtigall A. Lindner

Decision electronically authenticated