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**Datasheet for the decision  
of 22 September 2011**

**Case Number:** T 0739/10 - 3.3.08

**Application Number:** 93902851.0

**Publication Number:** 0618925

**IPC:** C07H 21/04

**Language of the proceedings:** EN

**Title of invention:**  
Antisense oligonucleotides

**Patentee:**  
Isis Pharmaceuticals, Inc.

**Opponents:**  
Vernalis (R & D) Limited  
Santaris Pharma A/S

**Headword:**  
RNase H gapmers/ISIS

**Relevant legal provisions:**

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**Relevant legal provisions (EPC 1973):**

-

**Keyword:**  
"Adaptation of the description after a decision to maintain the patent in amended form - consistent with the amended set of claims (yes)"

**Decisions cited:**

T 0506/04

**Catchword:**

-



Case Number: T 0739/10 - 3.3.08

**DECISION**  
of the Technical Board of Appeal 3.3.08  
of 22 September 2011

**Appellant:** Santaris Pharma A/S  
(Opponent 02) Kogle Allé 6  
DK-2970 Hørsholm (DK)

**Representative:** Polz, Leo  
Hoffmann Eitle  
Patent- und Rechtsanwälte  
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**Respondent:** Isis Pharmaceuticals, Inc.  
(Patent Proprietor) 2855 Gazelle Court  
Carlsbad, CA 92010 (US)

**Representative:** Hallybone, Huw George  
Carpmaels & Ransford  
One Southampton Row  
London WC1B 5HA (GB)

**Party as of rights:** Vernalis (R & D) Limited  
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**Representative:** Lawrence, Peter Robin Broughton  
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7 Eldon Street  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
15 December 2009 concerning maintenance of the  
European patent No. 0618925 in amended form.

**Composition of the Board:**

**Chairman:** M. Wieser  
**Members:** P. Julià  
C. Heath

## **Summary of Facts and Submissions**

- I. Two oppositions were filed against the European patent No. 0 618 925 (based on the European patent application No. 93 902 851.0 and published with the International publication No. WO 93/13121) on the grounds of Articles 100(a), (b) and (c) EPC. The patent was revoked by the opposition division.
- II. The patentee lodged an appeal against the decision of the opposition division and, in the decision T 506/04 of 5 December 2006, the then competent board of appeal considered an auxiliary request II filed on 3 November 2006 to fulfil the requirements of the EPC. The board remitted the case to the first instance with the order to maintain the patent in that form with a description to be adapted thereto.
- III. In the interlocutory decision of 15 December 2009, the opposition division provided its reasons to maintain the patent on the basis of an adapted description filed, as a sole auxiliary request, at oral proceedings held on 27 November 2009.
- IV. An appeal was lodged by opponent 02 (appellant) against this interlocutory decision. A notice of appeal and a statement setting out the grounds of appeal were filed, respectively, on 13 January 2010 and 7 April 2010. Oral proceedings were requested as a precautionary measure.
- V. With a letter dated 6 August 2010, the patentee (respondent) maintained, as its main request, the description allowed by the opposition division and filed, as auxiliary requests I and II, two new forms of

- an adapted description. The respondent also requested accelerated prosecution of appeal proceedings and, as a precautionary measure, oral proceedings.
- VI. On 13 May 2011, the board issued summons to oral proceedings to be held on 22 September 2011, accompanied by a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) informing the parties of the board's preliminary, non-binding opinion on the case.
- VII. With a letter dated 17 June 2011, opponent 01 (a party as of right to the appeal proceedings) informed the board that it would not attend oral proceedings.
- VIII. With a letter dated 15 July 2011, the respondent withdrew its previous requests on file and filed a new main request. In this letter and in the submissions made on 2 August 2011, the respondent withdrew its request for oral proceedings if the board intended to remit the case to the first instance with the order to maintain the patent on the basis of its main request.
- IX. With letter dated 17 August 2011, the appellant withdrew its request for oral proceedings on the condition that no further requests were filed by the respondent.
- X. On 1 September 2011, the board informed the parties that the scheduled oral proceedings were cancelled.
- XI. In the statement of grounds of appeal, the appellant objected to several paragraphs of the description considered allowable by the opposition division, namely

paragraph [0019] second sentence, paragraph [0020] first sentence, and paragraph [0021] first and second sentences (all under the heading "*Brief description of the invention*"), as well as paragraphs [0027], [0032], [0041] to [0042] and [0045] to [0061] (all under the heading "*Detailed description of the invention*").

In the appellant's view, respondent's interpretation of several parts of the original description as referring to the flanking sequences of the claimed phosphorothioate oligonucleotide sequence (the gapmer) was not correct. The limited subject-matter of the claims allowed by the board in decision T 504/06 (*supra*) could not be combined with selected embodiments - that were disclosed in the original description but referring only to the originally filed broad disclosure, when such a specific combination was not originally disclosed.

- XII. The respondent argued that the original description disclosed modifications that could be used in the oligonucleotides of the invention as a whole and not merely in the phosphorothioate oligonucleotide sequence (the gapmer). The fixing of certain nucleotides in the gapmer could not limit the skilled person's choice of modifications outside the gapmer. Thus, the objected paragraphs were relevant because they described modifications that could be used in embodiments embraced by the claims.

According to the respondent, its present main request addressed the objections raised in relation to paragraphs [0019] to [0021], [0027], [0032], [0041] to [0042], [0059] and [0060].

The objected paragraphs [0045] to [0047] and [0055] to [0058], remaining in the new main request, disclosed technical information about  $\alpha$  and  $\beta$  nucleosides, 4'-thionucleosides and carbocyclic nucleosides and how they could be incorporated into oligonucleotides. Oligonucleotides comprising these nucleosides were encompassed by the claims and were compatible with the phosphorothioate oligonucleotide sequence. Thus, these paragraphs remained relevant to the claimed invention and did not require amendment or deletion.

XIII. The appellant (opponent 02) requested that the decision under appeal be set aside and that the patent be revoked.

XIV. The respondent (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims filed on 3 December 2006 and allowed by the then competent board of appeal in the decision T 506/04 (*supra*) and the description adapted thereto according to the main request filed on 15 July 2011.

XV. No requests were on file from opponent 01, a party as of right to the appeal proceedings.

## **Reasons for the Decision**

1. The scope of the present appeal proceedings is exclusively limited to the adaptation of the description of the patent-in-suit to the set of claims allowed by the then competent board of appeal in the

decision T 506/04 (*supra*). Claim 1 of this set of claims is recited on page 3, Section X of that decision. The subject-matter of this claim is schematically represented on page 3 of the decision now under appeal (cf. first paragraph under the heading "*Reasons for the Decision*") and on page 3 of the respondent's reply to the appellant's grounds of appeal (cf. page 3, point 3.1).

The key issue of the present appeal proceedings arises from the "*comprising*" language present in claim 1 which allows the claimed oligonucleotide to include not only the gapmer sequence structurally defined in claim 1 but also undefined flanking sequences (cf. page 4, second and third paragraphs of the decision under appeal, page 3, point 3.2 of the respondent's submissions and point 25 of the decision T 506/04, *supra*).

2. In the statement setting out the grounds of appeal, the appellant objected to paragraph [0019] second sentence, paragraph [0020] first sentence, and paragraph [0021] first and second sentences (all under the heading "*Brief description of the invention*"), paragraphs [0027], [0032], [0041] to [0042] and [0045] to [0061] (all under the heading "*Detailed description of the invention*") of the adapted description considered allowable by the opposition division in the decision now under appeal (cf. point XI *supra*).
3. In the respondent's main request, paragraphs [0019] to [0021], [0027] and [0041] to [0042] have been amended taking into account the objections raised by the appellant. Whereas paragraphs [0048] to [0054] were already deleted in the description allowed by the

opposition division, paragraphs [0032], [0059] and [0060] have been deleted now in the respondent's main request. Thus, from these paragraphs objected by the appellant in its grounds of appeal, only paragraphs [0045] to [0047], [0055] to [0058] and [0061] remain unchanged in the respondent's main request.

4. The board is satisfied with the amendments introduced into paragraphs [0019] to [0021], [0027] and [0041] to [0042] and considers that they successfully overcome the objections raised by the appellant.

Paragraphs [0019] to [0021] and [0027] describe now only the subject-matter of the claims as allowed by the then competent board of appeal in the decision T 506/04 (*supra*). Paragraphs [0041] to [0042] set out a general technical discussion about how various structural modifications might possibly achieve their effects (mechanism of action of RNase H for recognizing and cleaving a DNA-RNA duplex) and the amendments introduced now into these paragraphs render them clear and avoid the possible original ambiguity pointed out by the appellant.

5. As for paragraphs [0045] to [0047], [0055] to [0058] and [0061], the board shares the respondent's view that they only disclose technical information on several nucleosides and how they can be incorporated into oligonucleotides (cf. point XII *supra*). In view of all the preceding paragraphs of the description in the respondent's main request, these paragraphs are not considered to raise any ambiguity or to describe possible embodiments not encompassed by and not related to the subject-matter of the claims as allowed by the



then competent board of appeal in decision T 506/04  
(*supra*).

6. Thus, the respondent's main request is considered to be in line with the claims as allowed by the then competent board of appeal in decision T 506/04 (*supra*).

## **Order**

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

1. The decision under appeal is set aside.
2. The patent is maintained on the basis of the claims filed on 3 December 2006 and allowed by the then competent board of appeal in the decision T 506/04 (*supra*) and the description adapted thereto filed as main request on 15 July 2011.

The Registrar:

The Chairman:

A. Wolinski

M. Wieser



Case Number: T 0739/10 - 3.3.08

**D E C I S I O N**

of 23 November 2011 correcting an error in the decision  
of the Technical Board of Appeal 3.3.08  
of 22 September 2011

**Appellant:** Santaris Pharma A/S  
(Opponent 02) Kogle Allé 6  
DK-2970 Hørsholm (DK)

**Representative:** Polz, Leo  
Hoffmann Eitle  
Patent- und Rechtsanwälte  
Arabellastraße 4  
D-81925 München (DE)

**Respondent:** Isis Pharmaceuticals, Inc.  
(Patent Proprietor) 2855 Gazelle Court  
Carlsbad, CA 92010 (US)

**Representative:** Hallybone, Huw George  
Carpmaels & Ransford  
One Southampton Row  
London WC1B 5HA (GB)

**Party as of rights:** Vernalis (R & D) Limited  
(Opponent 01) Warlington Road  
Oxford OX4 6LY (GB)

**Representative:** Lawrence, Peter Robin Broughton  
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7 Eldon Street  
London EC2M 7LH (GB)

**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
on 15 December 2009 concerning maintenance of  
the European patent No. 0618925 in amended  
form.**

**Composition of the Board:**

**Chairman:** M. Wieser  
**Members:** P. Julià  
C. Heath

In application of Rule 140 EPC, the decision in the appeal case T 739/10 of 22 September 2011 is corrected, in that on page 4, Section XIV and on page 7, point 2 of the Order, the basis for maintenance of the patent are the claims filed on 3 November 2006 (instead of 3 December 2006, as erroneously stated) as allowed by the then competent board of appeal in the decision T 506/04 of 5 December 2006.

The Registrar:

The Chairman:

A. Wolinski

M. Wieser