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**Datasheet for the decision  
of 9 December 2019**

**Case Number:** T 0795/16 - 3.3.08

**Application Number:** 10775037.4

**Publication Number:** 2431378

**IPC:** C07H21/00, C12N15/87

**Language of the proceedings:** EN

**Title of invention:**

METHOD FOR POLYMERIZING A SMALL OLIGONUCLEOTIDE, AND USE OF A HIGH-MOLECULAR OLIGONUCLEOTIDE PREPARED BY THE POLYMERIZATION METHOD

**Applicant:**

Korea Institute of Science and Technology

**Headword:**

Carrier system/KOREA INSTITUTE SCIENCE TECHNOLOGY

**Relevant legal provisions:**

EPC Art. 113(1), 114(2), 123(2)  
RPBA Art. 12(1), 12(2), 12(4), 15(1), 15(3)

**Keyword:**

Main request and auxiliary request - admission (yes)  
Main request and auxiliary request - added-subject matter (yes)

**Decisions cited:**

G 0002/10

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 0795/16 - 3.3.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.08**  
**of 9 December 2019**

**Appellant:** Korea Institute of Science and Technology  
(Applicant) 39-1, Hawolgok-2-dong  
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**Representative:** Grünberg, Thomas  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 24 September  
2015 refusing European patent application No.  
10775037.4 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** B. Stolz  
**Members:** P. Julià  
J. Geschwind

## Summary of Facts and Submissions

I. European patent application no. 10 775 037.4, published as EP 2 431 378, is based on the international patent application no. PCT/KR2010/001296, published as WO 2010/131835. The examining division considered the set of claims filed on 17 July 2015 to contravene Article 123(2) EPC and not to fulfil the requirements of Article 56 EPC. Accordingly, the patent application was refused.

II. Claim 1 of the set of claims refused by the examining division read as follows:

"1. A poly-oligonucleotide carrier system comprising:

(i) a poly-oligonucleotide comprising 5 to 2000 mono-oligonucleotides connected by chemical bonds, wherein the poly-oligonucleotide has 100 to less than 40000 bases in length; the mono-oligonucleotide has more than 1 and less than 100 bases in length; each of the chemical bond is one selected from the group consisting of disulfide bond, diamine bond, sulfide-amine bond, carboxyl-amine bond and ester bond; and

(ii) a hydrophilic polymer and a biocompatible inorganic material, connected with the poly-oligonucleotide via physical bond which is selected from the group consisting of hydrogen bonds, potential bonds, charge couplings, van der Waals bonds, hydrophobic bonds and hydrophilic bonds,

wherein the hydrophilic polymer is selected from the group consisting of poly-ethyleneimine (PEI), poly(N-2-(hydroxypropyl)methacrylamide), poly(divinyl ether-co-

maleic anhydroide), poly(styrene-co-maleic anhydride) and poly(ethylene glycol),

wherein the biocompatible inorganic material is selected from iron oxide and gold, and

wherein the poly-oligonucleotide carrier system comprises 1 to 99% by weight of the poly-oligonucleotide."

- III. As regards Article 123(2) EPC, the examining division decided that the combination of "a hydrophilic polymer and a biocompatible inorganic material" as defined in claim 1 (ii) had no basis in the patent application. Reference was made to claims 7 and 8 of the patent application as disclosing alternatives but not a combination of the subject-matter of both claims. This was in line with the disclosure on page 7, lines 14 to 18 of the patent application, wherein the term "alternatively" introduced the second alternative, namely the biocompatible inorganic materials, i.e. the subject-matter of claim 8. Therefore, the examining division decided that the claimed subject-matter contravened Article 123(2) EPC.
- IV. An appeal was lodged by the applicant (appellant). With the statement setting out its grounds of appeal, the appellant filed a new main request and an auxiliary request and, as an auxiliary measure, oral proceedings were also requested.
- V. The board summoned the appellant to oral proceedings and, in a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, informed the appellant of its

provisional, non-binding opinion on the issues of the case.

- VI. In reply thereto and without making any substantive submissions, the appellant informed the board that it would not attend the oral proceedings.
- VII. Oral proceedings took place on 9 December 2019 in the absence of the appellant.
- VIII. Claim 1 of the main request reads as claim 1 of the request underlying the decision under appeal, except for the preamble and the introduction of two additional features at the end of the claim, namely:
- "1. A poly-oligonucleotide carrier system which is a type of amphiphilic nanoparticle comprising:
- ... [as in claim 1 before the examining division] ...;
- wherein the poly-oligonucleotide carrier system forms spherical self-aggregates in water system, and
- wherein the amphiphilic nanoparticle is 10 to 2000 nm in size."
- IX. Claim 1 of the auxiliary request reads as claim 1 of the main request except for the limitation of the hydrophilic polymer to polyethylenimine (PEI), and the introduction of the additional feature "the mono-oligonucleotide is siRNA" between the characterisation of the poly-oligonucleotide carrier system by % weight and by forming spherical self-aggregates in water system.

- X. The submissions of the appellant, insofar as relevant to this decision, may be summarised as follows:

*Main request and auxiliary request*  
*Article 123(2) EPC*

Although the combination of "a hydrophilic polymer and a biocompatible inorganic material" was not explicitly described in the patent application, such a combination was implied by the disclosure on page 7, lines 13 to 18 of the patent application. Although the term "alternatively" was used therein, the patent application disclosed the use of both a hydrophilic polymer with high molecular weight and a biocompatible inorganic material concurrently. Thus, the combination of "a hydrophilic polymer and a biocompatible inorganic material" did not go beyond the disclosure of the patent application.

- XI. The appellant (applicant) requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or the auxiliary request filed with the grounds of appeal.

## **Reasons for the Decision**

Article 113(1) EPC

1. By its decision not to attend the oral proceedings and not to file substantive arguments in reply to the issues raised in the board's communication pursuant to Article 15(1) RPBA, the appellant has chosen not to make use of the opportunity to comment on the board's provisional, non-binding opinion, either in writing or at the oral proceedings, even though it was

unfavourable to the appellant. According to Article 15(3) RPBA, the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying on its written case.

2. In the light thereof, the present decision is based on the same grounds, arguments and evidence on which the provisional, non-binding opinion of the board was based.

Admission of the main request and the auxiliary request

3. The main request and the auxiliary request were filed by the appellant with the statement setting out its grounds of appeal. Therefore, according to Articles 12(1) and 12(2) RPBA, these requests are normally, as a rule, part of the appeal proceedings. However, with reference to Article 12(4) RPBA, this rule does not apply under all circumstances, since the provision refers to the power of the Boards of Appeal to hold inadmissible, i.e. to exclude, *inter alia* requests filed for the first time with the statement of grounds of appeal which could have been filed during the first instance proceedings.
4. In the statement of grounds of appeal, the appellant argued against the decision of the examining division on Article 123(2) EPC and put forward arguments to convince the board that the feature objected by the examining division under this article had indeed a basis in the patent application. The amendments introduced into the main request and the auxiliary request attempted to overcome the objection raised by the examining division under Article 56 EPC.



5. In its communication pursuant to Article 15(1) RPBA, the board asked the appellant whether the main request and the auxiliary request could not have been filed at an earlier stage of the proceedings before the examining division (Article 12(4) RPBA). The appellant did not reply in substance to the board's communication and thus, no reasons were given to explain why these requests were filed at this stage of the proceedings. The board observes, however, that the admission of the main request and the auxiliary request into the appeal proceedings results in the board being required, as a first step, to assess the feature objected to by the examining division under Article 123(2) EPC and to examine the reasons given by the examining division for refusing the patent application.
6. This is indeed in line with the function of an appeal as defined in the case law established by the Boards of Appeal, namely to give a judicial decision upon the correctness of a separate earlier decision taken by an examining or opposition division (cf. "Case Law of the Boards of Appeal of the EPO", 9th edition 2019, V.A.1, 1133, and V.A.4.11.4.b), 1241).
7. Therefore, the board, having regard to the particular circumstances of the case and in the exercise of its discretion (Article 114(2) EPC and Article 12(4) EPC), decides to admit the main request and the auxiliary request into the appeal proceedings.

Main request and auxiliary request

*Article 123(2) EPC*

8. In the decision under appeal, the examining division considered that there is no basis in the patent

application for the combination of "a hydrophilic polymer and a biocompatible inorganic material" (underlined by the board) as defined in claim 1 (ii) of the request before it, which therefore contravened Article 123(2) EPC (cf. point III *supra*). In the statement of grounds of appeal, the appellant argues that, although this combination is not explicitly described in the patent application, it is implied by the disclosure on page 7, lines 13 to 18 of the patent application (cf. point X *supra*).

9. It is thus necessary for the board to assess the disclosure on page 7, lines 13 to 18 of the patent application:

9.1 The disclosure on page 7 of the patent application starts by defining the "high-molecular oligonucleotide carrier system" as "a material for delivering a high-molecular oligonucleotide into a living body" which is further stated to be "prepared by binding a high-molecular oligonucleotide .... to hydrophilic high-molecular materials or inorganic materials" (underlined by the board) (cf. page 7, lines 1 to 6). Immediately thereafter, it is explained that "[s]ince the high-molecular oligonucleotide ... has a plurality of negative (-) charges, it may be bound to hydrophilic high molecules with positive potentials or inorganic materials" (underlined by the board) (cf. page 7, lines 6 to 8). It then goes on to describe - only and exclusively - the binding of the (high-molecular) oligonucleotide to "high-molecular materials with the positive potential" (cf. pages 7, lines 8 to 15). And only thereafter, introduced by the term "[a]lternatively", it is stated that "upon binding biocompatible inorganic materials, such as iron oxide, gold and the like, it may be useful because such

materials may have a further increased molecular weight to be retentive in a living body for a long term" (cf. page 7, lines 16 to 18).

9.2 In the context of this disclosure, the "high-molecular oligonucleotide carrier system" is - clearly and consistently - described as resulting from the combination of the high-molecular oligonucleotide with two possible alternatives, namely a high-molecular hydrophilic material or a (biocompatible) inorganic material. In the board's view, the above cited last sentence would be - directly and unambiguously - understood by a skilled person as referring only to the second possible alternative. Therefore, the term "further" would be understood as referring to an increase of the molecular weight of the high-molecular oligonucleotide achieved by its combination with the biocompatible inorganic material. This is in line with the common understanding of the term "[a]lternatively" as rightly interpreted by the examining division in the decision under appeal. To ignore this clear term and, on top of that, interpret the term "further" as referring to an additional increase of the molecular weight of the high-molecular oligonucleotide already combined with the high-molecular hydrophilic material is, in the board's view, too far fetched and not supported.

9.3 All the more so since the "high-molecular oligonucleotide carrier system" is disclosed in the patent application only as a product resulting from a method of preparation, i.e. by a product-by-process definition. As a consequence thereof, the "carrier system" is characterised, only and exclusively, by the products (components) used in its preparation, namely the high-molecular oligonucleotide ("prepared by the

method according to any of claims 1 to 6" of the patent application) either with "one or more types of a bio high-molecular material" (cf. claim 7 of the patent application) or with "biocompatible inorganic materials" (cf. claim 8 of the patent application).

10. In the light of the above, the board considers appellant's interpretation and thus, the contested feature, not to be directly and unambiguously derivable from the patent application (cf. decision G 2/10, OJ EPO 2012, 376, point 4.3 of the Reasons).
11. In the communication pursuant to Article 15(1) RPBA, the board not only considered the feature objected to by the examining division under Article 123(2) EPC in the decision under appeal, but drew the appellant's attention to further features present in claim 1 of both, the main request and the auxiliary request, the combination of which, in the board's view, had no basis in the patent application and contravened Article 123(2) EPC. However, in view of the board's decision on the feature objected to by the examining division, there is no need to assess these other features in further detail.
12. It follows from all the considerations above that the main request and the auxiliary request contravene Article 123(2) EPC.

### Conclusion

13. In the absence of any request fulfilling the requirements of the EPC, the appeal has to be dismissed.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:



L. Malécot-Grob

B. Stolz

Decision electronically authenticated