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Datasheet for the decision of 1 April 2025

Case Number: T 0036/23 - 3.3.08

Application Number: 17739936.7

Publication Number: 3481838

IPC: C07H1/00, C07H21/00, C12N9/00

Language of the proceedings: EN

Title of invention:
Novel processes for the production of oligonucleotides

Patent Proprietor:
GlaxoSmithKline Intellectual Property Development Limited

Opponents:
JG Oppositions Limited
Janssen Pharmaceutica N.V.

Headword:
Production of oligonucleotides/GSK

Relevant legal provisions:
EPC Art. 83, 100(b)
RPBA 2020 Art. 12(2), 12(3), 12(4), 12(5), 12(6)

Keyword:
Sufficiency of disclosure - (no) - undue burden (yes)
Amendment to case - reasons for submitting amendment in appeal proceedings (no)
Late-filed evidence - should have been submitted in first-instance proceedings (yes) - circumstances of appeal case justify admittance (no)
Statement of grounds of appeal - party's complete appeal case - reasons set out clearly and concisely (no)
Discretion not to admit submission - requirements of Art. 12(3) RPBA 2020 met (no)

Decisions cited:
T 0226/85, T 0292/85, T 0354/97, T 1475/15

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Case Number: T 0036/23 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 1 April 2025

Appellant I: (Patent Proprietor)	GlaxoSmithKline Intellectual Property Development Limited 980 Great West Road Brentford Middlesex TW8 9GS (GB)
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Appellant II: (Opponent 2)	Janssen Pharmaceutica N.V. Turnhoutsebaan 30 Beerse (BE)
Representative:	Kilburn & Strode LLP Lacon London 84 Theobalds Road Holborn London WC1X 8NL (GB)
Party as of right: (Opponent 1)	JG Oppositions Limited Floor 15 The Shard 32 London Bridge Street London SE1 9SG (GB)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 9 November 2022 concerning maintenance of the European Patent No. 3481838 in amended form**

Composition of the Board:

Chairwoman T. Sommerfeld
Members: A. Schmitt
L. Bühler

Summary of Facts and Submissions

I. The appeals lodged by the patent proprietor (appellant I) and by opponent 2 (appellant II) are against the opposition division's interlocutory decision concerning the maintenance of European patent No. 3 481 838 (the patent) in amended form based on auxiliary request 1 filed on 20 September 2022, first filed on 8 October 2021 as auxiliary request 9. The patent was granted on the basis of European patent application No. 17 739 936.7.

II. Two oppositions were filed against the patent. The opposition proceedings were based on the grounds for opposition under Article 100(a) EPC relating to inventive step (Article 56 EPC) and those under Article 100(b) and (c) EPC.

III. In their statement of grounds of appeal, appellant I contested the opposition division's opinion that the patent did not sufficiently disclose the invention as defined in claim 1 of the patent as granted (Article 100(b) EPC). They filed a document (A32), maintained auxiliary request 1 considered by the opposition division, re-filed auxiliary requests 1 to 8 filed on 8 October 2021 as auxiliary requests 2 to 9, and maintained auxiliary requests 10 to 15 filed on 8 October 2021 and auxiliary requests 16 to 31 filed on 20 July 2022.

Claim 1 of the main request (patent as granted) reads as follows:

"1. A process for producing a single stranded oligonucleotide product having at least one modified

nucleotide residue, wherein the modification is selected from the group consisting of modification at the 2' position of the sugar moiety, modification of the nucleobase, and modification of the backbone, and wherein the product is produced at gram or kilogram scale, or greater, and/or the process is carried out in a 1 L or larger reactor, comprising:
a) providing a template oligonucleotide (I) complementary to the sequence of the product, said template having properties that allow it to be separated from the product;
b) providing a pool of oligonucleotides (II) containing oligonucleotides that are segments of the product sequence, wherein at least one segment contains at least one modified nucleotide residue and wherein the modification is selected from the group consisting of modification at the 2' position of the sugar moiety, modification of the nucleobase, and modification of the backbone;
c) contacting (I) and (II) in conditions to allow annealing;
d) joining the segment oligonucleotides by enzymatic ligation with a ligase to form the product;
e) changing the conditions to separate any impurities, comprising denaturing the annealed template and impurity oligonucleotide strands and separating the impurities;
f) changing the conditions to separate the product, comprising denaturing the annealed template and product oligonucleotide strands and separating the product; and
g) recycling the template for use in future reactions."

Claim 1 of auxiliary request 1 differs from claim 1 of the patent as granted on account of the preamble and step b). Steps a) and c) to g) of claim 1 of auxiliary request 1 and of claim 1 of the main request are

identical. The preamble and step b) of claim 1 of auxiliary request 1 read as follows, respectively:

"1. A process for producing a single stranded oligonucleotide product having at least one modified nucleotide residue, wherein the modification is selected from the group consisting of a 2'-OMe or 2'MOE modification at the 2' position of the sugar moiety, a 5-methyl pyrimidine modification of the nucleobase, and a phosphorothioate modification of the backbone, and wherein the product is produced at gram or kilogram scale, or greater, and/or the process is carried out in a 1 L or larger reactor, comprising:
(...)
b) providing a pool of oligonucleotides (II) containing oligonucleotides that are segments of the product sequence, wherein at least one segment contains at least one modified nucleotide residue and wherein the modification is selected from the group consisting of a 2'-OMe or 2'MOE modification at the 2' position of the sugar moiety, a 5-methyl pyrimidine modification of the nucleobase, and a phosphorothioate modification of the backbone;
(...)".

IV. In their statement of grounds of appeal, appellant II submitted arguments as to why, in their opinion, the opposition division erred with respect to the sufficiency of disclosure and inventive step of claim 1 of auxiliary request 1, and they filed three documents (A33, A34 and A35).

V. Both appellants replied to the other's appeal. With their reply to appellant II's appeal, appellant I filed three documents (A36, A37 and A38).

VI. The board summoned the parties to oral proceedings in accordance with their requests and, in a communication under Article 15(1) RPBA, expressed its preliminary opinion on the sufficiency of disclosure of the invention as defined in claim 1 of the patent as granted and claim 1 of auxiliary request 1, and on the admittance of auxiliary requests 2 to 31 into the appeal proceedings.

VII. Oral proceedings were held as scheduled. As previously announced in writing, neither appellant II nor the party as of right attended the oral proceedings.

VIII. The following documents are referred to in this decision:

A32 Experimental report submitted by appellant I
A35 Experimental report submitted by appellant II
A36 Experimental report submitted by appellant I
A37 Declaration by Dr David Tew
A38 Kestemont D. et al., Chem. Commun. 54, 2018, 6408-11, and Supplementary Material

IX. Appellant I provided arguments supporting their view that documents A32 and A36 to A38 and auxiliary requests 26 to 29 were to be admitted and considered on appeal, and that the invention as defined in claim 1 of the main request and claim 1 of auxiliary request 1 was sufficiently disclosed in the patent. For details of appellant I's arguments, reference is made to the reasons for the decision set out below.

X. Appellant II provided arguments supporting their view that the invention as defined in claim 1 of the main request and each of the auxiliary requests was not sufficiently disclosed in the patent. For details of

appellant II's arguments, reference is made to the reasons for the decision set out below.

XI. The parties' requests, insofar as they are relevant for the decision, were as follows.

Appellant I requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, that appellant II's appeal be dismissed and that the patent be maintained in amended form on the basis of the set of claims of auxiliary request 1 filed on 8 October 2021 as auxiliary request 9 or, alternatively, that the patent be maintained on the basis of the sets of claims of any of auxiliary requests 2 to 31.

Appellant II requested that the decision under appeal be set aside and that the patent be revoked.

Opponent 1 (party as of right) did not formulate any requests in the appeal proceedings.

Reasons for the Decision

Admittance of documents (Article 12(6) RPBA)
Experimental reports A32, A35 and A36

1. Experimental reports A32 and A35 were filed by appellant I and appellant II, respectively, with their respective statements of grounds of appeal. Experimental report A36 was filed by appellant I with their reply to appellant II's appeal (see sections III., IV. and V. above).

2. According to Article 12(4) RPBA, with reference to Article 12(2) RPBA, these documents constitute an amendment to the respective party's case and may therefore be admitted only at the discretion of the board. Under Article 12(6) RPBA, the board must not admit, *inter alia*, evidence which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

3. Appellant I asserted that the filing of experimental report A32, which addressed the opposition division's criticism of Example 2, was justified since the importance and weight the opposition division gave to the data in this example had not been clear before the decision under appeal was received. A32 was filed at the earliest opportunity because it had not been available during opposition proceedings. With respect to experimental report A36, appellant I asserted that it was filed in response to appellant II's criticism of Example 9 of the patent raised in their statement of grounds of appeal.

4. These arguments are not persuasive, however. The objections raised regarding sufficiency of disclosure in the opponents' respective notices of opposition were based, *inter alia*, on the examples of the patent, in particular including Examples 2 and 9 (section 5.3 on pages 30 to 33 of opponent 1's notice of opposition; sections 3.7 and 4 on pages 8 to 11 and 14 of opponent 2's notice of opposition). These objections were therefore raised from the start of the opposition proceedings, and any experimental evidence addressing these objections, such as A32 and A36, should have already been filed during the opposition proceedings.

5. Likewise, the board cannot identify any special circumstances of the appeal proceedings that would justify admitting A32 and/or A36 into the appeal proceedings. A patent proprietor must expect that an opposition division would find an objection raised by an opponent persuasive, irrespective of its preliminary opinion in this matter. In the case in hand, it was also to be expected that those examples of the patent that demonstrate failure to identify a suitable ligase, such as Examples 2 and 9, would be particularly relevant in the opposition division's reasoning. Likewise, the fact that an opponent raises the same objections based on the same data - here, Example 9 of the patent - on appeal as were raised in the opposition proceedings is also to be expected and cannot justify the filing of new evidence on appeal.

6. Similar considerations apply to experimental report A35 filed by appellant II. A35 was submitted to underline appellant II's argument that experimental testing, presenting an undue burden, was necessary to determine which combinations of modifications, segments, sequences and ligases could result in an oligonucleotide product (section 2.3 on page 7 of appellant II's statement of grounds of appeal); however, any evidence supporting this line of argument, which had already been raised in the opposition proceedings, should likewise have been presented in the opposition proceedings.

7. In view of these considerations, the board decided not to consider experimental reports A32 and A36 filed by appellant I or experimental report A35 filed by appellant II in the appeal proceedings (Article 12(6) RPBA).

Documents A37 and A38

8. The expert declaration A37 and document A38 were filed by appellant I to address experimental report A35 filed by appellant II. Since the board decided not to admit and consider A35, no special circumstances presented themselves on appeal that could justify admittance of documents A37 and A38 into the appeal proceedings. The board hence decided not to admit A37 and A38, either (Article 12(6) RPBA).

Main request (patent as granted)
Sufficiency of disclosure (Article 100(b) EPC)

9. The claim concerns a process for producing a single-stranded oligonucleotide product having at least one nucleotide residue modified at the 2' position of the sugar moiety, at the nucleobase, or at the backbone (see section III. for the full wording of the claim). This process comprises the enzymatic ligation of oligonucleotide segments, at least one of which comprises at least one of these modified nucleotide residues.

10. The claimed method hence requires that oligonucleotides comprising any type of modification at any nucleobase, any position in the backbone and/or the 2' position of a sugar moiety are produced by enzymatically ligating oligonucleotide segments comprising these modification(s). In other words, the nature of the respective nucleotide modifications is not defined any further and encompasses any conceivable type of nucleotide modification.

11. However, as correctly pointed out in the decision under appeal (point 4.3) and by appellant II (section 2.1 of

their statement of grounds of appeal and section 1.2 of their reply to appellant I's appeal), a given ligase is not necessarily able to ligate oligonucleotide segments comprising modified nucleotides. This fact is demonstrated, *inter alia*, in Examples 2 and 12 of the patent and was not challenged by appellant I. Hence, except for the modified oligonucleotide segments for which a suitable ligase was identified in the examples of the patent, the skilled person must identify, in a screening process based on trial and error, whether a ligase might be able to ligate oligonucleotide segments comprising the desired nucleotide modifications.

12. This means that the skilled person must, for each new oligonucleotide product comprising modified nucleotide(s) other than those described in the examples of the patent, individually determine whether or not a given ligase candidate could produce the desired oligonucleotide product, but without any guidance as to which ligase might be suitable and without it being possible to predict or guarantee that a suitable ligase could be found among the available candidate ligases at all. It is established case law of the boards of appeal that the requirement of a research programme based on merely trial and error without adequate information leading necessarily and directly towards success amounts to an undue burden for the skilled person (e.g. point 8 of the Reasons of T 226/85).

13. Appellant I asserted that in the case in hand, the amount of trial and error necessary to identify a suitable ligase was not an undue burden because many ligases were known in the art, because the patent provided sufficient guidance on how to screen candidate ligases for their ability to ligate selected modified

oligonucleotide segments (e.g. Example 12), and because there were no serious doubts that the invention could be carried out across the entire ambit of the claim in view of the many successful examples in the patent and the lack of any evidence on file that segments containing modifications other than those described in the examples could not be joined by a ligase.

14. This line of argument cannot be accepted, however. As mentioned above (point 11.), the patent itself provides evidence that a given ligase is not necessarily able to ligate oligonucleotides containing modified nucleotide(s), a fact that demonstrates the necessity for experimentally testing multiple ligases for each new modified oligonucleotide product and set of modified oligonucleotide segments by trial and error.

15. The patent also demonstrates that such testing does not necessarily lead to success since no enzymatic ligation could be achieved in Example 2 of the patent when every nucleotide in the fragments was 2'-methoxy (2'-OMe) ribose-modified, i.e. when a 2'OMe-ribose-modified nucleotide was present at both sides of the junction and, in Example 9 of the patent, when a locked nucleic acid (LNA) was present at both oligonucleotide ends to be ligated. Additional evidence supporting these facts is therefore not required.

16. In this context, as asserted by appellant I, it is true that only T4 DNA ligase was tested in Example 2 and that in Example 9, ligases able to ligate oligonucleotides that contained an LNA at either the 3' or 5' end of the ligation site were identified; however, these facts are not evidence that further screening of ligase candidates would necessarily identify suitable ligases for these types of

modifications or that ligases could be found for ligating oligonucleotide fragments comprising other types of modifications.

17. Appellant I also referred to decision T 354/97, in which, with reference to decision T 14/83, the entrusted board held that an occasional lack of success of a claimed process did not impair its feasibility (point 22 of the Reasons).

18. However, in full, point 22 of the Reasons of decision T 354/97 recites that "*occasional lack of success of a claimed process does not impair its feasibility in the sense of Article 83 EPC, if, e.g., some experimentation is still to be done to transform the failure into success, provided that such experimentation is not undue and does not require inventive activity*". Some experimentation is thus acceptable, but only if turning failure into success is a matter of routine. This is different from the case in hand, in which the skilled person cannot reasonably expect to identify a ligase able to ligate oligonucleotide segments comprising any conceivable type of modified nucleotides merely by screening known ligases.

19. The patent also proposes overcoming the failure to identify a suitable ligase by mutation and evolution of known ligases and screening of these newly created ligase mutants (paragraphs [0156] and [0199] of the patent). This proposal underlines the fact that the identification of a suitable ligase for producing a given (new) modified oligonucleotide products amounts to an undue burden since the outcome of an enzyme mutation and screening process relies on chance events and is inherently unpredictable in terms of the enzymatic function of the mutated enzyme.

20. In this context, appellant I pointed to the fact that the patent provided the amino acid sequences of several mutant ligases that improved the ability of the respective wild-type ligases to ligate oligonucleotide segments comprising specific modified nucleotides and that had mutations at corresponding amino acid positions (paragraphs [0085], [0088], [0117], [0123], and [0137] of the patent). The patent hence taught which amino acid positions had to be mutated to improve the function of a ligase.

21. It is true that the patent describes the identification of mutant ligases able to ligate oligonucleotide fragments comprising 5-methyl pyrimidines, 2'OMe or fluoro substitutions on the ribose ring and/or phosphorothioate linkages; however, the patent also demonstrates that the different wild-type and mutant ligases differ in their ability to ligate different modified oligonucleotide segments. Hence, the skilled person cannot know or anticipate which mutation(s) in which ligase(s) would confer the required functionality to produce an oligonucleotide product comprising modified nucleotides other than those analysed in the patent. This means that for each oligonucleotide product comprising modified nucleotides other than those analysed in the patent, the skilled person must screen for a suitable, possibly mutated, ligase in an unpredictable screening process that is solely based on trial and error. This level of experimentation required to carry out the claimed method is undue.

22. Appellant I also proposed overcoming the failure to ligate oligonucleotides which comprised an LNA or a 2'-OMe-modified nucleotide at both the 3' and the 5' end of the ligation site by shifting the

oligonucleotide fragments accordingly; however, this proposed workaround is neither suitable for producing fully 2'-OMe-modified or LNA oligonucleotide products nor applicable for every position within the oligonucleotide product due to constraints in the length and nucleotide sequence of the segments to be ligated. In addition, it does not solve the lack of guidance in the patent for producing oligonucleotide products comprising other types of modified nucleotides for which no suitable ligase is known.

23. Appellant I also asserted that the claimed invention did not relate to providing new ligases for ligating modified oligonucleotide segments, but that it related to a process for the synthesis of oligonucleotides in solution, in contrast to the prior-art solid-phase synthesis methods. All of method steps a) to g) of the claim, including the recycling of the template, were generally applicable and inventive. A limitation to specific nucleotide modifications would hence unfairly limit the scope of protection and render the protection provided by the patent ineffective, a fact that should be avoided. The ligase was just a tool and future tools were not to be excluded from protection (T 292/85; points 3.1.5 and 3.2.1 of the Reasons).

24. The board is not persuaded by this line of argument. The issue before the board in decision T 292/85 was whether the fact that some variants fulfilling the functional definitions required by the invention might only become available after the filing of the claimed invention had an effect on its sufficiency (T 1475/15, point 11 of the Reasons). In contrast to this, the issue underlying the present case is whether the skilled person knows or can identify, without undue burden, those ligases with which oligonucleotide

segments comprising any conceivable modified nucleotides could be ligated. This situation is hence not comparable to that at issue in T 292/85.

25. The grounds for opposition in Article 100(b) EPC prejudice the maintenance of the patent as granted.

Auxiliary request 1
Sufficiency of disclosure (Article 83 EPC)

26. In the preamble of claim 1 of auxiliary request 1, the single-stranded oligonucleotide product is defined as "having at least one modified nucleotide residue, wherein the modification is selected from the group consisting of a 2'-OMe or 2'MOE modification at the 2' position of the sugar moiety, a 5-methyl pyrimidine modification of the nucleobase, and a phosphorothioate modification of the backbone". In line with this definition, step b) specifies that "at least one segment" in the pool of oligonucleotides that are segments of the product sequence "contains at least one modified nucleotide residue and wherein the modification is selected from the group consisting of a 2'-OMe or 2'MOE modification at the 2' position of the sugar moiety, a 5-methyl pyrimidine modification of the nucleobase, and a phosphorothioate modification of the backbone".

27. Contrary to the opposition division's opinion and appellant I's first line of argument, this wording of the claim does not restrict each of the modifications present in the single-stranded oligonucleotide product in each of the segments to one of the three types of modifications defined in the claim, such that only ligation of segments containing one or more of these

three types of modifications defined in the claim is encompassed by the claimed method.

28. The reason for this is that the above-recited wording only defines the type of modification of one modified nucleotide present in the single-stranded oligonucleotide product, but does not mention anything at all regarding the type(s) of the other modified nucleotides that can also be present in the single-stranded oligonucleotide product and in each of the segments to be ligated.

29. Consequently, the only restriction introduced in claim 1 of auxiliary request 1 compared with claim 1 of the main request is that one of the modified nucleotides must be selected from the list recited in the claim. Every other modified nucleotide could, however, be any type of modification, including LNA. The production of a single-stranded oligonucleotide in which each nucleotide comprises a 2'-OMe or 2'MOE modification at the 2' position of the sugar moiety is also encompassed within the ambit of the claim.

30. In view of this, the same considerations regarding sufficiency of disclosure as set out above (points 10. to 24.) for the invention as defined in claim 1 of the main request, apply, *mutatis mutandis*, to the invention as defined in claim 1 of auxiliary request 1. The requirements of Article 83 EPC are not met.

31. In another line of argument, appellant I asserted that even if the claim was construed as comprising open language with respect to the type of nucleotide modification in the oligonucleotide product, nucleotide modifications which would stop the ligase from working were not included in the claim. The exclusion of non-

working embodiments when open language was used was evident from, for example, section F IV-4.20 of the Guidelines for Examination in the European Patent Office ("the Guidelines"), decision T 292/85 (point 3.1.4 of the Reasons), and from the fact that a composition for therapeutic use could be defined as "comprising" certain ingredients, i.e. by using open language, which, however, did not result in the possibility of including any toxic substances that would render the composition unsuitable for the medical use.

32. The board does not follow the analogy drawn by appellant I in this line of argument between the open language of claims with respect to additional undefined features of products, methods or compositions when using the expression "comprising" and the issue in the claim in hand.

33. Section F IV-4.20 of the Guidelines is concerned with the interpretation of the terms "comprising" and "consisting of" when construing a claim and explains that "[a] *claim directed to an apparatus/method/product "comprising" certain features is interpreted as meaning that it includes those features, but that it does not exclude the presence of other features as long as they do not render the claim unworkable*". In other words, the open language of the claim does not include any features that are contrary to the implied function or purpose of the apparatus, method or product as expressed in the claim.

34. When applying this principle to the claimed process, which is "for producing a single stranded oligonucleotide product having at least one modified nucleotide residue" and is defined as "comprising"

process features or steps a) to g), this means that the process may comprise additional steps; however, steps which would prevent steps a) to g) from being carried out are not included.

35. In contrast to this, nucleotide modifications within the oligonucleotide fragments to be ligated which would stop a selected ligase from working are not - automatically - excluded from the scope of the claim, since the claimed process has the purpose of producing any oligonucleotide product comprising nucleotide modification(s) and the ligase is not defined in the claim. These embodiments are hence neither unreasonable in view of the features of the claim nor necessarily "unworkable", but, as assessed above in the context of claim 1 of the main request, require undue experimentation in order to identify a suitable ligase with which the claimed method could be carried out.

36. In point 3.1.4 of the Reasons of decision T 292/85, the entrusted board held that the objections raised against the generic terms "plasmid" and "bacteria" for being too broad were not tenable since generic terms that did not specify the actual features of an article other than the implied function were commonplace in many technical fields.

37. This principle is not relevant for the case in hand as the objection raised under Article 83 EPC against the present claim is not based on the question of whether or not the terms "nucleotide modification" and "ligase" are too broad, but on the question of whether or not the skilled person would know or could identify, without undue burden, with which ligase the claimed process could be carried out. Since the nucleotide modifications are not restricted in claim 1 of

auxiliary request 1 to only those for which the patent teaches a suitable ligase, the same considerations apply as for claim 1 of the main request (see points 10. to 24. above).

38. Appellant I also asserted that it was unfair to the patent proprietor that the mere possibility that other modifications which would render the claimed process unworkable should result in a lack of sufficiency of disclosure, in particular in view of the fact that the claimed process was inventive. This line of argument is untenable, however, as it is set out in Article 83 EPC that an invention is only patentable if it is sufficiently disclosed in the patent, and this requirement is independent of the question of inventive step under Article 56 EPC. Hence, it is up to the patent proprietor to ensure that the definition of the invention in the claim fulfils the requirements of Article 83 EPC, *inter alia*.

39. In view of these considerations, the invention defined in claim 1 of auxiliary request 1 is not sufficiently disclosed in the patent, contrary to the requirements of Article 83 EPC.

Auxiliary requests 2 to 31
Admittance (Article 12(3) and (5) RPBA)

40. With the statement of grounds of appeal, appellant I filed sets of claims in auxiliary requests 2 to 31, but did not substantiate any of these auxiliary requests, contrary to the requirements of Article 12(3) RPBA that the statement of grounds of appeal should contain a party's complete case and that a party should specify expressly all the requests, facts and arguments relied upon.

41. Under Article 12(5) RPBA, the board has discretion not to admit any part of a submission by a party that does not meet the requirements of Article 12(3) RPBA. In the oral proceedings before the board, appellant I requested that the board exercise its discretion to admit auxiliary requests 26 to 29 into the appeal proceedings because these requests had been filed in a timely manner under Rule 116(1) EPC in the opposition proceedings, and reasons for filing these requests had been presented in the submission accompanying the filing of these requests.

42. These arguments are not persuasive. Article 12(4) RPBA is not an exception to Article 12(3) and (5) RPBA; these provisions are complementary. Therefore, to the extent that sets of claims have been admissibly filed and maintained during opposition proceedings, they are part of the appeal proceedings on the condition that the requirements of Article 12(3) RPBA are met. This is because sets of claims which were filed during opposition proceedings, but were not considered in the decision under appeal, define the extent to which this decision should be amended by the board (Article 111(1) EPC).

43. It would be artificial to separate such sets of claims and their substantiation and to admit these sets of claims under Article 12(4) RPBA, but not the arguments, facts and evidence in support of their allowability under Article 12(5) RPBA. Therefore, in order for a set of claims to be considered on appeal, the arguments, facts and evidence in support of the allowability of such a set of claims must be presented in the statement of grounds of appeal or the reply to the appeal, as appropriate.

44. However, neither appellant I's statement of grounds of appeal nor their reply to appellant II's appeal contains any indication as to why any of auxiliary requests 2 to 31, including auxiliary requests 26 to 29, would overcome any of the objections raised against the main request and auxiliary request 1, including the objections raised with respect to sufficiency of disclosure. The requirements of Article 12(3) RPBA that the statement of grounds of appeal and the reply must contain a party's complete appeal case are hence not met.

45. For the sake of argument, irrespective of this, the patent proprietor's submission of 20 July 2022, which accompanied the filing of, *inter alia*, auxiliary requests 26 to 29 in the opposition proceedings, merely explained that claim 1 of each of auxiliary requests 26 to 29 was limited by incorporating claim 19 as granted, which recited that the oligonucleotide product was a gapmer, and explained how these auxiliary requests were related to earlier auxiliary requests. It hence neither provided a sufficient basis for each of the amendments to claim 1 of these requests compared with claim 1 as granted nor provided any explanation for filing these requests other than pointing out that "[t]*he examples of the patent specifically demonstrate the successful production of gapmers using a ligase*" (see section 4.14.10; see also sections 4.14.11 to 4.14.13 on page 38 of this submission). Hence, this submission did not provide sufficient substantiation for these auxiliary requests, either.

46. Appellant I also asserted that appellant II had not raised any objections against any of auxiliary requests 2 to 31 in their statement of grounds of

appeal. The board cannot recognise the relevance of this argument for deciding on the admittance of auxiliary requests 2 to 31 into the appeal proceedings under Article 12(5) RPBA.

47. Moreover, in the event of an interlocutory decision in opposition proceedings, the appeals by the patent proprietor and the opponent, if any, are directed against the decision under appeal to the extent that the respective party is adversely affected by it (Article 107, first sentence, EPC). An appeal by the opponent is thus directed against the amendments to the contested patent made during opposition proceedings which were found to meet the requirements of the EPC. An opponent cannot be expected to anticipate which of the auxiliary requests filed in the opposition proceedings will be maintained by the patent proprietor on appeal, or to address all the amendments submitted during the opposition proceedings, even if they are not considered by the opposition division.

48. Indeed, amendments to the patent which are more restricted than the amendments found to meet the requirements of the EPC by the opposition division will normally be filed with the patent proprietor's reply to the opponent's appeal. Only when presented with duly substantiated amendments is an opponent able to properly argue its case in full. In the present case it was thus not necessary for appellant II to provide, in their statement of grounds of appeal, objections or arguments concerning auxiliary requests that did not underlie the decision under appeal.

49. In view of the fact that appellant I had not provided any arguments with respect to auxiliary requests 2 to 31 in the written proceedings before the board and,

as conceded by appellant I during the oral proceedings and as is evident from the patent proprietor's submission of 20 July 2022 cited above, the amendments to auxiliary requests 26 to 29 were more complex than merely defining the oligonucleotide product as a gapmer, the board decided to exercise its discretion to not admit any of auxiliary requests 2 to 31 into the appeal proceedings under Article 12(5) RPBA.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

C. Rodríguez Rodríguez T. Sommerfeld

Decision electronically authenticated