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Datasheet for the decision of 15 January 2026

Case Number: T 1168/24 - 3.3.08

Application Number: 09731866.1

Publication Number: 2279254

IPC: C12N15/113, C12N15/88, A61K31/712, A61K31/713, A61K9/127, A61P35/00

Language of the proceedings: EN

Title of invention:
Novel lipid formulations for nucleic acid delivery

Patent Proprietor:
Arbutus Biopharma Corporation

Opponents:
Merck Sharp & Dohme LLC
ModernaTX, Inc.

Headword:
Lipid formulations for nucleic acid delivery/ARBUTUS BIOPHARMA CORPORATION

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 101(1), 106, 139
RPBA 2020 Art. 13(2)

Keyword:
Correction of error - (yes)
Admissibility of appeal - (yes)
Amendments - added subject-matter (yes)
Amendment to a party's appeal case - cogent reasons (no)

Decisions cited:
G 0009/92, G 0001/99, G 0001/12, T 0724/99, T 0972/04, T 1194/06, T 1843/09, T 2086/13, T 2129/14, T 1621/16, T 2635/18, T 0727/19, T 1442/19, T 0505/20, T 0974/21

Catchword:
See Reasons 12 to 34 for a discussion of the applicability of the principle of the prohibition of reformatio in peius

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Case Number: T 1168/24 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 15 January 2026

Appellant I: (Patent Proprietor)	Arbutus Biopharma Corporation 25th Floor, 700 West Georgia Street Vancouver, BC V7Y 1B3 (CA)
Representative:	Simmons & Simmons LLP (Munich) Lehel Carré Gewürzmühlstraße 11 80538 Munich (DE)
Appellant II: (Opponent 1)	Merck Sharp & Dohme LLC 126 East Lincoln Avenue Rahway, NJ 07065 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Appellant III: (Opponent 2)	ModernaTX, Inc. 325 Binney Street Cambridge, MA 02142 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 25 July 2024 concerning maintenance of the European Patent No. 2279254 in amended form**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	R. Morawetz
	D. Rogers

Summary of Facts and Submissions

I. European patent No. 2 279 254 ("the patent") was granted on European patent application No. 09 731 866.1 which was filed as an international application under the PCT and published as WO 2009/127060 A1. The patent is entitled "*Novel lipid formulations for nucleic acid delivery*".

II. Two oppositions to the granted patent were filed. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC), exceptions to patentability (Article 53(c) EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and (c) EPC.

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

D38: Experimental Report by M. Gindy, dated 28 April 2020

D42: Affidavit by W. Sekretaruk, dated 4 April 2024

D46: Affidavit by C. Rennie-Smith, dated 30 May 2024

First opposition decision

IV. In the decision dated 20 December 2019 ("First OD Decision"), the opposition division concluded that the patent could be maintained in amended form in accordance with auxiliary request 1 filed at the oral proceedings on 10 October 2019. In the version of auxiliary request 1 that was filed at the oral

proceedings, claim 1 did not contain the word "systematically". The opposition division, however, based its decision upon the basis of a version of auxiliary request 1 which contained the word "systematically" in claim 1 (First OD Decision, Reasons 4.2 and 4.5.1). The precise circumstances that led to this discrepancy are not decisive for the present case.

First appeal decision

V. All parties appealed against the First OD Decision. The proprietor, however, withdrew its appeal and had the status of respondent in the proceedings that led to the decision T 505/20 of 29 August 2023 (First Board Decision).

VI. The First Board Decision found that the appellants' (that is the opponents') right to be heard had been violated as the patent had been maintained for reasons that the appellants were not given the opportunity to comment on (see First Board Decision, Reasons 14). This was considered to be a substantial procedural violation.

VII. The First Board Decision set aside the decision under appeal (the First OD Decision) and remitted the case to the opposition division for further prosecution.

Second opposition decision

VIII. In the decision of the opposition division dated 25 July 2024 ("Second OD Decision"), the opposition division addressed, *inter alia*, (i) the admission of the proprietor's main request and auxiliary requests 1 to 12, and (ii) the admission of document D38, an experimental report. D38 was filed with opponent 1's

statement of grounds in the first appeal proceedings. The proprietor's objection to the admission of D38 was that in D38 the "*…spread of data points for sample D1-L073 in figure 1 on page 6/7 would lead a skilled person to dismiss these data*" (see Second OD Decision, Reasons 2.3.1). The opposition division decided to admit D38 into the proceedings.

IX. The opponents objected to the admission of the main request and auxiliary requests 1 to 12 upon the basis that such requests violated the principle of reformatio in peius ("PRP"), that is that the admission of these auxiliary requests would put the opponents in a worse position than if they had not appealed the First OD Decision.

X. The opposition division was of the view that PRP had to be taken into account, in line with T 1843/09 and CLBA 10th edition V.A.3.1.7.c (Second OD decision, Reasons 3.1.2).

XI. The opponents relied on D46, an affidavit entitled "Prohibition of reformatio in peius – legal observations". They argued that no exception to the principle of PRP was applicable in the present case. The case law cited by the proprietor was not pertinent and there were no reasons of equity not to apply this principle as the proprietor had decided to withdraw the appeal and no unexpected developments had occurred.

XII. The proprietor relied on D42, an affidavit entitled "Possibility of amendments to claims in proceedings before the Opposition Division after remittal". It argued that PRP did not apply since the First OD Decision was set aside due to a substantial procedural violation, thus the case had to be heard from the start

without any limitations for the proprietor to defend its patent.

XIII. Further, the proprietor argued that an exception to PRP was also justified for reasons of equity because the admittance of D38 (an experimental report filed by opponent 1) and the requirement to include the feature "systematically" in claim 1 created a new and unexpected situation. The proprietor relied on T 0727/19, T 0996/09 and T 1843/09.

XIV. The opposition division considered that as the proprietor had withdrawn its appeal, PRP applied to the opposition proceedings following this appeal. The exceptions set out in G 1/99 to PRP were limited in nature. The existence of any substantial procedural violation could not necessarily bring about an exception to PRP. Such a position was not supported by the case law, in particular T 0727/19. The admission into the proceedings of D38 did not lead to a substantial change in the factual basis of the proceedings that would justify an exception to PRP on equitable grounds.

XV. There was also no causal link between the filing of the main request and auxiliary requests 1 to 12 and the admission of D38. The opposition division found that the claim request for the application of PRP was the main request in the appeal proceedings leading to the First Board Decision (see Second OD Decision, Reasons 3.1.3 and 3.1.4). The opposition division thus decided that PRP meant that the main request and auxiliary requests 1 to 12 could not be admitted into the proceedings, these being broader than the main request before the Board in the First Board Decision.

XVI. The opposition division maintained the patent in amended form on the basis of auxiliary request 13.

Second appeal proceedings

XVII. The present appeals by the patent proprietor (appellant I), opponent 1 (appellant II) and opponent 2 (appellant III) are against the Second OD Decision. Since all parties are appellants, they are referred to as the proprietor and as opponent 1 and opponent 2.

XVIII. In their respective grounds of appeal, the opponents maintained, *inter alia*, objections under Article 123(2) EPC to claim 1 of auxiliary request 13.

XIX. With its statement setting out the grounds of appeal, the proprietor re-submitted sets of claims of the main request and auxiliary requests 1 to 12 previously submitted in the proceedings before the opposition division under cover of a letter dated 3 November 2023. The proprietor argued that PRP did not apply or that exceptions to PRP were justified.

XX. In their respective replies to the proprietor's appeal, the opponents objected to the admission of the main request and auxiliary requests 1 to 12 upon the basis that such requests violated the PRP.

XXI. In reply to the opponents' appeals, the proprietor submitted sets of claims of auxiliary requests 13 to 19 and arguments, *inter alia*, to the effect that the subject-matter of claim 1 of auxiliary request 13 satisfied the requirements of Article 123(2) EPC and that opponent 2's second appeal should be rejected as inadmissible because the statement of grounds of appeal

was filed by the wrong legal entity.

XXII. Under cover of a letter dated 9 July 2025, opponent 2 requested a correction of the appellant's name in their second statement of grounds of appeal.

XXIII. Under cover of a letter dated 15 July 2025, opponent 1 provided inter alia its counterarguments to the proprietor's arguments regarding claim 1 of auxiliary request 13 and Article 123(2) EPC.

XXIV. The board appointed oral proceedings and, in a communication pursuant to Article 15(1) RPBA, provided its preliminary appreciation on some matters concerning the appeal. With respect to claim 1 of auxiliary request 13, the board indicated that it was inclined to take the view that the subject-matter of claim 1 of auxiliary request 13 extended beyond the content of the application as filed, essentially for the reasons put forward by the opponents and that the patent proprietor's counter-arguments were not found persuasive, essentially for the reasons put forward by opponent 1's submission of 15 July 2025.

XXV. Under cover of a letter dated 14 November 2025, the proprietor provided further arguments as to why claim 1 of auxiliary request 13 satisfied the requirements of Article 123(2) EPC.

XXVI. During oral proceedings, the proprietor filed a Rule 106 EPC objection. After deliberation, the board dismissed the Rule 106 EPC objection. At the end of the oral proceedings, the Chairwoman announced the board's decision.

XXVII. The proprietor's arguments can be summarised as follows.

Admission of opponent 2's first and second appeal

Opponent 2 was Moderna TX, Inc. The second grounds of appeal were filed in the name of Moderna Therapeutics, Inc., which was not the adversely affected party. The deficiency was not remedied in time and the second appeal by opponent 2 was inadmissible. The request for correction under Rule 139, first sentence, EPC was not submitted without delay.

The first appeal by opponent 2 should have been rejected as inadmissible as well, as it was also filed in the name of Moderna Therapeutics, Inc. Opponent 2 should therefore have been treated as respondent in the first appeal proceedings and PRP applied to opponent 2 as well.

Main request and auxiliary requests 1 to 12
Admittance and consideration

The whole concept of PRP at the EPO was problematic and should not be applied.

There were two exceptions to PRP. The first exception was when cases were found to be suffering from a substantial procedural violation. In this respect, the following question should be referred to the Enlarged Board of Appeal:

"*Does the principle of prohibition of reformatio in peius apply also to situations where the Board of Appeal has set aside a first instance decision because it found that the first instance decision suffered from*

a substantial procedural violation, in particular from a violation of the right to be heard?"

The second exception was where the substance of the case had changed after the original decision of the opposition division. Both of these exceptions applied to the present case.

As regarded the first exception to PRP, T 727/19 should be followed, in which the existence of a substantial procedural violation in the original opposition proceedings led to the non-application of PRP. The violation of the right to be heard was a substantial procedural violation that should lead to the non-application of PRP. T 2086/13, Reasons 4.4, should be applied by analogy. Following a remittal after a substantial procedural violation, none of the decided issues remained.

As regarded the second exception to PRP, if amendments introduced by the proprietor were either: (i) made to address new objections raised for the first time in appeal proceedings; or (ii) made due to a change in the factual basis of the proceedings, then PRP was not to be applied.

In the present case, the admission into the proceedings of document D38 resulted in a change in the factual basis of the proceedings which justified the admission of the main request and auxiliary requests 1 to 12 into the proceedings. The proprietor referred to T 1843/09 in this respect, a case in which the admission of a document was considered to change the factual basis of the proceedings, and hence constituted an exception to PRP.

Auxiliary request 13

Amendments (Article 123(2) EPC) - claim 1

Starting from claim 1 as filed, the phospholipid and cholesterol ranges of feature (c) of claim 1 were disclosed in the first sentence of paragraph [0130] of the application as filed.

The skilled person would have recognised that the addition of the phospholipid and cholesterol ranges rendered the lower limit of 13 mol % in feature (c) of claim 1 superfluous. Thereby, the deletion of the lower limit was directly and unambiguously derivable for the skilled person.

The amendment of feature (b) was not a selection but an arithmetically necessary and logical consequence of the increase of the molar ratios of non-cationic lipids in feature (c) of claim 1. At most, it was the only selection required. As the existing molar ratio of cationic lipid in part (b) of original claim 1 was described as being from about 50 mol % to about 85 mol % this would have led the skilled person to look to the application as filed for a range of cationic lipid having a lower limit of 50% and an upper limit of cationic lipid of 65.5% or less. The skilled person would have turned to paragraph [0113] of the application as filed and would have noted that of the two applicable ranges, the range "50 mol % to 65 mol %" for cationic lipid was the most appropriate range as it allowed the maximum flexibility to use the available ranges of cholesterol or derivative, phospholipid and conjugated lipid that were defined in features (c) and (d) of claim 1.

The 1:57 formulation of the examples supported the combination of features (b) and (c) for two reasons.

First, the example section focused on the 1:57 formulation, it was used more often than the 1:62 formulation, see Examples 1 to 5 and 7 to 11, and the accompanying Figures 1 to 4 and 6 to 22. The titles of the Examples demonstrated that it was the preferred specific formulation. The 1:57 formulation fell under the ranges in paragraph [0130], first sentence, and provided a pointer to these ranges. The skilled person would have recognised the combination of the preferred feature of paragraph [0130] with feature (c) of claim 1 as directly and unambiguously disclosed in the application as filed. No selection was therefore required to arrive at feature (c). Feature (b) was not a selection or the only one.

Second, paragraph [0045], second half, zoomed in on the 1:57 formulation of the examples and put great emphasis on the 1:57 formulation as the most efficacious formulation for *in vivo* use. It was thus clear that four-component formulations comprising a cationic lipid, cholesterol and phospholipid as non-cationic lipids and a conjugated lipid were preferred. The 1:57 formulation of the examples, which was disclosed in paragraph [0045] as the most efficacious formulation for *in vivo* use and was the only four-component formulation extensively tested in the application as filed, was the most preferred composition of the present invention. The skilled person would have recognised the combination of the preferred feature of paragraph [0130] with feature (c) of claim 1 as directly and unambiguously disclosed in the application as filed. Again, no selection was therefore required to arrive at feature (c). Feature (b) was not a selection

or the only one.

Also claim 15 as filed supported the combination of features (b) and (c) of claim 1 for analogous reasons.

Alternatively, claim 1 of auxiliary request 13 was based on claim 1 as filed wherein, first, the upper limit for the amount of the cationic lipid in feature (b) of claim 1 was amended on the basis of paragraph [0113] of the application as filed and, second, the non-cationic lipid in feature (c) of claim 1 was amended on the basis of paragraph [0130], first sentence, of the application as filed.

Paragraph [0113] of the application as filed disclosed ranges for the cationic lipid which had the same lower limit as the range disclosed in claim 1 as filed, i.e. 50 mol %, and it disclosed the range of "*50 mol% to 65 mol %*". Paragraph [0118] also disclosed 50 mol% as the lowest limit. Paragraphs [0113] to [0118] read in conjunction disclosed converging ranges, see the lowest limits in paragraphs [0113] to [0118]. The range "*50 mol% to 65 mol %*" was therefore not arbitrarily selected or singled out, it was directly and unambiguously disclosed and no selection at all, see T 1621/16 (Catchword).

The 1:57 formulation of the examples was the most preferred formulation of the invention. It provided a pointer to paragraph [0130] of the application as filed. An additional pointer was provided by claim 15 as filed, which also singled out the ranges disclosed in paragraph [0130] of the application as filed in the context of the four-component formulation.

Claim 1 met the requirements of Article 123(2) EPC.

Auxiliary requests 14 to 19
Amendments (Article 123(2) EPC) - claim 1

Claim 1 of auxiliary requests 14 to 19 complied with the requirements of Article 123(2) EPC for the same reasons that claim 1 of auxiliary request 13 complied with Article 123(2) EPC.

The proprietor's requests that the case be remitted to the opposition division or that the Board issue an interlocutory decision

Depending on the Board's reasoning as to why there was no basis for the combination of features (b) and (c) in claim 1 of auxiliary request 13, one of the exceptions to PRP set out in G 1/99 could apply to the present case. These requests were procedural requests that were allowable at any time point of the proceedings.Article 13(2) RPBA was not applicable.

The board had not followed the decision of the opposition division on Article 123(2) EPC. This was the first time that it was decided that there was added matter in claim 1 of auxiliary request 13. The board's communication had referred to opponent 1's submissions dated 15 July 2025. Therefore, the factual situation had changed and the proprietor was allowed to rely on G 1/99.

There was no contradiction to the previous procedural requests. The reasons for a possible exception to PRP differed from those that had been considered at the start of the oral proceedings. The issue now was whether, as a result of the board's decision on added matter, exceptions to PRP applied. For reasons of

equity, if an amendment was unduly limiting, a broader claim was allowable, see T 2129/14, Reasons 5.5. In order to make the appropriate amendment, the proprietor required the board's reasoning for added matter in claim 1 of auxiliary request 13.

The proprietor's objection pursuant to Rule 106 EPC

The proprietor submitted the following objection: "*Pursuant to Rule 106 EPC, the patentee raises an objection that a fundamental procedural defect has occurred. The Board has rejected the patentee's request for a remittal to the first instance or, auxiliarily, a postponement of the proceedings and issuance of an interlocutory decision to enable the patentee to assess which auxiliary request(s) could be presented that overcome the Board's finding of added matter of AR13 and are entitled to the exceptions of the prohibition of reformatio in peius according to G1/99. This violates the patentee's right to be heard under Article 113(1) EPC.*"

XXVIII. Opponent 1's and opponent 2's arguments can be summarised as follows.

Admission of opponent 2's first and second appeal

Based on the second OD decision, the second notice of appeal and Form 1038, accompanying the second grounds of appeal, it was clear that the appellant in the statement of grounds of appeal was intended to be "ModernaTX, Inc.". In line with G 1/12, the appellant's name in the second grounds of appeal could therefore be corrected under Rule 139, first sentence, EPC. A period of three months for filing the request for correction was not an undue delay.

The admissibility of opponent 2's first appeal had been examined and accepted by the Board in the first appeal decision. It was res judicata.

Main request and auxiliary requests 1 to 12
Admittance and consideration

PRP had been established by several long standing decisions of the Enlarged Board and could not be considered to be "problematic".

Not all substantial procedural violations led to the non-application of PRP. T 727/19 was restricted to its facts that concerned a finding of partiality by the original opposition division. The proprietor had provided no reasons why a violation of the right to be heard, or a lack of reasoning in a decision, should also lead to the non-application of PRP. T 2086/13 was not about PRP and did not support the proprietor's argument that following a remittal after a finding of a substantial procedural violation, a case had always to be heard de novo.

The admission of D38 into the proceedings did not create a new factual basis for the proceedings, and hence did not fall within one of the exceptions to PRP set out in G 1/99. D38 provided experimental data demonstrating that the particles claimed in the patent did not exhibit any improvement when compared to the particles in D1. D38 merely supported the conclusions reached by the opposition division in the First OD Decision at page 16, Reasons 4.10.3. The admission of D38 was one of the "standard situations" identified in Reasons 2.4.8 of T 1843/09 that did not justify the non-application of PRP.

Even if one of the exceptions to PRP existed, as set out in G 1/99, these were to be interpreted narrowly. Further, in accordance with G 1/99, it had to be impossible to comply with the EPC by filing claim requests with narrower claims, before a proprietor was able to file broader claims. There was no reason why the proprietor had not narrowed its claims in the present case.

Auxiliary request 13

Amendments (Article 123(2) EPC) - claim 1

Claim 1 of auxiliary request 13 contravened Article 123(2) EPC.

Defining the identity of the non-cationic lipid required a first selection from the different alternatives disclosed in paragraph [0119] of the application as filed. Defining the specific amounts of the phospholipid and the cholesterol or a derivative thereof required a second selection between equally preferred amounts described in paragraphs [0130] and [0131] of the application as filed.

Claim 15 only referred to cholesterol and not to a derivative thereof and therefore could not provide any basis for the amendment in feature (c) of claim 1.

Even combining paragraph [0130], first sentence, of the application as filed with claim 1 as filed, as suggested by the proprietor, required at least one selection.

The amendment of the upper limit of the content of

cationic lipid made in feature (b) of claim 1 was not a mere adaptation to the amended contents of phospholipid and cholesterol in feature (c) of claim 1. A mere adaptation would have resulted in an upper limit of 65.5 mol % of cationic lipid. If the upper limit was deleted, it would then have been implicitly defined by the minima of the other components in the particle. 65.5 mol % was also the broadest option for the cationic lipid.

The proprietor's argument that the amendment in feature (b) of claim 1 was made for consistency and the range "50 mol % to 65 mol %" was the most appropriate range as it allowed the maximum flexibility was not correct. If the skilled person was looking to amend the amount of cationic lipid for consistency, they would have simply deleted the upper limit. This was the logical approach, it yielded the broadest option for the range and was consistent with the amendment made to the lower limit for non-cationic lipids in claim 1 of auxiliary request 13.

The limitation to 65 mol % as a new upper limit for the cationic lipid in feature (c) of claim 1 introduced a new technical requirement that went beyond a mere adaptation. It required a further selection from various options that were presented as equally preferable in the application as filed, see, e.g. paragraphs [0113], [0114], [0118] and claims 8 or 9 as filed.

The finding of the opposition division that no selection was required because the list in paragraph [0113] was converging was not correct. When considering the disclosure in paragraphs [0113] to [0118] as a whole, there was no convergent list.

In contrast to the appealed decision, therefore several selections were necessary to arrive at the claimed combination of features of claim 1. In the absence of any pointer to that particular combination, this combined selection of features did not, for the person skilled in the art, clearly and unambiguously emerge from the content of the application as filed. The decision did not identify any such a pointer and there was none.

The opposition division's allegation that the disclosure of the 1:57 formulation in the examples would render the definition in paragraph [0130] of the application as filed preferable over that in paragraph [0131] was mistaken. The 1:57 formulation and the 1:62 formulations were tested in the examples section and were found to show comparable activity, see Example 5 and paragraph [0358]. The 1:57 formulation and the 1:62 formulations were also disclosed as equally preferred in paragraphs [0016], [0017] and [0046] of the application as filed. The 1:57 formulation was not the most preferred embodiment of the application.

Contrary to the proprietor's assertion, the 1:57 and the 1:62 formulations were given equal prominence in the example section, see title of Example 5 and paragraph [0358]. The skilled person did not count the examples and the 1:57 formulation of the examples was not actually disclosed as being the most preferred. The 1:57 formulation of the examples therefore needed to be selected over the 1:62 formulation of the examples. The proprietor's assertion that paragraph [0045] of the application as filed zoomed in on the 1:57 formulation and put great emphasis on the 1:57 formulation as the most efficacious formulation for *in vivo* use was also

not correct. Paragraph [0045] did not zoom in on the 1:57 formulation, it was referred to as a non-limiting example and paragraph [0046] showed that in relation to the Examples, the 1:57 formulation was not preferred over the 1:62 formulation. Both were equal exemplary formulations. That there was no overall preference for the four-component composition was also apparent from paragraph [0237], first sentence.

The suggestion that the 1:57 formulation provided a pointer to paragraph [0130] of the application as filed because it fell within the ranges disclosed therein was also incorrect. The specific concentration values of the 1:57 formulation as defined in the working examples fell within different ranges for the non-cationic lipid and the cationic lipid described in the general description in paragraphs [0017], [0143] and [0144]. The embodiments in paragraphs [0143] and [0144] were more specific than paragraph [0130] and they were explicitly linked to the 1:57 formulation. Therefore the 1:57 formulation provided no pointer, see also T 1476/15, Reason 4.2; T 862/17, Reason 4 and T 1809/20, Reason 3.6.

The proprietor's assertion that claim 15 provided the required pointer was mistaken. Claims 15 and 16 as filed both referred back to claim 13 as filed and constituted two distinct, equally weighted alternatives. Thus, a selection needed to be made. That the choice of one dependent claim over another dependent claim required a selection was recognised in the case law.

The proprietor's separate line of argument was also not persuasive. The skilled person would not have derived directly and unambiguously from the application as

filed that the lower limit for the cationic lipid in claim 1 (b) as filed, i.e., 50 mol %, had to be kept, see dependent claims 8 and 9 as filed, the 1:57 formulation of Example 1 and all embodiments linked to the 1:57 formulation. In none of them, the lower amount was 50 mol %, all disclosed a lower limit of 52 mol % or higher. Instead, they would have understood that the lower limit, the higher limit, or both limits of the cationic lipid in feature (b) of claim 1 as filed could be changed. Choosing to only change the upper limit was therefore a selection.

Paragraphs [0113] to [0118] did not disclose converging ranges for the cationic lipid. Therefore, the considerations relating to non-converging alternatives in Reasons 1.7.1 and 1.7.2 of T 1621/16 applied. Picking "*50 mol % to 65 mol %*" from paragraph [0113] of the application as filed was a further selection. For the combination with paragraph [0130], first sentence, of the application as filed a pointer was needed. This pointer needed to be clear. The 1:57 formulation of the examples or claim 15 as filed provided no pointer to the combination of features (b) and (c).

The choice of the specific range of "*from 50 mol % to 65 mol %*" for the content of the cationic lipid therefore constituted an arbitrary selection which the application as filed failed to disclose in combination with the arbitrary selection of the identity and content of the non-cationic lipid in the first sentence in paragraph [0130] of the application as filed.

Auxiliary requests 14 to 19
Amendments (Article 123(2) EPC) - claim 1

The objections raised against claim 1 of auxiliary request 13 applied, mutatis mutandis.

The proprietor's requests that the case be remitted to the opposition division or that the Board issue an interlocutory decision

The proprietor's requests were an amendment to its case after the board had issued the communication under Article 15(1) RPBA and Article 13(2) RPBA applied. The requests were a delaying tactic and detrimental to procedural economy.

Objections under Article 123(2) EPC to claim 1 of auxiliary request 13 had been maintained by both opponents in their statements of grounds of appeal and opponent 1's submissions of 15 July 2025 were merely counterarguments to the proprietor's arguments, not new facts. The board's decision was in line with its preliminary opinion in the communication under Article 15(1) RPBA. That the board had decided that there is added matter was irrelevant. There were no exceptional circumstances justified by cogent reasons.

The board had already decided not to admit auxiliary requests 1 to 12, so there was no room for a remittal for an assessment of these requests. There were two requirements for G 1/99 to apply. However, no new objection had been raised and the proprietor had not explained why the objection under Article 123(2) EPC needed to be addressed by broadening the claims and could not be addressed by narrowing the claim, e.g. to the exemplified 1:57 formulation, see T 1843/09, Reasons 2.4.8. The requests should not be admitted.

The proprietor's objection pursuant to Rule 106 EPC

There was no violation of the proprietor's right to be heard.

XXIX. The parties' requests relevant to the present decision are as follows.

The patent proprietor requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the main request; alternatively, that the patent be maintained in amended form on the basis of the set of claims of one of auxiliary requests 1 to 12;
- further alternatively,
that the patent be maintained in amended form on the basis of the set of claims of auxiliary request 13 (implying a dismissal of the opponents' appeals);
- further alternatively, that the patent be maintained in amended form on the basis of the set of claims of one of auxiliary requests 14 to 19;
- further, as an auxiliary measure, that a question be referred to the Enlarged Board of Appeal;
- further, that the case be remitted to the opposition division for further prosecution;
- that opponent 2's appeal be rejected as inadmissible pursuant to Rule 101(1) EPC;
- that opponent 2 not be allowed to introduce a name correction under Rule 139 EPC;
- that the case be remitted to the opposition division for an assessment of auxiliary requests 1 to 12 and, as an auxiliary measure, that the Board issue an interlocutory decision solely on the issue of the compliance of claim 1 of auxiliary request 13 with Article 123(2) EPC.

Opponent 1 requested that the decision under appeal be set aside and the patent be revoked in its entirety;
- that the main request and auxiliary requests 1 to 12 not be admitted into the proceedings (implying dismissal of the patent proprietor's appeal);
- that auxiliary requests 14 to 19 not be admitted into the proceedings;
- that the case not be remitted to the opposition division;
- that no referral be made to the Enlarged Board of Appeal.

Opponent 2 requested that the decision under appeal be set aside and the patent be revoked in its entirety;
- that the patent proprietor's appeal be dismissed;
- that the main request and auxiliary requests 1 to 12 not be admitted into the proceedings;
- that auxiliary requests 14 to 19 not be admitted into the proceedings;
- that the patent proprietor's request for referral of a question to the Enlarged Board of Appeal be refused;
- correction of opponent 2's name in its letter dated 22 November 2024 under Rule 139 EPC to "ModernaTX,Inc.".

Reasons for the Decision

Admissibility of opponent 2's second appeal

1. Opponent 2 is identified as "ModernaTX,Inc." in the Second OD Decision. It is common ground that "ModernaTX,Inc." is a party adversely affected by the Second OD Decision. In opponent 2's second notice of appeal, the appellant was identified as

"ModernaTX,Inc.". Opponent 2's letter dated 22 November 2024, containing its second statement of grounds of appeal was submitted in the name of "Moderna Therapeutics, Inc.", a different legal entity. The accompanying filing form (Form 1038) indicated that the "Name of represented party" was "ModernaTX, Inc." (ibid).

2. The proprietor has argued that opponent 2's second appeal should be held inadmissible (Rule 101(1) EPC), because it was not filed by "Moderna TX, Inc.", as required by Rule 99(2) EPC, but by "Moderna Therapeutics, Inc.", a different legal entity.

3. Opponent 2 has requested a correction of opponent 2's name in its letter dated 22 November 2024 under Rule 139 EPC to "ModernaTX,Inc."

4. Rule 139, first sentence, EPC, allows the correction of linguistic errors, errors of transcription and mistakes in any document filed with the European Patent Office. Rule 139, first sentence, EPC, also applies to appeals (G 1/12, OJ EPO 2014, 114, Reasons 35) and to the correction of an error in the appellant's name (G 1/12, Reasons 32 to 40; Order, answer to question 3). In the event of a deficiency as to the appellant's identity, the board must establish the true intention of the appellant on the basis of the information in the appeal or otherwise on file (G 1/12, Reasons 28). An allowable correction under Rule 139 EPC has retrospective effect.

5. In the board's view, the information on file, including opponent 2's second notice of appeal and Form 1038 accompanying opponent 2's letter dated 22 November 2024 containing its second statement of grounds of appeal, clearly indicates that the letter dated 22 November

2024 by opponent 2 was also intended to be filed in the name of "ModernaTX, Inc.".

6. The board therefore considers that the reference to "Moderna Therapeutics, Inc." in opponent 2's letter dated 22 November 2024 was a simple clerical error in the opponent 2's name which can be corrected under Rule 139 EPC to "ModernaTX, Inc." (see also G 1/12, Reasons 32 to 40).

7. G 1/12 (Reasons 32 to 40) further confirms that an error in the appellant's identity may be corrected at any time pursuant to Rule 139 EPC, nonetheless, the request must be filed without undue delay once discovered. Opponent 2's request for correction (section XXII. above) was therefore not late, and the proprietor's assertion that the defect was not remedied in time is unfounded.

8. The board furthermore considers that, in the circumstances of the present case, three months for filing the request for correction is reasonable and complies with the requirement of G 1/12 (Reasons 37), according to which such a request must be "filed without delay".

9. For the above reasons, the board decided to grant opponent 2's request to correct the name in the statement of grounds of appeal (letter of 22 November 2024), which in turn leads to the conclusion that the statement of grounds is considered to be filed on behalf of ModernaTX, Inc. The requirements of Rule 99(2) EPC are thus met and the board comes to the conclusion that opponent 2's appeal is admissible (Rule 101(1) EPC).

Admissibility of opponent 2's first appeal

10. The patent proprietor has further argued that the first appeal filed by opponent 2 should have been rejected as inadmissible as well, as it was also filed in the name of "Moderna Therapeutics, Inc.", which was not the adversely affected party in the first opposition proceedings. As a result, opponent 2 should have been treated as respondent in the first appeal proceedings. Therefore, the principle of the prohibition of *reformatio in peius* (PRP) should apply to opponent 2 in the second appeal proceedings.

11. The admissibility of opponent 2's first appeal has been accepted by the board in the First Board Decision. It is thus *res judicata* and the binding effect of the earlier decision as to the procedural status of the parties in those proceedings cannot be challenged. There is therefore no merit in the proprietor's argument that PRP would apply to opponent 2 as well.

Main request and auxiliary requests 1 to 12
Admittance and consideration

Whether PRP is a generally applicable principle

12. PRP ensures that a sole appellant, whether they are the proprietor(s) or opponent(s), should not be put in a worse position by their appeal than if they had never appealed. In the circumstances of the present case this means that, if PRP is applied, the opponents should not find themselves in the situation where claims broader than those in the main request before the Board in the First Board Decision are maintained.

13. The proprietor has argued that PRP is a problematic concept and should not be applied at all. The proprietor argued that PRP was created by the Enlarged Board in G 9/92 (OJ EPO 1994, 875) without there being any basis for this in the EPC. PRP was not a principle of procedural law generally recognized in the Contracting States of the EPC. The proprietor also approved of the minority opinion in G 9/92, which considered PRP to be contrary to the principle of *ex officio* examination, and hence not applicable in proceedings before the EPO.

14. The Enlarged Board in G 9/92 stated that the EPC did not contain any provision that explicitly provided for PRP (see G 9/92, Reasons 7, last sentence). The Enlarged Board in G 9/92 also stated that the EPC did not contain any provision expressing the contrary principle (G 9/92, Reasons 12, first sentence): "*The idea that, irrespective of whether the opposing party appeals, an appellant might have to take the risk of its appeal endangering the result which is achieved before the first instance, is likewise not found in the EPC.*"

15. The Board also notes that the position of the Enlarged Board is that PRP is a principle of procedural law generally recognized by the Contracting States (see G 9/92, Reasons 1, first sentence, and G 1/99, OJ EPO 2001, 381, Reasons 2.1, last two sentences, and 9.2, last sentence).

16. Thus the Enlarged Board has already taken into consideration the issues that the proprietor considers are such as to render PRP problematic. That G 9/92 contained a minority opinion does not change this

finding.

17. Given the above, the Board does not find the proprietor's general criticisms of PRP to be persuasive as these have already been addressed by the Enlarged Board in the decisions that established PRP.

18. Accordingly, the Board sees no basis for departing from the established jurisprudence. PRP is a settled principle binding on the Boards of Appeal, and the proprietor's general objection cannot succeed.

Whether PRP applies after remittal for a substantial procedural violation

19. The proprietor has argued that PRP does not apply in the second first instance proceedings if the board finds that the first instance decision suffered from a substantial procedural violation and remits the case back to the first instance department. It based this argument upon T 727/19 and T 2086/13.

20. The Board does not agree that PRP does not apply in this case. The exception recognised in T 727/19 arose in fundamentally different circumstances from those of the present case: there was an objectively justified suspicion of partiality on the part of the opposition division (T 727/19, Reasons 2.18). A finding of partiality undermines the legitimacy of the entire earlier decision making process and accordingly justifies an exceptional departure from PRP. By contrast, in the First Board Decision, the substantial procedural violation was a violation of the right to be heard with respect to auxiliary request 1 submitted at the oral proceedings before the opposition division (see T 505/20, Reasons 14). This violation of the right

to be heard, while serious, does not undermine the legitimacy of the entire earlier decision making process.

21. Turning to T 2086/13, the proprietor submitted that the reasoning in Reasons 4.4 of that decision should be applied by analogy to the present case. In T 2086/13, the board, in the second appeal proceedings, concluded that the opposition division, in its second decision, had been correct not to limit its examination to the single issue addressed in its first decision, which had been set aside in its entirety by decision T 306/09 on account of a substantial procedural violation.

22. The proprietor appears to infer from this conclusion in T 2086/13 that, where a first-instance decision is set aside due to a substantial procedural violation, this necessarily entails that PRP no longer applies. The Board cannot follow this line of argument.

23. In the case underlying T 2086/13, all parties were appellants in the first appeal proceedings (T 306/09). Consequently, PRP did not arise in that case. Reasons 4.4 of T 2086/13 therefore does not address, let alone establish, any principle concerning the applicability of PRP. Rather, Reasons 4.4 of T 2086/13 merely confirms that, following the setting aside in full of the first opposition division decision in a procedural constellation where all parties are appellants, the opposition division is not restricted, in its subsequent decision, from examining additional grounds of opposition. Accordingly, T 2086/13 cannot support the proposition advanced by the proprietor.

24. The exceptions to PRP are to be construed narrowly (see T 1194/06, Reasons 3.5, and Case Law of the Boards of

Appeal of the European Patent Office, 11th edition 2025 ("CLBA, 11th edition"), V.A.3.1.7b and c). The substantial procedural violation that was identified in T 727/19 was that the opposition division had shown partiality. In the present case the substantial procedural violation is a violation of the right to be heard. The Board sees no reason to extend the exceptions to PRP to these circumstances.

25. The Board observes that its findings are in line with the findings in T 974/21 (Reasons 2.3.2). Here, too, the competent Board held that the breach of a party's right to be heard did not preclude the application of PRP.

Whether the admission of D38 created a new factual basis justifying an exception to PRP

26. The proprietor has also identified a second possible exception to PRP: the change of the factual basis of the proceedings caused by the admission of document D38 into the proceedings.

27. The Board does not consider that the admission of D38 changed the factual basis of the proceedings. D38 is an experimental report that confirms the conclusions reached by the opposition division in the First OD Decision at page 16, Reasons 4.10.3. D38 does not introduce any new factual issue, does not create any new line of attack, and does not alter the legal or technical framework of the case. Indeed, the proprietor’s objections to this document appear to be related to a technical assessment of its contents.

28. This can be distinguished from T 1843/09 (see Reasons 2.4.5) where the admission of D19 raised issues of

priority for the first time. That constituted a genuine change in the factual and legal structure of the case. In contrast, the present case corresponds to the "standard situation" set out in T 1843/09, Reasons 2.4.8, which does not justify an exception to PRP. The Board therefore finds that admission of D38 does not provide a basis for disregarding PRP.

Applying the approach of G 1/99

29. Even if it is assumed that the present case falls into one of the exceptions to PRP, the Board notes that a proprietor is first expected to attempt to comply with PRP by filing restricted claims according to the following scheme (see CLBA, 11th edition, V.A.3.1.7a) and T 724/99, Reasons 5.1 to 5.8 for an example of this approach):

- in the first place, for an amendment introducing one or more originally disclosed features which limit the scope of the patent as amended;
- if such a limitation is not possible, for an amendment introducing one or more originally disclosed features which extended the scope of the patent as maintained, but within the limits of Article 123(3) EPC; and
- finally, if such amendments are not possible, for deletion of the inadmissible amendment, but within the limits of Article 123(3) EPC, even if, as a result, the situation of the opponent is made worse (that is, PRP is not applied).

30. The proprietor has made no attempt to file such restricted claims, and the proprietor has not shown (nor is it apparent to the Board) that compliance was impossible by restriction; therefore the G 1/99

conditions are not met, hence it cannot rely upon any exception to the principle of PRP. The principles of G 1/99 are of general applicability, thus the Board does not see any reason to limit the above principles, which derive from G 1/99, solely to the fact situation of G 1/99.

Request for referral of a question to the Enlarged Board of Appeal

31. The proprietor requested a referral under Article 112(1)(a) EPC concerning the applicability of PRP after remittal for a substantial procedural violation (see section XXVII, under the heading "Main request and auxiliary requests 1 to 12 - Admittance and consideration").

32. A referral is only admissible where a point of law of fundamental importance arises, or where a decision of the Enlarged Board is required to ensure uniform application of the law. In the present case, existing Enlarged Board jurisprudence (notably G 9/92 and G 1/99) already provides clear guidance on the applicability and scope of PRP. The Board has been able to decide the present case on the basis of that established jurisprudence.

33. There is no divergence in the case law that has been identified by the proprietor, nor any unresolved point of law of fundamental importance. The criteria for a referral under Article 112(1)(a) EPC are therefore not fulfilled, and the referral request is refused.

34. In view of the above considerations, the board sees no reason to set aside the decision under appeal with respect to the non-admittance of the main request and

auxiliary requests 1 to 12.

Auxiliary request 13

Amendments (Article 123(2) EPC) - claim 1

35. Reference is made below to the page and line numbering of the A1 publication (section I. above), referred to as the application as filed.

36. Claim 1 reads as follows (the amendments with respect to claim 1 as filed are indicated by underlining and strikethrough):

"A nucleic acid-lipid particle comprising:
(a) a nucleic acid;
(b) a cationic lipid comprising from ~~about~~ 50 mol % to ~~about 85~~ 65 mol % of the total lipid present in the particle;
(c) a non-cationic lipid comprising ~~from about 13 mol %~~ up to ~~about~~ 49.5 mol % of the total lipid present in the particle and comprising a mixture of: (i) a phospholipid of from 4 mol % to 10 mol % of the total lipid present in the particle; and (ii) cholesterol or a derivative thereof of from 30 mol % to 40 mol % of the total lipid present in the particle; and
(d) a conjugated lipid that inhibits aggregation of particles comprising from ~~about~~ 0.5 mol % to ~~about~~ 2 mol % of the total lipid present in the particle, for use in a method for the in vivo delivery of a nucleic acid, the method comprising administering said nucleic acid-lipid particle to a mammalian subject.

37. The opposition division found that the subject-matter of claim 1 met the requirements of Article 123(2) EPC. This part of the decision under appeal was disputed by

the opponents, who maintained, *inter alia*, that the combination of features in claim 1 required multiple selections to which the application as filed provided no pointer.

38. It is common ground that claim 1 is based on claim 1 as filed. It is furthermore undisputed that the application as filed does not explicitly disclose a nucleic acid-lipid particle characterised by the claimed amounts of cationic lipid, phospholipid and cholesterol or a derivative thereof.

39. The issue addressed in this decision is whether the combination of the amendment of the upper limit for the ratio of the cationic lipid in feature (b) of claim 1, "*65 mol %*", with the amendment in feature (c) of claim 1 to define the non-cationic lipid as "*comprising a mixture of: (i) a phospholipid of from 4 mol % to 10 mol % of the total lipid present in the particle; and (ii) cholesterol or a derivative thereof of from 30 mol % to 40 mol % of the total lipid present in the particle*" results in subject-matter which extends beyond the content of the application as filed within the meaning of Article 123(2) EPC.

40. It is well established in the case law of the Boards of Appeal that the content of an application must not be considered to be a reservoir from which features pertaining to separate embodiments or separate lists can be combined in order to artificially create a particular embodiment. In the absence of any pointer to that particular combination, such a combined selection of features does not, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed (CLBA, 11th edition,

II.E.1.6.1 a) and I.E.1.6.2 a)).

41. In view of the arguments of the parties, the question to be answered is whether several selections occurred and, if so, whether the application as filed supports the combined selection.

Whether defining the identity and molar ratio of the non-cationic lipid in feature (c) involves a selection

42. While claim 1 as filed does not define the non-cationic lipid at all, claim 1 of auxiliary request 13 explicitly covers four-component formulations comprising a mixture of phospholipid and cholesterol or a derivative thereof as the non-cationic lipid.

43. In the decision under appeal, the opposition division held that the further definition of the non-cationic lipid in feature (c) of claim 1 had a basis in claim 13 and paragraph [0130] of the application as filed and did not require a selection from a list because choosing the mixture 'thread' from paragraph [0119] of the application as filed led directly to the two preferred embodiments in paragraphs [0130] and [0131] and because paragraph [0130] corresponded to the particle presented in the examples as preferred, i.e. the 1:57 particle (Second OD Decision, Table spanning pages 15 and 16; Reasons 8.1.1).

44. With respect to the non-cationic lipid, paragraph [0119] of the application as filed teaches that "[i]*n preferred embodiments, the non-cationic lipid comprises one of the following neutral lipid components: (1) cholesterol or a derivative thereof; (2) a phospholipid; or (3) a mixture of a phospholipid and cholesterol or a derivative thereof*". The same three

options are described in paragraph [0249] of the application as filed separately as "[*i*]*n some embodiments*", "[*i*]*n other embodiments*" and "[*i*]*n further embodiments*". Claims 10, 12 and 13 as filed, each of which depends on claim 1 as filed, individually define the same three alternatives for the non-cationic lipid.

45. The possibility that the non-cationic lipid comprises a mixture of a phospholipid and cholesterol or a derivative is thus disclosed in paragraph [0119] of the application as filed and in claim 13 as filed as one of several equivalent alternatives for the non-cationic lipid (point 44. above).

46. The board therefore agrees with the opponents that, as a consequence, the amendment in feature (c) of claim 1, according to which the non-cationic lipid is limited to a mixture of a phospholipid and cholesterol or a derivative thereof, requires a selection from a list of alternatives.

47. The molar ratios of the mixture of a phospholipid and cholesterol or derivative thereof of feature (c) of claim 1 are disclosed in the first sentence of paragraph [0130] of the application as filed. However, the application as filed discloses different molar ratios for a mixture of a phospholipid and cholesterol or a derivative thereof as an equally preferred alternative in the first sentence of paragraph [0131] of the application as filed. This is undisputed.

48. The board agrees with the opponents that, as a consequence, defining the molar ratios of the mixture of a phospholipid and cholesterol or derivative thereof in feature (c) of claim 1 on the basis of the first

sentence of paragraph [0130] of the application as filed requires a further selection.

49. Even if, as argued by the proprietor, the amendment to feature (c) of claim 1 is based exclusively on the first sentence in paragraph [0130] of the application as filed, this requires at least one selection.

50. While the proprietor had submitted in writing that the claimed phospholipid and cholesterol ranges were also expressly disclosed in original claims 13 and 15 (see the proprietor's letter dated 14 November 2025, points 17 and 38), the proprietor stated during oral proceedings before the board that it relied solely on paragraph [0130] of the application as filed as a basis for feature (c) of claim 1. In any event, the board agrees with the opponents that claim 15 as filed cannot provide any basis for feature (c) of claim 1 since it is silent about derivatives of cholesterol.

Whether defining the upper limit for the ratio of the cationic lipid in feature (b) to be "65 mol %" involves a selection

51. In feature (b) of claim 1, the upper limit for the ratio of the cationic lipid has been reduced from the originally disclosed "*about 85 mol %*" to "*65 mol %*".

52. The opposition division held that, as a result of the amendment to feature (c) of claim 1, the upper limit of the range for the cationic lipid in feature (b) had to be adapted, and that the application as filed contained only one passage on the basis of which the upper limit for the ratio of the cationic lipid could be amended, namely paragraph [0113]. The opposition division further held that the range of 50 mol % to 65 mol % was "*the broadest range that fits within the new limits*",

that the alternatives disclosed in paragraph [0113] of the application as filed were convergent and that the amendment of the upper lipid of cationic lipid to "*65 mol %*" was not a selection from a list (decision under appeal, Reasons 8.1.3).

53. It is undisputed that the person skilled in the art would recognise that, as a result of the amendments to feature (c) in claim 1 of auxiliary request 13 (point 42. above), the lipid particle of claim 1 can no longer comprise up to 85 mol % cationic lipid.

54. It is also common ground that, based on the minimum amounts of the other lipid components of the lipid particle, i.e., 4 mol % phospholipid, 30 mol % cholesterol or a derivative thereof and 0.5 mol % conjugated lipid, a person skilled in the art would directly and unambiguously understand that the theoretical maximum for the ratio of cationic lipid is 65.5 mol%.

55. A mere adaptation of the ratio of the cationic lipid to the changed molar ratios of phospholipid and cholesterol or a derivative thereof in feature (c) of claim 1 would thus result in an upper limit of 65.5 mol % for the ratio of cationic lipid in feature (b) of claim 1.

56. However this is not the amendment made to feature (b) of claim 1. Instead, the upper limit for the ratio of the cationic lipid in feature (b) was amended based on the range "*from 50 mol % to 65 mol %*" disclosed in paragraph [0113] of the application as filed.

57. Both the opposition division and the proprietor considered that the person skilled in the art would

have turned to paragraph [0113] of the application as filed to adapt the upper limit for the ratio of the cationic lipid in claim 1, since that paragraph discloses ranges with a lower limit of 50 mol%, which corresponds to the lower limit in claim 1 as filed.

58. However, the board shares the view of the opponents that a person skilled in the art would recognise that, in order to adjust the ratio of the cationic lipid to the changed ratios of phospholipid and cholesterol or derivative thereof in feature (c) of claim 1, it is sufficient simply to delete the upper limit for the ratio of the cationic lipid in feature (b) of claim 1. The maximum molar ratio of the cationic lipid is then implicitly defined as 65.5 mol % by the minimum molar ratios of the other components of the lipid particle.

59. The board also notes that a corresponding amendment has been made to claim 1 with respect to the lower limit for the non-cationic lipid in feature (c): the lower limit of "*13 mol %*" was deleted (point 42. above), and the proprietor has argued that, although the addition of the molar ratios of phospholipid and cholesterol in feature (c) has made the lower limit for the non-cationic lipid superfluous, this limit is still defined in the claim due to the minimal molar ratios of phospholipid and cholesterol.

60. Therefore, the assertion that the skilled person would have referred to paragraph [0113] of the application as filed to adjust the upper limit of the cationic lipid ratio in feature (b) of claim 1 is rejected.

61. As explained above (point 58.), deletion of the upper limit for the ratio of the cationic lipid would result in the theoretical maximum ratio, i.e. 65.5 mol %,

which is broader than the upper limit introduced in feature (b) of claim 1. Therefore, the proprietor's argument that the range "*from 50 mol % to 65 mol %*" was taken to allow for maximum flexibility is also not persuasive.

62. Based on the above considerations, the board concludes that, when aiming to adapt the upper limit of the ratio of the cationic lipid in feature (b) of claim 1 to the changed ratios of phospholipid and cholesterol or derivative thereof in feature (c) of claim 1, a person skilled in the art would simply delete the upper limit. This approach is logical and provides the broadest possible range for the amount of cationic lipid. It is also consistent with the amendment made to the lower limit for non-cationic lipids in feature (c) of claim 1 of auxiliary request 13.

63. Consequently, the proprietor's assertion that adapting the upper limit of the cationic lipid to 65 mol % was an arithmetically necessary and logical consequence of the increase of the lower limit of the non-cationic lipid is also not considered persuasive.

64. It remains to be assessed whether the amendment made to feature (b) in claim 1 involves a selection or not.

65. The application as filed discloses various different ranges and values for the ratio of cationic lipid, including "*from about 50 mol % to about 60 mol %*" (paragraph [0113]), "*from about 55 mol % to about 65 mol %*" (paragraph [0114]), "*from about 52 mol % to about 62 mol %*" (claim 9 as filed) "*about 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, [or] 65 … mol % (or any fraction thereof or range*

therein)" (paragraph [0118]).

66. Each of these different ranges and values constitutes a valid alternative to the range of "*from 50 mol % to 65 mol %*", which is consistent with the amended ratios of phospholipid and cholesterol or a derivative thereof in feature (c) of claim 1. The range of "*from 50 mol % to 65 mol %*" is therefore neither the only option, nor is it disclosed in the application as filed to be preferred over the other possible ranges and values for the cationic lipid, or the most preferred option.

67. Furthermore, although paragraph [0113] of the application as filed discloses converging ranges for the cationic lipid, the application as filed contains a coherent disclosure regarding the ratio of cationic lipid that extends from paragraph [0113] to paragraph [0118]. This disclosure encompasses various concentration ranges for the cationic lipid including, "*from about 50 mol % to about 65 mol %*" (paragraph [0113]), "*from about 55 mol % to about 75 mol %*" (paragraph [0114]), "*from about 60 mol % to about 70 mol %*" (paragraph [0115]), and "*from about 65 mol % to about 75 mol %*" (paragraph [0116]).

68. Clearly, the narrower ranges depicted in point 67. above are not fully encompassed by the broader ranges. Instead, the ranges partially overlap. When considering the disclosure in the application as filed as a whole, the various ranges of the cationic lipid therefore do not constitute a single list of successively convergent options, but are presented in paragraphs [0113] to [0118] as a non-convergent list of alternatives. These various alternatives are disclosed as follows: "[*i*]*n some embodiments*" (paragraph [0113]), "[*i*]*n other embodiments*" (paragraph [0114]), "[*i*]*n yet other*

embodiments" (paragraph [0115]), "[*i*]*n still yet other embodiments*" (paragraph [0116]). Each alternative is therefore disclosed as an equally preferred option for the amount of the cationic lipid.

69. The board therefore agrees with the opponents that amending the upper limit for the ratio of cationic lipid in claim 1, based on the range "*from 50 mol % to 65 mol %*" disclosed in paragraph [0113] of the application as filed, constitutes an arbitrary selection from a non-converging list.

Whether the 1:57 formulation supports the combination of features (b) and (c) of claim 1 when, first, feature (c) is amended based on paragraph [0130] of the application as filed

70. The application as filed describes two distinct preferred lipid particle formulations referred to as "*the '1:62' formulation*" (paragraph [0016], last sentence) and "*the '1:57' formulation*" (paragraph [0017], last sentence). The 1:62 formulation contains cholesterol or a derivative thereof (but no phospholipid), and the 1:57 formulation contains a mixture of a phospholipid and cholesterol or a derivative thereof. These two formulations are presented as equally preferred embodiments in paragraphs [0016] and [0017] of the application as filed. The 1:57 and 1:62 formulations are generally defined in paragraphs [0016] and [0017], as well as [0142] to [0144] of the application as filed, and are exemplified as specific embodiments in the examples.

71. As set out above (points 43. and 52.), in the decision under appeal, the opposition division held that no selection was required to arrive at feature (c) of claim 1, and that feature (b) did not constitute a

selection from a list.

72. The proprietor made a similar argument on appeal. It argued that the 1:57 formulation was presented as preferred in the examples and fell within the ranges specified in the first sentence of paragraph [0130] but not within the ranges specified in the first sentence of paragraph [0131]. Consequently, the skilled person would recognise the combination of the preferred feature of paragraph [0130] of the application as filed with feature (c) of claim 1 as directly and unambiguously disclosed in the application as filed. No selection was therefore required to arrive at feature (c) of claim 1. The 65 mol% upper limit in feature (b) followed logically from the increase of molar ratios of non-cationic lipids in feature (c), or constituted the only selection.

73. The Board has established (point 69. above), that the amendment of the upper lipid of cationic lipid to "65 mol %" in feature (b) of claim 1 is an arbitrary selection.

74. Therefore, the reasoning of the opposition division can only hold and the proprietor's argument can only succeed if the amendment to feature (b) of claim 1 is the only selection. This hinges on whether the 1:57 formulation is presented as the preferred option in the examples of the application as filed.

75. Example 1 of the application as filed discloses that siRNA molecules are encapsulated in one of two formulations. The 1:57 formulation has a cationic lipid molar ratio of 57.1 %, a phospholipid molar ratio of 7.1 %, a cholesterol molar ratio of 34.3 % and a lipid conjugate molar ratio of 1.4 %. The 1:62 formulation

has a cationic lipid molar ratio of 61.5 %, a cholesterol molar ratio of 36.9 % and a lipid conjugate molar ratio of 1.5 %.

76. Various 1:57 SNALP formulations were tested in Examples 2, 3, 4, 7, 8, 9, 10 and 11. A 1:62 SNALP formulation was tested in Example 6. And in Example 5, the *in vivo* silencing activity of ApoB siRNA formulated as either a 1:57 or a 1:62 SNALP was compared. Paragraph [0358] of the application concludes that "*Figure 4 shows that the 1:57 and 1:62 SNALP formulations had comparable ApoB silencing activity in vivo (see, e.g. Groups 2 & 3).*"

77. The example section of the application as filed contains no explicit indication that the 1:57 formulation (or "the 1:57 particle", as referred to in the decision under appeal) is preferred to the 1:62 formulation, nor that it is the most preferred formulation. Nor can any preference for the 1:57 formulation be inferred from the information provided explicitly. Both formulations were tested in the examples, exhibiting comparable *in vivo* activity in a direct comparison (point 76. above).

78. Considering the titles of the examples, as also suggested by the proprietor, does not lead to a different conclusion. The titles of the Examples carried out using the 1:57 formulation inform the skilled person that siRNA formulated as 1:57 SNALP exhibit potent activity *in vivo* (see, for example, page 92, lines 3 to 4, page 93, lines 18 to 19 and page 95, lines 15 and 16). However, the same information is provided for the 1:62 SNALP (page 97, lines 16 to 17).

79. Against this background, it cannot be inferred that a preference exists for the 1:57 formulation over the

1:62 formulation simply because more examples are carried out using the former. Rather than counting the examples, the skilled person considers the technical teaching of the examples in the light of the disclosure of the application as filed as a whole.

80. The Board concludes from the above considerations that the 1:57 formulation is not presented as preferred in the examples. As a consequence, it cannot establish any preference for the molar ratios of the mixture of a phospholipid and cholesterol or a derivative thereof disclosed in the first sentence of paragraph [0130] of the application as filed over the molar ratios of the mixture of a phospholipid and cholesterol or a derivative thereof disclosed in the first sentence of paragraph [0131] of the application as filed.

81. Therefore, the choice of the molar ratios of the mixture of a phospholipid and cholesterol or a derivative thereof as disclosed in the first sentence of paragraph [0130] of the application as filed, for the identity and the content of the non-cationic lipid in feature (c) of claim 1, is also an arbitrary selection.

82. Based on this analysis, two arbitrary selections are required to arrive at the combination of features (b) and (c) in claim 1 of auxiliary request 13.

83. Therefore, the opposition division's line of reasoning (point 71. above) does not hold. The proprietor's first line of argument (point 72. above) likewise fails.

84. As a further argument, the proprietor submitted that paragraph [0045] "zoomed in" on the 1:57 formulation, a four-lipid component system, and put great emphasis on

the 1:57 formulation as the most efficacious formulation for *in vivo* use. It argued that it was therefore clear that four-component formulations comprising a cationic lipid, cholesterol and phospholipid as non-cationic lipids and a conjugated lipid were preferred and that the exemplified 1:57 formulation was the most preferred composition of the present invention as it was the only four-component formulation extensively tested. Since the ranges in paragraph [0130] of the application as filed encompassed the exemplified 1:57 formulation, the 1:57 formulation of the examples pointed to paragraph [0130] and not to paragraph [0131] of the application as filed. Consequently, the skilled person would recognise the combination of the preferred feature of paragraph [0130] of the application as filed with feature (c) of claim 1 as directly and unambiguously disclosed in the application as filed.

85. The argument hinges on whether the 1:57 formulation is disclosed in the application as filed as the most efficacious formulation for *in vivo* use.

86. Paragraph [0045], second sentence, discloses that "[i]*n particular, as illustrated by the Examples herein, the present invention provides stable nucleic acid-lipid particles (SNALP) that advantageously impart increased activity of the encapsulated nucleic acid (e.g., an interfering RNA such as siRNA) and improved tolerability of the formulations in vivo, resulting in a significant increase in the therapeutic index as compared to nucleic acid-lipid particle compositions previously described*". Paragraph [0045], third sentence, adds that "[a]*dditionally, the SNALP of the invention are stable in circulation, e.g., resistant to degradation by nucleases in serum, and are*

substantially non-toxic to mammals such as humans." The penultimate and last sentences of paragraph [0045] read as follows "[a]*s a non-limiting example, Figure 3 of Example 4 shows that one SNALP embodiment of the invention ('1:57 SNALP') was more than 10 times as efficacious as compared to a nucleic acid-lipid particle previously described ('2:30 SNALP') in mediating target gene silencing at a 10-fold lower dose. Similarly, Figure 2 of Example 3 shows that the '1:57 SNALP formulation was substantially more effective at silencing the expression of a target gene as compared to nucleic acid-lipid particles previously described ('2:40 SNALP').*"

87. Contrary to the proprietor's submission, paragraph [0045] does not put emphasis on the 1:57 formulation as being the most efficacious formulation for *in vivo* use. In fact, the 1:57 formulation is not described as being more effective than the 1:62 formulation described in the Examples. It is merely described as being "*substantially more effective*" (paragraph [0045], last sentence) than a previously described nucleic acid-lipid particle. There is also no reason to assume that "*the Examples herein*" (second sentence of paragraph [0045]), which demonstrate that the present invention provides SNALPs with improved functionality *in vivo*, refer only to the Examples performed with the 1:57 formulation. Furthermore, the 1:57 SNALP embodiment of Example 4 is referred to merely as a "*non-limiting example*" (paragraph [0045], penultimate sentence).

88. The 1:57 formulation is thus not expressly described as being the most efficacious formulation for *in vivo* use, and a person skilled in the art would not infer from paragraph [0045] of the application as filed that the

1:57 formulation is the most effective formulation for *in vivo* use.

89. Moreover, paragraph [0046] of the application as filed states that "*the '1:57 SNALP' and '1:62 SNALP' formulations described herein are exemplary formulations of the present invention that are particularly advantageous because they provide improved efficacy and tolerability in vivo, are serum-stable, are substantially non-toxic, are capable of accessing extravascular sites, and are capable of reaching target cell populations*" (paragraph [0046], last sentence).

90. The board also agrees with the opponents that paragraph [0046] confirms that the 1:57 formulation and the 1:62 formulation of the examples are equally suitable for *in vivo* use.

91. Based on the above considerations, the Board concludes that the 1:57 formulation is not disclosed in the application as filed as the most efficacious formulation for *in vivo* use. Consequently, the proprietor's argument that four-component formulations are preferred, and that the exemplified 1:57 formulation is the most preferred composition of the present invention, also fails. This leads to the same conclusion as in point 81. above.

92. In view of the Board's finding with respect to the amendment in feature (b) of claim 1 (point 73. above), two arbitrary selections are thus required to arrive at the combination of features (b) and (c) of claim 1 of auxiliary request 13. The proprietor's further argument (point 84. above) thus also fails.

93. Consequently, there is no need to address the opponents' argument that the 1:57 formulation of the examples does not point to the molar ranges of the first sentence of paragraph [0130] of the application as filed, since its specific concentration values fall within different ranges for the non-cationic and the cationic lipids described in paragraphs [0143] and [0144] for embodiments that are explicitly linked to the 1:57 formulation.

Whether claim 15 as filed supports the combination of features (b) and (c) of claim 1 when, first, feature (c) is amended based on paragraph [0130] of the application as filed

94. As a further alternative argument, submitted during oral proceedings before the board, the proprietor argued that claim 15 as filed provided a pointer to paragraph [0130] of the application as filed and that in line with T 2635/18, choosing between alternatives in the claims as filed did not constitute a selection. No selection was therefore required to arrive at feature (c) of claim 1 and the amendment in feature (b) followed logically from the amendment in feature (c).

95. Claims 15 and 16 as filed disclose the same molar ratios of phospholipid and cholesterol as paragraphs [0130] and [0131] of the application as filed, except that they do not contain any information regarding derivatives of cholesterol. Both claims refer back to claim 13 as filed and constitute two distinct, equivalent alternatives, with neither being preferred.

96. The board agrees with the opponents that, in line with established case law of the Boards of Appeal (see CLBA, 11th edition, II.E.1.6.2 b) and e.g. decisions T 1442/19, Reasons 2.4.1 and T 972/04, Reasons 3.1.1 to

3.1.3), the choice of claim 15 over claim 16 as filed requires a selection to be made between equally preferred alternatives. Claim 15 does not render the definition in paragraph [0130] of the application as filed preferable over that in paragraph [0131] of the application as filed.

97. The proprietor's reliance on T 2635/18 is not convincing. The case underlying T 2635/18 differs from the present case in that the dependent claim as filed formed the basis for the subject-matter of the claim under examination, and there were no other dependent claims from which a selection had to be made. In this context, the competent Board held that "*the choice of a specific dependent claim in the original set of claims is not considered to be a selection but an individualised (preferred) embodiment of the application as filed.*" (Reasons 3.1.1).

98. In view of the Board's finding with respect to the amendment in feature (b) of claim 1 (point 73. above), two arbitrary selections are thus required to arrive at the combination of features (b) and (c) of claim 1 of auxiliary request 13. The proprietor's further alternative argument (point 94. above) must thus also be rejected.

Whether the 1:57 formulation or claim 15 as filed support the combination of features (b) and (c) of claim 1 when, first, feature (b) is amended based on paragraph [0113] of the application as filed

99. As a separate argument, submitted during oral proceedings before the board, the proprietor argued that claim 1 was based on claim 1 as filed wherein, first, the upper limit for the amount of the cationic

lipid was amended on the basis of paragraph [0113] of the application as filed and, second, the non-cationic lipid was amended on the basis of paragraph [0130], first sentence, of the application as filed.

100. The proprietor argued that the skilled person wishing to amend the upper limit for the cationic lipid would turn to paragraph [0113] because it disclosed the same lower limit for the ratio of the cationic lipid as claim 1 as filed. Furthermore, it submitted that the ranges disclosed in paragraph [0113] of the application as filed were converging, as were those disclosed in paragraphs [0113] to [0118], given the lower limits stated in each of these paragraphs. Therefore, selecting the range "from *50 mol% to 65 mol %*" in paragraph [0113] for the ratio of cationic lipid in feature (b) of claim 1 did not constitute a selection.

101. The Board notes that dependent claim 8 as filed discloses a range "*from about 56.5 mol % to about 66.5 mol %*" for the cationic lipid. Dependent claim 9 as filed discloses a range "*from about 52 mol % to about 62 mol %*". Furthermore, in the 1:57 formulation of Example 1, the ratio of the cationic lipid is 57.1 mol % (point 75. above) and all explicitly disclosed embodiments linked to the 1:57 formulation comprise at least 52 mol% cationic lipid, which is also higher than 50 mol% (see paragraphs [0017] and [0143] of the application as filed).

102. The Board therefore agrees with the opponents that the skilled person would not directly and unambiguously derive from the application as filed that the lower limit of 50 mol% for the ratio of the cationic lipid in feature (b) of claim 1 as filed is singled out as being

important and must be maintained.

103. Furthermore, the Board agrees with the opponents that the skilled person would also understand that the lower and/or upper limits of the molar ratio of the cationic lipid in feature (b) of claim 1 as filed can be altered.

104. When amending the molar ratio of the cationic lipid in feature (b) of claim 1, the skilled person therefore does not need to turn to paragraph [0113] of the application as filed, they can refer to any of the disclosures in the application as filed concerning the amount of the cationic lipid (e.g. points 65. to 67. and 101. above).

105. Furthermore, for the reasons set out above (points 65. to 68.), the disclosure in paragraphs [0113] to [0118] of the application as filed, when considered as a whole and read in conjunction, discloses non-converging ranges. The proprietor's argument to the contrary is rejected because the disclosure is not restricted to the lower limits stated in each of paragraphs [0113] to [0118] of the application as filed. The proprietor's reliance on T 1621/16 (Catchword) is therefore misplaced. Instead, the board agrees with the opponents that the present situation corresponds to the non-converging alternative scenario considered in Reasons 1.7.1 and 1.7.2 of T 1621/16.

106. The Board furthermore agrees with the opponents that selecting the specific range "from *50 mol% to 65 mol %*" in paragraph [0113] of the application as filed for the ratio of cationic lipid in feature (b) of claim 1 constitutes an arbitrary selection, also when

feature (b) is amended first.

107. Regarding the amendment to feature (c) of claim 1, the proprietor argued that the 1:57 formulation was the most preferred composition of the application and provided a pointer to paragraph [0130] of the application as filed. This argument was the same as the one considered in points 84. to 91. above, and it fails for the same reasons.

108. The proprietor also argued that claim 15 as filed provided an alternative pointer to paragraph [0130] of the application as filed. For the reasons set out in points 95. to 97. above, this argument also fails.

109. The Board therefore agrees with the opponents that a further arbitrary selection is required to arrive at feature (c) of claim 1.

110. Consequently, the proprietor's separate line of argument also fails.

111. In conclusion, at least two independent arbitrary selections are required to arrive at the claimed combination of features (b) and (c) in the context of the nucleic acid-lipid particle of claim 1. As there is no pointer to this particular combination of features, it does not emerge clearly and unambiguously from the content of the application as filed for the person skilled in the art.

112. Claim 1 of auxiliary request 13 does not satisfy the requirements of Article 123(2) EPC.

Auxiliary requests 14 to 19 - claim 1

Amendments (Article 123(2) EPC)

113. Claim 1 of auxiliary request 14 is identical to claim 1 of auxiliary request 13. Claim 1 of each of auxiliary requests 15 to 19 comprises features (b) and (c) of claim 1 of auxiliary request 13. The board considers that the objection under Article 123(2) EPC set out above for claim 1 of auxiliary request 13 applies, *mutatis mutandis*, to claim 1 of auxiliary requests 14 to 19. This was not disputed by the proprietor.

114. Claim 1 of each of auxiliary requests 14 to 19 does not satisfy the requirements of Article 123(2) EPC.

The proprietor's requests that the case be remitted to the opposition division or that the Board issue an interlocutory decision

115. After the board had indicated during the oral proceedings that it was the combination of amendments in features (b) and (c) of claim 1 of auxiliary request 13 that added matter, the proprietor submitted that depending on the Board's reasoning in the decision as to why there was no basis for the combination of features (b) and (c) in claim 1 of auxiliary request 13, one of the exceptions to PRP set out in G 1/99 could be applied to the present case.

116. The proprietor argued that it was not able to file the appropriate claim requests to address this issue during the oral proceedings, because it needed to first know the reasons for the decision. It therefore requested that, as a main request, the case be remitted to the opposition division for an assessment of auxiliary requests 1 to 12. As an auxiliary request, the proprietor requested that the Board issue an

interlocutory decision solely on the issue of the compliance of claim 1 of auxiliary request 13 with Article 123(2) EPC. The proprietor submitted that, since these requests were procedural, they were always to be admitted and Article 13(2) RPBA did not apply.

Whether Article 13(2) RPBA is applicable

117. Article 13(2) RPBA stipulates that any amendment to a party's appeal case made after notification of a communication under Article 15, paragraph 1, shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

118. With its argument (point 116. above), the proprietor is suggesting that requests that can be classified as "procedural" are not to be considered as an "amendment to a party's appeal case" in the sense that this is used in Article 13 RPBA. This is discussed in the CLBA 11th edition at V.A.4.2.3 j). The case law is not uniform on this issue.

119. The Board is of the view that the plain wording of Article 13 RPBA does not distinguish between a party's procedural requests and non-procedural requests and does not therefore classify the second as being an amendment to a party's appeal case and the first as not being such an amendment. Moreover, there is nothing in the other provisions of the RPBA, or in its structure, that supports the existence of such a distinction.

120. The requests at issue are the request to remit the case to the opposition division, and the request to issue an interlocutory decision solely on the issue of the compliance of claim 1 of auxiliary request 13 with

Article 123(2) EPC. In the light of the above considerations (point 119.) the provisions of Article 13(2) RPBA apply. Whether these requests are classified as procedural or non-procedural requests is thus irrelevant.

121. Under Article 13(2) RPBA "exceptional circumstances, which have been justified with cogent reasons by the party concerned" are necessary in order for a board to exercise its discretion to admit a request. No exceptional circumstances have been identified by the proprietor. Indeed, the Board notes that the Article 123(2) EPC objection was on file from the start and the Board's preliminary opinion indicated likely added matter. The proprietor could and should have prepared fallback requests in advance; it did not need the final written reasons in order to do so.

122. Furthermore, if it is assumed that the present case falls into one of the exceptions to the principle of PRP, the Board recalls that a proprietor is first expected to attempt to comply with the principle of PRP by introducing one or more originally disclosed features which limit the scope of the patent as maintained (G 1/99, *supra*, Headnote; point 29. above). Only if such an amendment is not possible, amendments introducing one or more originally disclosed features which extend the scope of the patent as maintained, but within the limits of Article 123(3) EPC may be filed. Nothing else can be derived from Reasons 5.5 of T 2129/14. Indeed, in this case, most of the amendments in claim 1 of the request considered by the board limited the scope and for those amendments which did not, the board was of the view that satisfying the first condition of G 1/99 was impossible. This differs from the case in hand, where the proprietor has made no

attempt to file a request that addresses the added matter issue of claim 1 of auxiliary request 13 by introducing one or more originally disclosed features that limit the scope and has also not explained why the added matter objection of claim 1 of auxiliary request 13 cannot be addressed by restriction.

123. As regards the request for an interlocutory decision restricted to Article 123(2) EPC and claim 1 of auxiliary request 13, such a decision is not part of a standard appeal procedure and would fragment proceedings and the proprietor has not put forward any special reasons for adopting such a non-standard approach.

124. In light of the above considerations, the board, exercising its discretion pursuant to Article 13(2) RPBA, decided not to admit the proprietor's request to remit the case to the opposition division for an assessment of auxiliary requests 1 to 12 or to issue an interlocutory decision.

Rule 106 EPC objection

125. During the hearing before the board, the proprietor raised an objection under Article 113(1) EPC and Rule 106 EPC (section XXVII. above).

126. The objection concerned the Board's decision not to admit the proprietor's request for a remittal to the first instance or its request for a postponement of the proceedings and issuance of an interlocutory decision.

127. The parties were given the opportunity to discuss the proprietor's request to remit the case to the opposition division, and its request to issue an

interlocutory decision solely on the issue of the compliance of claim 1 of auxiliary request 13 with Article 123(2) EPC. The proprietor has not explained why it was prevented from commenting on the grounds for the decisions the Board has taken on the non-admittance of these requests. Their objection is clearly not based on the fact that it did not have an opportunity to comment, but rather on the fact that it does not agree with the board's decision not to admit these requests pursuant to Article 13(2) RPBA.

128. Moreover, Article 113(1) EPC clearly does not confer an absolute right on parties to present comments as to the substance of a request even when such a request is not admitted. To safeguard the right to be heard, a party only has to be given the opportunity to comment on those grounds which are relevant for the decision to be taken. Thus, in the case of non-admittance of a request, the parties have to be given the opportunity to present their arguments in relation to the topic of admittance of the request concerned. It is a very common procedural situation that a party can no longer present arguments as to the substance whenever requests or appeals have not been admitted or are found inadmissible, respectively. This, *per se*, is not a violation of the right to be heard.

129. As the proprietor was given the opportunity to present its comments as regards the admittance of its requests, a violation of the right to be heard as guaranteed in Article 113(1) EPC cannot be established.

130. The board decided to dismiss the Rule 106 EPC objection.

Order

For these reasons it is decided that:

1. The appeal of opponent 2 is admissible.

2. The request to refer a question to the Enlarged Board of Appeal is rejected.

3. The proprietor's Rule 106 EPC objection is dismissed.

4. The decision under appeal is set aside.

5. The patent is revoked.

The Registrar: The Chairwoman:

C. Rodríguez Rodríguez T. Sommerfeld

Decision electronically authenticated