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Datasheet for the decision of 20 November 2018

Case Number: T 0754/16 - 3.3.07

Application Number: 04722345.8

Publication Number: 1613346

IPC: A61K39/39

Language of the proceedings: EN

Title of invention:
MICROFLUIDIZED OIL-IN-WATER EMULSIONS AND VACCINE COMPOSITIONS

Patent Proprietor:
Zoetis Services LLC

Opponents:
Intervet International BV
Merial, Inc.

Headword:
MICROFLUIDIZED OIL-IN-WATER EMULSIONS AND VACCINE COMPOSITIONS/Zoetis Services LLC

Relevant legal provisions:
RPBA Art. 11, 12(4), 13(2), 13(3)
EPC Art. 113(1), 54, 114(1), 114(2), 111(1)
EPC R. 103, 116

Keyword:
Substantial violation of the procedure by the opposition division (Yes)
Refund of the appeal fees (No)
Main request - Product by process - Novelty (No)
Auxiliary requests 1-3 - Novelty (No)
Auxiliary request 4 - Remittal to the opposition division

Decisions cited:
T 0273/04, G 0009/91

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 0754/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 November 2018

Appellant: (Patent Proprietor)	Zoetis Services LLC 10 Sylvan Way Parsippany, NJ 07054 (US)
Representative:	Mannion, Sally Kim Zoetis UK Limited Walton Oaks Dorking Road Tadworth Surrey KT20 7NS (GB)
Respondent: (Opponent 1)	Intervet International BV Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Representative:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Respondent: (Opponent 2)	Merial, Inc. 3239 Satellite Boulevard, Bldg. 500 Duluth, GA 30096 (US)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 February 2016 revoking European patent No. 1613346 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	D. Boulois
	P. Schmitz

Summary of Facts and Submissions

I. European patent No. 1 613 346 was granted on the basis of a set of 14 claims.

Claims 1 as granted read as follows:

"1. A submicron microfluidized oil-in-water emulsion comprising a light hydrocarbon non-metabolizable oil, a surfactant, and an aqueous component, said oil being dispersed in said aqueous component with a mean droplet size of less than 0.5 µm".

II. Two oppositions were filed against the granted patent under Article 100(a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

III. The appeal by the patent proprietor lies from the decision of the opposition division to revoke the patent. The decision was based on 10 sets of claims, namely the claims as granted as main request, auxiliary requests 1-7 filed with letter of 22 April 2014 and auxiliary requests 8-9 filed during oral proceedings on 15 January 2015.

The subject-matter of the independent product claims of auxiliary requests 1-4 read as follows, the difference(s) compared with the main request shown in bold:

Auxiliary request 1

"1. A submicron microfluidized oil-in-water emulsion comprising a **light mineral oil in an amount of 1 to**

50%v/v, a surfactant **comprising lecithin in an amount of 0.01% to 10%v/v**, wherein said oil is dispersed in said aqueous component and **the mean oil droplet size is between 0.1 µm to 0.5 µm".**

Auxiliary request 2

3. **A vaccine composition** comprising a submicron microfluidized oil-in-water emulsion comprising a light hydrocarbon non-metabolizable oil, a surfactant, and an aqueous component, said oil being dispersed in said aqueous component with a mean droplet size of less than 0.5 µm and an antigen, **wherein said antigen is dispersed in said emulsion**.

Auxiliary request 3

Independent claim 1 of auxiliary request 3 is identical to claim 3 of auxiliary request 2.

Auxiliary request 4

"4. **A vaccine composition** comprising a submicron microfluidized oil-in-water emulsion comprising a light hydrocarbon non-metabolizable oil, a surfactant, **an immunostimulatory molecule and an aqueous component**, said oil being dispersed in said aqueous component with a mean droplet size of less than 0.5 µm and an antigen, **wherein said antigen is dispersed in said emulsion."**

Moreover, the independent claims of the auxiliary requests 5-7 were modified as follows:

- Claim 1 of auxiliary request 5 has been restricted by the droplet size, namely **"a mean droplet size of 0.1 µm to 0.3 µm".**

- Claim 1 of auxiliary request 6 specifies the immunostimulatory molecule, namely **"selected from the group consisting of Quil A, cholesterol, GPI-0100, and dimethyldioctadecylammonium bromide (DDA)".**
- Claim 1 of auxiliary request 7 is a process claim, and this request does not comprise any product claim.

IV. The documents cited during the opposition proceedings included the following:
D1: EP 1 023 904
D5: EP 216 615 A
D6: US 6 451 325 B1
D11: US 5 961 970 A
D12: US 6 306 405 B1
D13: WO 93/15736
D14: EP 315 153 A2
D15: Ott G. et al., 1995 Nov; 13: 1557-62
D16: Allison A.C., Methods, 1999 Sep; 19: 87-93
D17: Lidgate D.M. et ai, Pharmaceutical Research, 1989 Sep; 6: 748-52
D23: Excerpts from "Vaccine adjuvants: preparation methods and research protocols"; edited by Derek T. O'Hagan; 2000

V. According to the decision under appeal:
a) The main request met the requirements of Article 123(2) EPC.
b) Since D1 did not disclose a microfluidized emulsion, claim 1 of the main request was novel over this document.
c) Since none of D5, D11 or D13 disclosed the passage of the compositions through a microfluidizer, these documents could not be seen as relevant for novelty. Documents D6, D12, D14, D15, D16 and D17 were also considered as not relevant for novelty by the opposition division.

d) With respect to inventive step, D1 was seen as the closest prior art. The difference of the claims over the disclosure of D1 consisted in the emulsion being microfluidized. The problem was seen as the identification of the homogenizing device used in D1. Since the microfluidization was known from several documents, the claimed subject-matter of the main request was not inventive over the prior art.
e) Since auxiliary requests 1-7 had been limited by features present in D1, they could not comply with the inventive step requirements.
f) Auxiliary requests 8 and 9 were not admitted into the proceedings, since they were filed during oral proceedings and potential issues of added subject-matter and clarity would have had to be discussed, and since none of these requests appeared to overcome the inventive step objections over D1.

VI. The patent proprietor (hereinafter the appellant) filed an appeal against that decision. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division with the order to examine the auxiliary requests and that the appeal fee be reimbursed. If the Board could not accede to this request, the appellant requested that the decision under appeal be set aside and the patent be maintained as granted or on the basis of one of auxiliary requests 1 to 9 submitted during the first instance proceedings or auxiliary requests 10 or 11 filed with the statement of grounds of appeal dated 28 June 2016. With the statement of grounds of appeal, the appellant submitted additionally a new document:
D38: Dominowski declaration.

VII. With a letter dated 27 October 2016, opponent 02 (hereinafter respondent 02) filed additional documents:
D39: Declaration of Dr Thomai Panagiotou
D40: Y, De Smet, L. Deriemaeker, and R. Finsy, Langmuir, 1999, 15 (20), 6745-6754.
D41: D. Lidgate, "Preparation of the Syntex Adjuvant Formulation (SAF, SAF-m, SAF-1)" Chapter 13, "Vaccine Adjuvants: Preparation Methods and Research Protocols", ed. D. O'Flagan, pub!. Humana Press, 2000, pp. 229-237.
D42: S. S. Kwon et al., Colloids and Surfaces, A: Physicochemical and Engineering Aspects 2002, 210, 95-104
D43: WO 97/34588
D44: Carlson, A., et al. Biotechnol. Bioeng., 1995, 48: 303-315.
D45: US 2001/0053376 A1
D46: Microfluidics International Corporation (MFIC) 2002 Annual Report
D47: 2nd Declaration of Alexis Parisot
D48: EP 0374817A2
D49: Masson et al., BioMed Research International, 2001, 1(2), 85-88

VIII. With a letter dated 28 March 2017 the appellant filed a new version of auxiliary requests 8 and 10 and a new document:
D50: Y.-F. Maa and C.C. Hsu, Pharmaceutical Development and Technology, 4(2), 1999, pages 233-240.

IX. With a letter dated 11 January 2018, respondent 02 filed following documents:
D4a: Microfluidizer® Processor User Guide
D14a: EP 315153 B
D51: Entry for "homogenizer" from Merriam-Webster dictionary (1993)

D52: McCarthy, R.D. Biochimica Biophysica Acta (1964) 84: 74-79
D53: Davies, J.T., Chemical Engineering Science, (1987) 42: 1671-1676
D54: Calabrese, R.V., 10th European Conference on Mixing, Elsevier Science (2000)
D55: S 4,352,573 A
D56: Model M-110Y Microfluidizer® processor: user's manual (2002)

X. In a communication from the Board, dated 10 October 2018, it was stated, in particular, that claim 1 of the main request was not considered novel over D1.

XI. With a letter dated 19 October 2018, the appellant submitted new auxiliary requests 3A, 4A and 6A and filed new documents:
D33a: Chidambaram and Burges, pages 238-248
D57: 2nd Declaration of Paul J. Dominowski
D58: WO 2011/112945
D59: US 2011/0162982

XII. With a letter dated 13 November 2018, respondent 02 filed new documents:
D60: 2nd Declaration of Dr Thomai Panagiotou
D61: Biotechnology Techniques, Vol. 11, No 7, July 1997, pages 451-453
D62: Drawing

XIII. Oral proceedings took place on 20 November 2018, therein the appellant renumbered auxiliary request 3A to become auxiliary request 12.

XIV. The arguments of the appellant may be summarised as follows:

Request for remittal of the case to the opposition division and refund of the appeal fee

The opposition division decided not to admit auxiliary requests 8 and 9 into the proceedings since they prima facie did not overcome the inventive step objections raised against the previous requests. In its preliminary opinion, the opposition division concluded however that "in the light of the available prior art and the arguments of opponents and proprietor, claims 1-14 of patent as granted appear to involve an inventive step in accordance with Article 56 EPC."

Quite surprisingly, the opposition division came to the opposite conclusion at oral proceedings. In a similar case T 273/04, the Board concluded that a violation of the right to be heard had occurred and decided to refund the appeal fee. The opposition division applied a prima facie approach and refused to admit auxiliary requests 8 and 9, although it had no discretion not to admit these requests filed in reaction to the complete reversal of its own preliminary opinion, and although the division was made aware of this violation during oral proceedings.

Furthermore, the patentee was not given an opportunity to comment on the patentability of auxiliary requests 1-7. As indicated in the minutes, the opposition division decided on auxiliary requests 1-7 together with the main request.

Therefore, the case had to be remitted to the first instance with the order to examine the auxiliary requests 1-7. At the very least, auxiliary requests 8-11 had to be admitted into the appeal proceedings and the appeal fee had to be refunded.

Main request - Novelty

The term "microfluidized" could be used as a distinguishing feature over D1. D33 and D33a showed that a microfluidizer had a specific defined architecture, and D1 did not relate to a microfluidization. Microfluidization influenced the emulsion droplets, in term not only of the particle size, but also on the polydispersity and uniformity, as shown by D33a, D4, D38. There was no way to describe the claimed emulsion by structural parameters, and the use of a product-by-process was justified.

Moreover, Figures 10A and 10B of the contested patent could also not provide a relevant comparison with the droplet size of the emulsions prepared in D1.

The experiments of D38 provided a valid comparison with the prior art, and showed all the differences implied in the structure of the emulsion droplets by the use of a microfluidizer in comparison to an homogenizer. The experiments of D38 could be generalized to any microfluidization condition. D38 showed that microfluidization had not only an effect on the particle size, but also provided other effects on the emulsions, such as the uniformity and polydispersity of the droplet size of the emulsion.

D57 made clear what the disadvantages of the use of microfluidizers and all parameters linked with the use of such devices were. There was clearly a technical prejudice as regards the use of a microfluidizer in the preparation of vaccine emulsions.

D4 was a user guide for microfluidization which showed that the skilled person would always apply a pressure of 10.000-15.000 PSI in the case of emulsions. These were the conditions showed in D38 and in the examples of the patent.

Paragraphs [0067] and [0087] and example 20 of the contested patent, disclosing a microfluidization performed at 4.500 PSI were obviously mistakes which could be suppressed from the description.

Other auxiliary requests - Novelty

D1 did not mention a vaccine composition as claimed in claim 1 of auxiliary requests 4 or 6, namely comprising an immunostimulatory molecule.

XV. The arguments of the respondents may be summarised as follows:

Request for remittal of the case to the opposition division and refund of the appeal fee

According to respondent 02, there was no fundamental deficiency present in the opposition proceedings, and the opposition division's decision on the auxiliary requests was correct. The patentee had no absolute right to be heard on every issue by two instances, and the opposition division's opinion issued with the summons to oral proceedings was preliminary and non-binding. Moreover, the opposition division considered the patentee's right to be heard in reaching its decision, as shown in the minutes.

Admission of D38 into the proceedings

According to respondent 01, D38 was late-filed and could have been submitted earlier in the opposition proceedings. This document was also not prima facie relevant, and was unconvincing in its argumentation. It did, in particular, not present a comparison with the compositions disclosed in D1 and the compositions according to the claimed inventions were also different, since they were nano-emulsions, while in the patent, the droplet sizes had an average of 0.4 µm. D8 presented emulsions with much smaller and much more uniform particle size than those of the opposed patent.

Main request - Novelty

According to respondent 01, D1 was novelty-destroying. The average particle size of the emulsions in D1 was 0.34 µm as shown in Figure 1 and in D31 and D32, and the amounts of lecithin and surfactant was the same as in the contested patent. The only feature allegedly providing novelty was the term "microfluidized", but there was no guidance in the patent or in the literature, on any technical effect of the term "microfluidized" other than an effect on particle size and distribution. The term "microfluidized" was without clear meaning, and was not properly claimed or described. The description of the patent did also not provide the required details for a proper product-by-process claim, as regards to the starting product and details of the process. D59 and D6 showed also that a microfluidizer could be used at low operating pressure.

According to respondent 02, claim 1 of the main request was not novel over D1. The sole alleged distinguishing feature over D1 was that the emulsion was

microfluidized, while homogenized in D1. However, this term had no general accepted precise meaning and cannot serve as a distinguishing feature. The list of devices in paragraph [0067] of the specification also clearly indicated that an homogenizer such as the Gaulin homogenizer was considered as a microfluidizer.

Other auxiliary requests and remittal of auxiliary request 4 to the opposition division

Auxiliary requests 1-3 were not novel, and auxiliary request 4 was also deficient as to Article 123(2) EPC and Article 84 EPC.

According to respondent 01, auxiliary request 4 could not be novel, since a vaccine composition as shown in D1 implicitly comprised an immunostimulatory molecule, in that parts of the antigen usually behaved as such. Respondent 02 further mentioned example 7 of D1, which comprised two antigens, one of them acting as immunostimulatory molecule, as particularly novelty-destroying for auxiliary request 4.

The case had not to be remitted to the opposition division, since the Board was in a position to examine all requests. Respondent 02 also reminded that the case was already 16 years old.

XVI. Requests

The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division with the order to examine the auxiliary requests and that the appeal fee be reimbursed. If the Board cannot accede to this request, the appellant requested that the decision under appeal

be set aside and the patent be maintained as granted or on the basis of one of the 14 auxiliary requests whereby:
- Auxiliary requests 1 to 7 were filed on 22 April 2014
- Auxiliary requests 3A, 4A and 6A filed on 19 October 2018
- Auxiliary requests 8 and 10 filed on 28 March 2017
- Auxiliary request 9 filed during oral proceedings before the opposition division and
- Auxiliary request 11 filed on 28 June 2016.

The appellant also requested that documents D4a, D14a and D51 to D56 not be admitted into the proceedings.

Respondent 01 requested that the appeal be dismissed. Respondent 01 also requested not to admit auxiliary requests 3A, 4A, 6A and 8 to 11 and document D38 into the proceedings.

Respondent 02 requested that the appeal be dismissed. Respondent 02 also requested that the appellant's request to remit the case to the opposition division for examination of the auxiliary requests and to have the appeal fee reimbursed be dismissed. Respondent 02 requested furthermore that auxiliary requests 3A, 4A and 6A, and that document D57 not be admitted into the proceedings.

Reasons for the Decision

1. Remittal of the case to the opposition division based on a substantial procedural violation

1.1 The appellant requested that the case be remitted to the opposition division because it had committed a substantial procedural violation by not not giving the opportunity to comment on the patentability of auxiliary requests 1 to 7 and not admitting auxiliary requests 8 and 9 into the proceedings based on a prima facie examination.

1.2 Right to be heard as regards auxiliary requests 1-7

1.2.1 The Board notes that the minutes of the oral proceedings before the opposition division mention the following:
"7.5. The proceedings were resumed at 18:00 and Ch announced the conclusion of OD that the MR does not meet the requirements of Article 56-100(a) EPC because the claims lack inventive step. A similar reasoning applies to AR1-AR7.
7.6. The partied had no further comments and P asked for a break to file a new AR."

The opposition division mentions further in its decision:
"3. Since Auxiliary Requests 1-7 have been limited by features already present in D1, they do not seem to provide the claims with inventive step for the same reasons as the Main Request. Therefore, it is considered that Auxiliary Requests 1-7 do not comply with the inventive step requirements of Article 56 EPC.".

It also mentions in the decision the following:
"1. P has not provided substantive arguments in the letter of 22 April 2014 with respect to the inventive step of auxiliary requests 1-7."

1.2.2 It appears therefore explicitly from the minutes that auxiliary requests 1-7 have not been discussed extensively but have indeed been examined as to inventive step during oral proceedings before the opposition division. The opposition division considered that the outcome of the discussion on inventive step for all auxiliary requests 1-7 was the same as for the main request.

More importantly, it is clear from the minutes of the oral proceedings that the appellant did not contest the conclusions of the opposition division as to inventive step of the auxiliary requests 1-7. After the opposition division announced its view, which was not final at this stage, the appellant had, at this moment, an opportunity to provide comments or additional arguments as to inventive step of the auxiliary requests, an opportunity he did not take advantage of. Instead, he only asked for a break in order to file new auxiliary requests.

It appears furthermore from the file hat the patentee did neither provide any comment as to novelty or inventive step regarding auxiliary requests 1-7 in the written opposition proceedings. Only a basis for the amendments brought to these requests was given in the letter accompanying the filing of said auxiliary requests 1-7.

1.2.3 Consequently, the Board is of the view that the appellant's right to be heard in this regard has been met.

1.3 Right to be heard as regards the admission of auxiliary requests 8 and 9 into the opposition proceedings

1.3.1 The appellant filed auxiliary requests 8 and 9 during the oral proceedings before the opposition division, after the opposition division had concluded to the absence of inventive step of the main request and auxiliary requests 1-7. Auxiliary requests 8 and 9 were not admitted in the proceedings by the opposition division because they were considered to be prima facie not allowable.

In its decision, the opposition division mentioned that "in the light of the substance of the new requests, the opposition division notices that indeed, potential issues of added subject-matter and clarity would have to be discussed before assessing inventive step and eventually, compliance with Article 100(b) EPC" and "that at first sight, none of the auxiliary requests appeared to overcome the inventive step objection raised against the previous requests".

The opposition division assumed that it had a discretion not to admit these requests on a prima facie basis and referred to Article 114(2) and Rule 116 EPC. This presupposes, in the first place, that the requests were late filed, which is however not the case.

1.3.2 The opposition division gave in its summons to oral proceedings a positive preliminary opinion as to the main request and auxiliary requests 1-7 as regards Articles 100(b), 54 and 56 EPC. It then reverted its opinion during oral proceedings and came to the conclusion that the main request, as well as auxiliary requests 1-7 lacked inventive step.

Thus, filing auxiliary requests 8 and 9 was a direct response to the opposition division's change of opinion. Under Rule 116(2) EPC, requests filed after

the final date set for making written submissions, can only then not be admitted if the patent proprietor had been notified of the grounds prejudicing the maintenance of the patent. This was clearly not the case. Neither does Article 114(2) EPC provide a basis for disregarding these requests, since, firstly, it does not apply to late filed requests in the form of amended claims, but only to late filed facts and arguments (see Bühler in Singer/Stauder, Europäisches Patentübereinkommen, 7. Auflage 2016, Artikel 114, point 52). Secondly, the auxiliary requests were filed in due time, as a direct and immediate response to the opposition division's changed opinion and since the proprietor had no earlier opportunity to react thereto.

The situation is comparable to the one underlying decision T 273/04. In this case, the opposition division came to a completely new conclusion during the oral proceedings. Hence, the patent proprietor was faced with a new situation to which he had the right to react, in particular by amending his requests. Such requests could not be considered to be late, since they were caused by the new and unexpected procedural development of the case to which the patent proprietor had no previous opportunity to react. According to T 273/04 a prima facie examination was only allowed if the requests are filed too late. Since this was not the case, a refusal based on a prima facie examination was not justified.

Consequently, by not admitting auxiliary requests 8 and 9, the opposition division committed a procedural violation.

1.3.3 However, this procedural violation cannot justify a remittal. According to Article 11 RPBA, the Board shall

remit a case to the department of first instance if fundamental deficiencies are apparent in the first instance proceedings, unless special reasons present themselves for doing otherwise. In the present case, the fundamental deficiencies only concern auxiliary requests 8 and 9, but not the higher ranking requests (including the the request for the patent as granted) which are still maintained by the appellant. A remittal based on the auxiliary requests, including auxiliary requests 1 to 7, is not justified because there is no link with the procedural violation.

The procedural violation does not justify the reimbursement of the appeal fee either. Under Rule 103(1)(a) EPC, the appeal fee shall be reimbursed if such reimbursement is equitable. For the reimbursement of the appeal fee to be equitable, there must be a causal link between the substantive procedural violation and the filing of the appeal (see Case Law of the Boards of Appeal, 8th edition 2016, IV.E.8.6). Since the appellant still pursues his main request, as well as auxiliary request 1 to 7, the appellant would have had to file the appeal in any case and it was not the procedural violation which forced him to file the appeal. The appellant submitted that he might not have filed an appeal if the auxiliary requests had been admitted. However, in order to decide whether the reimbursement of the appeal fee is equitable, the procedural situation as it stands has to be looked at. The appellant requests that the decision on the main request as well as auxiliary requests 1 to 7 be reviewed by the Board of Appeal. For this, he had to file the appeal, irrespective of the decision on auxiliary requests 8 and 9.

1.3.4 In view of the above, the Board notes that the opposition division committed the procedural violation, but it does not justify a remittal to the opposition division or a refund of the appeal fee.

2. Admission of D38 into the proceedings

D38 has been submitted by the appellant with the statement of grounds of appeal and is cited by the appellant in the frame of the discussion on inventive step. The filing of this document constitutes therefore an answer to the decision of the opposition division, and the Board does not see any reason not to admit it into the proceedings (Article 12(4) RPBA).

3. Admission of D4a, D14a, D51-D56, and D57

According to the appellant D57 has been filed in response to the respondent's arguments or documents and to some arguments of the Board in its communication.

D4a, D14a, D51-D56, were filed by respondent 02 in response to the documents or arguments filed by the appellant.

The Board considers these documents as a response to the parties' documents or arguments filed during the appeal proceedings. The Board exerts its discretionary power and admits all documents into the proceedings (Articles 13(2) and 13(3) RPBA).

4. Main request- Novelty

4.1 Claim 1 of the main request relates to a "submicron microfluidized oil-in-water emulsion" and is therefore in the form of a "product by process" claim, namely an

emulsion obtainable by microfluidization. According to the case law of the Boards of Appeal, such a feature can only distinguish it from known products if differences in the method of manufacture actually lead to differences in the product itself.

4.2 D1 was mentioned as novelty-destroying by respondents 01 and 02.

4.3 D1 discloses inter alia in examples 3, 4 or 6 a submicron oil-in-water emulsion comprising a surfactant and mineral oil which is passed through an homogenizer. According to the calculation of respondent 02, as demonstrated in documents D31 and D32, the mean particle size of the particles obtained in examples 4 and 6, as shown in Figure 1, is about 0.340 µm. This was not contested by the appellant.

Moreover, examples 7 and 8 of D1 disclose vaccine compositions made from the emulsion of example 4, and comprising one or more antigens. For instance, in example 7 the emulsion comprised 5% oil-lecithin adjuvant, namely 0.5 % of lecithin and 4.5% of oil, with 2% of surfactants in the vaccine compositions.

The Board notes that the microfluidization process involved in the preparation of the claimed submicron emulsion of claim 1 of the main request remains vaguely and broadly defined, without any restriction as to the microfluidization parameters and conditions. It is therefore not credible that such a generally defined process may systematically lead to a structural difference between the claimed emulsion and an emulsion as disclosed in D1, in particular as regards the uniformity and polydispersibility of the emulsions, as it was argued by the appellant.

In this context, Figure 1 of D1 shows the uniform and undispersed particle size of the submicron emulsions obtained in D1 in examples 4 or 6. The size distribution of the emulsion shown in Figure 1 of D1 appears in particular to be similar to the size distribution of the emulsion shown in Figures 10A and 10B of the contested patent, corresponding to the compositions prepared with a specific microfluidization pressure of 4.500 PSI in example 20 of the contested patent. In addition, the teaching of said example 20 does not appear to be a mistake, as argued by the appellant. There are indeed no reasons to question the teaching of example 20, as regards the operating pressure; the use of such pressures for making microemulsions is confirmed in the specification of the contested patent in paragraph [0069] and in documents D59 or D6 (see D509, par. [0066] and D6, col. 8, l. 38-41).

Figure 1 of D1 presents therefore a direct comparison between the emulsions of D1 and emulsions obtainable by a process of microfluidization, and shows undeniably and explicitly the absence of any difference with the claimed submicron emulsions.

It appears therefore impossible to conclude to the existence of a difference between the submicron emulsions disclosed in D1 and the submicron emulsions as claimed in claim 1 of the main request. Claim 1 of the main requests lack therefore novelty over D1.

4.4 The Board could in particular not follow the arguments of the appellant that a microfluidization process confers inevitably technical differences to the claimed emulsions. To support its argumentation, the appellant

relied on some examples of the patent, and on documents D38, D57 and D4.

4.4.1 According to the appellant, examples 5, 6, 8-10 of the patent provide a comparison between the prior art compositions and compositions according to the invention. The Board notes however that these examples provide a comparison between microfluidized compositions with a size around 0.1 µm and homogenized compositions having a size of around 1 µm in Example 5, or between compositions for which there is no information about the size of the emulsion droplets; it is therefore not possible to see in said examples a comparison with the emulsions of D1 with a mean droplet size of 0.340 µm.

Moreover, some of the emulsions as in example 6 have been prepared under specific microfluidization conditions, with in particular an operating pressure of 10.000 +/- 500 PSI (cf. example 3 of the contested patent), a specific feature which is not a characteristic of claim 1 of the main request.

Hence, the Board does not see how said examples could provide a comparison with the emulsions of D1.

4.4.2 D38 compares emulsions produced by homogenization during 3-5 minutes with emulsions made by microfluidization with 1 pass at 10k PSI and 3 passes at 18k PSI. D38 mentions that "microfluidization decreased particle size versus homogenization" and that "multiple passes increase the uniformity of the particle size distribution" (see point 7.). This document therefore clearly shows that a microfluidization process, processed under specific conditions, might provide an emulsion presenting a

different uniformity and polydispersity than an emulsion obtainable by homogenization.

As argued by respondent 01, the homogenized compositions disclosed in D38 do however not correspond to the compositions disclosed in D1, which renders impossible in any case a valid comparison.

Moreover, the subject-matter of claim 1 of the main request is not restricted by any specific processing condition, such as the operating pressures and the number of passes used in D38.

The extrapolation of the specific emulsion characteristics of the emulsions obtained in D38 by specific process conditions to the emulsions obtained by microfluidization as broadly defined in the claims is furthermore also not possible, since the specification of the contested patent shows in particular that its is possible to obtain an emulsion as claimed, namely having a mean droplet size of less than 0.5 µm under conditions different than those used in D38, i.e. by a microfluidization at 4.500 PSI, which is much less than the 10.000 and 18.000 PSI used in D38, as shown in example 20 and Figure 1 of the specification. Said emulsion of example 20 has a size uniformity and polydispersity which does not present any difference to those disclosed in D1 (see the patent, Figures 10A and 10B and D1, Figure 1)

4.4.3 As to the appellant's argument that a skilled person would exclusively use microfluidizing processing conditions as disclosed in D4, which is a user guide for the specific Microfluidics® microfluidizer, it can also not be followed. This argument was in particular given in D57 (see points 40-54).

First, this specific device is not the only one which can be used for the preparation of the claimed emulsions, in view of the lists of devices disclosed in paragraphs [0067] or [0087] of the specification.

Secondly, the user guide D4 states that emulsions should be passed in Y type devices, by using 10.000 to 15.000 PSI and multiple passes (see page 6 of D4). These specific conditions are, however, not given in the description of the contested patent, are not claimed and remain only general instructions. This is confirmed by the further mention in the same passage of D4 which mentions in particular that "overprocessing may cause droplet size to increase" and "try lower pressure and/or less passes".

There is also some evidence on file that operating pressures other than those given in D4 may be used to provide emulsions according to the claimed invention.

As shown in D38, the appellant obtained emulsions according to the invention with a pressure of 18.000 PSI and 3 passes, which is much higher than the operating pressure indicated in D4. The contested patent also teaches in paragraph [0069] and example 20 that a lower pressure of 4.500 PSI +/- 500 also provides emulsions according to the invention. Documents D59 and D6, which were mentioned by the appellant, also disclose an operating pressure of respectively 2.5000-40.000 in an undefined microfluidizer and 5.000-30.000 in a specific model 110Y microfluidizer for preparing submicron vaccine emulsions (see D509, par. [0066] and D6, col. 8, l. 38-41). All these disclosures show that the skilled

person has a large palette of processing conditions other than those given in D4.

4.4.4 As to the argument of the appellant that the type of microfluidizer covered by the feature "microfluidized" in claim 1 is the specific 110Y from Microfluidics, it is contradicted by the description which gives several equivalent microfluidizers, such as the Gaulin or the Minilab devices (see paragraphs [0067] and [0087]). Document D33a mentioned by the appellant does furthermore not make a particular distinction between homogenizers and microfluidizers and mentions specifically that "a microfluidizer is an example of a homogenizer" (see page 239).

4.4.5 More generally, the assessment of novelty of a claim relating to a product obtained by a process cannot be restricted to the assessment of embodiments covered by the claim presenting indeed a distinguishing technical feature over the product of the prior art. The discussion and evaluation of the product-by-process claim must also be extended to alternative embodiments covered by the claims which cannot be distinguished form the prior art product. It is indeed sufficient that one of said alternative cannot be differentiated from the prior art product to conclude to a lack of novelty of the product-by-process claim over the prior art product.

4.5 Consequently, claim 1 of the main request lacks novelty over D1, and the main request does not meet the requirements of Article 54 EPC.

5. Auxiliary requests 1-3

The appellant did not contest that D1 disclosed all features added in the independent product claims of auxiliary requests 1-3.

5.1 Auxiliary request 1 - Novelty

Claim 1 has been restricted as to the amounts of mineral oil, and by the specification of the amount and presence of lecithin as surfactant, as well as the size range of the mean oil droplet size comprised between 0.1 µm to 0.5 µm. As shown above under point 4.3, all these features were also present in D1.

Consequently, claim 1 of auxiliary request 1 lacks novelty over D1, and auxiliary request 1 does not meet the requirements of Article 54 EPC.

5.2 Auxiliary request 2 - Novelty

Independent product claim 3 has been restricted to a vaccine composition wherein said antigen is dispersed in said emulsion. These amendments have no impact on the conclusion reached as regards novelty over D1, since also present in the disclosure of D1, which shows in examples 7 and 8 vaccine compositions comprising one or more antigens.

Consequently, claim 3 of auxiliary request 2 lacks novelty over D1, and auxiliary request 2 does not meet the requirements of Article 54 EPC.

5.3 Auxiliary request 3 - Novelty

Independent claim 1 of auxiliary request 3 is identical to claim 3 of auxiliary request 2. Consequently, claim 1 of auxiliary request 3 lacks novelty over D1, and

auxiliary request 3 does not meet the requirements of Article 54 EPC.

6. Auxiliary request 4 - Remittal to the opposition division

6.1 When dealing with auxiliary requests 1-7, the opposition division mentioned in its decision that "since auxiliary requests 1-7 have been limited by features already present in D1, they do not seem to provide the claims with inventive step for the same reasons as the main request". Said decision on the auxiliary requests is limited to inventive step and does not give any further details what the limiting feature(s) of the auxiliary requests were and where to find them in document D1.

Moreover, the decision taken by the opposition division on auxiliary requests 1-7 as regards inventive step over D1 was based on a false postulate, namely that the difference of the claimed invention related to a "microfluidized" oil-in-water emulsion.

In view of these facts, it appears that the decision of the opposition division does not hold good and, with regard to the reasoning concerning auxiliary requests 1-7, is unacceptably incomplete and deficient.

6.2 In the Board's view, a remittal on the basis of auxiliary request 1 would have been a response to this decision.

It is however immediately obvious that the independent product claims of auxiliary requests 1-3 did not present any new features, and this was also not contested by the appellant during the oral proceedings

before the Board of Appeal. The Board considers therefore that a remittal based of any of auxiliary requests 1-3 as unjustified.

6.3 However, the objections of lack of novelty of auxiliary request 4 were contested by the appellant during the oral proceedings before the Board, while the respondents were of the opinion that auxiliary request 4 was also not novel either over document D1 or document D13, and in addition, involved problems with Articles 84 and 123(2) EPC.

As stated above, the Board could not identify from the decision of the opposition division where the new feature "immunostimulatory molecule" was disclosed in D1. The decision does not mention why and how auxiliary request 4 differed from D1 and where to find a basis in D1 for the added feature of the independent product claim of said requests.

The decision of the opposition division does also not deal with the grounds of lack of disclosure under Article 100(b) EPC raised by the respondents and the objections as to lack of clarity raised by respondent 02 against auxiliary request 4 already during the opposition proceedings (cf. letter of opponent 02 of 15 December 2015).

6.4 Hence, the Board finds itself discussing the novelty of a request, rejected for lack of inventive step based on a difference that has not been recognized by the Board, and on the basis of an amendment in claim 1 of auxiliary request 4 of a feature that has not been identified by the opposition division in D1.

The Board is also confronted with a situation where, even if it recognized the novelty of auxiliary request 4 on the basis of arguments never discussed during the opposition proceedings, the assessment of inventive step would be based on a different technical feature, namely the "immunostimulatory molecule", and the Board would still have to deal with points which have not been the basis of the decision, namely Articles 100(b) EPC, 84 EPC and 123(2) EPC.

This situation also applies also to any of the further auxiliary requests 5-7 which also comprise new technical features in their independent claim.

6.5 It is not the duty of the Boards of Appeal to consider and decide upon questions raised for the first time during the appeal proceedings. Instead, the main purpose of appeal proceedings is to give the losing party the opportunity to challenge the decision of the Opposition Division (cf. G 9/91, *loc. cit.*, point 18 of the Reasons).

In the present case, the Board considers it therefore appropriate to exercise its power conferred on it by Article 111(1) EPC to remit the case to the Opposition Division for further prosecution on the basis of the claims according to auxiliary request 4, because the Board does not have a proper basis for a review of the decision, due to the insufficient reasoning of the opposition division.

Respondent 2 pointed out that the case was already 16 years old. The Board notes however that the case was in fact 14 years old, among which 12 years before the first instance. Taking this into account and also considering the opposition division's poor reasoning in

its decision, this case should therefore be dealt with preferentially.

In view of Article 114(1) EPC, it will be the task of the opposition division to examine auxiliary request 4 and to decide on the grounds of opposition raised, namely novelty and inventive step under Articles 100(a) EPC, disclosure of the claimed invention under Article 100(b) EPC, as well as Article 84 EPC and Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

3. The appellant's request for reimbursement of the appeal fee is rejected.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated