Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 21 July 2016

Case Number: T 2112/12 - 3.3.07

Application Number: 07859275.5

Publication Number: 2029170

IPC: A61K39/39

Language of the proceedings: EN

Title of invention:
QUALITY CONTROL METHODS FOR OIL-IN-WATER EMULSIONS CONTAINING SQUALENE

Patent Proprietor:
Novartis AG

Opponents:
GLAXO SMITHKLINE BIOLOGICALS S.A.
Immune Design Corporation
Sanofi Pasteur SA

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - main request, auxiliary requests 1 and 9 (no)
Inventive step - auxiliary request 7 (no)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2112/12 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 21 July 2016

Appellant: (Patent Proprietor)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Marshall, Cameron John Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent 1)	GLAXO SMITHKLINE BIOLOGICALS S.A. Rue de l'Institut 89 B-1330 Rixensart (BE)
Representative:	Chiappinelli, Susan Ann GlaxoSmithKline Global Patents (CN925.1) 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Respondent: (Opponent 2)	Immune Design Corporation 1124 Columbia Street Suite 700 Seattle WA 98104 (US)
Representative:	Walker, Ross Thomson Forresters Skygarden Erika-Mann-Strasse 11 80636 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 July 2012 revoking European patent No. 2029170 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	R. Hauss
	D. T. Keeling

Summary of Facts and Submissions

I. European patent No. 2 029 170 was granted with thirty claims.

Claim 1 as granted reads as follows:

"1. A method for manufacturing an oil-in-water emulsion adjuvant, comprising the steps of:

(i) preparing a submicron oil-in-watcr emulsion using known amounts of an aqueous carrier, a surfactant and squalene;

(ii) subjecting the emulsion to filter sterilization, to provide a sterilized emulsion;

(iii) measuring the squalene content of the sterilized emulsion; and

(iv) comparing the squalene content measured in step (iii) to the squalene content known from step (i)

wherein, if the comparison in step (iv) reveals that the squalene content has significantly changed between steps (i) and (iii), the adjuvant is rejected."

II. Three notices of opposition were filed, opposing the patent under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was insufficiently disclosed and extended beyond the content of the application as filed.

III. The patent proprietor requested that the oppositions be rejected and filed nine auxiliary requests.

IV. The documents cited in the opposition and appeal proceedings include the following:

D1: Ott et al.: "The Adjuvant MF59: A 10-Year Perspective", Methods in Molecular Medicine, Vol. 42, 211-228 (2000)

D2: "Vaccine Design: The Subunit and Adjuvant Approach", ed.: Powell, Newman, Plenum Press New York, 1995, Chapter 10, 277-296

D3: WO 2006/100110 A1

V. The appeal lies from the decision of the opposition division, announced on 28 June 2012 and posted on 18 July 2012, revoking the patent.

In the decision under appeal, the opposition division found that the subject-matter of claim 1 of the main request and of claim 1 of each of auxiliary requests 1 to 6 lacked novelty relative to the disclosure of document D2. Auxiliary requests 7 and 8 were not admitted into the proceedings. Starting from the teaching of document D2, the subject-matter of the sole claim of auxiliary request 9 did not involve an inventive step.

VI. The patent proprietor (appellant) lodged an appeal against that decision.

VII. Opponent 3 subsequently withdrew its opposition.

VIII. With the statement setting out the grounds of appeal, the appellant submitted eleven auxiliary requests.

Claim 1 of auxiliary request 1 reads as follows (to facilitate comparison with claim 1 as granted, amendments are underlined):

"1. A method for manufacturing an oil-in-water emulsion adjuvant, comprising the steps of:

(i) preparing a submicron oil-in-water emulsion using known amounts of an aqueous carrier, a surfactant and squalene;

(ii) subjecting the emulsion to filter sterilization, to provide a sterilized emulsion;

(iii) measuring the squalene content of a small sample of bulk sterilized emulsion; and

(iv) comparing the squalene content measured in step (iii) to the squalene content known from step (i)

wherein, if the comparison in step (iv) reveals that the squalene content has significantly changed between steps (i) and (iii), there has been production failure and the adjuvant is rejected."

Claim 1 of auxiliary request 7 is identical to claim 1 of auxiliary request 1 as shown above, but contains the following additional feature:

"... and wherein the emulsion is an emulsion of squalene, a tocopherol and Tween 80."

Claim 1 of auxiliary request 9 is identical to claim 1 as granted.

IX. In reply to a summons to attend oral proceedings issued by the board, respondent-opponent 2 announced that it would not be attending the oral proceedings but maintained its request that the patent be revoked in its entirety.

X. In a communication issued in preparation for oral proceedings and advising the parties of the board's preliminary opinion, the board observed that

(a) the subject-matter of claim 1 as granted appeared to lack novelty over the disclosure of at least document D1;

(b) in oral proceedings, it might have to be discussed whether the additional features incorporated into claim 1 of, *inter alia*, auxiliary request 1 were limiting, and whether they distinguished the claimed subject-matter from the prior art;

(c) document D1 might, *inter alia*, be suitable as a starting point for the assessment of inventive step;

(d) tocopherol, identified as an emulsion component in claim 1 of auxiliary request 7, was a distinguishing feature in comparison with the disclosure of D1. No particular technical effect had been associated with the inclusion of tocopherol, which was furthermore known from document D3 as a component of oil-in-water (O/W) emulsion adjuvants.

XI. With letter of 19 July 2016, the appellant submitted a new version of **auxiliary request 9** corrected for typographical errors. The wording of claim 1 (see point VIII above) was not changed.

XII. Oral proceedings before the board took place on 21 July 2016, with the appellant and respondent-opponent 1 participating. During the oral proceedings, the appellant withdrew auxiliary requests 2 to 6, 8, 10 and 11.

XIII. The appellant's arguments may be summarised as follows:

Main request - novelty

Document D1, relating to the preparation of a submicron O/W emulsion adjuvant involving filter sterilisation, disclosed neither step (iii) nor step (iv) of the method defined in claim 1 of the main request.

- While document D1 taught that the emulsion bulk and final single-dose adjuvant were analysed by a battery of release assays which included the determination of the squalene content, it did not mention whether the squalene content should be determined in the emulsion bulk or in the single-dose product.

- The emulsion "bulk fill" in figure 1 of D1, issuing from a first filtration step through a 0.22 µm filter intended to remove large droplets, was not necessarily a sterilised emulsion, since D1 did not teach that it was mandatory to employ conditions which would keep the filtrate sterile.

- It was also contested that the release assay in question, which according to D1 merely required a comparison of the squalene content with an absolute "nominal value", involved the determination of a "yield" or any comparison of a final squalene content with the initial squalene content.

Thus neither the determination of the squalene content in the sterilised emulsion (step (iii)) nor a comparison of the result with the initial squalene content (step (iv)) were directly and unambiguously disclosed in document D1.

Nor did the term "release assay" imply that the rejection of the adjuvant was inevitable whenever the squalene content departed significantly from the "nominal value". Other conceivable options, which were not explicitly excluded by D1, might be dilution or, conversely, the addition of more squalene.

Furthermore, claim 1 of the main request required the comparison of squalene output to input for the purpose of quality control during an established manufacturing process (in the sense of an "in-process" assay), whereas document D1 only described a "release assay", which might well be carried out only after a period of storage.

The subject-matter of claim 1 was also novel over the disclosure of document D2, which related to tests carried out in the context of process design rather

than to quality control of an established manufacturing process.

Auxiliary request 1 - novelty

The term "bulk" used in claim 1 of auxiliary request 1 was a term of the art which indicated a large volume, to be processed to make products further downstream in a large-scale industrial manufacturing process.

Document D1 did not disclose a bulk of sterilised emulsion, since the so-called "bulk fill" shown in figure 1 of D1 was not sterilised, whereas the sterilised final material could not be regarded as "bulk". Furthermore, the release assay of D1 might provide an indication of storage stability rather than of production failure.

Auxiliary request 7 - inventive step

The claim feature requiring tocopherol as a mandatory component had been introduced into claim 1 of auxiliary request 7 to establish novelty, but did not contribute to inventive step, which was based on the claimed method as a whole. The purpose of the invention was the provision of an assay for detecting filtration problems during manufacture. Document D1 could serve as a starting point for the assessment of inventive step. The technical effect which the method of claim 1 provided over the disclosure of D1 was the indirect revelation of filtration problems. The objective technical problem was to find a simpler way of checking for filter failure during manufacture of the squalene emulsion. None of the cited prior-art documents suggested that concentration measurements of squalene after filter sterilisation could be used for evaluating filter performance. According to documents D1 and D2, the content of squalene was determined for different

reasons, viz. to test process conditions during test runs or to test for acceptable squalene levels and storage stability. The invention therefore consisted in a new use for the known parameter "squalene content".

XIV. Respondent-opponent 2 did not present any arguments during the appeal proceedings. The arguments of respondent-opponent 1 may be summarised as follows:

Main request - novelty

Document D1 disclosed the preparation of a submicron O/W emulsion adjuvant involving filter sterilisation, which corresponded to method steps (i) and (ii) defined in claim 1 of the main request. Release assays for the emulsion bulk and final single-dose adjuvant of D1 included the determination of the squalene content, corresponding to method step (iii).

- The "bulk fill" in figure 1 of document D1 was sterilised, due to having passed through a 0.22 µm filter (D1: page 214: lines 10 to 12). In any case, according to good manufacturing practice, the quality control assays including the determination of the squalene content would have to be carried out after each filtration step, including the final filter sterilisation.

- The release requirement that the quantity of squalene had to be within an acceptable range around the nominal concentration value corresponded to step (iv) and to the conditional rejection step defined in claim 1 of the main request.

Since the rejection step was a conditional step, the definition of claim 1 was also met whenever a method of manufacture involving steps (i) and (ii) yielded an emulsion adjuvant without a significant change in the

squalene level. That situation, at least, was covered in prior-art document D2.

Auxiliary request 1 - novelty

The vague expression "a small sample of bulk" which had been introduced into claim 1 of auxiliary request 1 could not establish novelty, since it covered any sample of a certain amount of filter-sterilised material at any point in the process. According to document D1, the sterilised emulsion was analysed using high-performance liquid chromatography (HPLC), which necessarily involved taking a "small" sample.

As set out in the context of the main request, if the manufactured adjuvant showed no significant change in squalene content, a rejection step was not required. If nevertheless a rejection step had to be taken into account in the assessment of novelty, then it was submitted that the term "production failure" present in claim 1 of auxiliary request 1 was not limiting, since it covered any production problem. Contrary to the appellant's assumptions, the release assay of document D1 did not concern storage stability or require a period of prior storage of the adjuvant.

Auxiliary request 7 - inventive step

Document D1, which disclosed the manufacture of the same adjuvant as the patent in suit, represented the closest prior art. The concept of testing the filter, relied on by the appellant in support of inventive step, was not reflected in the technical features of claim 1, which merely mentioned production failure.

The presence of a tocopherol according to claim 1 of auxiliary request 7, which was the distinguishing feature of the claimed subject-matter in comparison to

the disclosure of D1, had not been linked to any particular technical effect and therefore did not contribute to inventive step. It could not even be confirmed that any technical effect which might have been observed according to the patent in suit (with an emulsion consisting of squalene, Span 85, Tween 80, water and citrate buffer) would equally be obtained when tocopherol was present.

XV. The parties' final requests were the following:

- The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained unamended (main request) or on the basis of one of auxiliary requests 1 and 7 (both filed with the statement setting out the grounds of appeal) or of auxiliary request 9 (filed with letter of 19 July 2016).

- Respondent-opponent 1 requested that the appeal be dismissed.

- Respondent-opponent 2 requested that the patent be revoked in its entirety, which is understood by the board as a request that the appeal be dismissed.

Reasons for the Decision

1. Main request - novelty (Articles 100(a), 52(1) and 54(2) EPC)

1.1 The patent in suit is in the field of vaccine adjuvant manufacture. Claim 1 as granted is directed to a method for manufacturing an oil-in-water (O/W) emulsion adjuvant. In manufacturing steps (i) and (ii) a filter-sterilised submicron emulsion is obtained. Steps (iii)

and (iv) together with the condition for rejection describe a subsequent selection which results in the rejection of products with a "significantly changed" squalene content (as compared to the initial content).

1.2 Document D1 is concerned with the emulsion adjuvant MF59, which is a functional commercial adjuvant, and its second-generation successor MF59C.1, said to present enhanced stability characteristics.

The emulsion adjuvant MF59C.1 consists of the components squalene, Polysorbate 80, sorbitan trioleate, trisodium citrate dihydrate, citric acid monohydrate and water for injection (see D1: page 213, point 2). The 50-litre-scale manufacturing process for sterile clinical-grade MF59C.1 is shown in figure 1 and is further described on page 214 of document D1.

According to the description on page 214, a coarse emulsion of the components is formed which is fed into a "microfluidizer" apparatus to obtain a stable submicron emulsion. The bulk emulsion is filtered through a 0.22 µm filter under nitrogen to remove large droplets, yielding MF59C.1 adjuvant emulsion bulk that is filled into glass bottles.

For vaccine antigens that have demonstrated long-term stability in the presence of MF59 for shelf storage, the antigen and MF59 are combined and sterile-filtered through a 0.22 µm membrane. The combined "single-vial" vaccine is filled into single-dose containers.

For vaccine antigens where long-term stability has not been demonstrated, the adjuvant is supplied as a separate vial. In such cases, the MF59 bulk is filter-sterilised, filled, and packaged in final single-dose vials.

Figure 1 of D1 shows the continuation of the process after mixing of the oil phase and the aqueous phase as follows:

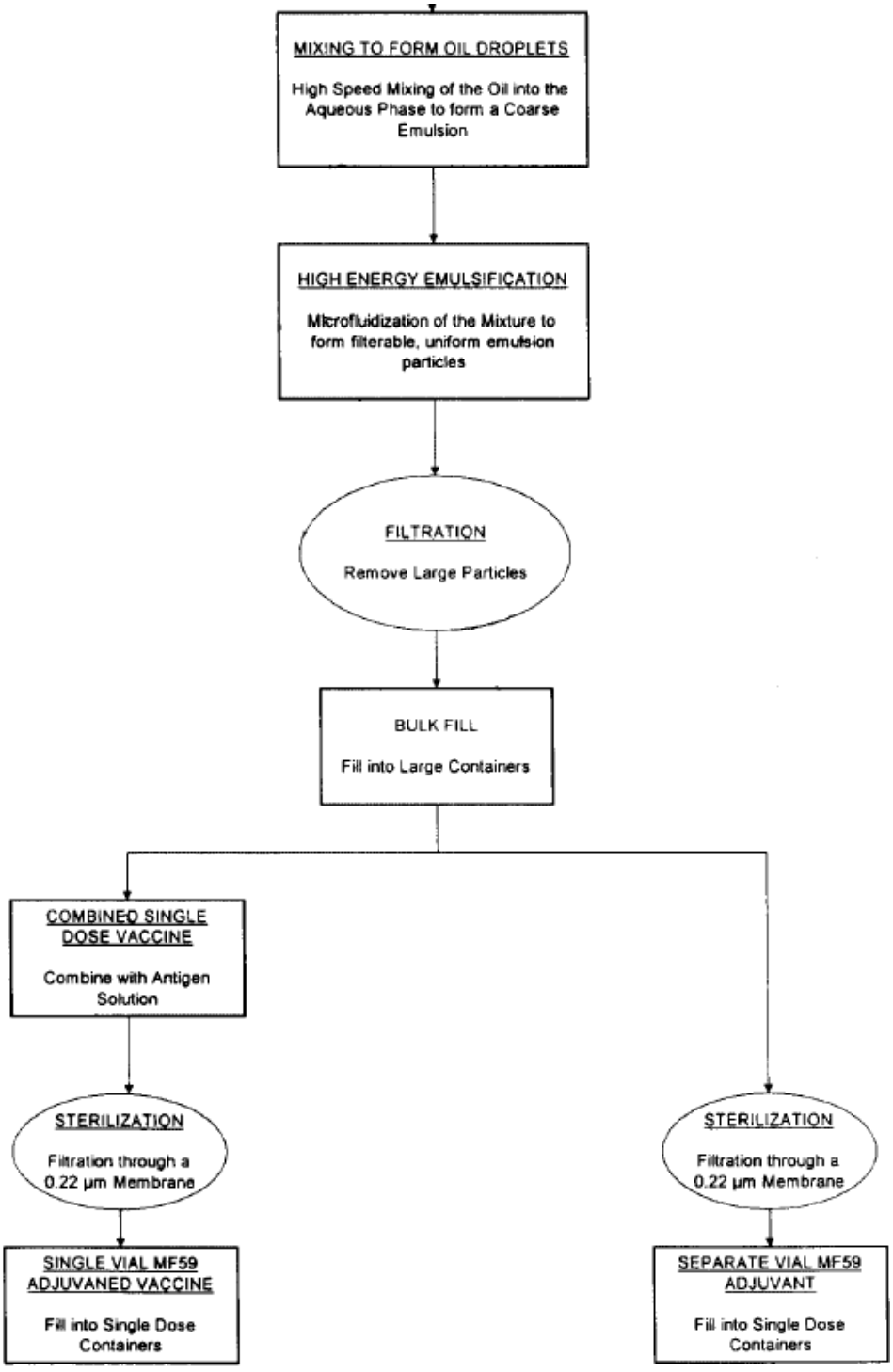

Figure 1 of document D1

Document D1 mentions in-process assays (section 3.2) and release assays (section 3.3) for MF59C.1. Release assays for the emulsion of D1 include the determination of the concentration of squalene, which must be within an acceptable range around a nominal concentration (see D1: point 3.3 on pages 216 to 217).

1.3 It was not contested by the appellant that document D1 discloses a method of manufacturing an O/W emulsion adjuvant including steps (i) and (ii) as defined in claim 1 of the main request.

1.4 Step (iii) as defined in claim 1 requires the determination of the squalene content of the sterilised emulsion.

Document D1 states in section 3.3 with the title *"Release assays for MF59C.1"* (page 216):

"MF59C.1 is a well-defined emulsion produced to preestablished release specifications. The emulsion bulk and final single-dose adjuvant are analyzed using a battery of assays in accordance with Chiron's standard operating procedures. Key assays include visual appearance, pH, mean particle size, and number of large particles per milliliter for quality, squalene, polysorbate 80, and sorbitan trioleate concentrations by high-performance liquid chromatography (HPLC) procedures for content and, endotoxin and bioburden content for safety."

Thus D1 discloses that the squalene concentration is determined as a release assay for the product MF59C.1.

Since no other meaning is specified, the expression "release assay" must be understood according to its usual meaning, viz. the final product is tested. In the present case, the final product is the sterilised

emulsion. This corresponds, in figure 1 of D1, to the product issuing from the step *"STERILIZATION/filtration through a 0.22 µm membrane"*. That product is the sterilised emulsion bulk, which is subsequently filled into single-dose containers.

Hence the appellant's argument that it is not clear from document D1 whether the squalene content is measured in the emulsion bulk or in the final single-dose adjuvant is not relevant, since in either case the squalene content would be measured in the sterilised emulsion.

The appellant's further argument that the emulsion bulk mentioned in section 3.3 of D1 must actually be the "BULK FILL" shown upstream of the sterilisation step in figure 1 of D1 is not convincing, since it is not technically plausible that a "release assay" would be carried out before the final step which might affect the product and the parameter to be determined - in the present case, the final filter-sterilisation step.

Hence document D1 also discloses step (iii) of the claimed method.

1.5 Claim 1 of the main request specifies in method step (iv) that the squalene content measured in step (iii) is compared to the squalene content known from step (i).

Irrespective of whether step (iv) should be regarded as a technical or as a non-technical feature, such a comparison is in any case disclosed in document D1, which states in section 3.3 in the context of the release assays:

"The quantities of squalene, polysorbate 80, and sorbitan trioleate must be within an acceptable range

around the nominal concentration values of 39, 4.7 and 4.7 mg/ml, respectively."

Thus the squalene content measured in a release assay is compared to a nominal value. It is self-evident to the person skilled in the art reading document D1 that the nominal value for the squalene content is a pre-established expected value which is directly linked to the content employed in the manufacturing process. The comparison with the nominal value thereby also involves a comparison with the squalene content initially employed (the squalene input).

The appellant's argument that the nominal squalene content might be independent of, and much lower than, the actual input of squalene into the manufacturing process has no basis in document D1 and is rather artificial, since a viable production process must give reproducible results and would not be based on random, low recovery values.

Hence document D1 also discloses step (iv) of the claimed method.

1.6 In the context of the discussion of post-production release assays in section 3.3 of D1, the requirement that the quantity of squalene measured in a release assay must be within an acceptable range around a nominal concentration value implies that only products which meet this requirement will be released. Conversely, products not meeting the requirement will not be released; in other words, they will be rejected.

Hence document D1 discloses a conditional rejection step as defined in claim 1 of the main request. In this context, the board considers that the concept of rejecting the product, as expressed in claim 1, or of

releasing it, as expressed in document D1, relates in both cases to its intended use as a vaccine adjuvant.

The appellant's argument that, conceivably, such rejected products might later be re-processed is not relevant in that context (irrespective of any considerations of practicality). The rather general expression "rejected" employed in claim 1 has no bearing on potential further uses (other than the use as a vaccine adjuvant) of the material in question and does not imply that it must be discarded or destroyed (i.e. cannot be re-processed).

1.7 Finally, it cannot be inferred from the general expression "method of manufacturing" that claim 1, in steps (iii) and (iv), relates to an "in-process" assay, as opposed to a "release" assay. After all, only steps (i) and (ii) relate to the actual process in which the sterilised emulsion is prepared. Since steps (iii) and (iv) and the conditional rejection step must take place after the sterilised emulsion has been prepared, the claimed "method of manufacturing" includes both the preparation of the product and a subsequent assay, but it is not implicit in the definition of the claim that this should be an "in-process" assay or that step (iii) should take place immediately after step (ii).

Nor does claim 1 contain any features which reflect the appellant's argument that the method is actually intended to provide an assay for identifying and repairing filter problems which occur during manufacture; in particular, claim 1 does not define any step of checking or exchanging filters in a production line. The only consequence of a finding of significant change in the squalene content which is mentioned in claim 1 is the rejection of the adjuvant.

Hence, it has not been established that the subject-matter of claim 1 of the main request differs from the disclosure of document D1 in the timing and purpose of the assay starting with step (iii).

1.8 For these reasons, the board has arrived at the conclusion that the subject-matter of claim 1 as granted lacks novelty relative to the disclosure of document D1.

2. Auxiliary request 1 - novelty (Articles 100(a), 52(1) and 54(2) EPC)

2.1 Claim 1 of auxiliary request 1 is largely identical to claim 1 of the main request (see point VIII above), except that it contains modifications in step (iii) and in the conditional rejection step. Thus it must be examined whether these modifications can establish novelty for the claimed subject-matter over the disclosure of document D1.

2.2 According to claim 1 of auxiliary request 1, step (iii) involves measuring the squalene content "*of a small sample of bulk sterilized emulsion*". Thus the terms "small sample" and "bulk" were introduced into the definition of step (iii).

2.2.1 Contrary to the appellant's interpretation, the rather general term "bulk" does not imply that step (iii) is somehow an "in-process" assay and thereby distinguished from the release assay of document D1.

Claim 1 does not include any specialised definition of the term "bulk". The term as such, as it is normally understood, does not necessarily refer to a large-scale industrial process or to a particularly large volume which is only found "upstream" in a production process.

In the present context, the term "bulk" would simply be understood by the technically skilled reader to designate the total volume processed.

2.2.2 In the context of the release assays, document D1 indicates that the emulsion bulk and final single-dose adjuvant are analysed, and that the concentration of squalene is determined by high-performance liquid chromatography (see D1: point 3.3 on page 216).

- As explained above (see point 1.4 above and figure 1 of D1), the emulsion bulk which is to be analysed in the release assay of D1 is the sterilised emulsion bulk which is obtained at the end of the manufacturing process, i.e. the product issuing from the step "*STERILIZATION/filtration through a 0.22 µm membrane*".

- As already mentioned, the appellant contended that it was not clear from the instructions in document D1 whether the squalene content was to be measured in the emulsion bulk or in the final single-dose adjuvant. However, the sample would be taken in any case from the sterilised emulsion bulk, either before or after it was filled into single-dose containers (see point 1.4 above). The board considers that it is irrelevant in that context whether the reduction in volume takes place in one step or in two. In either case the upshot will be that the squalene content is measured in a sample of sterilised emulsion bulk.

- It is commonly known that analysis by high-performance liquid chromatography (HPLC) requires comparatively small samples. In any case, claim 1 of the first auxiliary request relies on the vague and indefinite term "small", but does not define any upper limit for the ratio of sample size to bulk size or for the absolute sample size. Thus, the sample undergoing

HPLC analysis for squalene content according to D1 may certainly be regarded as "small" within the terms of claim 1.

2.2.3 For these reasons, the board has arrived at the conclusion that the release assay for squalene content according to document D1 anticipates step (iii) as defined in auxiliary request 1.

2.3 The conditional rejection step is defined as follows in claim 1 of auxiliary request 1:

"*...if the comparison in step (iv) reveals that the squalene content has significantly changed between steps (i) and (iii), there has been production failure and the adjuvant is rejected.*"

2.3.1 In this context, the appellant submitted that the release assay according to document D1 provided an indication of storage stability rather than of production failure. Thus, the phrase "there has been production failure" which was inserted into claim 1 seems to be intended to convey the impression to the reader of the claim that measuring the squalene content according to step (iii) of the claim must be an in-process assay and must be distinguished from a release assay.

2.3.2 The board does not arrive at the same conclusion with regard to the meaning and impact of this feature. Firstly, the board sees no reason to assume that a release assay (as carried out according to document D1) cannot reflect problems which are associated with production failure. Secondly, just as in claim 1 of the main request, the conditional rejection of the adjuvant still depends exclusively upon the finding of a significant change in the squalene content. Thus, the

introduction of the phrase "there has been production failure" (which, moreover, expresses a mental evaluation rather than a technical feature) has no limiting effect and cannot serve to establish novelty.

2.4 In summary, the modifications introduced into claim 1 of auxiliary request 1 in comparison with claim 1 of the main request cannot change the assessment with regard to novelty explained in section 1 above. As a consequence, the board has come to the conclusion that the subject-matter of claim 1 of auxiliary request 1 lacks novelty relative to the disclosure of document D1.

3. Auxiliary request 7 - inventive step (Articles 100(a), 52(1) and 56 EPC)

3.1 The wording of claim 1 of auxiliary request 7 differs from that of claim 1 of auxiliary request 1 solely by the additional requirement that the emulsion is an emulsion of squalene, a tocopherol and Tween 80.

3.2 Tween 80 is a surfactant, as required according to step (i), and is identical to Polysorbate 80 used in D1. The mandatory presence of a tocopherol as an emulsion component is thus the only feature which distinguishes the subject-matter of claim 1 from the disclosure of document D1.

3.3 The inclusion of tocopherol in the formula has not been associated with any particular technical effect. As conceded by the appellant, that technical feature was introduced to establish novelty, but does not contribute to inventive step.

3.4 It was not contested that document D1 may be used as a starting point for the assessment of inventive step.

3.5 When starting from the disclosure of document D1, the technical problem in respect of claim 1 of auxiliary request 7 must be defined, in the absence of evidence of any more specific technical effect, as the provision of a method for manufacturing a further oil-in-water emulsion adjuvant.

3.6 Tocopherol is known from document D3 as a suitable component of filter-sterilised O/W emulsion adjuvants also containing squalene and Tween 80 (see D3: claims 2 and 7; page 17, line 13, to page 18, line 16, and example II.1 on pages 43 and 44). Hence, it would not have required inventive skill for the person skilled in the art to introduce tocopherol into the composition of the adjuvant, in order to solve the above-mentioned technical problem.

3.7 The appellant argued that inventive step was based, not on the presence of tocopherol, but on the claimed method as a whole, which according to the appellant provided a non-obvious assay for detecting filtration problems during the manufacturing process of the emulsion adjuvant, based on the determination of the squalene content.

According to the problem-and-solution approach employed by the boards for assessing inventive step, the objective technical problem must be defined on the basis of the technical effects actually achieved by the claimed subject-matter when compared with the starting point in the prior art. Thus in the present case, the definition of the objective technical problem may only be based upon a technical effect which is linked to the presence of tocopherol in the formulation, which is the only technical feature distinguishing the claimed method from the disclosure of document D1.

Therefore the appellant's suggested approach cannot succeed.

3.8 As a consequence, the subject-matter of claim 1 of auxiliary request 7 does not involve an inventive step within the meaning of Article 56 EPC.

4. Auxiliary request 9 - novelty (Articles 100(a), 52(1) and 54(2) EPC)

4.1 Claim 1 of auxiliary request 9 is identical to claim 1 as granted.

4.2 As a consequence, the subject-matter of claim 1 of auxiliary request 9 lacks novelty relative to the disclosure of document D1 for the same reasons as set out in the context of the main request (see section 1 above).

5. Document D2

In view of this outcome, a discussion of the issue of novelty of any of the present requests in view of the disclosure of document D2 is not required.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani A. Usuelli

Decision electronically authenticated