

Internal distribution code:

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

**Datasheet for the decision
of 26 June 2008**

Case Number: T 0083/04 - 3.3.02

Application Number: 95200166.7

Publication Number: 0653204

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:
Medicinal aerosol formulations

Applicant:
RIKER LABORATORIES, INC.

Opponent:
-

Headword:
Aerosol formulation comprising salbutamol/RIKER LABORATORIES

Relevant legal provisions:
EPC Art. 123(2), 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request and first auxiliary request (no): unallowable combination of features"
"Second auxiliary request (yes): claim 1 directly and unambiguously derivable; novel and inventive subject-matter"

Decisions cited:
-

Catchword:
-



Case Number: T 0083/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 26 June 2008

Appellant:

RIKER LABORATORIES, INC.
19901 Nordhoff Street
Northridge
CA 91324 (US)

Representative:

Weinberger, Rudolf
Vossius & Partner
Postfach 86 07 67
D-81634 München (DE)

Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 3 July 2003
refusing European application No. 95200166.7
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
J. Van Moer

Summary of Facts and Submissions

- I. European patent application EP-A-0 653 204, based on the application No 95 200 166.7, which was filed as a divisional application of the parent application EP-A-0 499 344, based on application No 92 201 264.6, which was filed as a divisional application of the parent application EP-A-0 372 777, based on application No 89 312 270.5, was filed with 13 claims.

Claims 1 as filed (single independent claim) read as follows:

"1. An aerosol formulation comprising a medicament, 1,1,1,2-tetrafluoroethane, a surface active agent and at least one compound having a higher polarity than 1,1,1,2-tetrafluoroethane."

- II. The following documents were cited inter alia during the proceedings:

- (1) EP-A-0 275 404
- (3) Dupont "UPDATE", Fluorocarbon/Ozone, March 1987
- (5) The Theory and Practice of Industrial Pharmacy, Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, Lea & Febiger Philadelphia, second edition, 1976, Chapter 9
- (9) Dictionnaire Vidal 1979 (Ventoline)
- (10) WO 86/04233

- III. The present appeal lies from the decision of the examining division refusing the application under Article 97(1) EPC 1973, pursuant to the requirements of Articles 123(2) and 56 EPC.

IV. The examining division considered that the main request and the first and fourth auxiliary requests did not meet the requirements of Article 123(2) EPC. Moreover, in the examining division's opinion, the subject-matter claimed in the second and third auxiliary requests did not involve an inventive step. In particular, the examining division considered document (1) to represent the closest prior art. The examining division defined the problem to be solved as to provide medicinal aerosol formulations having acceptable therapeutic effectiveness but being less destructive to ozone. The examining division considered the solution defined in the claims to be obvious for the skilled person and cited document (2).

V. The appellant lodged an appeal against this decision.

VI. The board sent a communication dated 5 September 2007 conveying its preliminary opinion in respect of the requirements of Articles 123(2), 84 and 56 EPC.

The appellant filed with its response of 15 January 2008 a main request (five claims) and a technical report as appendix A.

Claim 1 of the main request read as follows:

"1. An aerosol formulation suitable for drug delivery to the human lung by administration to a patient by oral or nasal inhalation comprising salbutamol sulphate, 1,1,1,2-tetrafluoroethane, oleic acid and ethyl alcohol, the formulation being in the form of a suspension of

drug particles having a median particle size of less than 10 microns."

Claim 5 of the main request read as follows:

"5. A medicinal product for drug delivery to the human lung by administration to a patient by oral or nasal inhalation comprising an aerosol container equipped with a metered dose dispensing valve, the aerosol container containing a medicinal aerosol formulation as claimed in any preceding claim."

Moreover, the appellant stated in its letter of 15 January 2008:

"Furthermore, the designation for all contracting states except GB is herewith withdrawn".

- VII. The board issued an invitation to attend oral proceedings accompanied by a communication in which it was mentioned *inter alia* that Article 123(2) EPC had to be discussed at the oral proceedings as a first issue.
- VIII. The board informed the appellant in a brief communication sent by fax on 23 June 2008 that, if the objections re Article 123(2) EPC were to be overcome, the dictionary document (9), as well as document (10) (both known to the appellant from the parent application file), would have to be considered when assessing inventive step.
- IX. Oral proceedings took place on 26 June 2008.

X. At the beginning of the oral proceedings the board conveyed its preliminary opinion in relation to the requirements of Article 123(2) EPC regarding the main request. In response thereto the appellant filed two auxiliary requests. The first auxiliary request differed from the main request in that claim 5 had been deleted. The second auxiliary request contained only one single claim, which was identical to claim 1 of the main request.

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

The amended claims of the main request derived directly and unambiguously from the application as filed. The basis for the amended claims was to be found in claims 1 and 2 as originally filed, in which the constituents had been specified in the light of the exemplified formulations (particularly in examples 5 and 24(6) of the application as filed). Having regard to the fact that the specific combination was exemplified, the now claimed subject-matter did not represent a new selection out of three lists from the originally filed claim 1. Moreover, dependent claims 2 to 4 were already present in the set of claims as originally filed as claims 8, 9 and 11. It should be possible to allow these three dependent claims in combination with the specific formulation of amended claim 1, since no new information had been introduced as regards the specific ranges which were meant, in the application as filed, to be applied for the generic formulations and for any specific formulation as well. As regards claim 5, it was intended to cover the commercial medicinal product which comprises an aerosol container containing the formulation claimed in claim 1.

It was self-evident reading the application as filed that the aerosol formulation of claim 1 had to be contained in an aerosol container equipped with a metered dose-dispensing valve (in particular pages 5, 11 and 12 of the application as filed). The aerosol container was a conventional aerosol container.

The appellant submitted that the same arguments applied *mutatis mutandis* to the two auxiliary requests, which differed from the main request only in that some claims had been deleted.

The appellant stressed that the application in suit (as well as the parent and grandparent applications) related to the first medicinal aerosol formulations for oral or nasal inhalation in which 1,1,1,2-tetrafluoroethane (HFA 134a) was used as propellant. Moreover, the formulation of claim 1 was a commercial product.

As regards inventive step the appellant submitted that the formulation Ventoline ("Aérosol-doseur") disclosed in "Dictionnaire Vidal" (document (9)) represented the closest prior art. This aerosol formulation comprised salbutamol as active ingredient and, as excipients, oleic acid, trichlorofluoroethane and dichlorofluoroethane. The prior art aerosol formulation Ventoline did not contain ethanol.

The problem to be solved was the provision of a stable salbutamol aerosol formulation for oral or nasal inhalation.

The solution as defined in claim 1 related to a particular aerosol system consisting of 1,1,1,2-tetrafluoroethane (HFA 134a), oleic acid as surfactant and ethanol as substance with higher polarity than HFA 134a.

Ethanol had been disclosed as co-solvent in aerosol formulations comprising chlorofluorocarbons as propellants (see document (10)) for providing solutions, rather than suspensions, of the active drug. Indeed, since it was known that salbutamol was soluble in ethanol, it would not represent a satisfactory choice for providing stable suspensions of the drug in view of the phenomena related to Ostwald ripening.

In this context the appellant also cited document (5) (in particular page 279), the content of which could be considered to illustrate the general knowledge of the skilled person of the time of the invention. Moreover, the appellant also pointed to the results of the technical data report as an indication of the presence of an inventive step.

In the appellant's opinion it would not have been obvious for the skilled person at the time of the invention (priority date 6 December 1988, date of filing 27 November 1989) to provide the propellant system proposed in claim 1. In the appellant's view, the skilled person would not have considered adding ethanol in view of the solubility, density and pressure requirements known from document (5). Moreover, the appellant submitted that chlorofluorocarbon (CFC) propellants have a relatively high density in relation to the suspended drug. The appellant also submitted

that the densities of CFC 11 and CFC 12 are 1.48 and 1.32 g/ml, and according to the handbook document (5), propellant density was typically adjusted to a value of around 1.44 g/ml (page 279). Propellant HFA 134a had in this regard a low density of 1.22 g/ml. Hence, it was not obvious at the priority date to admix very low density ethanol (0.789 g/ml) with HFA 134a for preparing very stable aerosol formulations in the form of a suspension.

- XII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with the letter of 15 January 2008 or, in the alternative, on the basis of the first or second auxiliary requests submitted during the oral proceedings.

Reasons for the Decision

1. Admissibility

1.1 The appeal is admissible.

1.2 The two auxiliary requests filed during the oral proceedings are admissible since they are a clear and direct response (deletion of claims) to the objections raised by the board in relation to Article 123(2) EPC.

2. Amendments

The content of the application in suit as originally filed does not go beyond the content of the parent and grandparent applications as originally filed, since

these three documents do not differ from one other (Article 76(1) EPC).

Hence, the assessment of the amendments will be undertaken in the light of the content of the application in suit as originally filed (Article 123(2) EPC).

- 2.1 There is no *verbatim* counterpart in the application as originally filed for claim 1 of all requests on file (main request, first and second auxiliary requests).

Claim 1 as originally filed, which is reproduced above (point I of facts and submissions), relates to a generic aerosol formulation which is broadly defined (active drug defined as "medicament" and propellant system defined as comprising HFA 134a, a surface active agent and at least one compound having a higher polarity than HFA 134a). The wording of claim 1 of the application as originally filed does not require the aerosol formulation to be suitable for oral or nasal administration. Such feature appears only in claim 2 as originally filed, which is a dependent claim of originally filed claim 1. It is to be stressed, however, that claim 2 of the application as originally filed includes the following definition: "the formulation being in the form of a **solution or a suspension** of medicament particles having a median particle size of less than 10 microns" (emphasis added).

Claim 1 of all the requests on file is directed to aerosol formulations in which the ingredients are specified as follows: salbutamol sulphate (active drug), oleic acid, ethanol and HFA 134a (propellant system);

the formulations are in the form of a suspension of the active drug (medicament) particles having a median particle size of less than 10 microns. The formulations in the form of a solution of the medicament (active drug) particles are not encompassed by the amended claim.

Having regard to the fact that none of the dependent claims of the originally filed application relates either to the choice of suspension or to the choice of the specific propellant system now claimed, it is necessary to look for a basis for amended claim 1 in the description (including the examples) of the application as originally filed.

The description of the application as originally filed discloses HFA 134a as a propellant for aerosol formulations suitable for inhalation therapy when used in combination with an adjuvant (alone or in combination). One of the options disclosed for the adjuvant is ethyl alcohol (page 3).

The generic disclosure mentions as preferred compounds of higher polarity than Propellant 134a (i.e. as adjuvant) ethanol, pentane, isopentane and neopentane (page 8, lines 2-5).

However, there is no indication in the generic disclosure of the application as originally filed for the choice of ethyl alcohol as adjuvant together with oleic acid as surfactant.

Indeed, the generic disclosure concerning the surfactant is quite broad as shown by the definitions given on pages 8 and 9. These include "oils derived from natural sources, such as corn oil, olive oil, cotton seed oil and sunflower seed oil"; several sorbitan and polyoxyethylene sorbitan derivatives, lecithins, several fatty acid and polyoxyethylene derivatives, particular block polymers, etc.

Oleic acid appears as one of a number of options mentioned at the top of page 9 of the application as originally filed. Moreover, there is no hint or indication for preferring oleic acid when ethanol is used as adjuvant.

Page 9 of the application as originally filed gives a long list of "suitable solid medicament(s)". Salbutamol (as the free base) is mentioned in this list (line 28, page 9).

Furthermore, on page 10 of the application as filed it is disclosed that the active drug (medicament) may be used as a free base or as one or more salts known to the art. Again, a long list of possible salts is given. Sulphate is mentioned as an option in line 22, page 10.

Therefore, the part of the description corresponding to the generic disclosure does not suffice as a basis for the singling out of the specific suspensions of salbutamol sulphate in HFA 134a/ethanol/oleic acid claimed in amended claim 1.

The disclosure of the illustrative examples begins on page 12 of the application as originally filed. Three active drugs are mentioned as components of the formulations specifically disclosed, with salbutamol sulphate (micronised) being one of them (page 12 of the application as originally filed makes it clear that the term "salbutamol" as used in the specific examples means "salbutamol sulphate"). As regards the surfactant, three are chosen for the examples. Oleic acid is one of them. Moreover, the adjuvant chosen for the illustrative examples is either ethanol or n-pentane. Finally, HFA 134a (P134a) is a mandatory component.

Examples 1 to 6 are dedicated to suspensions of salbutamol sulphate and example 5 specifically exemplifies the propellant system HFA 134a/ethanol/oleic acid. Furthermore, example 24 exemplifies stable suspensions for the basic formulation salbutamol sulphate HFA 134a/ethanol/surfactant in which the surfactant chosen according to number 6 is oleic acid.

All the formulations illustrated in the application as originally filed and which comprise the specific combination of salbutamol sulphate in the propellant system HFA 134a/ethanol/oleic acid are in the form of suspensions. Moreover, the specific amounts disclosed in the particular examples are illustrative for specific formulations, but they do not set specific limitations beyond those linked to the technical feasibility required when preparing the suspensions by means known in the art.

Finally, the expression "suitable for delivery to the lung" is considered to be a self-explanatory feature linked to the physiological reasons, known to the skilled person, for providing solid particles smaller than 25 microns (see also page 11, line 3 of the application as filed).

Therefore, the application as originally filed discloses in an unambiguous and direct manner the formulations claimed in amended claim 1 of all the requests on file.

- 2.2 However, both sets of claims of the main request and the first auxiliary request contain dependent claims 2 to 4, which have to be investigated.

Therefore, it has to be assessed whether or not dependent claims 2 to 4, in combination with amended claim 1, individualise in a specific manner subject-matter not specifically disclosed in the application as originally filed.

Moreover, it should be borne in mind that the specific disclosure (i.e. the illustrative examples) of the application as originally filed had to be invoked for providing a basis for amended claim 1.

Dependent claim 2 of the main request and first auxiliary request relates to an aerosol formulation as claimed in claim 1 in which the HFA 134a is present in an amount in the range **60 to 95%** by weight of the formulation and the **weight ratio of HFA 134a:ethanol is in the range 70:30 and 98:2.**

Claim 8 (which was dependent on claim 7, which was dependent on any of the preceding claims) of the application as originally filed defines the amount ranges by weight of HFA 134a and the weight ratio of HFA 134a:ethanol, with the values appearing in claim 2 of the main request and first auxiliary request.

However, the specific weight ratio of HFA 134a:ethanol for the lower and upper values of the range was defined in connection with the broadly defined generic formulation, which (according to claim 2 as originally filed) could be either a solution or a suspension, and for which the active drug and the surfactant were not specifically identified.

In fact, none of the claims 1 to 6 (on which originally filed claims 7 and 8 are dependent) of the application as originally filed mentions salbutamol (or salbutamol sulphate), or oleic acid. Furthermore, the specific choice of the active drug and the specific choice of the surfactant together with the fact that the formulation is in the form of a suspension **has a direct bearing** on the ratio to be employed of propellant HFA 134a to the adjuvant (and co-solvent) ethanol.

It is reflected by a consistent case law of the boards of appeal that the lower and upper value defining a range are considered as specifically disclosed.

Therefore, the combination of dependent claim 2 with the specific formulation of amended claim 1 (in both sets of claims: main request and auxiliary request 1) individualises **suspensions** of **salbutamol sulphate** in the propellant system HFA 134a/ethanol/**oleic acid** in

which the weight ratio of HFA 134a:ethanol is **70:30** and those in which the weight ratio of HFA 134a:ethanol is **98:2**. This **specific** information is not directly and unambiguously derivable from the application as originally filed (including the claims), since these specific limit values for the weight ratio were disclosed together with the generic formulations. This means that they were disclosed in an indeterminate manner in relation to the choice of the essential constituents (active drug and surfactant), together with the actual physical form of the formulation (solution or suspension).

As regards the specific examples which serve as a basis (together with originally filed claims 1 and 2) for amended claim 1, it has to be stressed that they illustrate the definite weight ratio values 75:25 and 90:10 (examples 5 and 24, respectively) and thus cannot serve as an allowable basis for the subject-matter of the dependent claim 2 of the main request and first auxiliary request.

In other words, the information as to whether a formulation of **salbutamol sulphate** in the propellant system HFA 134a/ethanol/**oleic acid** with the specific weight ratio **HFA 134a/ethanol of 70:30** is still a **suspension** of the drug particles, cannot be directly and unambiguously derived from the illustrative examples of the application as originally filed.

- 2.3 The appellant's argument that the application as originally filed discloses the particulate weight ratio of HFA 134a:ethanol in the range defined in claim 2 in combination with any specific formulation, since the

range was disclosed in relation to the generic formulation, is only applicable if the medicament and the surfactant were to be defined as a group of possible options (as in claims 10 and 12 of the application as originally filed), without any specific pointer to a specific combination of features as is the case now. The specific suspension of salbutamol sulphate in the specific propellant system HFA 134a/ethanol/oleic acid does not appear individualised in any of the claims (or combination of claims) of the application as originally filed.

- 2.4 Consequently, the main request and first auxiliary request fail because the subject-matter claimed extends beyond the content of the application as originally filed (Article 123(2) EPC).

Hence, the second auxiliary request which contains one single claim (claim 1 of the second auxiliary request is identical to claim 1 of the main request), meets the requirements of Article 123(2) EPC.

3. Novelty is not an issue at stake in the present appeal proceedings, since aerosol formulations suitable for oral or nasal inhalation comprising salbutamol sulphate and HFA 134a are not disclosed in the prior art at the effective filing date of the application in suit.

4. *Inventive step*

- 4.1 Document (9), which specifically discloses the aerosol formulation (suitable for administration to a patient by oral inhalation) comprising salbutamol, oleic acid, trichlorofluoromethane and dichlorodifluoromethane

(commercial product "Ventoline, aérosol-doseur"), represents the closest prior art. This was not disputed by the appellant.

- 4.2 In the light of this closest prior art, the problem to be solved lies in the provision of stable aerosol formulations (suitable for oral or nasal inhalation) of salbutamol.

The solution as defined in claim 1 of the second auxiliary request (single claim) relates to suspensions of salbutamol sulphate particles in the propellant system HFA 134a/ethanol/oleic acid.

The board is satisfied that the problem has been credibly solved in the light of the additional technical data submitted as Appendix A with the letter of 15 January 2008.

In particular, in view of the stability results shown in part B (point 1, minimal propensity towards sedimentation/creaming; point 2, long-term chemical and physical stability; and point 3, low-temperature suspension stability) of the above-mentioned technical report.

- 4.3 Therefore, it has to be assessed whether the proposed solution is obvious in the light of the prior art.

The skilled person looking for a solution to the above problem is aware of document (10), which discloses medicinal aerosol formulations suitable for "endopulmonary or nasal inhalation" (page 1).

Document (10) discloses that medicinal aerosol formulations generally contain a mixture of chlorofluorocabons, e.g. trichlorofluoromethane (Propellant 11), dichlorofluoroethane (propellant 114) and dichlorodifluoromethane (propellant 12). Furthermore, document (10) states: "the drug is either present as a solution in the aerosol formulation or as a dispersion of fine particles." (page 1, lines 10-19)

Document (10) further states that "there are very few drugs which can be solubilised in chlorofluorocarbon aerosol propellants alone. Generally, it is necessary to utilise a polar co-solvent, such as ethanol, in order to achieve solubilisation of the drug. However, the resulting solutions can be chemically unstable due to reaction between the co-solvent and the drug or the co-solvent and the propellant system." (page 1, lines 20-27)

Although document (10) states that the suspension of drug particles in aerosol propellants can be achieved with the aid of a surfactant (page 2, lines 1-4), the aerosol formulations disclosed in document (10) comprise one or more chlorofluorocarbon aerosol propellants, a glycerol phosphatide and a drug, the drug being dissolved in the composition (page 2, lines 15-19).

Moreover, document (10) further states that certain drugs which are practically insoluble in chlorofluorocarbon propellants alone can be solubilised in the propellant/glycerol phosphatide system by the addition of a small amount of a co-solvent such as ethanol (page 4, lines 3-7).

Salbutamol **base** is mentioned in document (10) as one of the drugs suitable for the aerosol formulation (page 4, line 26). Example 2 illustrates an aerosol formulation comprising a solubilised salbutamol base in propellant 11 and propellant 12, together with Epikuron 200. Ethanol is not present.

Document (10) clearly discloses the use of ethanol as co-solvent for attaining a solution of the drug, and explicitly discourages the skilled person from using highly polar ionic salts of the drugs because it may not be possible to solubilise the drug in sufficient quantity (page 4, lines 19-22).

Therefore, even if it is considered that there is a clear indication (see *inter alia* document (3)) just before the effective filing date of the application in suit prompting the skilled person to use propellant HFA 134a as a chlorine-free substitute for the commonly used chlorofluorocarbon propellants (such as propellant 12), the skilled person would not have arrived at the proposed solution since document (10) does not teach the use of ethanol for providing stable suspensions of salbutamol (as salbutamol sulphate).

Apart from document (10), there is another document, document (1), known to the skilled person in the field of medicinal aerosol formulations.

However, the aerosol formulations disclosed in document (1) comprise **luteinizing hormone releasing hormone (LHRH) analogues** as the active drug, propellant dichlorodifluoroethane (Freon 12), a co-solvent, and a

surfactant (**sorbitantriolate** is the surfactant of choice; oleic acid is not mentioned as an option) (page 3).

The active drug, i.e. LHRH analogues, of the formulations according to document (1) is chemically and physically remote from salbutamol sulphate. Moreover, although document (1) discloses the use of Freon 11 and/or ethanol as co-solvent, the **preferred co-solvent** for providing suspensions **is trichlorofluoromethane** (Freon 11)) (page 3, lines 32-40).

Finally, document (5), Chapter 9 ("Pharmaceutical Aerosols") of the book "Theory and Practice of Industrial Pharmacy", which can be considered to illustrate the general knowledge of the skilled person in relation to the physicochemical requirements of medicinal aerosol formulations, does not help the skilled person further when looking for a solution to the above-stated problem.

Document (5) states: "The type of (aerosol) system selected is dependent on many factors including the following: (1) physical, chemical, and pharmacological properties of active ingredients; and (2) site of application." (page 277, left-hand column)

Document (5) discloses several types of aerosol formulations. Among those suitable for inhalation are solution systems and suspension or dispersion systems.

Document (5) recommends the use of ethanol as co-solvent for obtaining solution systems by means of lowering the vapour pressure of the propellant system comprising, for example, propellant 12 (page 277).

Contrary to this prior art teaching, the addition of ethanol to the propellant HFA 134a system defined in claim 1 shows very little effect on the vapour pressure of the aerosol system (see experiment A, technical report submitted by the appellant as Appendix A).

Additionally, there is clearly a warning in document (5) directly related to stability considerations of suspension systems and the use of co-solvents:
"Materials suspended in a vehicle in which they are partially soluble show signs of particle size growth." ... "The physical stability of a dispersed system is dependent primarily on the rate of agglomeration of the suspensoid." (page 279)

In this context it has to be stressed that, when providing aerosol formulations for inhalation therapy the skilled person must attain not only the proper particle size but also must ensure the uniformity of the formulation for consistent penetration of the pulmonary tree and uniform effects. All this would not be achieved if there were variations in the particle size and physical stability of the suspension.

Document (5) also teaches: "Consideration must also be given to the density of the suspensoid and the propellant vehicle... The density of both the propellant and/or suspensoid may be changed by the addition of a compound of higher or lower density, so

that the density of the suspensoid may be made equal to the propellant density. In many cases, however, it has been found easier to adjust the density of the propellant to about 1.44 Gm/ml..." (page 279)

It is known to the skilled person that the density of propellant HFA 134a (1.22 g/ml) is already lower than the value 1.44 (g/ml) recommended in document (5). Hence, there is no evident reason in the light of the prior art knowledge for adding a low-density additive such as ethanol.

Consequently, to arrive at the proposed solution involves an inventive step in the light of the cited prior art.

- 4.4 Therefore, the subject-matter of claim 1 (single claim) of the second auxiliary request meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent with the following documents:
Claim 1 of the second auxiliary request and a description to be adapted.

The Registrar:

The Chairman:

N. Maslin

U. Oswald