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**Datasheet for the decision
of 19 May 2011**

Case Number: T 1177/07 - 3.3.02

Application Number: 99931790.2

Publication Number: 1011728

IPC: A61K 47/44

Language of the proceedings: EN

Title of invention:

Polypropylene containers for prostaglandin products

Patentee:

Alcon Manufacturing, Ltd.

Opponent:

SANTEN PHARMACEUTICAL CO., LTD.

Headword:

Polypropylene Containers/ALCON MANUFACTURING CO., LTD.

Relevant legal provisions:

EPC Art. 54, 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request - novelty (no)"

"Auxiliary requests 1-6 - inventive step (no): obvious to try"

Decisions cited:

-

Catchword:

-



Case Number: T 1177/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 19 May 2011

Appellant: Alcon Manufacturing, Ltd.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
21 May 2007 concerning maintenance of European
patent No. 1011728 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 011 728 based on application No. 99 931 790.2 was granted on the basis of 27 claims. The independent claims read as follows:

"1. Use of a polypropylene container for increasing the stability of an aqueous prostaglandin composition which is packaged within the container and which comprises a prostaglandin and a pharmaceutically acceptable surfactant.

10. A method of increasing the stability of an aqueous prostaglandin composition comprising a prostaglandin and a pharmaceutically acceptable surfactant wherein the method comprises: packaging the aqueous prostaglandin composition in a polypropylene container.

19. A prostaglandin product comprising:

a) an aqueous prostaglandin composition comprising a therapeutically effective amount of at least one prostaglandin and a pharmaceutically acceptable surfactant; and

b) a polypropylene container; wherein the aqueous prostaglandin composition is packaged in the polypropylene container."

II. An opposition was filed against the patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for amendments that contained subject-matter extending beyond the content of the application as originally filed.

III. The documents cited during the opposition and appeal proceedings included the following:

- (1) EP-A-0 242 580
- (2) US-A-5 631 287
- (26) JP 10-101863 (English translation filed by the respondent with a letter dated 16 May 2011).

IV. The present appeal lies from an interlocutory decision of the opposition division, pronounced on 26 April 2007, to maintain the patent in amended form on the basis of auxiliary request 3, filed during oral proceedings before the opposition division.

V. Regarding the main request, the opposition division came to the conclusion that the subject-matter of claim 19 was not novel over the polypropylene containers according to document (1). The subject-matter of claims 19 and 24 to 26 of auxiliary request 1 did not meet the requirements of Article 123(2) EPC, as the application as filed did not provide a basis for polypropylene bottles of any shape and any size. As regards an inventive step of the prostaglandin product claimed in claim 19 of auxiliary request 2, the opposition division defined the problem to be solved as the provision of containers for prostaglandin solutions which improve the stability of the solutions vis-à-vis any other container and concluded that the problem had not been solved over the whole scope of the claims, so that the requirements of Article 56 EPC were not met.

The subject-matter of auxiliary request 3 was based on claims 1 and 4-9 as well as the passages on page 4,

line 25 and page 7, lines 1-3 of the application as filed and therefore met the requirements of Article 123(2) EPC. Moreover, the invention defined therein was sufficiently disclosed, as the skilled person was able to provide polypropylene containers holding aqueous solutions comprising the active agent (5Z-(9R,11R,15R)-9-chloro-15-cyclohexyl-11,15-dihydroxy-3-oxa-16,17,18,19,20-pentanon-5-prostenoic acid isopropyl ester. The requirements of Article 54 EPC were also met, as document (1) did not disclose the active agent as defined in claim 1. Furthermore, the data provided in the contested patent showed that the selection of a propylene container enhanced stability of (5Z-(9R,11R, 15R)-9-chloro-15-cyclohexyl-11,15-dihydroxy-3-oxa-16,17,18,19,20-pentanon-5-prostenoic acid isopropyl ester as compared to polyethylene or glass containers. As a consequence, the requirements of Article 56 EPC were also met.

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

VII. With the statement of the grounds of appeal dated 28 September 2007, the appellant filed auxiliary requests 1 to 6. The independent claims of auxiliary requests 1 to 5 read as follows:

(i) Auxiliary request 1:

Claims 1 and 10 are identical to claims 1 and 10 as granted.

"19. A prostaglandin product comprising:

a) an aqueous prostaglandin composition comprising a therapeutically effective amount of at least one prostaglandin and a pharmaceutically acceptable surfactant; and

b) a polypropylene container; wherein the aqueous prostaglandin composition is packaged in the polypropylene container;

wherein the polypropylene container is a polypropylene bottle adapted for topical delivery and wherein the polypropylene is selected from the group consisting of isotactic polypropylene, syndiotactic polypropylene and blends of isotactic and syndiotactic polypropylene."

(ii) Auxiliary request 2:

"1. Use of a polypropylene container for increasing the stability of an aqueous prostaglandin composition which is packaged within the container and which comprises a prostaglandin and a pharmaceutically acceptable surfactant, wherein the polypropylene container is a polypropylene bottle adapted for topical delivery and wherein the polypropylene is selected from the group consisting of isotactic polypropylene, syndiotactic polypropylene and blends of isotactic and syndiotactic polypropylene.

9. A method of increasing the stability of an aqueous prostaglandin composition comprising a prostaglandin and a pharmaceutically acceptable surfactant wherein the method comprises: packaging the aqueous prostaglandin composition in a polypropylene container, wherein the polypropylene container is a polypropylene bottle adapted for topical delivery and wherein the polypropylene is selected from the group consisting of

isotactic polypropylene, syndiotactic polypropylene and blends of isotactic and syndiotactic polypropylene."

Claim 17 is identical to claim 19 of auxiliary request 1.

(iii) Auxiliary request 3:

"1. Use of a polypropylene container for increasing the stability of an aqueous prostaglandin composition prepared for topical administration to the eye, which is packaged within the container and which comprises a prostaglandin and a pharmaceutically acceptable surfactant, wherein the polypropylene container is a polypropylene bottle adapted for topical delivery and wherein the polypropylene is selected from the group consisting of isotactic polypropylene, syndiotactic polypropylene and blends of isotactic and syndiotactic polypropylene.

9. A method of increasing the stability of an aqueous prostaglandin composition comprising a prostaglandin and a pharmaceutically acceptable surfactant and which is prepared for topical administration to the eye, wherein the method comprises: packaging the aqueous prostaglandin composition in a polypropylene container, wherein the polypropylene container is a polypropylene bottle adapted for topical delivery and wherein the polypropylene is selected from the group consisting of isotactic polypropylene, syndiotactic polypropylene and blends of isotactic and syndiotactic polypropylene.

17. A prostaglandin product comprising:

a) an aqueous prostaglandin composition comprising a therapeutically effective amount of at least one prostaglandin and a pharmaceutically acceptable surfactant and which is prepared for topical administration to the eye; and
b) a polypropylene container; wherein the aqueous prostaglandin composition is packaged in the polypropylene container;
wherein the polypropylene container is a polypropylene bottle adapted for topical delivery and wherein the polypropylene is selected from the group consisting of isotactic polypropylene, syndiotactic polypropylene and blends of isotactic and syndiotactic polypropylene."

(iv) Auxiliary request 4:

Claims 1 and 9 are identical to claims 1 and 9 of auxiliary request 3 except for the addition of the following feature at the end of each claim: "and wherein the composition is more stable than that packaged in polyethylene containers".

Claim 17 is identical to claim 17 of auxiliary request 3.

(v) Auxiliary request 5:

The sole independent claim 1 is identical to claim 17 of auxiliary request 3.

VIII. With a letter dated 20 November 2009, a third-party observation was filed under Article 115 EPC.

IX. With a letter dated 19 April 2011, the appellant filed auxiliary requests 6 and 7. Auxiliary request 7 corresponds to former auxiliary request 3, which the opposition division had found to meet the requirements of the EPC. The sole independent claims 1 of auxiliary requests 6 and 7 read as follows:

(i) Auxiliary request 6:

"1. A prostaglandin product comprising:

- a) an aqueous prostaglandin composition comprising a therapeutically effective amount of at least one prostaglandin and a pharmaceutically acceptable surfactant; and
- b) a polypropylene container; wherein the aqueous prostaglandin composition is packaged in the polypropylene container, wherein the prostaglandin is selected from the group consisting of (5Z)-(9R,11R,15R)-9-chloro-15-cyclohexyl-11,15-dihydroxy-3-oxa-16,17,18,19,20-pentanoic acid isopropyl ester; latanoprost (PhX A41); and fluprostenol isopropyl ester."

(ii) Auxiliary request 7:

"1. A prostaglandin product comprising:

- a) an aqueous prostaglandin composition comprising a therapeutically effective amount of at least one prostaglandin and a pharmaceutically acceptable surfactant; and
- b) a polypropylene container; wherein the aqueous prostaglandin composition is packaged in the polypropylene container, wherein the prostaglandin is (5Z)-(9R,11R,15R)-9-chloro-15-cyclohexyl-11,15-

dihydroxy-3-oxa-16,17,18,19,20-pentanor-5-prostenoic acid isopropyl ester."

X. Oral proceedings were held before the board on 19 May 2011.

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

In connection with the admissibility of document (26), the appellant argued that the respondent had not given any convincing reason for the late filing. As a consequence, document (26) should not be admitted.

As regards the admissibility of auxiliary request 6, the appellant pointed out that claim 1 was restricted to those three specific active agents for which comparative tests had been performed. Auxiliary request 6 was submitted in case the board concluded that the beneficial effect of the polypropylene containers on drug stability was not credible for prostaglandins in general. The appellant had not wanted to submit auxiliary request 6 until the above-mentioned comparative tests had been supplemented by data comparing drug stability after 12 weeks at 65°C. As a consequence, it had not been possible to file auxiliary request 6 with the statement of the grounds of appeal, as these data had not yet been available then.

Regarding novelty of the main request, the appellant held that the subject-matter of claim 19 was not directed to any product in any container, but was restricted to a type of product that could be commercialised and was suitable for administration to a patient. This was not the case with the product

according to document (1), where an aqueous prostaglandin solution was kept in a polypropylene microcentrifuge tube.

In connection with inventive step of the subject-matter according to claim 19 of auxiliary request 1, the appellant held that the commercial product Xalatan^R mentioned in paragraph [0008] of the contested patent constituted the closest prior art rather than document (2), which did not disclose any container material. Xalatan^R concerned an aqueous solution of latanoprost which was stored in a polyethylene container. The problem to be solved with regard to this prior art could be defined as the provision of a composition comprising an aqueous prostaglandin solution stored in a container providing improved stability as compared to polyethylene containers. The appellant had provided sufficient evidence to show that the problem defined above was indeed solved. Regarding the argument that the problem defined above had not been solved in view of the fact that the claimed subject-matter comprised prostaglandin solutions stabilised by ethanol where an additional stabilising effect of the container material was not detectable, he held that the tests provided by the respondent with a letter dated 22 February 2007 were not meaningful, as the experimental conditions had not been chosen *lege artis*. It was well known that there were several ways of stabilising aqueous prostaglandin solutions, including the addition of stabilisers such as surfactants or ethanol or physical means such as lowering the temperature. The appellant had shown an additional way of stabilising aqueous prostaglandin solutions by storing them in a polypropylene container. This stabilising effect was

always there, even if supplementary stabilising measures such as addition of ethanol were applied. There, the stabilising effect of ethanol was so strong that the additional stabilisation of the container material was no longer detectable. Similar results would have been obtained by storing the samples at very low temperatures. Test conditions had to be chosen in such a way that a meaningful comparison could be made, which was not the case with the tests mentioned above. The same reasoning applied if document (2) instead of Xalatan^R was defined as closest prior art. Regarding the product claims of auxiliary requests 2-5, the appellant held that the amendments introduced therein had been made in connection with potential novelty objections.

XII. The respondent's arguments can be summarised as follows:

In connection with the admissibility of document (26), the respondent said that he had only become aware of this document when it was cited in parallel proceedings in Japan. As document (26) was pertinent and as the appellant had had sufficient time to study it, it should be admitted.

As regards the admissibility of auxiliary request 6, the appellant had not given any convincing reason for its late filing. Auxiliary request 6 should therefore not be admitted.

Regarding novelty of claim 19 of the main request, it was the wording of the claim and not the intended use which was important. Claim 19 of the main request lacked novelty as the compositions disclosed in document (1) comprised all features claimed therein.

In connection with inventive step the respondent contested that the appellant had demonstrated an enhanced stability of aqueous prostaglandin solutions stored in polypropylene containers as compared to the same solutions stored in polyethylene containers. Either there was no improvement at all, as was shown by the tests filed by the respondent with the letter of 22 February 2007, or the improvement in terms of stability was within the margin of error. As a consequence, the invention merely consisted in the provision of an alternative container for aqueous prostaglandin solutions. The selection of a polypropylene container was, however, obvious in the light of document (26) which stated that syndiotactic polypropylene was a good material for packaging eye drops.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims as granted (main request) or, alternatively, on the basis of one of auxiliary requests 1 to 5, all filed with the statement of grounds of appeal dated 28 September 2007, or, alternatively, of auxiliary request 6 filed with a letter dated 19 April 2011, or, as auxiliary request 7, that the appeal be dismissed.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Admission of late-filed evidence and requests

2.1 Auxiliary request 6

This request was filed with a letter dated 19 April 2011, i.e. at a late stage of the appeal proceedings. The admissibility of this request is therefore at the board's discretion and depends upon the overall circumstances of the case (see Article 13(1) RPBA). Although the reasons given by the appellant for the late filing were doubtful and the board considers that it would have been possible to file auxiliary request 6 with the statement of the grounds of appeal, the amendments were of a simple and predictable nature, as the list of active agents was restricted to the three most preferred prostaglandins. The respondent was therefore not surprised by the amendments. Moreover, auxiliary request 6 did not raise new issues that would have delayed the board's decision and could be easily dealt with by the board at the oral proceedings. As a consequence, the board decided to admit auxiliary request 6 into the proceedings (Article 13(1) RPBA).

2.2 Document (26)

Document (26) was filed with a letter dated 8 February 2010, i.e. after the reply to the statement of the grounds of appeal (see Article 13(1) RPBA). It was submitted in order to substantiate that polypropylene was a preferred material for eye-drop containers. Since it was filed more than one year before the oral proceedings, the appellant had sufficient time to

familiarise himself with its content. The board therefore decided to admit document (26) into the proceedings (Article 13(1) RPBA).

3. Main request - novelty of claim 19

Claim 19 relates to a prostaglandin product comprising an aqueous prostaglandin composition comprising a therapeutically effective amount of at least one prostaglandin, wherein said aqueous composition is packaged in a polypropylene container.

Document (1) (see page 24, lines 24-35) discloses an initial stock solution comprising PGA_2 which is stored in transparent polypropylene microcentrifuge tubes. According to the passage on page 24, lines 24-26, the preparation of these stock solutions is disclosed in the "First Series of Experiments", which includes the preparation of an ophthalmic vehicle solution comprising 0.5% polysorbate 80 (surfactant) and 0.01% benzalkonium chloride in normal saline, to which 10 μL of a prostaglandin such as PGA_2 is added (see page 17, lines 13-23). It is noted that the term "normal saline" indicates that the ophthalmic vehicle solution is aqueous. As regards the functional term "therapeutically effective amount", the board notes that the product claimed in claim 19 as granted is not limited to any particular treatment, so that any amount of active agent capable of achieving a pharmacological effect is therapeutically effective. As a consequence, the PGA_2 compositions according to document (1) comprise all the features defined in part a) of claim 19. In addition, the feature "wherein the aqueous prostaglandin composition is packaged in the

polypropylene container" cannot establish novelty either, as the polypropylene microtubes according to document (1) constitute specific embodiments of the more general term "polypropylene container" and as the terms "packaged in" (claim 19) and "stored in" (document (1)) have an identical meaning in the sense of "contained in". As a consequence, the subject-matter of claim 19 of the main request lacks novelty over document (1). The requirements of Article 54 EPC are therefore not met.

4. Auxiliary request 1 - claim 19

4.1 Formal aspects

Claim 19 of auxiliary request 1 is based on claims 1 and 6 as originally filed and therefore allowable under Article 123(2) EPC. In view of the fact that the container material is now limited to specific types of polypropylene, the requirements of Article 123(3) EPC are also met.

4.2 Novelty

Claim 19 of auxiliary request 1 specifies that the polypropylene container is a polypropylene bottle adapted for topical delivery and that the polypropylene is selected from the group consisting of isotactic polypropylene, syndiotactic polypropylene and blends of isotactic and syndiotactic polypropylene. The subject-matter claimed therein is therefore novel over the PGA_2 solutions stored in transparent polypropylene microcentrifuge tubes according to document (1) (see

point 3, second paragraph above). The requirements of Article 54 EPC are therefore met.

4.3 Inventive step

4.3.1 The subject-matter of the present invention concerns stable aqueous compositions comprising a prostaglandin and a pharmaceutically acceptable surfactant such as polyethoxylated castor oil. The aqueous prostaglandin compositions, which are preferably used for topical application to the eye, are packaged in polypropylene containers (see paragraphs [0009] and [0018] and claims 1 and 4 of the contested patent).

4.3.2 Document (2), which constitutes the closest prior art, is also concerned with stable aqueous prostaglandin compositions for topical application to the eye and which are stabilised by addition of a polyethoxylated castor oil (see column 1, lines 5-8 and column 6, lines 42-43). The active agents (see column 4, line 11 to column 5, line 62) are identical to the prostaglandins specifically disclosed in the contested patent (see page 3, line 25 to page 4, line 26). The sole example of document (2) (see column 7) describes the preparation of such a solution, which is then sterile-filtered into sterile containers, which are then aseptically plugged, capped and labelled. Document (2) does not disclose the use of polypropylene as container material.

4.3.3 For defining the technical problem vis-à-vis document (2), and in particular for determining whether or not the subject-matter as defined in present claim 19 constitutes an improvement, the following

point has to be taken into consideration: if comparative tests are chosen to demonstrate an inventive step on the basis of an improved effect, said effect must be detectable for the entire scope of the claims. In the present case, several comparative tests were submitted, including experiments submitted by the respondent (then opponent) with a letter dated 22 February 2007. In this series of experiments, formulations 1-2 and 4-5 in the form of aqueous solutions comprising among others a prostaglandin (0.012% travoprost in formulations 1-2 or 0.012% latanoprost in formulations 4-5), 0.5% (formulations 1 and 4) or 1.5% (formulations 2 and 5) HCO-40 (polyoxyl 40 hydrogenated castor oil) and 1.27% of ethanol were packaged in either aluminium-encased polyethylene bottles or in aluminium-encased polypropylene bottles, which were then stored at 65°C for four weeks. No significant difference as regards stability could be detected (see the tables in appendix III of said letter dated 22 February 2007). These results were confirmed by further tests submitted by the appellant with the statement of the grounds of appeal dated 28 September 2007 in which the solution according to formulation 4 as defined above and a further solution identical to formulation 4 except for a lower latanoprost content of 0.001% were packaged either in clear glass ampoules or in aluminium-encased polyethylene containers and stored at 65°C for up to eight weeks (see table 3 at page 17 of the statement of the grounds of appeal). Analysis of the samples after four and eight weeks revealed no significant degradation of latanoprost packaged in the aluminium-encased polyethylene containers (see the paragraph bridging pages 17 and 18 of the statement of the grounds of appeal. It follows therefrom that the

appellant did not show any improved stability for ethanol containing prostaglandin solutions packaged in polypropylene containers, which are encompassed by the subject-matter according to present claim 19. In this context, it is noted that addition of small amounts of ethanol for stabilising aqueous ophthalmic solutions constitutes a step the skilled person would consider if stability is a problem, as was confirmed by the appellant at the oral proceedings before the board. As a consequence, the selection of compositions used in the comparative tests submitted by the respondent with a letter dated 22 February 2007 was not useless as alleged by the appellant (see last sentence of the paragraph bridging pages 17 and 18 of the statement of the grounds of appeal) but meaningful and adequate.

4.3.4 In the absence of any evidence for an improvement vis-à-vis the closest state of the art, the problem underlying the present invention can be seen as the provision of a further composition comprising an aqueous prostaglandin solution. The solution to this problem proposed by the subject-matter of claim 19 concerns a composition where the aqueous solution is packaged in a polypropylene container, wherein the polypropylene is selected from the group consisting of isotactic polypropylene, syndiotactic polypropylene and blends thereof. In view of the examples figuring in the contested patent, the board is convinced that the above problem was plausibly solved.

4.3.5 The skilled person, starting from the teaching of document (2) and trying to find a suitable container material, knows from document (26) that syndiotactic polypropylene is a useful polymer for eye-drop

containers (see last sentence of paragraph [0023] and paragraph [0024]). As a consequence, the selection of such containers is obvious for the skilled person. The requirements of Article 56 EPC are not met.

4.3.6 Additional arguments of the patentee

4.3.6.1 Xalatan^R rather than document (2) constitutes the closest prior art

Xalatan^R is an ophthalmological product comprising a latanoprost solution stored in a polyethylene container. The board is of the opinion that Xalatan^R is less pertinent than document (2) in view of the fact that it does not disclose the 32 prostaglandins specifically mentioned in the contested patent (see paragraph [0016]) but is limited to latanoprost. However, even if Xalatan^R were taken as closest prior art, the conclusions drawn from the comparative tests of 22 February 2007 in connection with formulations 1-2 and 4-5 would also apply (see point 4.3.3 above). As a consequence, the replacement of the polyethylene container of Xalatan^R by a polypropylene container would also be devoid of a non-obvious effect and the subject-matter of claim 19 would lack inventive step for the same reasons as given in point 4.3 above.

4.3.6.2 The appellant further argued that if ethanol containing prostaglandin solutions were stored in polypropylene containers, the stabilising effect of polypropylene was superseded by the stabilising activity of ethanol and therefore not detectable. However, the effect was still there.

The board cannot follow this argumentation. The comparative tests discussed in point 4.3.3 show that no stabilising effect could be detected for formulations 1-2 and 4-5. The board concludes therefrom that for these formulations, which constitute embodiments of the invention as claimed, the selection of polypropylene as container material is devoid of any technical effect and therefore obvious for the reasons outlined in paragraphs 4.3.3 to 4.3.5.

5. Auxiliary request 2

Claim 17 of auxiliary request 2 is identical to claim 19 of auxiliary request 1. As a consequence, the reasoning of point 4.3 applies also to the subject-matter of claim 17 of auxiliary request 2. The requirements of Article 56 EPC are therefore not met.

6. Auxiliary request 3

Claim 17 of auxiliary request 3 is identical to claim 19 of auxiliary request 1, except that it further indicates that the aqueous prostaglandin solution is prepared for topical administration to the eye. However, in view of the fact that the compositions of document (2) are also used for topical application to the eye (see point 4.3.2 above), the reasoning of point 4.3 applies *mutatis mutandis* to claim 17 of auxiliary request 3. The requirements of Article 56 are therefore not met.

7. Auxiliary requests 4 and 5

Claim 17 of auxiliary request 4 and claim 1 of auxiliary request 5 are identical to claim 17 of auxiliary request 3. As a consequence, the reasoning of point 6 above applies also to these claims. The subject-matter of claim 17 of auxiliary request 4 and of claim 1 of auxiliary request 5 therefore does not meet the requirements of Article 56 EPC either.

8. Auxiliary request 6

As compared to claim 19 of auxiliary request 1, the aqueous prostaglandin compositions according to claim 1 of auxiliary request 6 are now restricted to the three specific prostaglandins (5Z)-(9R,11R,15R)-9-chloro-15-cyclohexyl-11,15-dihydroxy-3-oxa-16,17,18,19,20-pentanoic acid isopropyl ester, latanoprost and fluprostenol isopropyl ester. Moreover, the container material is no longer limited to polypropylene bottles made of isotactic or syndiotactic polypropylene or blends thereof but relates to polypropylene containers in general.

In view of the fact that the active agents specifically disclosed in document (2) include the three compounds of claim 1 of auxiliary request 6 (see compounds 2, 24 and 32 of the list of compounds in column 4, line 11 to column 5, line 62) and that compound 2 is used in the sole example of document (2), the reasoning of point 4.3 above applies *mutatis mutandis* to claim 1 of auxiliary request 6. As a consequence, the requirements of Article 56 EPC are not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Counillon

U. Oswald