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Datasheet for the decision of 25 February 2025

Case Number: T 2275/22 - 3.3.07

Application Number: 17000440.2

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Language of the proceedings: EN

Title of invention:
METHOD AND COMPOSITION FOR TREATING OCULAR HYPERTENSION AND GLAUCOMA

Patent Proprietor:
Santen Pharmaceutical Co., Ltd.
AGC Inc.

Opponent:
Cooke, Richard

Headword:
Glaucoma II/SANTEN

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - obvious modification

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 2275/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 25 February 2025

Appellant: (Patent Proprietor 1)	Santen Pharmaceutical Co., Ltd. 9-19, Shimoshinjo 3-chome Higashiyodogawa-ku Osaka-shi Osaka 533-8651 (JP)
Appellant: (Patent Proprietor 2)	AGC Inc. 5-1, Marunouchi 1-chome, Chiyoda-ku Tokyo 100-8405 (JP)
Representative:	Müller-Boré & Partner Patentanwälte PartG mbB Friedenheimer Brücke 21 80639 München (DE)
Appellant: (Opponent)	Cooke, Richard Elkington and Fife LLP Patents Department 3-4 Holborn Circus London EC1N 2HA (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 August 2022 concerning maintenance of the European Patent No. 3205334 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	A. Jimenez

Summary of Facts and Submissions

I. European patent 3 205 334 ("the patent"), which resulted from a divisional application with respect to the earlier ("parent") application EP14001862.3 published as EP 2772 249 A1, was granted on the basis of sixteen claims.

Claim 1 as granted defined an ophthalmic aqueous solution consisting of 0.0015% w/v tafluprost , 0.075% w/v polysorbate 80, 0.05% w/v disodium edetate, 2.25% w/v glycerol, 0.2% w/v sodium dihydrogen phosphate dihydrate, water and pH adjusters as excipients, in a container consisting essentially of polyethylene. Claim 6 as granted defined such solution in a single or unit dose container consisting essentially of low density polyethylene (LDPE) wherein the pH adjuster is sodium hydroxide and/or hydrochloric acid.

II. The patent was opposed on the grounds that its subject-matter lacked an inventive step and that the patent comprised subject-matter extending beyond the content of the applications as originally filed.

The patent proprietors and the opponent filed appeals against the decision of the opposition division that the patent as amended in accordance with the patent proprietor's auxiliary request 5 filed during the oral proceedings of 29 April 2022 met the requirements of the EPC.

The decision under appeal was based on the claims as granted (main request), auxiliary requests 1 and 3-4 as filed on 23 June 2021, auxiliary request 2 as filed on

23 February 2022 and the mentioned auxiliary request 5 of 29 April 2022.

Claim 1 of auxiliary request 4 defined:

"An ophthalmic aqueous solution consisting of 0.0015% w/v tafluprost as an active ingredient, 0.075% w/v polysorbate 80, 0.05% w/v disodium edetate, 2.25% w/v glycerol, 0.2% w/v sodium dihydrogen phosphate dihydrate, water and pH adjusters as excipients in a unit dose container consisting essentially of low density polyethylene, wherein the pH adjuster is sodium hydroxide and/or hydrochloric acid, wherein 0.3 mL of the ophthalmic aqueous solution is filled in the body part of the unit dose container and inner volume of the unit dose container is 1 mL, and wherein the ophthalmic aqueous solution has a pH of from 5.0 to 6.7."

Claim 1 of auxiliary request 5 included all the features of claim 1 of auxiliary request 4 and additionally defined the following feature:

"the container being packaged into paper-coated aluminium-polyethylene foil."

In its decision the opposition division cited *inter alia* the following documents:

D1: EP 1 321 144 A
D13: Timoptic ® Data Sheet, 2005
D16: Guideline on the categorisation of extension applications (EA) versus variations applications (V), October 2003, European Commission

The opposition division came to the following conclusions:

(a) The main request and auxiliary requests 1-4 did not comply with the requirement of Article 76(1) EPC.

(b) Auxiliary request 5 complied with Article 76(1) EPC.

Document D1, in particular the composition of formulation 5 in paragraph [0031], represented the closest prior art. The differences with this prior art concerned the definition of the particular amounts of tafluprost (1) and polysorbate 80 (2), the disodium EDTA (3), the glycerol (4), the sodium dihydrogen phosphate dihydrate (5), the water (6) and the pH adjusters (7), the polyethylene of the container (8), the volume of 0.3 mL for the solution (9), the unit dose container (10), the inner volume of 1ml of the container (11), the pH from 5.0-6.7 (12) and the packaging into paper coated aluminium-polyethylene foil (13).

The features defining the composition of the solution were not to be considered separately from the features defining the container, because the container material and its packaging affected the composition of the solution.

The effect of a reduction of tafluprost adhesion by the 1.5 times higher concentration of polysorbate 80 demonstrated in Figures 2 and 3 of the patent was already suggested in document D1. The post-published experimental results submitted with proprietors' letter of 23 February 2022 did not demonstrate that the higher concentration of

polysorbate 80 defined for the claimed composition was associated with any beneficial effect regarding the bioavailability of tafluprost in view of the lower resulting tafluprost concentrations and the margin of error reported therein. The objective technical problem therefore concerned the provision of an alternative ophthalmic composition comprising tafluprost.

The claimed subject-matter was not obvious as solution, because

- document D1 taught away from using the polyethylene material,

- the opponent had not substantiated why the defined foil was obvious

- the skilled person had to undertake numerous modifications, whereas in the field of pharmaceutical compositions the relevant features had to be carefully selected.

III. The patent proprietors filed with the statement of grounds of appeal a new main request and auxiliary requests 1-4, which corresponded to auxiliary requests 1-5 on which the decision under appeal was based.

IV. The opponent filed with the statement of grounds of appeal the following documents:

A21: EP 2 123 278 A1
A22: Extract from Handbook of Pharmaceutical Excipients, 5th edition, pages 696-698, Sodium Phosphate, Monobasic

A23: Paper and Paperboard Packaging Technology, 2005, pages 21-26 and 106-107

V. With their reply to the opponent's appeal the patent proprietors presented in addition to the experimental results relied upon before the opposition division further results from comparative experiments regarding the bioavailability of tafluprost from the claimed composition.

With their reply the patent proprietors also filed the following document:

A24: Paper and Paperboard Packaging Technology, 2005, pages 101-106.

VI. The Board expressed in a communication pursuant to Article 15(1) RPBA *inter alia* the preliminary opinion that the subject-matter defined according to the main request and auxiliary requests 1-4 did not involve an inventive step.

VII. Oral proceedings were held on 25 February 2025.

During the oral proceedings the patent proprietors withdrew the main request and auxiliary requests 1-2 as filed with the statement of grounds of appeal. The remaining requests were the auxiliary requests 3 and 4 filed with their statement of grounds of appeal, which correspond to auxiliary requests 4 and 5 on which the decision under appeal was based with independent claims as presented herein in section II above.

VIII. The arguments of the patent proprietors relevant to the present decision are summarized as follows:

The crucial distinguishing features of the subject-matter of claim 1 of the main request with the composition of Table 7 in document D1 representing the closest prior art concerned:

(i) the lower concentration of the tafluprost, namely 0.0015% instead of 0.005%

(ii) the higher concentration of the polysorbate 80, namely 0.075% instead of 0.05%

(iii) the formulation of a unit dose of 0.3 mL of the solution in a container having an inner volume of 1.0 ml

(iv) the nature of the material of the container, namely low density polyethylene (LDPE).

The formulation of an ophthalmic solution in a unit dose container allowed for dispensing with a preservative. However, the formulation in a resinous unit dose container resulted in a relatively low amount of tafluprost agent being exposed to a relatively large contact area for the problematic absorption of the tafluprost, in particular in case of the low concentration of the tafluprost as defined in claim 1 of the main request. As demonstrated in Figure 3 of the patent the specific increase of the polysorbate 80 concentration as defined in claim 1 of the main request optimally prevented the absorption of

tafluprost to the surface of the LDPE container. As indicated by Figure 4 of the patent and as further substantiated by the additional experimental results reported in the patent proprietors' letter of 23 February 2022 and their reply to the opponent's appeal the defined polysorbate 80 concentration still maintained a satisfactory bioavailability of the tafluprost, which is normally compromised at higher polysorbate 80 concentrations. The objective technical problem should therefore be formulated as the provision of an ophthalmic aqueous solution comprising tafluprost, wherein the absorption of tafluprost to the container walls is prevented and at the same time the bioavailability of tafluprost is maintained.

Document D1 itself provided no suggestion towards the claimed subject-matter as solution to this problem, which involved the change from a 10-fold to a 50-fold excess of the polysorbate 80 over the tafluprost in comparison with the composition of Table 7 in document D1. Document D1 recommended a 10-fold excess of the surfactant to promote and assure the water-solubility of the prostaglandin, but also indicated in Figure 1 that at a tafluprost concentration as low as 0.0015% no polysorbate is actually required to solubilize the tafluprost. Document D1 furthermore failed to recognize any issue regarding the polysorbate 80 concentration in relation to the bioavailability. No other prior art suggested the effects of the defined polysorbate 80 concentration on the absorption of tafluprost by resinous containers and the bioavailability of tafluprost. Moreover, no prior art described the formulation of tafluprost in a unit dose container.

The higher absorption of tafluprost in a polyethylene container than in a polypropylene container reported in document D1 even dissuaded the skilled person from the use of a container consisting essentially of LDPE for the unit dose container with the small volume as defined in claim 1 of the main request, in which relatively low amount of tafluprost is exposed to a relatively large contact area for absorption.

In line with the considerations in the decision under appeal it would furthermore not be obvious for the skilled person to carry out the totality of modifications as defined in claim 1 of the main request and claim 1 of auxiliary request 1.

IX. The arguments of the opponent relevant to the present decision are summarized as follows:

Starting from the composition of Table 7 of document D1 the objective technical problem could be formulated as the provision of a formulation for the convenient administration of tafluprost which is free of preservatives and combines a reduced absorption of tafluprost by the container with adequate bioavailability for an effective low dose of tafluprost.

The tafluprost concentration of 0.0015% and a polysorbate concentration of 0.075% as defined in claim 1 of the main request were in line with the teaching of document D1 that the prostaglandin concentration may range from 0.00005% to 0.05% and that the concentration of the nonionic surfactant is preferably 10 or more times higher, but usually less than 0.5% to avoid adverse effects. The

skilled person would have expected a reduced absorption of tafluprost from a solution with a polysorbate 80 concentration of 0.075% as compared to 0.05% in a LDPE container as demonstrated in Figure 3 of the patent following the teaching in document D1 that nonionic surfactants such as polysorbate 80 reduce the absorption of prostaglandin derivatives such as tafluprost to containers made of a resinous material such as polyethylene. As evidenced by documents D13 and D16 it was common general knowledge that ophthalmic solutions may be conveniently formulated in LDPE unit dose containers. It would in view of the prevention of the tafluprost absorption by polysorbate 80 as described in document D1 therefore be obvious for the skilled person to also formulate solutions of tafluprost with polysorbate 80 in LDPE unit dose containers as defined in claim 1 of the main request.

The information in Figure 1 of document D1 regarding the increased solubility of tafluprost depending on the polysorbate 80 concentration did not affect the skilled person's considerations concerning the prevention of the absorption of tafluprost to the resinous containers by polysorbate 80.

Document D1 mentioned polyethylene as one of the preferred container materials and reported its only marginally lower performance in terms of absorption compared to polypropylene. Document D1 would therefore not dissuade the skilled person from the use of a container made of LDPE as defined in claim 1 of the main request.

The reduction in the bioavailability of tafluprost when the polysorbate 80 concentration is increased from 0.05% to 0.2% as indicated in Figure 4 of the patent or from 0.05% to 0.075% as indicated by the additional experimental results subsequently presented by the patent proprietors did not represent an unexpected beneficial effect over the prior art that could support an inventive step for the claimed subject-matter.

The definition of the 2.25% w/v of glycerol, the 0.2% w/v of sodium dihydrogen phosphate dihydrate, the pH adjusters sodium hydroxide and/or hydrochloric acid, the pH of 5.0-6.7 and the packaging into paper-coated aluminium-polyethylene foil represented, as for instance evidenced by documents A21-A23, conventional features for ophthalmic compositions and did therefore not contribute to any inventive step of the subject-matter of claim 1 of the main request and claim 1 of auxiliary request 1.

X. The patent proprietors requested that the decision under appeal be set aside and that the patent be maintained on the basis of their new main request filed as auxiliary request 3 with their statement of grounds of appeal or on the basis of auxiliary request 1 filed as auxiliary request 4 with their statement of grounds of appeal. These requests correspond to auxiliary requests 4 and 5 on which the decision under appeal was based.

XI. The opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

Reasons for the Decision

1. Main request, inventive step

1.1 Closest prior art

Document D1 describes the use of nonionic surfactants to enhance the solubility of prostaglandin derivatives and to inhibit the absorption of the prostaglandin derivatives by containers made of a resinous material (see D1, paragraph [0004]). In this context document D1 presents a stability test for an example of an ophthalmic solution (see D1, paragraphs [0031] to [0032]), which comprises 0.005 tafluprost, 0.05% polysorbate 80 and 0.05% EDTA salt (see Table 7) filled in a container made of polypropylene.

It was not in dispute that the composition of Table 7 of document D1 represented the closest prior art and that the subject-matter of claim 1 of the main request differed from that composition in

- the lower amount of tafluprost, namely 0.0015% w/v instead of 0.005%
- the higher amount of polysorbate, namely 0.075% w/v instead of 0.05%
- the presence of 2.25% w/v of glycerol
- the presence of 0.2% w/v of sodium dihydrogen phosphate dihydrate
- the presence of the pH adjusters sodium hydroxide and/or hydrochloric acid,
- the pH of 5.0-6.7
- the unit dose container having an inner volume of 1 mL and filled with 0.3 mL of the solution

- the container consisting essentially of low density polyethylene (LDPE) instead of polypropylene

It was also common ground that in as far as the definition of 0.05% w/v disodium edetate in claim 1 of the main request instead of the 0.05% w/w disodium EDTA disclosed in document D1 represented a difference, this difference was of no relevance in the assessment of inventive step.

1.2 Objective technical problem

The patent presents in Example 1 (see paragraphs [0033] to [0034]) an experiment involving the storage of unit doses of 0.3 mL of solutions comprising 0.0015% tafluprost in combination with 0.05%, 0.075% or 0.1% polysorbate 80 in an approximately 1 mL LDPE container. The results after 20 weeks storage at 40°C (see Figure 3) indicate for the solutions with 0.075% and 0.1% polysorbate 80 a reduced absorption of the tafluprost (ca. 88% remaining) compared to the solution with 0.05% polysorbate 80 (ca. 82% remaining).

The patent further provides experimental results demonstrating the reduced bioavailability of tafluprost from a solution comprising 0.0015% tafluprost in the presence of polysorbate 80 at a concentration of 0.2% as compared to 0.05% (see Example 2, paragraphs [0035] to [0039] and Figure 4). Moreover, the additional experimental results presented by the patent proprietors in their letter of 23 February 2022 and their reply to the opponent's appeal indicate that the bioavailability of tafluprost is also reduced at a polysorbate concentration of 0.075%, but to a lesser extent than at 0.2%.

Taking account of the nature of the distinguishing features of the claimed subject-matter and in view of the experimental results on file the Board formulates the objective technical problem as the provision of a convenient formulation for the administration of tafluprost which is free of preservatives and combines reduced absorption of tafluprost by the container with adequate bioavailability for an effective low dose of tafluprost.

1.3 Assessment of the solution

1.3.1 As evidenced by document D16 (see pages 3 and 9) and exemplified by document D13 (see page 1, under "DESCRIPTION" and page 7 under "HOW SUPPLIED") unit dose formulations, including formulations in containers of LDPE containing 0.2 mL of solution and wrapped in a foil laminate, were well known in the field of ophthalmic solutions. Such unit dose formulations represent as a matter of course convenient administration forms which may dispense with preservatives typically present in formulations intended for multiple administration. Faced with the objective technical problem identified in section 1.2 above the skilled person would therefore as a matter of obviousness consider the possibility of adapting the composition of Table 7 in document D1 to a unit dose formulation in a LDPE container as defined in claim 1 of the main request.

1.3.2 Document D1 teaches explicitly that nonionic surfactants such as preferably polysorbate 80 (see D1, paragraph [0010]) inhibit the absorption of prostaglandin derivatives such as tafluprost (see D1, paragraph [0024]) by containers made of resinous material such as preferably polypropylene and

polyethylene of the high or low density type (see D1, paragraph [0014]). In this context document D1 presents results of a stability test showing after six months storage at 40°C a remaining concentration of tafluprost of 72% in a polyethylene container and of 83% in a polypropylene container (see D1, paragraphs [0025] to [0026], Tables 1-2). In view of the effective absorption inhibition by polysorbate 80 described in document D1 the skilled person would not be discouraged from adapting the composition of Table 7 in document D1 to a unit dose formulation as defined in claim 1 of the main request by the less favourable surface to volume ratio of such unit dose formulations. Moreover, in view of the recommendation in document D1 that polyethylene represents a suitable and preferred container material, the skilled person would not be dissuaded from using polyethylene as a container material for such a unit dose formulation by the reported marginally higher tafluprost absorption in a polyethylene container than in a polypropylene container. Faced with the identified objective technical problem the skilled person would therefore consider it an obvious solution to adapt the composition of Table 7 in document D1 by formulating it in a unit dose container made of LDPE as defined in the claim 1 of the main request.

1.3.3 Document D1 describes for the concentration of the prostaglandins in general a range of 0.00005 to 0.05% (see D1, paragraph [0015]). In this context document D1 describes in addition to the composition of Table 7 comprising 0.005% tafluprost also an example of the intended compositions comprising only 0.001% tafluprost, be it without the EDTA (see D1, paragraph [0025], Table 1). Accordingly, the tafluprost concentration of 0.0015% as defined in claim 1 of the main request falls well within the teaching regarding

suitable concentrations for tafluprost as described in document D1.

In adapting the composition of Table 7 of document D1 by formulating it in a unit dose container the skilled person would therefore consider the reduced concentration of the tafluprost as defined in claim 1 of the main request an obvious modification.

1.3.4 As argued by the opponent with reference to documents A21 and A22 the 2.25% w/v of glycerol, the 0.2% w/v of sodium dihydrogen phosphate dihydrate, the pH adjusters sodium hydroxide and/or hydrochloric acid and the pH of 5.0-6.7 as defined in claim 1 of the main request represent conventional features in ophthalmic solutions. The patent proprietors did not rely on any specific advantage associated with these features or contest the conventional nature of thereof.

In adapting the composition of Table 7 of document D1 by formulating it in a unit dose container the skilled person would therefore consider the incorporation of these features as defined in claim 1 of the main request obvious as a matter of practical implementation.

1.3.5 Document D1 describes for the nonionic surfactant a concentration of preferably ten or more times the concentration of the prostaglandin derivative, which should in view of the potential for adverse effects from the nonionic surfactant normally not exceed 0.5% (see D1, paragraph [0016]). The increased polysorbate 80 concentration of 0.075% defined in claim 1 of the main request amounts to fifty times the tafluprost concentration and thereby still corresponds to a

concentration of the nonionic surfactant in the range indicated as preferred in document D1.

Taking account of the purpose of the presence of the nonionic surfactant as described in document D1, in particular the inhibition of the absorption of the prostaglandin derivative by the resinous container, it therefore required no more than routine experimentation to verify that an increased polysorbate 80 concentration of 0.075% further reduces the absorption of tafluprost when adapting the composition of Table 7 of document D1 for a unit dose formulation.

1.3.6 The patent proprietors argued that according to Figure 1 of document D1 tafluprost is already soluble up to a concentration of 0.02% without the presence of a nonionic surfactant. According to the appellants the skilled person would therefore not expect any further effect from an increase in the concentration of the polysorbate 80 when the concentration of the tafluprost is reduced to a level of 0.0015 as defined in claim 1 of the main request.

However, Figure 1 of document D1 concerns the effect of the nonionic surfactant on the solubility of the prostaglandin derivative and not the effect on the absorption of the tafluprost by the container. The effect of the nonionic surfactant on the absorption of the prostaglandin derivative is instead demonstrated in document D1 in Table 2 in relation to a composition comprising 0.001% tafluprost (see D1, paragraphs [0025] to [0026]). As explained in section 1.3.4 it required in view of this known effect of polysorbate 80 from document D1 no more than routine experimentation to verify the reduction of the absorption of tafluprost by

the increased polysorbate 80 concentration of 0.075% as defined in the claim of the remaining request.

Accordingly, the patent proprietors' argument based on the solubility data from Figure 1 of document D1 is not considered convincing.

1.3.7 The patent proprietors further argued that the patent showed with the experimental results in Figure 4 involving solutions comprising 0.05% and 0.2% polysorbate 80 that the skilled person would be confronted with a reduced bioavailability of the tafluprost associated with an increase in the polysorbate 80 concentration. According to the appellants the skilled person could not have expected that, as demonstrated by the additional experimental results presented in the letter of 23 February 2022 and the reply to the opponent's appeal, the polysorbate 80 concentration to 0.075% representing an excess of fifty times with respect to tafluprost still preserved an adequate biovailability.

As explained in sections 1.3.4 and 1.3.6 above it required in view of document D1 no more than routine experimentation to verify that an increased polysorbate 80 concentration of 0.075% further reduces the absorption of tafluprost. The experimental results in Figure 4 of the patent indicate that an increase in the polysorbate 80 concentration from 0.05% to 0.2% reduces the bioavailability of tafluprost. However, the discovery of this negative effect in a solution comprising 0.2% polysorbate 80 does not imply any contribution over the prior art associated with the claimed formulation comprising 0.075% polysorbate 80, which according to the presented additional experimental results also reduces the bioavailability

of tafluprost as compared to a formulation with 0.05% polysorbate 80, be it to a lesser extent. At the same time, the prior art provided the skilled person with no reason to doubt that an ophthalmic solution comprising tafluprost with 0.075% polysorbate 80 would still provide adequate bioavailability of the tafluprost.

The patent proprietors' argument based on the presented experimental results regarding the bioavailability from solutions with 0.05%, 0.075% and 0.2% is therefore also not considered convincing.

1.3.8 Accordingly, starting from the composition of Table 7 of document D1 the skilled person would consider the claimed formulation obvious as a solution to the objective technical problem of providing a formulation for the convenient administration of tafluprost which is free of preservatives and combines reduced absorption of tafluprost by the container with adequate bioavailability for an effective low dose of tafluprost.

The Board therefore concludes that the main request does not comply with the requirement of inventive step (Article 56 EPC).

2. Auxiliary request 1, inventive step

The only additional feature of claim 1 of auxiliary request 1 with respect to claim 1 of the main request concerns the definition that the container is packaged into paper-coated aluminium-polyethylene foil.

The patent proprietors did not rely on any unexpected effect from this additional feature.

The objective technical problem may therefore be formulated in the same terms as set out above for the main request.

As argued by the opponent with reference to document A23 the packaging of the container into paper coated with an aluminium-polyethylene foil was conventional.

The patent proprietors argued with reference to document A24, which was taken from the same textbook as document A23, that the mention of an aluminium incorporating foil as a packaging material in document A23 related to the packaging of medical devices and did therefore not concern an ophthalmic solution in a container as defined in claim 1 of auxiliary request 1. However, the Board considers that a container for an ophthalmic solution may well be regarded to represent a medical device which according to document A23 may be packaged in a conventional manner in paper coated with an aluminium-polyethylene foil.

In adapting the composition of Table 7 of document D1 by formulating it in a unit dose container the skilled person would therefore consider the packaging of the container into paper-coated aluminium-polyethylene foil additionally defined in claim 1 of auxiliary request 1 also obvious as a matter of practical implementation.

The Board therefore concludes that auxiliary request 1 does also not comply with the requirement of inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated