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**Datasheet for the decision
of 24 June 2022**

Case Number: T 3227/19 - 3.3.07

Application Number: 13795432.7

Publication Number: 2922533

IPC: A61K9/70, A61K31/381

Language of the proceedings: EN

Title of invention:

MULTI-DAY PATCH FOR THE TRANSDERMAL ADMINISTRATION OF
ROTIGOTINE

Patent Proprietor:

LTS Lohmann Therapie-Systeme AG

Opponents:

AMW GmbH
Hexal AG

Headword:

Rotigotine patch / LTS LOHMANN

Relevant legal provisions:

EPC Art. 123(2)
RPBA 2020 Art. 12(2), 13(2)

Keyword:

Amendments - allowable (no)

primary object of appeal proceedings to review decision -

appeal case directed to arguments on which decision was based
(yes)

Amendment after summons - exceptional circumstances (no)

Decisions cited:

G 0009/92, G 0001/99



Beschwerdekammern

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
Fax +49 (0)89 2399-4465

Case Number: T 3227/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 24 June 2022

Appellant:
(Opponent 1)

AMW GmbH
Birkerfeld 11
83627 Warngau (DE)

Representative:

Beckord & Niedlich Patentanwälte PartG mbB
Marktplatz 17
83607 Holzkirchen (DE)

Appellant:
(Opponent 2)

Hexal AG
Industriestrasse 25
83607 Holzkirchen (DE)

Representative:

Lederer & Keller Patentanwälte
Partnerschaft mbB
Unsöldstraße 2
80538 München (DE)

Respondent:
(Patent Proprietor)

LTS Lohmann Therapie-Systeme AG
Lohmannstrasse 2
56626 Andernach (DE)

Representative:

Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 October 2019 concerning maintenance of the
European Patent No. 2922533 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. European patent 2 922 533 ("the patent") was granted on the basis of thirty-seven claims. Independent claim 1 as granted defined:

"Transdermal therapeutic system, comprising

(a) a backing layer,

(b) a solvent-based self-adhesive matrix layer containing rotigotine as active ingredient, and

(c) a release liner,

wherein the self-adhesive matrix layer has a coating weight of about 75-400 g/m² and comprises a reservoir layer containing about 9-25 wt.-% rotigotine based on the weight of the reservoir layer."

- II. Two oppositions had been filed against the grant of the patent on the grounds that its subject-matter lacked novelty and inventive step and that the claimed invention was not sufficiently disclosed.

Appeals were filed by both opponents against the interlocutory decision of the opposition division that the patent as amended in accordance with auxiliary request 1 was found to meet the requirements of the EPC.

The decision under appeal was based on the main request relating to the patent as granted and on auxiliary request 1 filed on 10 July 2019.

Claim 1 of this auxiliary requests defines:

"Transdermal therapeutic system, comprising
(a) a backing layer,
(b) a solvent-based self-adhesive matrix layer
containing rotigotine as active ingredient, and
(c) a release liner,
wherein
the self-adhesive matrix layer comprises a reservoir
layer,
the reservoir layer has a coating weight of 150 g/m²
and contains 9 wt.-% or 18 wt.-% rotigotine based on
the weight of the reservoir layer, and
the reservoir layer further contains polyvinyl-
pyrrolidone and the rotigotine to polyvinylpyrrolidone
weight ratio in the layer is 9:2 to 9:5 or multiples
thereof."

III. The opposition division arrived at the following
conclusions:

- (a) The subject-matter of claim 1 and claim 25 as
granted lacked novelty.
- (b) Claim 1 of auxiliary request 1 related to a
transdermal therapeutic system (TTS) comprising
rotigotine as active ingredient in a reservoir
layer as defined in claim 1 as granted with
restriction of the rotigotine concentration to
9 wt.% or 18 wt.%, specification of the coating
weight as 150 g/m² and introduction of the
definition of the presence of polyvinylpyrrolidone
(PVP) in the reservoir layer in a rotigotine to PVP
weight ratio of 9:2 to 9:5 or multiples thereof.

These amendments were based on the originally
disclosed most preferred values for the coating

weight and the rotigotine concentrations and originally disclosed values for the rotigotine to PVP weight ratio. The combination of these features represented a restriction towards the originally described core invention which did not extend beyond the content of the application as originally filed.

- (c) The subject-matter of claim 1 of auxiliary request 1 was new over the prior art in view of the combination of features concerning the rotigotine to PVP weight ratio and the coating weight.
- (d) In view of the results of the vivo study reported in the patent, which indicated a drug saving effect from patches as defined in the claims, the problem to be solved in view of the closest prior art identified as WO 2011/076879 (D3) was seen in the provision of an improved TTS which allows bio-equivalent administration of rotigotin for at least 3-7 days using minor total drug amounts with respect to the use of corresponding single-day patches. The prior art indicated that a 7-day patch required a higher drug content. It was unexpected that the value of 150 g/m² in combination with a reduced drug amount still allowed to achieve bioequivalence.

Accordingly the subject-matter of auxiliary request 1 also involved an inventive step.

- IV. Appellant-opponent 1 argued in its statement of grounds of appeal (see pages 7-8 section II.1.2) *inter alia* that claim 1 of auxiliary request 1 as filed before the opposition division did not comply with Article 123(2) EPC, because claim 1 of this request did not define the

feature of the originally filed claim 1 that the matrix layer itself has a coating weight of 75-400 g/m². The amendment introduced the new information that the defined coating weight applied to the reservoir layer and not to the matrix layer.

In its statement of grounds of appeal and in the letter of 3 February 2021 appellant-opponent 2 contested the the decision under appeal with respect to the findings concerning novelty and inventive step of the claims of auxiliary request 1 as filed before the opposition division.

With the reply to the appeals the respondent-patent proprietor maintained auxiliary request 1 as filed before the opposition division as main request. The respondent-patent proprietor argued *inter alia* (see reply, pages 5-6, bridging paragraph) that claim 1 of this request as well as claim 1 as originally filed referred to a matrix layer comprising a reservoir layer without reference to any additional layer so that both defined monolayer matrices wherein the reservoir layer represents the self-adhesive matrix layer and that the definition of a matrix layer comprising a reservoir layer having a coating weight of 150 g/m² did therefore not introduce subject-matter extending beyond the original disclosure. With the reply the respondent-patent proprietor also filed auxiliary request 1-18.

- V. The Board invited the parties to attend oral proceedings with the summons of 12 July 2021.

In the communication pursuant to Article 15(1) RPBA of 28 October 2021 the Board observed *inter alia* that it seemed questionable in view of the omission of the originally defined coating weight of the matrix layer

whether claim 1 of the main request complied with Article 123(2) EPC (see section 2.1.3 of the communication). The Board indicated that this observation appeared also relevant to auxiliary requests 1, 2, 4-6, 8-10, 12-14 and 16-18. The Board further informed that it intended not to admit auxiliary requests 3, 7, 11 and 15 having regard to the principle of prohibition of reformatio in peius.

Appellant-opponent 1 announced in its letter of 29 April 2022 not to attend the oral proceedings.

In reply to the Board's communication and in preparation of the oral proceedings the respondent-patent proprietor argued in its letter of 31 May 2022 that the objection under Article 123(2) EPC regarding the omission of the definition of the coating weight of the matrix layer was for the first time raised in the statement of grounds of appeal filed by appellant-opponent 1. In its view the objection should therefore not be admitted into the appeal proceedings. With the letter of 31 May 2022 the respondent-patent proprietor also filed auxiliary requests 19-33.

The oral proceedings were held on 24 June 2022.

VI. Claim 1 of **auxiliary request 1** defines with respect to claim 1 of the main request the additional feature:

"and the reservoir layer contains at least one amine-resistant silicone pressure sensitive adhesive."

Claim 1 of **auxiliary request 2** defines with respect to claim 1 of auxiliary request 1 the additional feature:

"and rotigotine and polyvinylpyrrolidone are contained in the transdermal therapeutic system in a multitude of microreservoirs."

Claim 1 of **auxiliary request 3** defines with respect claim 1 as granted the additional feature:

"wherein the transdermal therapeutic system is prepared by a method wherein a solvent system consisting of an aprotic polar solvent and a protic polar solvent in a ratio of 2:1 to 9:1 is used."

Claim 1 of **auxiliary request 7** corresponds to claim 1 of auxiliary request 3 in which the solvent system is defined as "consisting of ethyl acetate and ethanol in a ratio of 2:1 to 9:1".

Claim 1 of **auxiliary requests 11** defines a method for the preparation of a TTS defined in terms of auxiliary request 3 as follows:

"Method for the preparation of a transdermal therapeutic system comprising

- (a) a backing layer,
- (b) a solvent-based self-adhesive matrix layer containing rotigotine as active ingredient, and
- (c) a release liner,

wherein the self-adhesive matrix layer has a coating weight of about 100-400 g/m² and comprises a reservoir layer containing about 9-20 wt.-% rotigotine based on the weight of the reservoir layer, and wherein a solvent system consisting of an aprotic polar solvent and a protic polar solvent in a ratio of 2:1 to 9:1 is used."

Claim 1 of **auxiliary requests 15** corresponds to claim 1 of auxiliary request 11 in which the solvent system is defined as "consisting of ethyl acetate and ethanol in a ratio of 2:1 to 9:1".

Auxiliary requests 4, 8, 12 and 16 combine in independent claim 1 the respective amendments of auxiliary request 3, 7, 11 and 15 with the amendment of claim 1 of the main request.

Auxiliary requests 5, 9, 13 and 17 combine in independent claim 1 the respective amendments of auxiliary request 3, 7, 11 and 15 with the amendment of claim 1 of auxiliary request 1.

Auxiliary requests 6, 10, 14 and 18 combine in independent claim 1 the respective amendments of auxiliary request 3, 7, 11 and 15 with the amendment of claim 1 of auxiliary request 2.

Auxiliary requests 19-33 combine in independent claim 1 the respective amendments of the main request and auxiliary requests 1, 2, 4-6, 8-10, 12-14 and 16-18 with the additional feature:

"the self adhesive matrix layer has a coating weight of about 100-400 g/m²".

VII. The arguments presented on behalf of the appellant-opponents in as far as relevant to the present decision are summarized as follows:

The argument in the statement of grounds of appeal filed by respondent 1 that claim 1 of the main request did not comply with Article 123(2) EPC, because it defined the coating weight of the reservoir layer

instead of the matrix layer as a whole, represented merely the development of the objection under Article 123(2) EPC as originally raised before the opposition division in reaction to the findings in the decision under appeal. In contrast, the respondent amended its appeal case by raising the issue admittance of this argument for the first time in its letter of 31 May 2022.

The application as originally filed only disclosed the defined TTS with a coating weight of the matrix layer of 75-400 g/m². This feature was of technical significance, because due to practical constrains this weight cannot be arbitrarily chosen. Claim 1 of the main request comprised subject-matter which was not disclosed in the application as filed as a result of the omission of the originally defined limitation of the coating weight of the matrix layer. The main request did therefore not comply with Article 123(2) EPC.

Auxiliary requests 1, 2, 4-6, 8-10, 12-14 and 16-18 did not comply with Article 123(2) for the same reason as the main request.

Auxiliary requests 3, 7, 11 and 15 were not admissible in view of the principle of prohibition of reformatio in peius.

Auxiliary requests 19-33 were not to be admitted under Article 13(2) RPBA 2020.

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

The argument that claim 1 of the main request did not comply with Article 123(2) EPC due to the omission of the definition of the coating weight of matrix layer had not been raised before the opposition division. This argument therefore represented an unjustified amendment to the appellants' case, which should not be admitted in view of Articles 12(2) and 12(4) RPBA 2020.

The application as filed described on pages 13-14 (bridging paragraph) a TTS without any particular limitation of the coating weight of the matrix layer. The original disclosure further specified on page 17 (lines 29-32), page 18 (lines 15-21) and page 31 (lines 1-8) preferred embodiments in which the matrix layer comprises a reservoir layer with the coating weight, the rotigotine content and the rotigotine to PVP weight as defined in claim 1 of the main request. The main request therefore complied with Article 123(2) EPC.

Auxiliary requests 19-33 were filed in reaction to the communication of 28 October 2021, in which the Board questioned whether the claims allowed by the opposition division complied with Article 123(2) EPC. These requests were admissible in analogy with the considerations in G 1/99, according to which a request for an amendment introducing one or more originally disclosed features in order to overcome an objection raised during the appeal proceedings was exceptionally admissible. The requests further overcame prima facie the Board's concerns regarding the issue of added matter and did not give rise to any new objections.

IX. Appellant-opponents 1 and 2 requested that the decision under appeal be set aside and that the patent be revoked in its entirety. Appellant-opponent 2 also requested that auxiliary requests 3, 7, 11 and 15 as

well as auxiliary requests 19 to 33 not be admitted into the appeal proceedings.

- X. The respondent-patent proprietor requested that the appeals be dismissed. Subsidiarily the respondent requested that the patent be maintained on the basis of one of auxiliary requests 1-18 as filed with the reply to the appeals or auxiliary requests 19-33 as filed with the letter of 31 May 2022.

The respondent-patent proprietor further requested that the argument under Article 123(2) EPC raised by the appellant-opponent 1 relating to the omission of the coating weight of the entire self-adhesive matrix layer not be admitted into the proceedings.

Reasons for the Decision

Main request

1. Article 123(2) EPC

- 1.1 Claim 1 of the main request defines:

"Transdermal therapeutic system, comprising
(a) a backing layer,
(b) a solvent-based self-adhesive matrix layer containing rotigotine as active ingredient, and
(c) a release liner,
wherein the self-adhesive matrix layer ~~has a coating weight of about 75-400 g/m² and comprises a reservoir layer containing about 9-25 wt.-% rotigotine based on the weight of the reservoir layer,~~ the reservoir layer has a coating weight of 150 g/m² and contains 9 wt.-% or 18 wt.-% rotigotine based on the weight of the reservoir layer, and the reservoir layer further

contains polyvinylpyrrolidone and the rotigotine to polyvinylpyrrolidone weight ratio in the layer is 9:2 to 9:5 or multiples thereof."

The Board's underlining and striking of definitions identify the amendments with respect to claim 1 as originally filed.

1.2 Request regarding the admittance of the objection

The argument that claim 1 of the main request comprised subject-matter extending beyond the content of the application as originally filed, because this claim defined the coating weight of the reservoir layer, but not the matrix layer as a whole, had been presented by appellant-opponent 1 in its statement of grounds of appeal (see pages 7-8 section II.1.2).

The respondent contested this objection on substantial grounds in the reply to the appeals and only questioned the admittance of the objection in the letter of 31 May 2022. At that time the Board had already issued the summons to oral proceedings and its communication pursuant to Article 15(1) RPBA 2020. The respondent's request not to admit the objection therefore represents an amendment to the respondent's appeal case which is in accordance with Article 13(2) RPBA 2020, in principle, not to be taken into account unless cogent reasons justify exceptional circumstances for consideration of the late amendment. The Board does not recognize any such justification in the respondent's submissions. The circumstance that in line with the argument in the statement of grounds of appeal filed by opponent respondent 1 the Board questioned in its communication the correctness of the finding in the

decision under appeal can in this context not be qualified as exceptional.

The Board further observes that according to the minutes of the oral proceedings before the opposition division (see page 1, lines 18-20) appellant-opponent 2 objected that claim 1 of the auxiliary request 1 as filed in preparation of the oral proceedings before the opposition division, corresponding to the main request in appeal, comprised added subject-matter and that in particular the feature of the weight ratio of the PVP and rotigotine in the reservoir ratio was discussed. In the decision under appeal the opposition division concluded, however, that the defined subject-matter was adequately based on originally disclosed convergent limitations representing a restriction towards the original core invention (see pages 6-7, section 3.1). In this context the Board considers the argument regarding the coating weight of the matrix layer in the statement of grounds of appeal filed by appellant-opponent 1 not as an amendment of the opponents' case, but as a development of the objection as already raised before the opposition division in reaction to the findings in the decision under appeal.

Accordingly, even if the question of admittance raised by the respondent is taken into account, the Board still considers the relevant argument to be part of the appeal proceedings under Article 12(2) RPBA 2020.

1.3 Assessment of the basis for the amendments

1.3.1 As indicated in section 1.1 above, the amendment in claim 1 of the main request involves with respect to claim 1 as originally filed the omission of the definition of the coating weight of 75-400 g/m² for the

entire self-adhesive matrix layer and the introduction of definitions regarding the constitution of the reservoir layer, including its coating weight.

The definition of a coating weight of 150 g/m² for the reservoir layer in claim 1 of the main request does not imply a corresponding restriction of the coating weight of the self-adhesive matrix layer as a whole. In fact, this matrix layer may in addition to the defined reservoir layer with a coating weight of 150 g/m² contain additional layers, including further reservoir layers or a skin adhesive layer (see the patent, paragraphs [0071] and [0076], see also claim 2 of the main request). Accordingly for claim 1 of the main request to comply with Article 123(2) EPC an adequate basis for both the omission and the introduction of the indicated features must be identifiable in the application as originally filed.

- 1.3.2 According to the respondent the following passages in the original disclosure describe a TTS with a reservoir layer as defined in claim 1 of the main request without requiring a particular limitation of the coating weight of the matrix layer:

"In one embodiment, the self-adhesive matrix layer comprises a reservoir layer. The reservoir layer represents a matrix layer and is formed by a solid dispersion in terms of the foregoing. In a preferred embodiment, the self-adhesive matrix layer only comprises one reservoir layer and does not contain any additional matrix layer, i.e., in a preferred embodiment, the self-adhesive matrix layer represents a "mono -layer" matrix." (see page 17, lines 29-36)

"In a further embodiment, the reservoir layer of the transdermal therapeutic system has a coating weight of about 75-300 g/m², preferably about 75-200 g/m², more preferably about 100-150 g/m² and most preferably about 150 g/m² and contains about 9-25 wt.-% rotigotine, preferably about 9-20 wt.-% rotigotine, more preferably about 9 wt.-% or about 18 wt.-% rotigotine based on the weight of the reservoir layer." (see page 18, lines 15-21)

"In a preferred embodiment, the self-adhesive matrix layer of the transdermal therapeutic system of the present invention comprises a reservoir layer and the reservoir layer contains rotigotine and polyvinylpyrrolidone and the rotigotine to polyvinylpyrrolidone weight ratio in the reservoir layer is 9:2 to 9:5, preferably 9:3 to 9:5, and particularly preferred 9:4, or multiples thereof." (see page 31, lines 1-8)

- 1.3.3 The Board notes that the passages cited by the respondent explicitly concern embodiments involving a particular constitution of the "the self-adhesive matrix layer" and "the reservoir layer" and thereby evidently refer to a generic antecedent in the disclosure.

According to the respondent the skilled person would recognize that the mentioned embodiments refer to the generic definition of a TTS requiring no particular range for the coating weight of the matrix layer presented in the following passage of the application as originally filed:

"The term "transdermal therapeutic system" (TTS) as used herein refers to a matrix-type patch having a

continuous self-adhesive matrix layer in its centre portion. Such a patch consists of a backing layer, the self-adhesive matrix layer and a release liner, which is removed before use. In the present application, the terms "transdermal therapeutic system" , "TTS" and "patch" are equivalently used in order to describe the transdermal therapeutic system of the present invention" (see pages 13-14, bridging paragraph) "

The Board observes, however, that this passage presents merely the definition of what is intended with the term "transdermal therapeutic system" (TTS) in the context of the original disclosure. This definition provides information concerning the TTS described in the application as filed, but does as such not represent itself the generic antecedent for the subsequently disclosed embodiments. According to the Board the actually disclosed generic antecedent for the mentioned embodiments is to be found in the presentation of the invention preceding the definition of the used terminology (see page 13, lines 14-23), which recites the very same features as claim 1 as originally filed, including the feature limiting the coating weight of the matrix layer to 75-400 g/m².

The Board therefore considers that the TTS defined in claim 1 of the main request without specific limitation of the coating weight of the matrix layer cannot be directly and unambiguously derived from the application as originally filed. Accordingly, the Board concludes that claim 1 of the main request does not comply with Article 123(2) EPC.

Auxiliary requests 1-18

2. Auxiliary requests 1, 2, 4-6, 8-10, 12-14 and 16-18

The coating weight of the matrix layer as a whole is not further defined in claim 1 of any of auxiliary requests 1, 2, 4-6, 8-10, 12-14 and 16-18. These auxiliary requests do therefore not comply with Article 123(2) EPC for the same reason as explained above in section 1.3 in relation to the main request.

3. Auxiliary requests 3, 7, 11 and 15

The respondent has not filed an appeal of its own against the decision under appeal, in which the claims of the main request (then auxiliary request 1) were held allowable. In accordance with the principle of prohibition of reformatio in peius as recognized in G 9/92 and G 1/99 the respondent is therefore in principle restricted to defending the patent within the limits of the subject-matter as defined in the main request.

The subject-matter defined in accordance with the claims of auxiliary requests 3, 7, 11 and 15 is not restricted by the limiting features of the coating weight of the reservoir layer, the content of the rotigotine and the weight ratio between the rotigotine and PVP as defined in the in claim 1 of the main request. These requests thus include claims to subject-matter which extends at least partially beyond the subject-matter defined in the claims of the main request. Accordingly, these requests fall under the prohibition of reformatio in peius and are therefore not admitted into the appeal proceedings.

The Board observes in this context that the exception to the prohibition of reformatio in peius formulated in

G 1/99 concerns a remedy in appeal proceedings in case of the introduction of an impermissible limiting amendment, which had been held allowable by the opposition division (see point 14 of the Reasons). In contrast, the amendment held allowable by the opposition division in the present case involves, as explained in section 1.3 above, the impermissible omission of a limiting feature. The exception formulated in G 1/99 does therefore not apply to the present case.

Accordingly, auxiliary requests 3, 7, 11 and 15 are not admitted into the appeal proceedings.

Auxiliary requests 19-33

4. Admittance under Article 13(2) RPBA 2020

4.1 Auxiliary requests 19-33 were filed with the respondent's letter of 31 May 2022 well after the Board had issued the summons to oral proceedings and its communication pursuant to Article 15(1) RPBA 2020.

The filing of auxiliary requests 19-33 thus represents an amendment to the respondent's case which is in accordance with Article 13(2) RPBA 2020 in principle not to be taken into account unless cogent reasons justify exceptional circumstances for taking these requests into consideration.

4.2 The respondent argued that auxiliary requests 19-33 were filed in reaction to the communication of 28 October 2021, in which the Board questioned whether the claims allowed by the opposition division complied with Article 123(2) EPC. The Board observes, however, that in section 2.1.3 of its communication the Board

did not introduce any new argument, but merely expressed its preliminary assessment with respect to the objection under Article 123(2) as presented in the statement of grounds of appeal filed by appellant-opponent 1. The circumstance that in view of the arguments in the appellant's statement of grounds of appeal the Board questioned the correctness of the assessment of the opposition division cannot be regarded as exceptional.

4.3 The respondent further referred to the considerations in G 1/99, in which a request for an amendment introducing one or more originally disclosed features was exceptionally considered admissible in order to overcome an objection raised during the appeal proceedings. The Board observes, however, that the considerations in G 1/99 merely concern the exception to the principle of prohibition of reformatio in peius in appeal proceedings. This exception only relates to the content of requests intended to remedy the impermissible introduction of a limiting amendment and is therefore unrelated to the exceptional circumstances for the admittance of late amendments to a party's appeal case under Article 13(2) RBPA 2020.

4.4 For the sake of completeness the Board further notes that the feature of a coating weight of 100 to 400 g/m² for the matrix layer as introduced in the independent claims of auxiliary requests 19-33 does not seem consistent with the feature that this matrix layer comprises a reservoir layer with a coating weight of 150 g/m². Accordingly, auxiliary requests 19-33 do not prima facie overcome the objection under Article 123(2) EPC against the main request and auxiliary requests 1-2, 4-6, 8-10, 12-14 and 16-18 without giving rise to any new objection.

4.5 Accordingly, the Board concludes that the respondent has not presented cogent reasons for exceptional circumstances justifying the late submission of auxiliary requests 19-33. These requests are therefore not admitted into the appeal proceedings.

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. Uselli

Decision electronically authenticated