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Datasheet for the decision of 2 September 2020

Case Number: T 0778/18 - 3.3.07

Application Number: 11159754.8

Publication Number: 2363114

IPC: A61K9/127, A61K31/7036, A61P11/00

Language of the proceedings: EN

Title of invention:
Sustained release of antiinfectives

Patent Proprietor:
Insmed Incorporated

Opponent:
Generics [UK] Limited

Headword:
Sustained release of antiinfectives/Insmed Incorporated

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(2), 12(4)

Keyword:
Main request and auxiliary request 2 - Inventive step (No)
Frequency of a dose administration - Inventive (No)
Auxiliary requests 1 and 3 - Not admitted into the proceedings

Decisions cited:
T 1979/09

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 0778/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 2 September 2020

Appellant: (Patent Proprietor)	Insmed Incorporated 10 Finderne Ave, Building 10 Bridgewater NJ 08807-3365 (US)
Representative:	CMS Cameron McKenna Nabarro Olswang LLP Cannon Place 78 Cannon Street London EC4N 6AF (GB)
Respondent: (Opponent)	Generics [UK] Limited Station Close Potters Bar Hertfordshire EN6 1TL (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 February 2018 revoking European patent No. 2363114 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	C. Schmidt

Summary of Facts and Submissions

I. European patent No. 2 363 114 was granted on the basis of a set of 11 claims.

Independent claims 1 and 2 as granted read as follows:

"1. A liposomal anti-infective for use in treating or ameliorating a pulmonary infection in a patient wherein the anti-infective is amikacin, for pulmonary administration to the patient by inhalation, the dosing of the anti-infective is once a day or less and the lipids used to form the liposomes consist of dipalmitoyl phosphatidylcholine (DPPC) and cholesterol."

"2. The use of a liposomal anti-infective in the manufacture of a medicament for treating or ameliorating a pulmonary infection in a patient, wherein the medicament Is amikacin, for pulmonary administration to the patient by inhalation, the dosing of the medicament is once a day or less and the lipids used to form the liposomes consist of DPPC and cholesterol."

II. The patent was opposed under Article 100 (a), (b), (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division to revoke the patent. The decision was based on the claims as granted.

IV. The documents cited during the opposition proceedings included the following:

D1: US 5 958 449
D5: WO 03/075890
D8: Wichert B. V. et al., "Amikacin liposomes: characterization, aerosolization, and in vitro activity against Mycobacterium avium-intracellular in alveolar macrophages" Int. J. of Pharm., Elsevier BV, NL, vol. 78, no 1-3, 1 January 1992, pages 227-235, XP025557898
D9: Schreier H. et al.: "Pulmonary delivery of amikacin liposomes and acute liposomes toxicity in the sheep", Int. J. of Pharm., Elsevier BV, NL, vo. 87, no 1-3, 10 November 1992, pages 183-193, XP025793923
D10: Blaser at al.: "Once Daily Dosing of Aminoglycosides", Eur. Clin. Microbiol. Infect. Dis., 1995, 1029-1038
D16: Zeng et al.: "The controlled delivery of drugs to the lung", Int., J. of Pharm., 124, 1994, p. 149-164
D17: Weers et al.: Poster presentation 2005, ATS2005, International Conferences

V. The opposition division decided to admit document D17 into the proceedings. It further considered that the patent was sufficiently disclosed and met the requirements of Article 76(1) and 123(2) EPC.

D5 was the closest prior art, as agreed by all parties and disclosed liposomal compositions with amikacin as active ingredient. The difference with the claimed subject-matter was the lack of explicit disclosure of a specific dosage regimen of once a day or less. Effects for this difference were neither shown in the patent, nor in D17, and the solution was found to be an

arbitrary selection that could not involve an inventive step.

VI. The patent proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 14 June 2018 the appellant filed auxiliary request 1 and submitted the following items of evidence:

D18: Moore and Proffitt (2002), "AmBisome: liposome formulation structure, mechanism of action and preclinical experience. Journal of Antimicrobial" Chemotherapy, 49, Suppl. S1, pp. 21-30
D19: Craig (1998), "Pharmacokinetic/Pharmacodynamic Parameters: Rationale for Antibacterial Dosing of Mice and Men", Clinical Infectious Diseases, 26, pp. 1-12
D20: Declaration of Dr Lee Leserman dated June 1, 2018.

The subject-matter of independent claims 1 and 2 of auxiliary request 1 read as follows, the difference with respect to the main request being indicated in **bold**:

"1. A liposomal anti-infective for use in treating or ameliorating a pulmonary **M. avium complex (M. avium and M. intracellulare)** infection in a patient wherein the anti-infective is amikacin, for pulmonary administration to the patient by inhalation, the dosing of the anti-infective is once a day or less and the lipids used to form the liposomes consist of dipalmitoyl phophatidylcholine (DPPC) and cholesterol."

"2. The use of a liposomal anti-infective in the manufacture of a medicament for treating or ameliorating a pulmonary **M. avium complex (M. avium and**

M. intracellulare) infection in a patient, wherein the medicament is amikacin, for pulmonary administration to the patient by inhalation, the dosing of the medicament is once a day or less and the lipids used to form the liposomes consist of DPPC and cholesterol."

VII. With a letter dated 30 October 2018, the opponent (hereinafter the respondent) submitted the following items of evidence:

D21: McCullough et al. : "Organ-Selective Action of an Antitumour Drug: Pharmacologic Studies of Liposome-Encapsulated b-Cytosine Arabinoside Administered via the Respiratory System of the Rat", Ntl. Cancer Inst., 63, 1979, pp. 727-731
D22: Taylor et al. : "The influence of liposomal Encapsulation on Sodium Cromoglycate Pharmacokinetics in Man", Pharma. Res., Vol. 6, No 7, 1989, pp. 633-636
D23: Liu et al.: "Pulmonary Delivery of Free and Liposomal Insulin", Pharma. Res., Vol. 10, No 2, 1993, pp. 228-232
D24: Freeman et al.: "Liposomal-mediated Augmentation of Superoxide Dismutase in Endothelial Cells Prevents Oxygen Injury", J. Biol. Chem., Vol. 258, No 20, 1983, pp. 12534-12542.

The respondent also requested that documents D17, D18-D20 and auxiliary request 1 not be admitted into the proceedings.

VIII. In a communication pursuant to article 15(1) RPBA,the Board expressed its doubts with regard to the requirements of Article 123(2) EPC, Article 76(1) EPC and inventive step.

IX. With a letter dated 31 December 2019, the appellant filed auxiliary requests 2 and 3. These requests corresponded respectively to the main request and auxiliary request 1 on file with the dependent claims suppressed.

X. With letters dated 5 and 6 August 2020 respectively, the respondent and the appellant requested the oral proceedings to be held by video-conference.

XI. With a letter dated 28 August 2020, the appellant submitted the decision T 1979/09 as document D26.

XII. Oral proceedings took place on 2nd September 2020 by video-conference.

XIII. The arguments of the appellant may be summarised as follows:

Admission of D21-D24 into the proceedings

The prima facie relevance of D21-D24 had not been established and they should not be admitted into the appeal proceedings. None of D21 to D24 was concerned with an anti-infective, let alone an aminoglycoside or amikacin. Therefore, these disclosures were not relevant to the point made by the Patentee. D21 to D24 could be contrasted with D8 and D9 which were concerned with amikacin liposomes. Thus, D21 to D24 had far less relevance as compared with documents already in the proceedings. For this reason, they should not have been admitted.

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Main request - Inventive step

At the filing date of the present patent, relatively little work had been done in the field of pulmonary infection treatment via liposomal inhalation therapies (cf. D20, D8 and D9). D1 and D10 instructed IV administration of amikacin. There was in particular neither disclosure nor exemplification in D1 of inhalation of a liposomal amikacin formulation. Moreover, where liposomal amikacin was studied with respect to inhalation treatment, studies indicated that the use of negatively charged lipids in the lipid component of the liposome were more efficacious than net neutrally charged liposomes (see D8 and D9).

If D5 was taken as the closest prior art, then taking the disclosure of D5 as a whole,, the skilled person should have made multiple selections, namely "pulmonary infection", the inhalation as the route of administration , the amikacin as the bioactive agent, DPPC and cholesterol as lipids, and also decide not to include any additional lipids. There was no pointer in D5 for the administration per inhalation and that the liposomes provided a sustained release delivery into the lungs.

A surprising effect linked with the claimed composition was clearly shown by Figure 7 of the patent and D17. The results of Figure 7 of the patent showed that dosing every day, or less frequently, by inhalation in a rat model, provided an effective concentration of drug even at day 9, because there was a remarkable residence time and accumulation of the drug formulation in the lungs. This was also demonstrated by D17 which showed that, after a single inhaled dose, the amount of liposomal amikacin remaining in the lungs of humans was essentially identical after 12 and 24 hours.

The difference between the claimed invention and the disclosure of D5 (when taken as a whole) was the provision of a treatment for pulmonary infection whereby a liposomal amikacin having a lipid component consisting of DPPC and cholesterol was administered via inhalation once a day or less. This represented an improved inhalation treatment for pulmonary infection and the objective technical problem should be defined as to provide an improved inhalation treatment for pulmonary infection. The solution to this problem was not obvious and was unpredictable from the disclosure of D5 alone. The solutions was not obvious, in particular because there was no expectation of success, since the lung accumulation of amikacin was neither known nor deducible from any cited documents.

It was not predictable that the liposomes of example 1 of D5 could be administered once per day and would provide a sustained release in the lungs. D16 taught that the usual administration would rather be 3-4 times per day.

In view of D8, the skilled person would anyway not use a cationic liposome as claimed, but rather a negatively charged liposome.

The solution could not be seen as an obvious optimisation of a dosage regimen as given in decision T 1979/09; in the present case, the dosage regimen was indeed not a simple replacement, in view of the surprising effect. It was therefore not a routine variation of the dosage regimen, since the skilled person would not have administered the claimed composition once a day or less.

Admission of auxiliary requests 1 and 3 into the proceedings

The amendment came from the dependent claim 5 as granted, and could not constitute a surprise for the respondent, and for this reason it does also not change the case. The claimed compositions corresponded to the commercial product.

XIV. The arguments of the respondent may be summarised as follows:

Admission of D21-D24 into the proceedings

D21 to D24 were filed in response to the patentee's argument that a technical prejudice existed against the use of non-negatively charged liposomes. This argument was first raised at oral proceedings before the opposition division, and therefore the present submissions represented the first opportunity for the opponent to file arguments and evidence in reply. Therefore, D21 to D24 should be admitted to the proceedings because they could not have been filed before the opposition division.

Main request - Inventive step

The closest prior art was D5, which related to processes for preparing liposomal formulations comprising a high proportion of bioactive ingredient, giving a composition useful for administration by therapy by intravenous administration or inhalation (page 3, lines 15-17). The compositions had sustained release thereby allowing less frequent administration (page 7, lines 13-14).

The distinguishing feature was once-daily administration.

The appellant defined the objective technical problem as the provision of an improved treatment of pulmonary infections because of the advantages associated with less frequent administration.

The only issue to determine when considering obviousness of the solution was whether the skilled person would have had a reasonable expectation that once-daily dosing would have been effective.If the skilled person would have expected effective treatment, the advantages of improved patient compliance associated with a less frequent method of administration would have been entirely predictable.

D5 specifically stated that liposomal formulations had "sustained therapeutic effect" thereby "allowing less frequent administration", and there was therefore an expectation of success in choosing a less frequent administration (D5, page 15).

Moreover, the use of liposomal compositions for treating pulmonary infections by inhalation was known from the common general knowledge, such as from D16 and D8.

As regards D8 this document merely stated that negatively charged lipids would have certain advantages, not that these lipids were essential. Therefore, D8 did not establish the alleged prejudice against the use of a formulation not containing a negatively charged lipid.There were also several examples in the prior art of non-negatively charged

lipids successfully used in pulmonary drug delivery, as shown by several citations in D16 (D21 to D24).

In summary, there was no prejudice existed against the use of non-negatively charged liposomal compositions in pulmonary drug administration at the priority date and the claimed solution could not be inventive.

The same arguments applied to claim 1 of auxiliary request 2.

Admission of auxiliary requests 1 and 3 into the proceedings

No aspect of the reasoning of the decision of the opposition division was surprising. The appellant chose not to file any auxiliary requests in the opposition proceedings. At oral proceedings, after the patent was found to lack an inventive step, the patentee confirmed that they had no further requests. However, on appeal, the appellant had filed further requests in which the claims are limited to the treatment of a specific pulmonary infection. The respondent did not have the opportunity to prepare evidence and arguments why this request was obvious at first instance. Moreover, the appellant had provided no explanation why these requests could not have been presented at first instance, since these requests were not discussed at all in the patentee's submissions. Accordingly, the Board should use their discretion under Article 12(4) of the RPBA not to admit them.

XV. Requests

The appellant requested that the decision under appeal be set aside and that the patent be maintained as

granted (main request) or on the basis of one of the auxiliary requests 1 to 3 filed with letter dated 14 June 2018 (auxiliary request 1) or with letter dated 31 December 2019 (auxiliary requests 2 and 3). It further requested not to admit documents D21 to D24 into the proceedings.

The respondent requested that the appeal be dismissed. It further requested that auxiliary requests 1 and 3 were not admitted into the proceedings.

Reasons for the Decision

1. Admissibility of documents D21 to D24 into the proceedings

D21-D24 have been filed by the respondent in response to the statement of grounds of appeal, thus at the earliest possible stage of the appeal proceedings for the respondent.

They have been filed in response to a point raised for the first time during the oral proceedings before the opposition division and mentioned in the decision of the opposition division, namely a supposed existing technical prejudice against the use of non-negatively charged liposomes. The documents have therefore been filed in response to questions raised during the opposition proceedings, these questions being possibly still relevant in the appeal proceedings. The present submissions represented also the first opportunity for the respondent opponent to file arguments and evidence in reply to this point.

Consequently, the Board admits these documents into the appeal proceedings (Rule 12(4) RPBA 2007).

2. Main request - Inventive step

2.1 The claimed invention relates to a liposomal composition for use in a method of treating or ameliorating pulmonary infections, comprising administration of amikacin encapsulated in liposomes consisting of dipalmitoyl phosphatidylcholine (DPPC) and cholesterol (Chol).

2.2 D5 is considered by all parties as the closest prior art, and was also the closest prior art of the opposition division in its decision.

D5 discloses the preparation of liposomes specifically adapted for intravenous administration or inhalation (see D3 page 3, lines 15-17). The liposome disclosed in example 1 of D5 is a liposome comprising amikacin sulfate and a lipid structure consisting of DPPC-Chol , which is identical to the liposome of the contested patent (see D3, examples 1, 1a, 1b, 1c). The treatment of lung diseases is also explicitly disclosed in the description of D5 (see page 4 lines 17-29, example 1d and figures 7 and 10). D5 discloses furthermore in the combination of claim 12 and dependent claims 43 and 52 a method for preparing a liposomal composition adapted for administration by inhalation consisting of amikacin, DPPC and Chol.

A liposomal structure made from amikacin, DPPC and Chol, for use in treating a pulmonary infection by inhalation is therefore immediately identifiable from the disclosure of D5 and explicitly disclosed. There is indeed no need to make multiple selections to arrive at

such disclosure as argued by the appellant; all these points taught by D5 can be read together, since belonging to the same specific and preferred liposomes disclosed in D5.

Moreover, document D5 mentions on page 7:
"Liposomal bioactive agents can be designed to have a sustained therapeutic effect or lower toxicity allowing less frequent administration and an enhanced therapeutic index. Liposomes are composed of bilayers that entrap the desired pharmaceutical. These can be configured as multilamellar vesicles of concentric bilayers with the pharmaceutical trapped within either the lipid of the different layers or the aqueous space between the layers" (see page 7, l. 13-17).

Said passage was interpretated by the appellant as being extremely general without regard to route of administration, infection to be treated or active agent-lipid combination to be employed. In the Board's view, this statement applies however to the specific liposome formulations disclosed in D5, and there is no reason to consider that D5 would refer in the passage of page 7 to properties which do not apply to the formulations disclosed in D5 itself; this conclusion is furthermore supported and reinforced by the reference in the same passage to the configuration of the liposomes in multilamellar vesicles, which is the general structure obtained in the methods of preparation disclosed in D5 (see pages 8 and 9 and corresponding Figures 1 and 2). A sustained therapeutic effect, i.e. a sustained release of amikacin, and a lower toxicity allowing less frequent administration, as well as an enhanced therapeutic index are therefore clearly disclosed in D5.

This document does not disclose any specific frequency of administration, in particular that that "the dosing is once a day or less".

2.3 According to the appellant the problem is the provision of an improved treatment of pulmonary infections, since such a once per day dosing minimises the potential side effects and provides increased patient benefit and compliance.

During oral proceedings, the respondent agreed with the definition of the problem as posed by the appellant.

2.4 As a solution, claims 1 and 2 of the main request propose that "the dosing of the anti-infective is once a day or less".

2.5 Figure 7 of the patent and Figure 3 of D17 have been mentioned by the appellant as supporting an effect as to minimising the potential side effects and providing increased patient benefit and compliance.

Figure 7 of the patent shows results of different dosing frequencies, either as a single dose (day 1), daily dosing (days 1,2,3,4,5) or every other day dosing (day 1,3,5). The results of Figure 7 indicate that dosing every day, or less frequently, by inhalation in a rat model, provides an effective concentration of drug even at day 9.

Figure 3 of D17 shows that about 40% of the initial dosing of amikacin remained in the lungs after 50 hours.

Figure 7 and D17 are experiments limited to a frequency of administration of once-a-day or less, and do not

show any comparison with pulmonary residence time obtained with other dosing frequencies. However, they show that the pulmonary administration of the claimed liposome provides a sustained concentration over a prolonged period of time of the anti-infective agent in the lungs.Thus, an increased patient benefit and compliance are very likely to occur, as well as a minimisation of the potential side effects of amikacin. In view of this, the Board is convinced that the problem formulated in paragraph 2.3 above has been credibly solved.

2.6 The question remaining is whether the skilled person confronted with this problem and starting from the teaching of D5, would arrive at the subject-matter of claim 1 of the main request in an obvious manner.

2.6.1 The skilled person generally knows that the efficiency of a drug administration is dependent on the dose administered and on the frequency of administration of said dose, and that both parameters must be adapted depending on the drug residence time and clearance, in the present case the pulmonary residence time and pulmonary clearance of liposomal amikacin. The skilled person knows also that a sustained release delivery allows a reduction in frequency of intakes, hence a better patient compliance and a reduction of the side effects.

2.6.2 In the specific present case, the skilled person is aware of the disclosure of D5, namely that the liposomes disclosed therein have a pulmonary sustained therapeutic effect allowing a less frequent administration and an enhanced therapeutic index, even if said sustained release or pulmonary residence time has not been quantified in D5 (cf. point 2.2 above). A

pulmonary sustained release of the claimed liposomal amikacin can therefore not be considered as unexpected or unpredictable.

In view of the information given in D5, the skilled person would investigate the frequency of administration and would inevitably start with a low frequency of administration. In the absence of any evidence or technical argument from the side of the appellant, the Board considers that such activity of investigation is a matter of routine experimentation for the skilled person, which, in the present specific case, does not present any technical difficulty. The person skilled in the art, on the basis of the teaching of D5 and of its general knowledge, would conceive a straightforward approach to solve the technical problem, which is to choose as starting point of its investigation a frequency of administration of once a day. In the Board's view this appears to represent a natural start for experimenting a frequency of administration and also a general standard frequency of administration of a sustained release form.

In this context, the expectation of success is reasonable, because D5 provides on page 7 an explicit pointer to the claimed solution. Indeed, once the sustained therapeutic effect is known, a once-a-day dosing is an usual frequency of administration for a sustained release formulation and the skilled person would reasonably expect for such a formulation good results as regards the pulmonary residence time.

This expectation of success is not contradicted by the teaching of D16 as argued by the appellant. D16 discloses that the usual administration of most medication in aerosol for inhalation would be at least

3-4 times daily because of the short duration of resultant clinical effects (see Abstract). However said document also mentions that a pulmonary sustained release form would be beneficial, and refers to a liposomal form of amikacin, which provides a half-life greater than 10 hours and an increased pulmonary drug activity by approximately 100 fold (see pages 150 and 152). These results confirm therefore the interest in liposomal forms of amikacin, and indicate that a sustained residence time could be expected.

Consequently, in the present case, a once a day dosing does not require inventive skill and cannot establish an inventive step.

Moreover, if the skilled person were confronted with unsatisfactory results in view of a very high drug residence time with a once-a-day dosing, he would inevitably experiment a lower frequency of administration, hence less than once a day, which is still encompassed in claim 1. In the Board's view, this would be a matter of routine experimentation for a skilled person.

Consequently, the claimed solution is not inventive over the teaching of the closest prior art D5.

2.6.3 The appellant referred to decision T 1979/09 in which it was considered that the replacement of a dosage regimen by another dosage regimen for the same purpose was considered to be a matter of routine experimentation. The Board concurs with the appellant that since D5 does not disclose any frequency of administration it is not possible in the present case to discuss the replacement of a frequency of administration by another one. Accordingly, the reasons

given in T 1979/09 are irrelevant for the present case. However, this does not imply the further conclusion that in the present case an inventive step must be present because the closest prior art does not disclose any specific frequency of administration.

2.7 Consequently, the subject-matter of claims 1 and 2 of the main request lacks inventive step (Article 56 EPC).

3. Admission of auxiliary request 1 into the proceedings

3.1 Auxiliary request 1 has been filed with the statement of grounds of appeal. Claims 1 and 2 of auxiliary request 1 have been amended by the specification of the pulmonary disease to be treated, namely "a pulmonary **M. avium complex (M. avium and M. intracellulare)** infection". Said amendment is a selection from the list of infections to be treated of dependent claim 5 as granted and was not presented in dependent claim 5 as a preferred embodiment, such as the preferred infections to be treated present in claims 6-8 as granted. During the proceedings before the opposition division, the appellant decided to not file and defend any other request than the main request.

3.2 The appeal was filed before 1 January 2020, and therefore Article 12(4) RPBA 2007 applies (Article 25(2) RPBA 2020, OJ 2019, A63). It provides that everything filed with the appeal shall be taken into account, to the extent that the requirements of Article 12(2) RPBA 2007 are fulfilled. Article 12(2) RPBA 2007 requires that the appeal shall set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify expressly all the facts, arguments and evidence relied on.

In the present case, the appellant did not provide any argument or comment in its statement of ground of appeal as to auxiliary request 1 to explain how the issues could be changed for any ground of opposition. Such an unsubstantiated request filed with the grounds of appeal cannot be admitted in the appeal proceedings if it has not been specified why the contested decision should be amended or the patent maintained.

Consequently, this request is not admitted to the proceedings under Article 12(4) RPBA 2007 as it does not meet the requirements of Article 12(2) RPBA 2007.

4. Auxiliary request 2 - Inventive step

This request corresponds to the main request on file with the dependent claims suppressed. Claims 1 and 2 of auxiliary request are identical to claims 1 and 2 of the main request.

Consequently, the conclusions reached above for the main request apply *mutatis mutandis* for the independent claims 1 and 2 of auxiliary request 2, which do also not meet the requirements of inventive step (Article 56 EPC).

5. Admission of auxiliary request 3 into the appeal proceedings

This request has been filed after the Board had issued a communication and summoned the parties. It corresponds to auxiliary request 1 on file with the dependent claims suppressed. The appellant did not provide any reason for submitting auxiliary request 3 at this stage of the appeal proceedings. Nor did it

indicate why this request should overcome the inventive step issues. Accordingly, the filing of auxiliary request 3 is not in line with the requirements of Article 13(1) RPBA 2020.

Additionally, the limitation to a specific infection to be treated opens a new discussion as regards inventive step at a late stage of the proceedings. Consequently, admitting such request would be contrary to the principle of procedural economy.

Hence, in the exercise of its discretion the Board decides not to admit auxiliary request 3 into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated