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Datasheet for the decision of 26 October 2023

Case Number: T 1928/21 - 3.3.07

Application Number: 10182218.7

Publication Number: 2298279

IPC: A61K9/00, A61K47/28

Language of the proceedings: EN

Title of invention:
Pharmaceutical compositions for inhalation

Patent Proprietor:
Vectura Limited

Opponent:
GLAXO GROUP LIMITED

Headword:
Pharmaceutical compositions for inhalation/ VECTURA

Relevant legal provisions:
RPBA 2020 Art. 12(4), 12(6)
EPC Art. 83

Keyword:
New evidence - Not admissible
All requests - Sufficiency of disclosure (No)

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Case Number: T 1928/21 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 26 October 2023

Appellant: (Patent Proprietor)	Vectura Limited 1 Prospect West Chippenham, Wiltshire SN14 6FH (GB)
Representative:	Summersell, Richard John Vectura Limited 205 Cambridge Science Park Milton Road Cambridge CB4 0GZ (GB)
Respondent: (Opponent)	GLAXO GROUP LIMITED 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Representative:	J A Kemp LLP 80 Turnmill Street London EC1M 5QU (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 July 2021 revoking European patent No. 2298279 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	Y. Podbielski

Summary of Facts and Submissions

I. European patent No. 2 298 279 was granted on the basis of a set of 11 claims.

Independent claim 1 as granted read as follows:

"1. Microparticles for use in a pharmaceutical composition for pulmonary administration, comprising particles of an active substance having, on their surfaces, particles of magnesium stearate present as a discontinuous coating covering on average at least 70% of the surfaces of the active particles and wherein the coating is on average less than 1 µm thick."

II. The patent had been 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 as the main request, on auxiliary requests 1-12 filed with letter of 6 January 2020 and auxiliary requests 13-19 filed with letter of 16 April 2021.

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

D1: Judgment of the High Court of England and Wales dated 13 December 2018

D2: Declaration from Professor Rik Morgan Drummond-Brydson, originally filed in related opposition proceedings concerning EP2283817
D5: WO 02/43700
D7: WO 2001/076575
D8: International Journal of Pharmaceutics, 173, 1998, 243-251
D10: WO 96/023485
D11: WO 00/53157
D13: The Handbook of Pharmaceutical Excipients, 2nd Edition, 1994, pages 280-282
D16: First Technical report I Prof. Alan John Reynolds
D17: Second Technical report I Prof. Alan John Reynolds
D23: Handbook of Pharmaceutical Additives, 1995
D24: Pharmaceutical Powder Compaction Technology, 1996
D25: Analytical Methods in Fine Particle Technology, 1997
D30: Brown et al., "The Particle Atlas"
D31: Vectura submission on opposition against EP2283818, 25 July 2019
D32: Hosokawa Micron Ltd, Instruction Manual for Mechanofusion AMS-Mini
D33: Preliminary opinion of the opposition division in EP2266549
D34: Technical Report Example 1 of US Patent Publication US 2003/0068280 A1

V. According to the decision under appeal, auxiliary requests 13-19, D32 and D34 were admitted into the proceedings, while D31 and D33 were not admitted.

The claimed invention was not sufficiently disclosed. It was not possible for the skilled person to determine whether the requirements of the discontinuous coating and coating thickness were met, neither by scanning electron microscopy (SEM), nor by energy-dispersive X-

ray spectroscopy (EDX). There was no teaching in the patent how to adjust the process parameters to ensure the specific structural arrangements of claim 1. Neither did the examples teach how to determine the claimed parameters.

The same conclusion applied to all auxiliary requests.

VI. The patent proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 6 December 2021, the appellant filed a main request corresponding to the claims as granted and auxiliary requests 1-19. The appellant also submitted the following items of evidence:

D35: Technical Report with Annex 1
D36: Secondary Ion Mass Spectrometry SIMS XI 1st Edition, 7-12 September 1997
D37: Zhou et al., International Journal of Pharmaceutics 413 (2011) 36- 43

Independent claim 1 of the auxiliary requests read as follows, the differences, indicated in bold, relating to a comparison with the main request or a previous auxiliary request.

Auxiliary request 1-3

In comparison to claim 1 of the main request, claim 1 of these requests was amended respectively by the additional features **"wherein the microparticles have a mass median aerodynamic diameter of not more than 10 µm", "wherein the microparticles have a mass median aerodynamic diameter of not more than 5 µm"**, and

"wherein the microparticles have a mass median aerodynamic diameter of not more than 3 µm".

Auxiliary requests 4-6

In comparison to claim 1 of the main request, claim 1 of auxiliary requests 4-6 was amended respectively by the additional features **"wherein the microparticles have a mass median aerodynamic diameter of not more than 10 µm, wherein the microparticles being such that the active substance exerts its pharmacological effect over a period greater than 12 hours", "wherein the microparticles have a mass median aerodynamic diameter of not more than 5 µm, wherein the microparticles being such that the active substance exerts its pharmacological effect over a period greater than 12 hours"** and **"wherein the microparticles have a mass median aerodynamic diameter of not more than 3 µm, wherein the microparticles being such that the active substance exerts its pharmacological effect over a period greater than 12 hours".**

Auxiliary requests 7-12, 17-19

Claim 1 of auxiliary request 7 read:

"1. **A method of preparing** microparticles for use in a pharmaceutical composition for pulmonary administration, **the method comprising a step of combining particles of an active substance with particles of magnesium stearate in a milling step, preferably wherein the milling step involves compressing a mixture of active particles and magnesium stearate in a gap of predetermined width, most preferably wherein the milling step comprises cyclomixing or mechanofusion, wherein the**

microparticles comprise particles of an active substance having, on their surfaces, particles of magnesium stearate present as a discontinuous coating covering on average at least 70% of the surfaces of the active particles and wherein the coating is on average less than 1 µm thick **and wherein the microparticles have a mass median aerodynamic diameter of not more than 10 µm.**

In comparison to claim 1 of auxiliary request 7, claim 1 of auxiliary requests 8 and 9 had its final feature replaced respectively by the feature **"and wherein the microparticles have a mass median aerodynamic diameter of not more than 5 µm"** and **"and wherein the microparticles have a mass median aerodynamic diameter of not more than 3 µm".**

In comparison to claim 1 of auxiliary requests 7-9, claim 1 of auxiliary requests 10-12 had the following supplementary feature **"wherein the microparticles being such that the active substance exerts its pharmacological effect over a period greater than 12 hours".**

In comparison to claim 1 of auxiliary request 7, claim 1 of auxiliary requests 17-19 had the following respective amendments shown in bold, namely "particles of magnesium stearate present as a discontinuous coating covering on average at least **90%** of the surfaces of the active particles and wherein the coating is on average less than **200 nm** thick and **wherein the microparticles have a mass median aerodynamic diameter of not more than 10 µm"**, "particles of magnesium stearate present as a discontinuous coating covering on average at least **90%** of the surfaces of the active particles and wherein the

coating is on average less than **200 nm** thick and **wherein the microparticles have a mass median aerodynamic diameter of not more than 5 µm"**, and "particles of magnesium stearate present as a discontinuous coating covering on average at least **90%** of the surfaces of the active particles and wherein the coating is on average less than **200 nm** thick and **wherein the microparticles have a mass median aerodynamic diameter of not more than 3 µm"**

Auxiliary request 13-16

In comparison to claim 1 of the main request, claim 1 of auxiliary request 13 had the following amendments shown in bold "particles of magnesium stearate present as a discontinuous coating covering on average at least **90%** of the surfaces of the active particles and wherein the coating is on average less than **200 nm** thick.

In comparison to claim 1 of auxiliary request 13, claim 1 of auxiliary requests 14-16 have been amended by the respective following added features **"wherein the microparticles have a mass median aerodynamic diameter of not more than 10 µm"**, **"wherein the microparticles have a mass median aerodynamic diameter of not more than 5 µm"**, and **"wherein the microparticles have a mass median aerodynamic diameter of not more than 3 µm"**.

VII. With its reply to the statement of grounds of appeal dated 4 April 2022, the opponent (hereinafter the respondent) submitted new items of evidence and requested that documents D35 to D37 not be admitted into the appeal proceedings.

VIII. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA issued on

14 August 2023. In this communication the Board expressed its preliminary opinion that none of the requests on file met the requirements of Article 83 EPC.

IX. With a letter dated 20 September 2023, the appellant informed the Board and the respondent that it will not attend the oral proceedings and will not be represented.

X. The oral proceedings were cancelled.

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

Admission of D35-D37 into the appeal proceedings

Document D35 was provided in response to the impugned decision and provides evidence that it was possible for the skilled person to determine whether the requirements of the discontinuous coating and coating thickness are met. This evidence was submitted at the earliest opportunity following the notification of a change in opinion from the opposition division on the morning of the oral proceedings with regards to sufficiency of the opposed patent.

Document D36 was provided in response to the impugned decision and provides evidence that time-of-flight secondary ion mass spectrometry (ToF-SIMS) was routinely used in a variety of technical fields including the biological sciences and thus ToF-SIMS was part of the skilled person’s common general knowledge before the priority date of the opposed patent.

Document D37 was also provided in response to the impugned decision and was a paper entitled "Investigation of the extent of surface coating via mechanofusion with varying additive levels and the influences on bulk powder flow properties". D37 also provided evidence that ToF-SIMS was routinely used in the field and thus ToF-SIMS was part of the skilled person's common general knowledge prior to the priority date of the opposed patent.

Main request - Sufficiency of disclosure

The opposition division found that Scanning Electron Microscopy (SEM) did not allow for the determination of a discontinuous coating of magnesium stearate or the coating thickness. However, this point was never contested by the appellant in the opposition proceedings. Scanning Electron Micrographs permitted examination of the particle topography without the ability to identify the material involved. Nevertheless, it permitted a comparison of the starting material and the processed material to establish whether any rounding of characteristic edges has occurred due to the addition of an additive.

Energy-dispersive X-ray spectroscopy (EDX) enabled the determination of a magnesium stearate coating that is less than 1 µm thick, as shown by Figures 17(a) – 17(c) in D17. The skilled person could conclude that the particles in question were indeed coated with a magnesium containing molecule and that this was magnesium stearate. D17 showed that SEM and SEM-EDX allowed the skilled person to identify the shape of the particles and the co-location of the magnesium stearate on the surface of the active particles after these particles have been aerosolised.

With regard to the process parameters, the skilled person working in this field was aware of a variety of techniques and associated apparatuses.

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

Admission of D35-D37 into the appeal proceedings

The new evidence which was filed for the first time on appeal related to an entirely new and complex analytical technique. In this regard, throughout these opposition proceedings, the appellant had not once sought to rely on time of flight secondary mass spectrometry (ToF SIMS) as a suitable technique for analysing a coating of magnesium stearate. The appellant was seeking to run a completely new case on sufficiency which was not linked at all to the discussion on sufficiency at first instance. The complexity of the amendment to the appellant's case on sufficiency to refer to ToF-SIMS techniques was therefore a factor suggesting that this new material should not be admitted to the proceedings.

Moreover, the appellant had provided no proof that ToF SIMS was indeed part of the common general knowledge of a skilled person at the filing date, and for this reason, the new material was not suitable for addressing the issues which led to the decision under appeal. It was also not procedurally expedient to raise a wholly new technical issue, requiring a detailed exchange of experimental reports at this late stage in the proceedings.

Main request - Sufficiency of disclosure

ToF-SIMS was not common general knowledge at the priority date and not a suitable technique for determining the coverage or thickness of a coating as shown in D1. Neither scanning electron microscopy (SEM) nor energy-dispersive X-ray spectroscopy (EDX) could be used to determine the coverage or thickness of the magnesium stearate coating as specified in the claims. The skilled person was not able to establish whether or not any given microparticles had the required discontinuous coating. Finally, the patent did not teach what process steps could be carried out to obtain any microparticles as set out in the claims.

XIII. Requests

The appellant requested that the decision under appeal be set aside and the patent be maintained as granted, or alternatively according to the sets of claims filed as auxiliary requests 1-19 with letter of 6 December 2021.

The respondent requested that the appeal be dismissed. The respondent also requested that documents D35 to D37 not be admitted into the appeal proceedings.

Reasons for the Decision

1. Admission of D35-D37 into the appeal proceedings

1.1 Documents D35-D37 have been submitted by the appellant with its statement of grounds of appellant in the context of the discussion on sufficiency of disclosure. According to the appellant, they have been filed in response to the decision of the opposition division

regarding sufficiency of disclosure, and in particular in view of the change of opinion of the opposition division regarding lack of disclosure during the oral proceedings. They have been filed to show that the ToF-SIMS technique allows to determine the particle size distribution and surface area of the active agent and magnesium stearate, and that this was common general knowledge at the priority date of the contested patent.

1.1.1 Document D35 is in particular provided to show that it is possible for the skilled person to determine whether the requirements of the discontinuous coating and coating thickness are met. It studies the coating of model particles of lactose with magnesium stearate. The processed blends were transported to an independent contractor (Nanopharm Limited) for ToF SIMS analysis and the report on the findings is appended to D35 as Annex 1. The data produced from the investigation (D35 Annex 1) allowed to demonstrate a clear trend in magnesium stearate coverage of the supporting particles (Table 2 in D35).

1.1.2 D36 is an extract from a book on SIMS-X1 from 1997, which is submitted to show that the technique of secondary Ion Mass Spectrometry technique (ToF-SIMS) was routinely used in a variety of technical fields including the biological sciences and thus ToF-SIMS was part of the skilled person’s common general knowledge before the priority date of the opposed patent. D36 is a book that includes 252 contributions made available at the 11th International Conference on Secondary Ion Mass Spectrometry (SIMSXI) held in September 1997.

1.1.3 D37 is the first page of an article from the International Journal of Pharmaceutics with the title "Investigation of the extent of surface coating via

mechanofusion with varying additive levels and the influences" which was published in 2011. This document was filed to show that ToF-SIMS was routinely used in the field and was part of the common general knowledge prior to the priority date of the contested patent.

1.2 The objection of lack of sufficient disclosure as it stands was already present in the notice of opposition and mentioned the same two points, namely that there was no teaching in the patent enabling to control the nature of the coating on the active particles so as to achieve the specific structural arrangement of claim 1, and that it was not possible to determine whether or not a structural arrangement as claimed in claim 1 was satisfied by any given population of microparticles.

In its response to the notice of opposition, the appellant argued essentially on this point that the skilled person would need to know the surface area for the uncoated active material and then, based upon the total amount of active they wish to blend, the skilled person would then select the amount of magnesium stearate based upon the magnesium stearate's measured surface area to ensure that the magnesium stearate amount has a surface area which is on average at least 70%. With regard to the coating thickness, it was possible to make the measurement by using laser diffraction or BET to determine their uncoated size.

In its first and second summons to oral proceedings, the opposition division considered that the argumentation of the patent proprietor was plausible.

During the oral proceedings, the appellant argued again that the laser diffraction method being part of the common general knowledge allowed to determine the

particle size distribution and surface area of the active agent and magnesium stearate. However, the opposition division reversed its preliminary opinion and concluded that the requirement of sufficiency of disclosure was not met.

1.3 In view of the file history, the Board concludes that the ToF SIMS is a technique that has never been discussed or mentioned by any party during the opposition proceedings, in particular not by the appellant.

A discussion on this technique therefore constitutes a new fact and the filing of documents supporting this new line of argumentation constitutes an amendment to the appellant's case. Hence, the filing of D35-D37 amounts to an amendment of the appellant's case and the Board has discretion to admit them pursuant to Article 12(4) RPBA 2020. Relevant criteria for the exercise of the Board's discretion are the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal and the need for procedural economy.

1.3.1 The introduction of document D35 introduces a new and complex discussion about the experiments performed therein and their relevance, as well as their belonging to common general knowledge at the priority date; for this reason it is considered to have a negative impact on procedural economy and it is also questionable whether it is relevant to overcome the objection of insufficiency of disclosure. A complex point of discussion regarding the experiments of D35 is for instance the analysis of the specific methodology used in D35 for preparing the microparticles, with the use

of specific parameters such as D[v,50] or D_{50}, while other possibilities existed for the methodology.

The absence of any reference in the contested patent to the methods used in D35 constitutes also a further point of discussion.

In the Board's view, the complexity of the data disclosed in D35 raises new questions which are detrimental to the procedural economy of the proceedings.

1.3.2 With regard to D36, the Board notes that the mere provision of a book title and a brief description of its content is of limited evidential value. It thus appears to the Board that this document cannot be considered as suitable for evidence of common general knowledge.

1.3.3 D37 is a scientific article from 2011, and it is not clear to the Board how this document might represent evidence that the method used in D35 was common general knowledge at the effective filing date of the contested patent, since the contested patent has a priority date from 2000. This document is therefore irrelevant.

1.4 Hence, none of the criteria of admissibility, i.e the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal, and the need for procedural economy, speak in favour of admitting the documents D35-D37.

Moreover, the request was filed to overcome objections of lack of sufficiency that were present since the beginning of the opposition proceedings. Therefore, it

should have been filed in the opposition proceedings during which the appellant had an opportunity to do so (Article 12(6) RPBA 2020). The change of the opinion of the opposition division regarding sufficiency of disclosure during the oral proceedings cannot as such constitute a reason to file new documents in support of a new line of argumentation only in the appeal proceedings, since such a change belongs to the normal course of the proceedings.

Consequently, the documents D35-D37 are not admitted into the appeal proceedings (Article 12(4) and 12(6) RPBA 2020).

2. Main request - Sufficiency of disclosure

2.1 The relevant issues in relation to the requirement of sufficiency of disclosure are the possibility for the skilled person to determine whether the requirements of the discontinuous coating and coating thickness are met and whether the patent teaches how to adjust the coating to achieve the specific structural arrangements defined in claim 1.

2.2 According to the jurisprudence of the Boards, the requirements of sufficiency of disclosure are met if the patent in suit contains sufficient information to enable the skilled person to carry out the invention, i.e. when at least one way is clearly indicated in the patent specification enabling the skilled person to carry out the invention, and when the disclosure allows the invention to be performed in the whole area claimed without undue burden, applying common general knowledge.

2.3 In the present case, none of the examples of the patent indicate whether they disclose microparticles with a discontinuous coating covering on average at least 70% of the surfaces of the active particles and wherein the coating is on average less than 1 µm thick. Furthermore, there is no general disclosure in the description on how to prepare such kind of coated microparticles and how to measure the claimed coating coverage and thickness.

The Board notes also that the disclosure of the application as originally filed was not restricted to microparticles with a coverage of at least 70% of their surfaces, but to microparticles either with a continuous coating or with on average at least 50% coverage of the surface of the microparticles, so that it is questionable in any case whether the description and the examples in general relate to the now specifically claimed microparticles (see par. [0058] and [0075] of EP 2 298 279 A2).

2.4 It remains to be determined whether the common general knowledge at the filing date of the contested patent allows the preparation of the claimed microparticles and the measurement of the claimed parameters, i.e a discontinuous coating covering at least 70% of the surfaces of the active particles and wherein the coating is on average less than 1 µm thick. Several methods, i.e scanning electron microscopy (SEM), energy-dispersive X-ray spectroscopy (EDX), laser diffraction, the Brunauer-Emmet-Teller (BET) technique and time-of-Flight Secondary Ion Mass Spectrometry Analysis (ToF SIMS), were mentioned in this regard in the appeal proceedings.

2.4.1 In its decision the opposition division found that scanning electron microscopy (SEM) could not be used to determine the discontinuous coating or the coating thickness. This point was not contested by the appellant.

2.4.2 The opposition division also found that energy-dispersive X-ray spectroscopy (EDX) did also not enable the determination of a magnesium stearate coating, in particular that the coating was less than 1 µm thick. This conclusion was reached in particular referring to D2 and to the Judgment of the High Court of England and Wales dated 13 December 2018 (D1).

In its statement of grounds of appeal, the appellant relies on D17 (Figures 17(a)-(c) on page 29, (6a)-(6c) and 18(a)-18(c) on page 31) and D16 to argue that, by X-ray spectroscopy (EDX), the skilled person would be able to identify the shape of the particles and the co-location of the magnesium stearate on the surface of the active particles after these particles have been aerosolised.

Figures 17(a)–17(c) in D17 provide an image matrix where the images appearing in column (ii) are those representing a magnesium signal. A skilled person can conclude from the image matrix that the particles in question are indeed coated with a magnesium containing molecule. Said figures do however not allow the determination of the average coverage percentage of a coating and also the average thickness of the microparticles. The appellant did in particular not provide any clear method of calculation allowing the determination of the average coating coverage, and did not provide any evidence that it can be determined from the figures.

The same conclusion applies for figures 6(a)-6(c) and 18(a)-18(c) of D17.

2.4.3 With regard to laser diffraction, the contested patent discloses the use of this method in example 4, for determining the particle size D_{50} of the magnesium stearate by Malvern laser diffraction. As explained by the appellant, the method of laser diffraction provides several parameters for a particulate sampling including D_{10}, D_{50} and D_{90} in addition to surface area, wherefrom it would be possible to determine increases in particle sizes and calculate the volume associated with increase in particle size.

The Board notes that D_{50} is used in example 4 to determine the median particle size of magnesium stearate, but there is no link in this example or in the description between this parameter and the determination of the average coating coverage or coating thickness; there is furthermore no teaching in said example about the further particle size parameters mentioned by the appellant and no evidence that the increase in particle sizes and the calculation of the volume associated with the increase in particle size can lead to the determination of the average coating coverage and the average coating thickness.

2.4.4 With regard to the Brunauer-Emmett-Teller (BET), method, the appellant mentioned document D25 in support of the use of this technique without providing any evidence or calculation. The BET theory explains the physical adsorption of gas molecules on a solid surface and may serve as the basis for a technical analysis for the measurement of the specific surface area of materials. Again, there is no reference in the

description of the contested patent to this technique, and the appellant did not provide any further argument or evidence on how it can be used to determine the average coverage percentage of a coating and also the average thickness of the microparticles.

2.4.5 With regard to the ToF SIMS technique, there is no reference to this technique in the contested patent and any other cited document, nor any evidence on file that this technique was common general knowledge at the filing date of the contested patent, in particular in this field and in this context.

2.5 With regard to the adjustment of the process parameters to ensure the specific structural arrangements in claim 1, the appellant argues that the skilled person is aware of a variety of techniques and associated apparatus. The Board comes however to the same conclusion as the opposition division, namely that the patent does not give any teaching, or reference to common general knowledge, on which steps could be carried out in order to obtain the microparticles as set out in the claims (cf. also point 2.3 above).

2.6 In view of the points above, the Board does not see any reason to reverse the decision of the opposition division. Hence, the claimed invention according to the main request is not sufficiently disclosed (Article 83 EPC).

3. Auxiliary requests 1-19

All auxiliary request 1-12 comprise the same requirements of the discontinuous coating and coating thickness, namely the feature of a discontinuous coating of at least 70% of the surfaces of the active

particles which is on average less than 1 µm thick, while auxiliary requests 13-19 specify that the discontinuous coating covers on average at least 90% of the surfaces of the active particles and that the coating is less than 200 nm.

As for the main request and for the same reasons, the skilled person cannot determine whether the requirements of the discontinuous coating and coating thickness are met and the patent does not teach how to adjust the coating to achieve the specific structural arrangements defined in claim 1.

Consequently, the invention according to all auxiliary requests 1-19 lacks sufficiency of disclosure for the same reasons as for the main request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Sanchez Chiquero A. Usuelli

Decision electronically authenticated