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Datasheet for the decision of 20 July 2023

Case Number: T 2048/19 - 3.3.04

Application Number: 12709151.0

Publication Number: 2680841

IPC: A61K31/40, A61K31/167, A61K31/4704, A61K45/06, A61K9/14, A61M15/00, A61K9/00, A61P9/00, A61P9/06

Language of the proceedings: EN

Title of invention:
Use of glycopyrrolate for treating tachycardia

Patent Proprietor:
Heptares Therapeutics Limited

Opponent:
Teva Pharmaceuticals International GmbH

Headword:
Glycopyrrolate for treating tachycardia /TEVA

Relevant legal provisions:
EPC Art. 100(a), 54, 83, 56
RPBA 2020 Art. 13(1)
RPBA Art. 12(4) (2007)

Keyword:
Main request - novelty (no)
Auxiliary request 1 - late-filed - could have been filed in first instance proceedings (yes)
Auxiliary request 2 - novelty (no)
Auxiliary request 3 - late-filed - admitted (yes)
Auxiliary request 3 - sufficiency of disclosure, novelty, inventive step (yes)

Decisions cited:
T 0134/11

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Case Number: T 2048/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 20 July 2023

Appellant: (Patent Proprietor)	Heptares Therapeutics Limited Granta Park Great Abington Cambridge, Cambridgeshire CB21 6DG (GB)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Respondent: (Opponent)	Teva Pharmaceuticals International GmbH Elisabethenstrasse 15 4051 Basel (CH)
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 10 May 2019 revoking European patent No. 2680841 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chair	A. Chakravarty
Members:	S. Albrecht
	R. Romandini

Summary of Facts and Submissions

I. The patent proprietor ("appellant") filed an appeal against the opposition division's decision to revoke European patent No. 2 680 841 ("patent").

II. The patent was opposed by a single opponent. The opponent is respondent to the patent proprietor's appeal. The grounds for opposition relied on were Article 100(a) EPC for lack of novelty and lack of inventive step and Article 100(b) EPC.

III. In the decision under appeal, the opposition division considered the patent proprietor's main request, which was that the patent be maintained as granted and twenty one sets of auxiliary claim requests. It held that the subject-matter of claim 1 as granted was novel over the disclosure in documents D1 and D2 and involved an inventive step starting from either of these two documents as the closest prior art. The opposition division further considered that the invention defined in claim 1 as granted was sufficiently disclosed. By contrast, the subject-matter of claim 15 as granted lacked novelty over the disclosure in document D1. Moreover, claim 16 was to be construed as a product claim relating to an inhalable pharmaceutical composition comprising glycopyrrolate or a pharmaceutically acceptable salt thereof suitable for the stated use. Document D1 disclosed such a composition, which therefore lacked novelty.

IV. The following documents are mentioned in this decision:

D1: WO 2005/107872 A2
D2: WO 2005/107873 A2

D4: R. W. Neumar *et al.*, "Part 8: Adult Advanced Cardiovascular Life Support: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care", Circulation 122(3), 2010, 729-67
D13: R. K. Mirakhur *et al.*, "Comparison of the effects of atropine and glycopyrrolate on various end-organs", Journal of the Royal Society of Medicine 73, October 1980, 727-30
D18: C. Bartels *et al.*, "Determination of the pharmacokinetics of glycopyrronium in the lung using a population pharmacokinetic modelling approach", Br J Clin Pharmacol 76(6), 19 March 2013, 868-79

V. In its statement of grounds of appeal, the appellant's main request was that the patent be maintained as granted. It also filed sets of claims of auxiliary requests 1 to 6.

VI. In its reply to the statement of grounds of appeal, the respondent requested that the appeal be dismissed and that auxiliary requests 1 to 6 not be admitted into the proceedings.

VII. With a letter dated 23 March 2020, the appellant filed four further sets of claims as auxiliary requests 7 to 10, respectively.

VIII. In a communication pursuant to Article 15(1) RPBA issued on 30 May 2023 ("communication"), the board drew the parties' attention to the points to be discussed during the oral proceedings. With regard to claim 16 as granted, the board remarked, *inter alia*, that the purpose recited in this claim appeared to include non-medical uses. As a consequence, the opposition

division finding's that the subject-matter of claim 16 lacked novelty over document D1 appeared to be correct.

IX. In a letter dated 19 June 2023, the respondent withdrew its request for oral proceedings and informed the board that it would not be attending the oral proceedings.

X. Oral proceedings were held on 20 July 2023 by videoconference in the presence of the appellant. In the course of these proceedings, the appellant filed a new set of claims labelled as auxiliary request 3 and renumbered auxiliary requests 3 to 6, filed with the statement of grounds of appeal, as auxiliary requests 4 to 7, respectively. It further renumbered auxiliary requests 7 to 10, filed with letter of 23 March 2020, as auxiliary requests 8 to 11, respectively, and withdrew its request for reimbursement of the appeal fee. At the end of the oral proceedings, the Chair announced the board's decision.

XI. Claim 1 of the main request reads:

"1. An inhalable pharmaceutical composition comprising glycopyrrolate or a pharmaceutically acceptable salt thereof for use in the treatment or prophylaxis of tachycardia."

Claims 13 to 16 of the main request read:

"13. An inhalable unit dose comprising the pharmaceutical composition as defined in any of claims 1 to 12 for use in the treatment or prophylaxis of tachycardia.

14. An inhalation delivery device comprising one or more unit doses as defined in claim 13 for use in the treatment or prophylaxis of tachycardia.

15. The delivery device as defined in claim 14, wherein the delivery device is a dry powder inhaler.

16. An inhalable pharmaceutical composition comprising glycopyrrolate or a pharmaceutically acceptable salt thereof for use as a heart rate suppression agent under resting conditions."

The set of claims of auxiliary request 1 is identical to the set of claims of the main request except that claims 16 and 17 have been deleted and claims 18 to 20 renumbered as claims 16 to 18, respectively.

The set of claims of auxiliary request 2 differs from the set of claims of auxiliary request 1 in that the term "as defined in" in claim 15 has been replaced by the expression "for use in the treatment or prophylaxis of tachycardia according to". In addition, claims 17 and 18 have been amended to specify that the claimed unit dose (claim 17) and delivery device (claim 18) are for use in the treatment or prophylaxis of tachycardia.

The set of claims of auxiliary request 3 differs from the set of claims of auxiliary request 2 in that claims 14, 15, 17 and 18 have been deleted and in that claim 16 has been renumbered as claim 14.

XII. The appellant's written and oral submissions relevant for the present decision are summarised as follows.

Main request (patent as granted) - claim 16 - claim construction and novelty over document D1

As explained in paragraph [0028] of the patent, a therapeutic effect within the scope of claim 16 was the prophylactic treatment of patients having a heart rate under resting conditions so high that an increase in this heart rate would lead to ill effects. Hence, the opposition division should have found that this claim was a purpose-limited product claim pursuant to Article 54(5) EPC.

Contrary to the respondent's contention, the purpose recited in claim 16 did not include non-medical uses. The purpose of suppressing heart rate under resting conditions was based on the therapeutic mechanism of action of glycopyrrolate or a pharmaceutically acceptable salt thereof ("glycopyrrolate (salt)"), which was therefore a method of treatment encompassed by Article 53(c) EPC.

Since none of the cited prior art disclosed the use of glycopyrrolate as a heart rate suppression agent, the subject-matter of claim 16 was novel.

Auxiliary request 1 - admittance into the appeal proceedings

The respondent's request to hold this request inadmissible should be rejected. The amendments made to auxiliary request 1 were simple deletions of two claims (claims 16 and 17). These amendments had been made as a *bona fide* attempt to address the opposition division's objection of lack of novelty of claims 16 and 17 of the main request set out in points 12.3.2.3 and 12.3.2.4 of the impugned decision, and clearly overcame this objection. What is more, the same amendments had been

made to auxiliary request 3 underlying the impugned decision.

Considering that a number of new facts and arguments had been raised against the then pending auxiliary requests at the oral proceedings before the opposition division which had isolated the aspect defined in claims 16 and 17 of the main request, the filing of auxiliary request 1 to deal with this aspect had taken place at the earliest possible point in time, i.e. with the filing of the statement of grounds of appeal.

In any event, as set out in the Case law of the Boards of Appeal, 10th edition 2022, V.A.5.11.3, subsection g) in relation to decision T 134/11, the mere fact that a request could have been filed in the first-instance proceedings did not automatically lead to the inadmissibility of this request. On the contrary, such a request was only inadmissible in exceptional circumstances. In the case at hand, there were no such circumstances.

Auxiliary request 2 - admittance into the appeal proceedings

The opposition division's surprising finding of lack of novelty of claim 15 of the then pending auxiliary request 1 prompted the filing of auxiliary request 2 with the statement of grounds of appeal. Consequently, this request could not reasonably have been filed earlier.

Auxiliary requests 2 and 3 - claim 1 - sufficiency of disclosure

A skilled person working in the technical field of the claimed invention would understand the term "treatment"

in claim 1 to mean the reduction of a patient's abnormally high resting heart rate for a meaningful length of time, i.e. longer than transient.

The patent made it credible that the inhalable pharmaceutical composition comprising glycopyrrolate, as claimed, was suitable for treating or preventing tachycardia in any of its forms. In particular, Table 3 contained clinical data demonstrating the ability of glycopyrrolate to cause a meaningful reduction in the subjects' heart rates for a significant duration.

The respondent, who bore the burden of proof, had not raised serious doubts substantiated by verifiable facts that the clinical data disclosed in the patent were indicative of the claimed medical uses.

Auxiliary request 2 - claim 15 - novelty over document D1

Claim 15 was a purpose-limited product claim in accordance with Article 54(5) EPC. It was directed to a device containing a pharmaceutical composition and this composition was for use in the treatment of or prophylaxis of tachycardia. Document D1 did not disclose the medical uses recited in claim 15 and therefore did not anticipate the subject-matter of this claim.

Auxiliary request 3 - claim 1 - novelty over documents D1 and D2

The opposition division had been correct to find the subject-matter of claim 1 to be novel over the disclosure in documents D1 and D2. Neither of these two documents disclosed that the patients suffered from tachycardia or enabled the conclusion that the disclosed inhalable composition comprising

glycopyrrolate was capable of treating or preventing tachycardia.

Auxiliary request 3 - claim 1 - inventive step

The opposition division correctly identified that the subject-matter of claim 1 differed from the disclosure in document D1 in that the group of patients to be treated suffered from tachycardia. The opposition division's definition of the objective technical problem as the provision of a treatment of tachycardia which was particularly beneficial was equally correct. As set out in the decision under appeal, the solution defined in claim 1 would not have been obvious to the skilled person in view of document D1 taken alone or in combination with document D13.

XIII. The respondent's written submissions relevant for the present decision are summarised as follows.

Main request (patent as granted) - claim 16 - claim construction and novelty over document D1

Suppression of heart rate could only be seen as a treatment of a disease in cases where the heart rate was abnormally increased. However, the subject-matter of claim 16 was not limited in this manner and included suppression of heart rate in cases where it was not so increased. The claimed subject-matter thus also included non-medical uses. To the extent it included non-medical uses, the claim was not for a purpose-limited product under Article 54(5) EPC and so the recited use did not limit the claimed subject-matter. This had the consequence that claim 16 lacked novelty over document D1.

Auxiliary request 1 - admittance into the appeal proceedings

This request should not be admitted into the appeal proceedings. The appellant had not given a credible justification as to why this request had not been filed in the proceedings before the opposition division.

Auxiliary request 2 - admittance into the appeal proceedings

As explained for auxiliary request 1, auxiliary request 2 should not be admitted into the appeal proceedings.

The appellant was not present at the oral proceedings before the opposition division of its own choice. Had the appellant attended, it would have been able to take advantage of its opportunity to respond to the opposition division's reasoning concerning the lack of novelty of claim 15 of auxiliary request 1 underlying the decision under appeal.

Auxiliary requests 2 and 3 - claim 1 - sufficiency of disclosure

To effectively treat a patient suffering from any of the types of tachycardia mentioned in paragraphs [0004] to [0010] of the patent, a treatment must be able to reduce the patient's heart rate from anywhere between 100 to 250 beats per minute (depending on the type of tachycardia) to below 100 beats per minute ("bpm").

The clinical data set out in the patent were not indicative of a treatment of tachycardia in any of its forms. Firstly, these data were obtained in COPD patients with normal heart rates. Secondly, of all the glycopyrrolate doses tested in these patients, only the

400 µg dose showed some heart rate-lowering effects at some time points, but these effects did not translate to an effective treatment of tachycardia in any of its forms. What is more, higher doses of inhaled glycopyrrolate caused the opposite effect of increased heart rate. Considering that tachycardia was often a symptom of an underlying disease or condition such as COPD, it was more plausible that glycopyrrolate simply performed its known function of treating COPD, and a consequence was a reduction in this symptom of COPD.

Auxiliary request 3 - claim 1 - novelty over documents D1 and D2

Document D1 disclosed a clinical study using glycopyrrolate by inhalation in subjects with COPD. As a result of this treatment, a small and transient decrease in heart rate was observed. If one were to conclude in the context of sufficiency of disclosure that the small and transient reduction observed in the clinical study described in the patent was known from the skilled person's common general knowledge to be a reliable model for tachycardia, that same common general knowledge had to be applied to the interpretation of document D1. Consequently, claim 1 lacked novelty over document D1.

Document D2 had essentially the same teaching as document D1 and was thus prejudicial to the novelty of claim 1 as well.

Auxiliary request 3 - claim 1 - inventive step

The subject-matter of claim 1 differed from the disclosure in the closest prior art, document D1, in the appreciation that a reduction in heart rate in COPD

patients were applicable to a treatment of tachycardia. The objective technical problem was the provision of a further medical use for inhaled glycopyrrolate. The solution defined in claim 1 would have been obvious to the skilled person in view of the disclosure in document D1 taken alone or in combination with that in document D13.

XIV. The parties' final requests, in so far as relevant to the present decision, were as follows.

The appellant requested that the decision under appeal be set aside and the patent be maintained as granted or, in the alternative, that the patent be maintained as amended

(a) on the basis of one of the sets of claims of auxiliary requests 1 and 2, filed with the statement of grounds of appeal, or

(b) on the basis of the set of claims of auxiliary request 3, filed during the oral proceedings before the board, or

(c) on the basis of one of the sets of claims of auxiliary requests 4 to 7, filed as auxiliary requests 3 to 6 with the statement of grounds of appeal, or

(d) on the basis of one of the sets of claims of auxiliary requests 8 to 11, filed as auxiliary requests 7 to 10 with letter of 23 March 2020.

The respondent requested in writing that the appeal be dismissed and that auxiliary requests 1, 2, 4 to 7, and 9 to 11 not be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

Absence of the respondent from the oral proceedings

2. The respondent, although duly summoned, did not to attend the oral proceedings, as it had announced in its letter dated 19 June 2023. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the board continued the proceedings in the respondent's absence. The respondent is treated as relying on its written case. By absenting itself from the oral proceedings the respondent waived the opportunity to make any further submissions on the relevant issues of the case. Hence, the board was in a position to announce a decision at the conclusion of the oral proceedings, as provided for in Article 15(6) RPBA.

Main request (patent as granted) - claim 16

Claim construction and novelty over document D1 (Article 100(a) EPC in conjunction with Article 54 EPC)

3. Claim 16 is for a purpose-limited product under Article 54(5) EPC. The product is "an inhalable pharmaceutical composition comprising glycopyrrolate or a pharmaceutically acceptable salt thereof". The claimed purpose is the "*use as a heart rate suppression agent under resting conditions*".

3.1 It is common ground between the parties, and the board agrees, that this purpose includes uses in a method of treatment by therapy referred to in Article 53(c) EPC. As an example, the therapeutic treatment of patients

with an abnormally increased heart rate may be cited. Another example is the prophylactic treatment of patients having a heart rate under resting conditions so high that an increase in heart rate would lead to ill effects.

3.2 In its communication under Article 15(1) RPBA (see point 4.7.3), the board provisionally agreed with the respondent that the purpose recited in claim 16 was both medical and non-medical.

3.3 In reply to this communication (see appellant's letter dated 7 June 2023, sections 3.1. to 3.4), the appellant stated that the purpose of suppressing heart rate under resting conditions was based on a therapeutic mechanism of action of the glycopyrrolate (salt) but did not further elaborate on this point, neither in writing nor at the oral proceedings.

3.4 As argued by the respondent (see paragraph (86) of its reply to the statement of grounds of appeal), having a heart rate is not a disease. Claim 16 does not further define the subjects to be treated with the claimed composition. The purpose defined in the claim therefore includes both the therapeutic and prophylactic treatment, set out in point 3.1 above, and also the non-therapeutic treatment of healthy subjects who are not in need of heart rate suppression to prevent ill effects that would otherwise arise. In the absence of any explanation by the appellant why the claimed composition has a therapeutic mechanism of action in this group of subjects, the board sees no reason to change its preliminary opinion. The purpose recited in claim 16 thus includes non-medical uses to which the special concept of novelty under Article 54(5) EPC does not apply (see Case Law of the Boards of

Appeal of the European Patent Office, 10th edition 2022, I.C. 7.1 and 7.2). Thus, the subject-matter of claim 16 includes, *inter alia*, an inhalable pharmaceutical composition comprising glycopyrrolate (salt) *suitable* for use as a heart rate suppression agent under resting conditions, i.e. a composition as such, where the therapeutic purpose is not a feature of the claim.

3.5 It was not in dispute that such a pharmaceutical composition was known from document D1. Hence, the subject-matter of claim 16 lacks novelty over the disclosure in this document.

Overall conclusion on the main request

3.6 The board concludes that the ground for opposition under Article 100(a) EPC in conjunction with Article 54 EPC prejudices the maintenance of the patent as granted.

Auxiliary request 1

Admittance (Article 12(4) RPBA 2007)

4. Auxiliary request 1 was filed for the first time with the statement of grounds of appeal. It differs from the claims of the main request in that claims 16 and 17 have been deleted and claims 18 to 20 renumbered as claims 16 to 18.

4.1 The respondent requested that auxiliary request 1 be held inadmissible.

4.2 According to Article 12(4) RPBA 2007, first half-sentence, the board has the discretionary power to

hold inadmissible facts, evidence and requests which could have been presented or were not admitted in the proceedings before the opposition division.

4.3 In the case at hand, it is undisputed that the amendments made to auxiliary request 1 are straightforward. What is more, the amendments made overcome the opposition division's objection of lack of novelty of claims 16 and 17 of the main request (see points 12.3.2.3 and 12.3.2.4 of the decision under appeal).

4.4 However, the respondent had put forward the aforementioned objection of lack of novelty of claims 16 and 17 of the main request and the claim construction underlying it in the notice of opposition (see section 5.3).

4.4.1 What is more, in the communication annexed to the summons to attend oral proceedings (see points 6.2.2.3.2 and 6.2.2.3.3), the opposition division had already informed the parties of its intention to establish at the oral proceedings whether the use recited in claim 16 of the main request constituted a purpose-limitation under Article 54(5) EPC. The opposition division further observed that, were it to conclude that the claimed use did not fall under the provisions of Article 53(c) EPC, it would appear that the subject-matter of claims 16 and 17 of the main request lacked novelty over the disclosure in document D1 (or D2).

4.4.2 In reply to this communication (see letter dated 24 January 2019), the appellant withdrew its request for oral proceedings and informed the opposition

division that it would not be represented at the oral proceedings, should these be maintained.

4.4.3 With this same letter, the appellant filed seven auxiliary requests, labelled as auxiliary requests 1 to 6 and 21, respectively. As noted by the appellant itself at the oral proceedings before the board, the claim set of auxiliary request 3 filed with this letter includes the amendments made to auxiliary request 1.

4.5 As a consequence, the appellant could and should have filed auxiliary request 1 at the latest with its letter dated 24 January 2019.

4.6 The appellant's reference to decision T 134/11 does not alter the board's conclusion for the following reasons.

4.6.1 That decision was taken under the legal framework of Article 12(4) RPBA 2007 which also applies to the present proceedings. It sets out the following principles:

"the mere fact that a request could have been filed in the first instance is not a reason to consider it inadmissible; [o]n the contrary, normally such a request is inadmissible only in exceptional circumstances. For example, such circumstances may arise where, by the filing of a request only at the appeal stage, a decision by the opposition division on certain issues is avoided and the decision is shifted to the second instance (this is referred to as "forum shopping" in decision T 1067/08 of 10 February 2011; not published in OJ EPO)".

4.6.2 While the view expressed in decision T 134/11 is obviously not in line with the current legal framework,

under which the primary function of the appeal procedure is to review the decision under appeal in a judicial manner (Article 12(2) RPBA 2020) and considering new requests filed in appeal is rather the exception than the rule, the considerations set out in that decision do not change the board's assessment on admittance of auxiliary request 1 for the simple reason that the circumstances underlying the decision in T 134/11 and the circumstances of the present case differ significantly in the aspects relevant here. In decision T 134/11, the objection that the request in question attempted to address had been raised for the first time during the oral proceedings before the opposition division. According to that decision, the patent proprietor had relied on an auxiliary request submitted prior to the oral proceedings rather than drafting a new request in view of the little time available during the oral proceedings. In contrast, in the present case, the objection that auxiliary request 1 aims to address had already been raised in the notice of opposition. What is more, the appellant absented itself from the oral proceedings before the opposition division, thereby effectively waiving the opportunity to file auxiliary request 1 at those oral proceedings.

4.7 As a final point, the board notes that even if, as alleged by the appellant at the oral proceedings, the respondent's reasoning in support of its request to hold auxiliary request 1 inadmissible was inconsistent with the respondent's position on the admittance of auxiliary requests 4 to 6, this would not alter the fact established above, that when taking the circumstances underlying the present case into account, the appellant could and should have filed auxiliary request 1 earlier.

4.8 In view of the foregoing considerations, the board decided to hold auxiliary request 1 inadmissible under Article 12(4) RPBA 2007.

Auxiliary request 2

Admittance (Article 12(4) RPBA 2007)

5. Auxiliary request 2 was filed with the statement of grounds of appeal. It differs from auxiliary request 1 in that claims 15, 17 and 18 have been amended to exclusively use the language "for use in the treatment or prophylaxis of tachycardia" (see point XI. above).

5.1 These amendments aim to overcome the opposition division's finding of lack of novelty of claim 15 of the main request (see point 12.3.2.2 of this decision). The opposition division had come to this conclusion by interpreting claim 15 as not being a purpose-limited product claim under Article 54(5) EPC.

5.2 As correctly observed by the respondent, the appellant had chosen not to attend the oral proceedings before the opposition division.

5.3 However, given the circumstances of the case, the appellant could not reasonably have been expected to file auxiliary request 2 earlier than with the statement of grounds of appeal.

5.3.1 First of all, the opposition division's finding of lack of novelty of claim 15 of the main request and the claim interpretation underlying it stand in contradiction to the opposition division's preliminary view expressed in point 6.2.2.3.1 of its communication annexed to the summons to attend oral proceedings.

5.3.2 Moreover, the respondent had not objected to the status of claim 15 of the main request as a purpose-limited product claim during the entire written proceedings before the opposition division.

5.3.3 As a consequence, the opposition division's change of mind at the oral proceedings as regards the interpretation of this claim and the subsequent finding of lack of novelty of this claim constitute an unforeseeable development in the opposition proceedings justifying the filing of auxiliary request 2 with the statement of grounds of appeal.

5.4 The board therefore decided to take auxiliary request 2 into account under Article 12(4) RPBA 2007.

Article 83 EPC - Disclosure of the invention

The term "treatment" in claim 1

6. Claim 1 is worded as a purpose-limited product claim under Article 54(5) EPC.

6.1 According to the case law of the boards of appeal (see Case Law of the Boards of Appeal, 10th edition 2022, II.C.7.2.1), when assessing claims pertaining to a therapeutic use such as purpose-limited product claims in accordance with Article 54(5) EPC, attaining the claimed therapeutic effect is a functional technical feature of the claims.

6.2 In the case at hand, the claimed therapeutic effect is the treatment or prophylaxis of tachycardia. It was common ground that

(a) tachycardia is a type of arrhythmia which presents with a high heart rate, typically above 100 bpm for an adult (see paragraph [0002] of the patent);

(b) the term "tachycardia" encompasses different forms of tachycardias including potentially life-threatening cardiac arrhythmias with heart rates exceeding 200 bpm (see paragraphs [0004] to [0010] of the patent).

6.3 As a consequence, the provision of an effective treatment or prophylaxis of tachycardia in any if its forms is a functional technical feature of claim 1.

6.4 The parties had diverging views on what constitutes an effective treatment of tachycardia.

6.5 At the oral proceedings before the board, the appellant argued that the respondent's interpretation was too narrow and not technically sensible. According to the boards' case law, treatment by therapy was not restricted to curing a disease but also encompassed relief, alleviation and reduction of symptoms (see Case Law of the Boards of Appeal, 10th edition 2022, I.B. 4.5.1a)). In the technical field of tachycardia therapy, therapeutic effectiveness did not require a reduction of the patient's resting heart rate to a level as low as 100 bpm. Treatments which controlled a patient's high resting heart rate, i.e. reduced it for a meaningful length of time (longer than transient), were considered to be therapeutically effective treatments of tachycardia of any kind, including severe forms thereof, as evidenced by pre-published document D4, page S755, left-hand column, fourth full paragraph, first sentence, and page S756, right-hand column, third sentence.

6.6 These passages teach that tachycardia treatments focus on heart rate control, heart rhythm control, or both, and thus corroborate the appellant's definition of an effective treatment of tachycardia.

6.7 In contrast, the respondent has not put forward any evidence to suggest that a skilled person working in the technical field of the claimed invention would understand an effective treatment of tachycardia to require a reduction in resting heart to a level below 100 bpm.

6.8 Under these circumstances, the board does not see any reason to call into question the appellant's definition of an effective treatment of tachycardia.

Sufficiency of disclosure in respect of the claimed medical uses

7. In the board's view, the experimental data disclosed in the patent are sufficient to show that the pharmaceutical composition recited in claim 1 is suitable for the claimed medical uses (treatment and prophylaxis of tachycardia in all of its forms) for the following reasons.

7.1 The data stems from a placebo-controlled, crossover, dose-ranging clinical study (see paragraphs [0137] to [0163] of the patent) using four dose levels of glycopyrronium bromide (20, 125, 250 and 400 µg, respectively) by inhalation in subjects with COPD. During the clinical study, the heart rate of the subjects was measured before receiving study medication and at 45, 90 minutes and 5, 10, 20 and 30 hours post-treatment on study days. The results on heart

rates are displayed in Tables 2 to 4 of the patent. As conceded by the respondent, inhaled glycopyrronium bromide at a dose of 400 µg provides a statistically significant reduction in heart rate up to 10 hours post-dose compared to placebo (see Table 4 of the patent).

7.2 The board considers the aforementioned heart-rate lowering effects of the 400 µg dose to be meaningful reductions of the subjects' heart rate for a significant period of time.

7.3 Concerning the results in Table 4 for the other doses of glycopyrronium bromide (20, 125 and 250 µg), the board acknowledges that

(a) these results are not statistically significant at any time point,

(b) the 20 and 125 µg dose show increased heart rate compared to placebo at 10 hours post-dose,

(c) the 125 and 250 µg doses show increased heart rate compared to placebo at 30 hours post-dose.

7.4 However, despite the observed lack of statistical significance and with the exception of the 20 and the 125 µg doses at 5 hours post-dose, all three doses of glycopyrronium bromide caused a measurable decrease in mean heart rate up to 20 hours post-dose. There was no such overall trend with placebo (see Table 3 of the patent). Taken together with the results associated with the 400 µg dose (see point 7.1 above), the board is satisfied that the experimental data contained in the patent show that the pharmaceutical composition recited in claim 1 is suitable for the treatment or

prophylaxis of any type of tachycardia, including severe forms thereof.

7.5 A successful objection based on insufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts, that the invention is disclosed sufficiently clear and complete for it to be carried out by a person skilled in the art (see Case Law of the Boards of Appeal, 10th edition 2022, II.C. 9).

7.6 However, the respondent did not provide any verifiable facts which would raise serious doubts that these effects could be extrapolated to patients with tachycardia. As correctly pointed out by the respondent in writing, the heart rate lowering effects of glycopyrronium bromide disclosed in the patent have been obtained in COPD patients with normal heart rates at the time of screening. In the absence of such serious doubts, the respondent's reasoning must fail.

7.7 In a further line of argument, the respondent contended that the heart rate-lowering effects reported in Table 4 of the patent were so trivial as not to suggest any material treatment of tachycardia, let alone any material treatment of severe tachycardia. This contention is based on an interpretation of the term "treatment" in claim 1 which the board does not adhere to (see points 6.4 to 6.8 above). For the reasons set out in points 7.1 to 7.4 above, the board is satisfied that the clinical data contained in the patent are indicative of a treatment or prophylaxis of tachycardia in any of its forms.

7.8 In reaching this conclusion, the board took into account the respondent's observation that tachycardia

is often a symptom in patients suffering from COPD. However, as the appellant correctly pointed out at the hearing, the COPD patients who underwent the clinical trial described in the patent did not suffer from tachycardia.

7.9 For the sake of completeness, the board notes that even if it were assumed in the respondent's favour that inhaled glycopyrrolate at doses beyond 400 µg caused the opposite effect of increased heart rate, it remains true that the clinical data disclosed in the patent credibly show the suitability of the pharmaceutical composition recited in claim 1 for the stated medical uses over a dose range of 20 to 400 µg.

Overall conclusion on sufficiency of disclosure of the subject-matter defined in claim 1

7.10 The board concludes that the subject-matter defined in claim 1 complies with the requirement of sufficiency of disclosure.

Claims 14 and 15

Claim construction

8. It is immediately apparent from the wording of claims 14 and 15 that their subject-matter is a device rather than a pharmaceutical composition. Consequently, claims 14 and 15 are not open for a medical use under Article 54(5) EPC because they do not relate to a substance or composition (see Case Law of the Boards of Appeal, 10th edition 2022, I.C.7.2.4.g)).

Novelty (Article 54 EPC)

over document D1

9. The device defined in claim 15 is known from document D1 (see point 12.3.2.2 of the decision under appeal, the last two paragraphs). This was not disputed by the appellant.

9.1 Consequently, claim 15 lacks novelty over document D1.

9.2 At the oral proceedings, the board informed the appellant that the same conclusions would apply to claim 14 since this claim was also directed to a device. The appellant did not object to the board raising this objection *ex officio*.

Overall conclusion on auxiliary request 2

9.3 The board concludes that the subject-matter of claims 14 and 15 of auxiliary request 2 lacks novelty under Article 54 EPC.

Auxiliary request 3

Admittance (Article 13(1) RPBA)

10. This claim request is identical to the set of claims filed as auxiliary request 7 on 23 March 2020 except that claims 14 and 15 have been deleted.

10.1 These deletions overcome the board's objection of lack of novelty of the subject-matter of claims 14 and 15 over the disclosure in document D1 raised for the first time at the oral proceedings (see points 9. to 9.2 above).

10.2 In view of the foregoing, the board, exercising its discretion under Article 13(1) RPBA, decided to admit this request into the proceedings.

Claim 1

Disclosure of the invention (Article 83 EPC)

11. Claim 1 of auxiliary request 3 is identical to claim 1 of auxiliary request 2. Hence, the considerations set out above regarding sufficiency of disclosure of claim 1 of auxiliary request 2 apply equally to claim 1 of auxiliary request 3.

It follows that the subject-matter defined in this claim complies with the requirement under Article 83 EPC for sufficiency of disclosure.

Novelty (Article 54 EPC)

over documents D1 and D2

12. Document D1 (see page 9, bottom half, to page 10) discloses a placebo-controlled clinical study in subjects with COPD whose heart rate status is not specified ("clinical study of document D1"). The treatment consisted of glycopyrrolate by inhalation at doses of 20, 125, 250 and 400 µg, respectively. The effects reported include a small, transient decrease in heart rate following dosing (see page 10, penultimate line).

12.1 Contrary to the respondent's position, the skilled person reading document D1 in light of their common general knowledge would not understand this small,

transient decrease to be a reliable indication of an effective treatment of tachycardia. An effective treatment of tachycardia as required by claim 1 implies a reduction of a patient's high resting heart rate for a meaningful length of time, i.e. longer than transient (see above, point 6.8 in conjunction with points 6.5 and 6.6). No such heart rate reduction is disclosed in document D1.

12.2 Consequently, the disclosure in document D1 does not anticipate the subject-matter of claim 1.

12.3 Since document D2 has essentially the same teaching as document D1, it is not prejudicial to the novelty of claim 1 either.

Inventive step (Article 56 EPC)

The closest prior art

13. In agreement with the parties, the board considers the disclosure of the clinical study of document D1 (see point 12. above) to be a suitable starting point for the assessment of inventive step of the subject-matter of claim 1.

Distinguishing features vis-à-vis document D1

14. It was not in dispute that the composition used in the clinical study of document D1 is an inhalable pharmaceutical composition according to claim 1.

14.1 The respondent, noting the overlapping inventors on document D1 and the patent and the close similarity of the clinical studies described in these two disclosures, asserted that the clinical study of

document D1 reported the same therapeutic effect as the patent, namely a decrease in heart rate, the only difference being that the patent gave numerical values for "small" and "transient" in document D1.

14.2 The board does not agree. The inventor overlap and the close similarity of the two studies are not sufficient to conclude that the heart-rate lowering effects described in document D1 and the patent must be the same or substantially the same. As explained in point 12.1 above, the decrease in heart rate disclosed in document D1 is transient and thus too short to be considered as a reliable indication of an effective treatment of tachycardia.

14.3 The general statement on page 2, lines 17 to 18, of document D1 that problems associated with anti-muscarinics (eg glycopyrrolate), such as tachycardia, are apparently absent, does not allow to draw a different conclusion. The fact that a compound does not cause an unwanted effect (tachycardia) does not necessarily imply that this compound is effective in combating this effect.

14.4 It follows that the subject-matter of claim 1 differs from the closest prior art in terms of the claimed use, i.e. the treatment or prophylaxis of tachycardia.

Objective technical problem and solution

15. The objective technical problem to be solved by the claimed invention is, accordingly, to provide a further use for the inhalable pharmaceutical composition used in the clinical study of document D1.

As a solution to this problem, the claimed invention proposes the treatment or prophylaxis of tachycardia.

Obviousness

16. Contrary to the respondent's position, the proposed solution would not have been obvious based on the disclosure of document D1 alone or taken in combination with document D13.

Document D1 alone

16.1 Undisputedly, the skilled person reading document D1 knew that tachycardia is a common symptom of COPD. They would also have inferred from the experimental results on page 10, in conjunction with page 2, lines 17 to 18, that inhaled glycopyrrolate could be used to treat COPD without leading to tachycardia.

16.2 However, contrary to the respondent's assertion, the skilled person would not have drawn the conclusion that by treating COPD, inhaled glycopyrrolate will treat tachycardia as well. Document D1's observation that glycopyrrolate did not give rise to any tachycardia rather implies the opposite, namely that the participants of the clinical study of document D1 did not have any tachycardic symptoms at study begin.

16.3 As regards document D1's disclosure of a small, transient decrease in heart rate (see point 12. above), the skilled person would have concluded from this fact that glycopyrrolate's duration of action was too short for use in the treatment or prophylaxis of tachycardia (see point 12.1 above).

16.4 Consequently, the skilled person reading document D1 would not have had a a reasonable expectation that inhaled glycopyrrolate could be used for the treatment or prophylaxis of tachycardia.

Document D1 taken in combination with document D13

16.5 Document D13 (see title, summary) compares the effects of atropine and glycopyrrolate on various end-organs following intramuscular administration to volunteers. Glycopyrrolate at doses of 0.1 mg, 0.2 mg and 0.4 mg gave rise to various degrees of bradycardia over a period of time of six hours (see page 728, fourth full paragraph and Figure 3).

16.6 The skilled person would have understood that the heart-rate lowering effects disclosed in document D13 represented an effective treatment of tachycardia.

16.7 However, document D13 does not mention inhaled drug delivery. Consequently, it is questionable whether the skilled person looking for a solution to the objective technical problem defined above would have turned to this document.

16.8 As submitted by the respondent, it was commonly known that inhalation constitutes an alternative route for delivering drugs having a systemic effect.

16.9 However, even if the skilled person had turned to document D13 in view of this common general knowledge, they would not have found any indication or suggestion therein that glycopyrrolate would give rise to the same or similar heart-rate lowering effects via the intramuscular and the inhalational route of administration.

16.10 The respondent's argument based on document D18 cannot succeed either. This document was published after the filing date of the patent and is therefore not prior art under Article 54(2) EPC.

Overall conclusion on inventive step of auxiliary request 3

17. The claimed subject-matter of auxiliary request 3 involves an inventive step (Article 56 EPC).

Overall conclusion

18. Auxiliary request 3 is allowable. Accordingly, there is no need for the board to consider the respondent's lower ranking auxiliary requests 4 to 11.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the set of claims of auxiliary request 3 filed during the oral proceedings before the board and a description to be adapted thereto as necessary.

The Registrar: The Chair:

I. Aperribay A. Chakravarty

Decision electronically authenticated