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Datasheet for the decision of 8 June 2018

T 2504/13 - 3.3.01 Case Number:

Application Number: 06830792.5

Publication Number: 1971332

IPC: A61K31/381, A61P11/06

Language of the proceedings: EN

Title of invention:

USE OF TIOTROPIUM SALTS IN THE TREATMENT OF MODERATE PERSISTENT ASTHMA

Patent Proprietor:

Boehringer Ingelheim International GmbH Boehringer Ingelheim Pharma GmbH & Co. KG

Opponents:

NORTON HEALTHCARE LIMITED

Relevant legal provisions:

EPC Art. 54, 56, 123(2)

Keyword:

Novelty - (yes)

Inventive step - (no) - main request, auxiliary requests 1-2 Amendments - allowable (no) - auxiliary request 3



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Case Number: T 2504/13 - 3.3.01

D E C I S I O N

of Technical Board of Appeal 3.3.01

of 8 June 2018

Appellant:

(Patent Proprietor 1)

(Patent Proprietor 2)

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Decision under appeal:

Decision of the Opposition Division of the European Patent Office posted on 15 October 2013 revoking European patent No. 1971332 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman A. Lindner Members: R. Hauss

P. de Heij

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Summary of Facts and Submissions

- I. European patent No. 1 971 332 was granted with eight claims. Independent claim 1 reads as follows:
 - "1. Use of tiotropium salts 1

wherein

 X^- denotes an anion with a single negative charge, preferably an anion which is selected from among chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate, optionally in form of the hydrates and/or solvates thereof

for the manufacture of a medicament for the treatment of asthma in the severity GINA step 3."

- II. Two notices of opposition were filed opposing the patent under Article 100(a) and (b) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step and was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- III. The patent proprietors requested the rejection of the oppositions and, with a letter dated 19 July 2013, filed three sets of claims as auxiliary requests 1 to 3.

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IV. Claim 1 of auxiliary request 1 is identical to claim 1 of the patent as granted, except that the words "and/or solvates" were deleted.

Claim 1 of auxiliary request 2 is identical to claim 1 of auxiliary request 1, except that the medical indication was amended as follows (additions underlined):

"for the manufacture of a medicament for the treatment of asthma in the severity GINA step 3 in patients who receive already maintenance controller treatment with inhaled corticosteroids."

Claim 1 of auxiliary request 3 is identical to claim 1 of auxiliary request 1, except that the medical indication was amended as follows (additions underlined):

"for the manufacture of a medicament for the treatment of asthma in the severity GINA step 3 to prevent asthma attacks and/or exacerbations in patients who receive already maintenance controller treatment with inhaled corticosteroids."

- V. The documents cited in the opposition and appeal proceedings included the following:
 - D4: Exp. Opin. Invest. Drugs 10(4), 733-740 (2001)
 - D5: Boehringer Inhgelheim, Spiriva® Respimat® inhaler, Tabulated Trial Report (14 August 2009)
 - D6: Global Initiative for Asthma, Pocket Guide for Asthma Management and Prevention (Updated 2005)
 - D15: Am J Respir Crit Care Med 159, A625 (1999)
 - D26: Can Respir J 16(3), 99-101 (2009)
- VI. The decision under appeal is the decision of the opposition division, announced on 20 September 2013 and posted on 15 October 2013, revoking the patent.

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VII. According to the decision under appeal, while the ground pursuant to Article 100(b) EPC did not prejudice the maintenance of the patent, the subject-matter of claim 1 as granted and of claim 1 of auxiliary request 1 lacked novelty over the disclosure of document D15 ("Bronchodilator Effect of Tiotropium in Moderate-Severe Asthmatics") since the terms "moderate asthma" employed in D15 and "asthma in the severity GINA step 3" employed in claim 1 designated the same group of patients (Articles 100(a), 52(1) and 54(1)-(2) EPC).

The novelty of the subject-matter of claim 1 of auxiliary request 2 over the disclosure of D15 was established by the additional feature "in patients who receive already maintenance controller treatment with inhaled corticosteroids". Document D6, which disclosed the treatment of GINA step 3 patients with a low- to medium-dose glucocorticosteroid combined with LABAs (long-acting β_2 adrenergic receptor agonists), was regarded as the closest prior art. Starting from the teaching of D6, the objective technical problem was the provision of an alternative treatment of GINA step 3 asthma patients already receiving maintenance controller treatment with inhaled corticosteroids. On the basis of the technical teaching of document D6 itself combined with the teaching of D15, the treatment defined in claim 1, which involved tiotropium, would have been considered an obvious alternative to therapies according to document D6 using a LABA, ipratropium or oxitropium. Contrary to the patent proprietors' view, the other prior-art documents cited in the proceedings did not provide a disincentive against making the combination of D6 and D15. Thus, the subject-matter of claim 1 of auxiliary request 2 did

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not involve an inventive step (Articles 100(a), 52(1) and 56 EPC).

Claim 1 of auxiliary request 3 contained added subject-matter (Article 123(2) EPC) since the term "to prevent asthma attacks and/or exacerbations" was mentioned in the application as filed only in the part relating to the background of the invention, and was not disclosed in a context relating to patients receiving already maintenance controller treatment with inhaled corticosteroids.

- VIII. The patent proprietors (appellants) filed an appeal against that decision.
- IX. Subsequently, respondent-opponent 2 withdrew its opposition, leaving opponent 1 as the sole respondent.
- X. Oral proceedings before the board were held on 8 June 2018.
- XI. The appellants' arguments may be summarised as follows: $Novelty\ relative\ to\ D15$

Document D15 did not disclose an actual therapy but merely studied the bronchodilator effect of tiotropium. The document did not refer at all to persistent asthma or to the GINA classification defining steps of asthma severity. Moreover, document D6 describing the GINA classification and the category "step 3" had been published six years later than D15. It could thus not be inferred from the information presented in D15 that the same degree of asthma severity had been treated. Rather, D15 seemed to suggest that the placebo group was untreated, which would have been unethical if patients having asthma of GINA step 3 or 4 severity had actually been involved. Thus, it appeared that only

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patients with low asthma severity had been treated in the trial reported in D15.

Inventive step - main request and auxiliary request 1

Document D6 represented the closest prior art since it related, like the appellants' current requests, to the treatment of patients presenting asthma of GINA step 3 severity. While it was not contested that document D15 was a possible starting point for the assessment of inventive step, the technical problem which could be formulated on this basis, i.e. the problem of providing a new use for existing medication, was unrealistic and did not reflect the usual approach of the clinician. Furthermore, document D15 did not disclose a therapy but merely observed the bronchodilatory effect of tiotropium in comparison with a placebo. It could not have been derived from the information presented in D15 that tiotropium could be used as an alternative to LABAs in the treatment of asthma in the severity GINA step 3. While prior-art document D4 suggested that tiotropium would be rather less useful than inhaled LABAs, the appellants had shown, against the expectation of D4, the surprising non-inferiority of tiotropium versus salmeterol (D5).

Inventive step - auxiliary request 2

Apart from lacking a pointer to the treatment of asthma in the severity GINA step 3, document D15 did not disclose or suggest maintenance controller treatment with inhaled corticosteroids, either. Based on the teaching of D15, there could have been no expectation that the treatment according to claim 1 of auxiliary request 2 would actually work and even allow for a reduction of the administered dosage of corticosteroid, as shown by post-published data (D26).

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Amendments - auxiliary request 3

The feature "to prevent asthma attacks and/or exacerbations" found support in the application as filed on page 1, lines 9 to 11 and 21 to 24. Since the prevention of asthma attacks and/or exacerbations was the inherent purpose of any asthma treatment, it did not matter that these passages were included in a discussion of the background art. It would in any case be evident to the reader that tiotropium, known as a long-acting bronchodilator with a slow onset of action, could only be intended for use as a component of the controller medications, which typically had the function of preventing attacks and exacerbations.

XII. The respondent's arguments may be summarised as follows:

Novelty relative to D15

GINA step 3 and moderate asthma were synonymous terms for describing the third quartile in the spectrum of asthma symptoms. The reference in D15 to "moderate to severe asthmatics" would simply be read by the person skilled in the art as relating to asthma severity corresponding to GINA steps 3 and 4, in accordance with common general knowledge. Since D15 was only an abstract, it did not present details of the patients' drug regimens. However, it could not be concluded from that, as argued by the appellants, that only patients with mild asthma not requiring conventional maintenance controller treatment had been included in the clinical trial of D15. If the terms "GINA step 3" and "moderate" were to be regarded as non-identical, the term "GINA step 3" could still not delimit the claimed subjectmatter from the disclosure of D15 in the absence of clearly defined boundaries between the GINA steps.

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Inventive step - main request and auxiliary request 1

Document D15, which related to the treatment of asthma using tiotropium, was a suitable starting point for the assessment of inventive step. Assuming that the specific reference to asthma of the severity classified as "GINA step 3" distinguished the subject-matter of claim 1 from the disclosure of document D15, the objective technical problem was to suggest an alternative use for tiotropium. It was known from document D15 that tiotropium was suitable for the treatment of moderate to severe asthma. In light of the common general knowledge as represented by document D6, the person skilled in the art would have immediately recognised the applicability of that teaching to moderate asthma classified as GINA step 3. As to the benefits to be expected, it was known that tiotropium was an anticholinergic useful as a bronchodilator in more severe asthma (D15), and that anticholinergics were an alternative for patients with intolerance for β_2 -agonists (D6).

Inventive step - auxiliary request 2

The subject-matter of claim 1 of auxiliary request 2 additionally differed from the disclosure of document D15 in the mandatory combined use of tiotropium with inhaled glucocorticosteroid. Thus, a combination partner for tiotropium was suggested. Since it was common general knowledge that maintenance controller treatment of persistent asthma (GINA steps 2 to 4) typically included the use of inhaled glucocorticosteroid for treating chronic inflammation, in combination with a bronchodilator, this additional technical feature of the treatment could not support a case in favour of an inventive step.

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Amendments - auxiliary request 3

There was no basis in the application as filed for linking the feature "to prevent asthma attacks and/or exacerbations" to the teaching of the invention, and particularly not to the combination of tiotropium with inhaled glucocorticosteroids. The passages cited by the appellants on page 1 of the application as filed were part of a general discussion of the background art.

- XIII. The appellants requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims of one of auxiliary requests 1 to 3 filed with the letter of 19 July 2013.
- XIV. The respondent requested that the appeal be dismissed.

Reasons for the Decision

- 1. Admissibility of the appeal
 - The appeal complies with Articles 106 to 108 EPC and Rule 99 EPC and is therefore admissible.
- 2. Technical background: Asthma, "GINA" classification
- 2.1 As explained in the patent in suit (paragraphs [0002] to [0003]) and in document D6 (pages 4, 5, 16), asthma is a chronic inflammatory disorder of the airways.

 Asthma attacks (also called exacerbations) are episodic, but airway inflammation is chronically present.

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- Hence, controller medications, typically including inhaled glucocorticosteroid (to treat the underlying inflammation) which may further be combined with a bronchodilator, may be administered daily to control symptoms, improve lung function and prevent attacks (maintenance controller treatment).
- Additionally, rapid-acting reliever (or rescue) medications may be required to be administered when needed to treat attacks and relieve acute symptoms such as wheezing, chest tightness and cough.
- 2.2 Asthma severity can vary. According to the guidelines of GINA (Global Initiative for Asthma, Inc.), asthma severity can be classified into four categories, namely GINA steps 1 to 4 (see the patent in suit: paragraphs [0004] to [0006] and [0011]; D6: figures 3 and 8). It was common ground that the GINA guidelines are widely accepted in the health sector.
 - GINA step 1 asthma is also called intermittent asthma, with symptoms occurring usually less than once per week. GINA step 1 asthma does not, as a rule, require daily maintenance controller treatment.
 - In mild persistent asthma (GINA step 2) with, typically, symptoms occurring more than once per week or nocturnal symptoms more than twice per month, the recommended controller medication is daily treatment with low-dose inhaled corticosteroids.
 - Moderate persistent asthma (GINA step 3) is characterised by daily symptoms over a prolonged time or nocturnal symptoms more than once per week. Daily administration of low- to medium-dose corticosteroids in combination with inhaled LABAs (long-acting β_2 adrenergic receptor agonists) the latter being bronchodilators is recommended.

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- Severe persistent asthma (GINA step 4) is usually treated with high-dose inhaled corticosteroids in combination with inhaled LABAs, plus certain further drugs if needed.
- 3. The patent in suit
- 3.1 The patent in suit (see paragraph [0007]) seeks to provide pharmaceutical compositions for the treatment of patients suffering from moderate persistent asthma (GINA step 3).
- 3.2 The solution according to claim 1 as granted, which is directed to a further medical use drafted in "Swiss type" format, involves the use of tiotropium salts for the manufacture of a medicament for the treatment of asthma of a severity according to GINA step 3.
- 4. Novelty relative to D15 main request
- 4.1 As reported in document D15 (which is a conference abstract), a multi-centre, randomised, double-blind, placebo-controlled, parallel-group clinical study was conducted over a period of three weeks to evaluate the safety and efficacy of four dosages of tiotropium vs placebo, taken once daily, in moderate to severe asthmatics. The GINA classification is not explicitly mentioned. Based on the results observed, which included significant improvements in several relevant parameters (inter alia, FEV1) compared with placebo treatment, it was concluded that "in moderate to severe asthmatics tiotropium is a safe, well tolerated and effective bronchodilator". Since tiotropium is a cation, it is implicit that a tiotropium salt was used in the study of D15. Spiriva $^{\text{\tiny{TM}}}$ (explicitly mentioned

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and presumably used in the study of D15) contains tiotropium bromide.

- 4.2 Contrary to the appellants' view, it is readily apparent that document D15 discloses not merely the isolated observation of a bronchodilatory effect, but the actual treatment, in the context of a clinical trial, of asthma patients, involving the administration of tiotropium, which was moreover found to be safe and effective.
- 4.3 It remains to be established whether the feature "asthma in the severity GINA step 3" can distinguish the patients addressed in granted claim 1 from the "moderate to severe asthmatics" of D15.
- In this context, the appellants pointed out that document D15 does not mention that the subjects received the controller maintenance treatment that would be required for asthma severity of GINA steps 3 and 4 (namely, daily administration of corticosteroids in combination with inhaled LABAs; see point 2.2 above). The appellants inferred from this that the study subjects had not actually obtained any controller maintenance treatment, and therefore they must have suffered from only a mild form of asthma not requiring such treatment.
- 4.5 This argument is unconvincing. It is not plausible that the description "moderate to severe asthmatics" (irrespective of whether this category corresponds precisely to GINA steps 3 and 4) would be used by a clinician for subjects suffering from only a "mild" non-persistent form of asthma. D15 is merely an abstract which focuses on the benefits of tiotropium, and accordingly not of a scope which would necessarily include patient details or precise treatment protocols,

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which may explain why maintenance controller treatment is not discussed. Given that the subjects tested were moderate to severe asthmatics, it must, however, be presumed that they received the standard maintenance treatment for their asthma, in particular since the patients on placebo would otherwise have been dangerously untreated.

- 4.6 It is not certain that the intended meaning, or the only reasonable interpretation, of the term "moderate to severe asthmatics" in D15 "is patients suffering from asthma according to GINA steps 3 or 4". While it appears plausible that the general conceptual category of "moderate" asthma may at least have a large overlap with asthma classified as presenting a severity according to GINA step 3, the actual study reported in document D15 was carried out on a group of 204 persons designated as "moderate to severe asthmatics". No information is provided concerning the overlap of that particular group of persons with the general category of patients having asthma of a severity of GINA step 3. It cannot be derived directly and unambiguously from the limited information presented in D15 that any of the patients taking part in the clinical study and receiving tiotropium indeed suffered from asthma of a severity according to GINA step 3.
- 4.7 As a consequence, the subject-matter of claim 1 as granted is novel relative to the disclosure of document D15 (Articles 100(a), 52(1) and 54(1)-(2) EPC).
- 5. Inventive step main request
- 5.1 The objective of the patent in suit and the subject-matter of independent claim 1 as granted are as set out in points I and 3 above.

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Starting point in the prior art

- 5.2 It was common ground that both document D6 and document D15 were suitable starting points for the assessment of inventive step of the subject-matter of claim 1, although the appellants preferred D6, arguing that the technical problem in view of D15 (namely, to find a new use for existing medication) did not reflect the usual approach of the clinician.
- 5.3 If the person skilled in the art had a choice of several workable approaches that might suggest the invention (in terms of several possible starting points), the rationale of the problem-and-solution approach requires that the invention be assessed relative to all these possible approaches before any decision confirming inventive step is taken.
- 5.4 In the present case, document D15 is certainly suitable as a starting point since it discloses that the same drug (tiotropium) was employed for treating the same disease (asthma) as defined in claim 1.

Objective technical problem and solution

- 5.5 The subject-matter of claim 1 differs from the disclosure of document D15 in the definition of the severity of asthma in the patients to be treated, which is defined as meeting the criteria according to "GINA step 3". According to the patent in suit and document D6, GINA step 3 designates moderate persistent asthma (see point 2.2 above).
- 5.6 The technical effect of the claimed subject-matter when compared with the disclosure of D15 is thus the therapeutic benefit in the treatment of, specifically, GINA step 3 asthma patients.

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- 5.7 As explained above (see points 2.1 and 2.2), patients suffering from moderate persistent asthma (GINA step 3) receive controller medications, typically including inhaled glucocorticosteroid combined with a bronchodilator such as a long-acting β_2 adrenergic receptor agonist (LABA).
- 5.7.1 Making reference to the experimental data reported in document D5, the appellants argued that it had been shown that tiotropium (a long-acting anticholinergic) unexpectedly was not inferior to salmeterol (a long-acting β_2 adrenergic receptor agonist) and was therefore suitable for replacing, as an equivalent, the conventional LABAs as the bronchodilator component in the controller maintenance treatment of moderate persistent asthma with a severity of GINA step 3.
- 5.7.2 However (and irrespective of the fact that claim 1 does not rule out the co-administration of LABAs), this alleged advantage is linked to the selection of tiotropium and not to the sole feature distinguishing the claimed subject-matter from the disclosure of D15, namely, GINA step 3 asthma severity. Hence, the alleged advantage cannot be taken into account in the formulation of the objective technical problem.
- 5.8 Accordingly, on the basis of the technical effect mentioned in point 5.6 above, the objective technical problem starting from the teaching of document D15 is the provision of a medicament based on tiotropium for a specific use in asthma therapy.
- 5.9 Since the desired application remains within the same therapeutic context already known from D15 (namely, asthma therapy), this technical problem is not unrealistic as an approach for a clinician.

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5.10 The solution to the objective technical problem is the further medical use as defined in claim 1.

Obviousness of the solution

- 5.11 The information presented in document D15 renders it credible that tiotropium is safe and effective as a bronchodilator in the treatment of moderate to severe asthma. Irrespective of the precise intended delimitation of the categories "moderate" and "severe" in D15, these terms would reasonably not have been considered to designate mild forms of asthma (also see point 4.5 above), but would rather have been understood to refer to the same general part of the spectrum of asthma severity as GINA steps 3 and 4 (although, as pointed out in point 4.6 above in the discussion of novelty, it cannot be derived from the disclosure of D15 that any specific patient treated indeed suffered from asthma of a severity according to GINA step 3).
- 5.12 While prior-art document D4 (see page 739: column 1, second paragraph) speculates that tiotropium may be less effective in asthma than inhaled β_2 agonists, the author of D4 still states in the same passage that it is likely that tiotropium will be used in asthma treatment, in particular as an additional bronchodilator in patients with severe disease. Since some benefit is thus expected even in the treatment of patients with severe asthma, the teaching of D4 clearly does not provide a disincentive against the use of tiotropium in the treatment of patients with moderate asthma.
- 5.13 Thus, the person skilled in the art would have had no reason to doubt that the administration of tiotropium would be effective against moderate asthma meeting the known criteria according to GINA step 3 and, in order

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to solve the objective technical problem, would have gone on to formulate a medicament for that purpose.

- 5.14 As a consequence, the subject-matter of claim 1 as granted does not involve an inventive step within the meaning of Article 56 EPC.
- 6. Novelty and inventive step auxiliary request 1
- 6.1 Claim 1 of auxiliary request 1 (see point IV above)
 has the same definition and scope as granted claim 1
 since the only difference in the wording of those
 claims consists in the deletion of an optional feature
 ("optionally in form of ... solvates thereof"), which
 does not alter the scope claimed.
- As a consequence, the conclusions set out above with regard to claim 1 of the main request (see sections 4 and 5) equally apply to claim 1 of auxiliary request 1; namely, the claimed subject-matter is novel over the disclosure of document D15 but does not involve an inventive step (Articles 52(1), 54(1)-(2) and 56 EPC).
- 7. Inventive step auxiliary request 2
- 7.1 In comparison with claim 1 as granted and claim 1 of auxiliary request 1, claim 1 of auxiliary request 2 specifies additionally that the asthma patients to be treated already receive maintenance controller treatment with inhaled corticosteroids.
- 7.2 The appellants contended that maintenance controller treatment was not mentioned in document D15 and, furthermore, that it had been surprisingly shown according to post-published data (see document D26) that the administration of tiotropium enabled patients to reduce the dosage of corticosteroids.

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- 7.3 Actually, the disclosure of document D26 is not pertinent in the present context of a technical feature which requires the administration of inhaled corticosteroids since D26 relates to the case of a patient with severe asthma who was dependent on oral rather than inhaled corticosteroids. Moreover, claim 1 does not define a quantitative limitation with regard to the intake of corticosteroids.
- 7.4 Document D15 is still a suitable starting point for the assessment of inventive step. As already discussed (see point 4.5 above), the moderate to severe asthmatics who took part in the study of D15 presumably received standard maintenance controller treatment (such treatment being necessary in moderate to severe asthma). If the administration of inhaled corticosteroids is not considered implicit in D15, the objective technical problem may be formulated as the provision of a medicament based on tiotropium for a specific use in asthma therapy in combination with further drugs.
- 7.5 The solution to that problem is the subject-matter as defined in claim 1 of auxiliary request 2, which envisages the treatment of GINA step 3 patients who already receive maintenance controller treatment with inhaled corticosteroids.
- 7.6 Since patients suffering from persistent asthma, which includes moderate persistent asthma according to GINA step 3, typically receive maintenance controller treatment involving the daily administration of inhaled corticosteroids (see points 2.1 and 2.2 above and D6: figures 6 to 8 and pages 15 to 16), this technical feature merely reflects the conventional standard treatment recommended for such patients

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providing the known effect of treating chronic inflammation and does not add any aspect which could support an argument in favour of an inventive step. No prejudice in the art against the combination of tiotropium and inhaled corticosteroids is known.

- 7.7 Thus, the added feature cannot change the outcome of the inventive-step assessment set out in section 5 above. For these reasons, the subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step within the meaning of Article 56 EPC.
- 8. Amendments auxiliary request 3
- 8.1 The passages on page 1, lines 9 to 11 and 21 to 24, of the application as filed (published as WO 2007/077162) which were indicated by the appellants in support of the amendment introduced into claim 1 of auxiliary request 3, relate to the general background of the invention (page 1, line 7). These passages explain that asthma is characterised by chronic inflammation and episodic attacks and that, therefore, many patients require daily medication to control symptoms, improve lung function and prevent attacks (also called exacerbations), and that, optionally, further medications may be required to relieve acute symptoms (see also point 2.1 above).
- 8.2 The appellants contended that a person skilled in the art reading the application would readily infer that tiotropium, as a long-acting cholinergic and a bronchdilator, was clearly a drug to be used in the context of maintenance controller treatment and therefore the purpose of preventing asthma attacks and/or exacerbations must be inherent to its administration.

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- 8.3 However, this argument is based on obviousness rather than on a demonstration of a direct and unambiguous disclosure combining the stated purpose of preventing asthma attacks and/or exacerbations with the remaining technical features of claim 1, namely, the administration of the medicament containing tiotropium, for that specific purpose, to patients suffering from asthma of a severity according to GINA step 3 who also receive maintenance controller treatment with inhaled corticosteroids.
- 8.4 Therefore, the subject-matter of claim 1 of auxiliary request 3 extends beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC.
- 8.5 It may be added that, if the amendment in question simply sets out one of the implicit goals of asthma treatment and is inherent to the treatment envisaged, as argued by the appellants, it could not provide a contribution to novelty and inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated