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Datasheet for the decision of 18 September 2015

Case Number: T 1184/12 - 3.3.02

Application Number: 99930103.9

Publication Number: 1085877

IPC: A61K31/57, A61P11/06

Language of the proceedings: EN

Title of invention:
Use of a composition comprising formoterol and budesonide for the prevention or treatment of an acute condition of asthma

Patent Proprietor:
AstraZeneca AB

Opponents:
Vectura Limited
Ratiopharm GmbH
Generics [UK] Limited
Norton Healthcare Limited

Headword:
Formoterol and budesonide in the therapy of asthma/ASTRAZENECA

Relevant legal provisions:
RPBA Art. 15(3), 13
EPC Art. 54(2), 54(5), 56, 84

Keyword:
Novelty - second (or further) medical use (yes)
Inventive step - main request (no)
Claims - clarity - auxiliary requests (no)

Decisions cited:
G 0002/08

Catchword:

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Case Number: T 1184/12 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 18 September 2015

Appellant: (Patent Proprietor)	AstraZeneca AB Kvarnbergagatan 16 151 85 Södertälje (SE)
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Respondent II: (Opponent 2)	Ratiopharm GmbH 89070-Ulm (DE)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 15 March 2012 revoking European patent No. 1085877 pursuant to Article 101(2) and 101(3)(b) EPC.**

Composition of the Board:

Chairwoman M.C. Ortega Plaza
Members: T. Sommerfeld
M. Blasi

Summary of Facts and Submissions

I. European patent 1085877, based on application 99930103.9, entitled "Use of a composition comprising formoterol and budesonide for the prevention or treatment of an acute condition of asthma" and published as international application WO 99/64014, was granted with 20 claims.

II. Four oppositions were filed against the granted patent, all opponents requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC); lack of sufficiency of disclosure (Article 100(b) EPC) was also filed as ground of opposition by opponents 3 and 4, and added subject-matter (Article 100(c) EPC) was filed as a ground of opposition by opponents 2 and 3.

III. During the proceedings before the opposition division, the patent proprietor requested that the oppositions be rejected and the patent maintained as granted (main request) or alternatively that the patent be maintained in amended form according to the first auxiliary request (filed during oral proceedings before the opposition division) or to the second auxiliary request (filed with letter of 28 September 2011).

IV. The opposition division revoked the patent under Article 101(2) and Article 101(3)(b) EPC.

It decided that the claims according to the main request (claims as granted) lacked inventive step, and considered that the first and second auxiliary requests were not admissible on the grounds of late filing and non-compliance with Article 123(2) EPC (first auxiliary

request) and on the grounds of non-compliance with Rule 80 EPC and Articles 84, 123(2) and 123(3) EPC (second auxiliary request). As regards the main request, the opposition division considered that the requirements of Articles 123(2), 83 and 54 EPC were fulfilled.

V. The patent proprietor (appellant) lodged an appeal against that decision. With the statement of the grounds of appeal, the appellant requested that the decision of the opposition division be set aside and that the patent be maintained as granted (main request) or alternatively that it be maintained in amended form on the basis of the first, second, third or fourth auxiliary requests, all filed with the grounds of appeal. It also filed new documents, including D46 and D47.

VI. With their replies to the statement of grounds of appeal, opponent 1 (respondent I), opponent 3 (respondent III) and opponent 4 (respondent IV) requested that the appeal be dismissed and the patent revoked in its entirety. The objections of lack of novelty and sufficiency of disclosure which had been raised before the opposition division were maintained. Opponent 2 (respondent II) did not submit any substantive reply to the grounds of appeal.

VII. With its reply to the respondent's letters, the appellant submitted new first to fourth auxiliary requests and renumbered the previous first to fourth auxiliary requests (filed with the grounds of appeal) as fifth to eighth auxiliary requests. It also submitted new documents, including D38a, D49, D50 and D56.

VIII. Respondent IV submitted a reply to the appellant's submissions, requesting that appellant's new facts, evidence and requests be held inadmissible; it also submitted new documents. With a further letter, respondent IV noted that the patent was the subject of litigation at national level and submitted a copy of the judgment of the UK High Court of Justice as evidence. With a further letter, respondent IV submitted a copy of the judgment of the Hague District Court.

IX. By letter of 5 February 2015 the Finnish Market Court, in view of revocation and infringement actions concerning the patent in Finland, asked the board to accelerate the present appeal case.

X. Summons for oral proceedings before the board were issued on 30 March 2015, scheduling oral proceedings for 17 and 18 September 2015.

XI. Further letters from the parties followed. With letter dated 27 July 2015, the appellant maintained its main request and submitted new auxiliary requests 1 to 5 to replace the auxiliary requests on file. It also filed a translation of the "key parts" of the judgement of the District Court of Stockholm. With a letter dated 5 August 2015, respondent IV raised substantive objections against the newly filed auxiliary requests.

XII. Oral proceedings before the board took place on 17 and 18 September 2015 as scheduled. Respondent II, who had been duly summoned, did not attend. During the oral proceedings, the appellant filed a new auxiliary request 2a. At the end of the oral proceedings, the Chairwoman announced the decision of the board.

The **main request** consists of the set of claims as granted. Independent claim 1 reads as follows:

"1. Use of a composition comprising, in admixture
(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and
(b) a second active ingredient which is budesonide;
for the manufacture of a medicament for use in the prevention or treatment of an acute condition of asthma and/or intermittent asthma and/or episodes in chronic asthma **characterised in that** the use is for symptomatic relief, when needed, in addition to treating chronic asthma on a regular basis."

Auxiliary request 1 consists of one claim only, which differs from claim 1 of the main request by deletion of the term "prevention" and addition of the feature "wherein the when-needed use reduces the severity of asthma exacerbations" at the end of the claim.

Auxiliary request 2 consists of two independent claims; each of the claims differs from claim 1 of the main request by deletion of the term "prevention", further definition of the first active agent as being formoterol fumarate dihydrate, and addition of features further defining the treatment, as follows:

"1. ...
wherein the treatment of chronic asthma on a regular basis consists of twice daily administration of 4.5/80 µg or 4.5/160 µg formoterol fumarate dihydrate/ budesonide, and
wherein the use for symptomatic relief consists of once or twice daily administration of 4.5/80 µg or

4.5/160 µg formoterol fumarate dihydrate/budesonide to treat sporadic breakthrough symptoms.

2. ...

wherein the treatment of chronic asthma on a regular basis consists of twice daily administration of 4.5/80 µg or 4.5/160 µg formoterol fumarate dihydrate/budesonide, and

wherein the use for symptomatic relief consists of as-needed administrations of 4.5/80 µg or 4.5/160 µg formoterol fumarate dihydrate/budesonide to treat exacerbations during one or two weeks, and

wherein the maximum daily dose corresponds to 8 administrations, i.e. 36/640 µg when each administration is 4.5/80 µg and 36/1280 µg when each administration is 4.5/160 µg."

In **auxiliary request 2a**, claims 1 and 2 of auxiliary request 2 were amended by adding the feature "wherein the same combination is used for treatment of chronic asthma on a regular basis and for symptomatic relief", at the end of the claim. Moreover, in claim 2, the term "administration/s" was replaced by the term "puff/s" in the part of the claim relating to the maximum daily dose.

Auxiliary request 3 consists of one claim only, which is identical to claim 1 of auxiliary request 2.

Auxiliary request 4 consists of one claim only, which is identical to claim 2 of auxiliary request 2.

Auxiliary request 5 consists of one claim only, which differs from claim 2 of auxiliary request 2 by the addition of the feature "wherein the when-needed use

reduces the severity of asthma exacerbations" at the end of the claim.

XIII. The following documents are cited in this decision:

D1 WO 93/11773
D3 SCRIP 1562, page 21, 1990
D8 WO 98/15280
D14 Foradil, Compendium Suisse des Medicaments 1997
D18 Pauwels et al., New Engl. J. of Medicine 1997, 337, 1405-1411
D32 Slides based on D32a
D32a Rabe et al., Lancet 2006, 368, 744-753
D33 Slides based on D33a
D33a Kuna et al., Int. J. of Clinical Practice 2007, 61(5), 725-736
D38a Asthma, ed. P.J. Barnes, 1997, chapter 135
D43 Thorax 1993, 48, S1-S24
D46 NIH Clinical Practice Guidelines 1997, 97-4051
D47 Thorax 1997, 52, S1
D49 EP 0416950
D50 EP 0416951
D56 1993-1994 SmPC for Ventide®

XIV. The appellant's submissions, in so far as relevant for the present decision, may be summarised as follows:

Admission of late-filed documents

The submission of the documents D38a, D49, D50 and D56, *inter alia*, had been occasioned by the respondents' replies to the grounds of appeal, and in particular by the novelty objections raised. Since the opposition division had decided novelty positively, there had been no need to address novelty in the statement of grounds of appeal.

Main request - Novelty

D1 should be interpreted as it would have been read by the skilled person at its publication date. The skilled person, an asthma specialist with clinical and academic exposure to asthma treatment, would know that asthma was an inflammatory disease which was mainly controlled by inhalation drugs, in particular bronchodilators (usually a β_2-agonist) for symptom relief, and steroids to dampen the underlying inflammation. At the time of D1, asthma therapy required at least two inhalers: one (or two) for maintenance and one for symptom relief. There was only one combination inhaler in the market, namely Ventide®, which contained salbutamol (a short-acting β_2-agonist) and beclomethasone (a steroid), which was to be used for maintenance therapy but not for acute attacks (D56, page 1, right column). D1 addressed the problem that a considerable number of patients did not take inhaled steroids regularly (D1, page 2, first full paragraph). To overcome this problem, D1 suggested combining formoterol, which is a long-acting β_2-agonist with a rapid onset of action (page 2, line 21), with the steroid budesonide: through the long-lasting action of formoterol, a maintenance therapy comprising these two active ingredients would be effective in preventing nocturnal asthma (page 3, lines 10 to 12). Moreover, the morning asthmatic symptoms associated with the "morning dip" (D38a) would be controlled just by administering the morning's maintenance dose. D1's combination had the advantage over other available combinations of β_2-agonists and steroids, such as salmeterol and fluticasone (D1, page 3, lines 19 to 23), of providing an efficient and long-lasting bronchodilation effect which had a rapid

onset of action. The reference in D1 to the need to carry only one inhaler was to be interpreted as referring to one combination inhaler in contrast to two single inhalers for maintenance therapy: no patient ever needed to carry more than one inhaler because during the day only a short-acting symptom reliever was needed; the other one or two maintenance inhalers were only needed in the morning and at night. D1 foresaw that only the maintenance therapy was required, under a twice-daily regime (page 4, lines 19 to 21; page 6, line 22), which provided long-term treatment and at the same time short-term alleviation, needed particularly in the morning. The passage on page 4 of D1 should be read in the whole context of D1. D1's teaching was not even limited to simultaneous delivery of formoterol and budesonide, but also encompassed sequential or separate administration (page 4, lines 23 to 28; page 4, line 36 to page 6, line 5; page 6, lines 13 to 25; claims 1 and 3 to 7). D1's statement about rescue medicine could therefore only be interpreted as meaning that D1's therapy led to a significantly lower amount of exacerbations (due to better asthma control) and thus avoided the need for the rescue inhaler.

Main request - Inventive step

D1 was the closest prior art; the difference to the patent was that it failed to disclose that the combination therapy was both for maintenance treatment and for symptom relief. With the patent's therapy, surprisingly, a very good asthma control was achieved: patent, paragraph [0012], describing clinical improvement, an effect that was further supported by the data in D32. The data in D33 further showed that the improvement was not due to the steroid, since there was a lower steroid load in the group according to the

invention: improvement was thus achieved with less medication. To be able to use less steroid was important (D46, page 71, left side, third sub-bullet point, and figure 3-5b on page 88). Thus the invention had a double effect: clinical improvement (reduction of exacerbations) and use of a lower steroid dose. The objective technical problem was thus to achieve a significant clinical improvement while optimising steroid dose. The solution was not obvious but rather represented a paradigm shift: at the time it had been firmly believed that maintenance inhalers and relief inhalers were two separate inhalers, and that inhaled steroids had no role in symptom relief (D46, page 59). D43 and D47 referred to doubling of steroids, but in maintenance therapy; they did not teach steroids as part of the as-needed therapy. The same was true for D18, a huge trial by the patentee which rather increased steroid in the maintenance dose instead of using the patentee's own combination. The skilled person knew that budesonide did not give immediate relief, and thus would consider that it was not reasonable to use it just to make the patient’s life more convenient. Moreover, it was not generally accepted that formoterol could also be used as a reliever. Even the combination of D1 with D3 or D14 still did not lead to the invention, but rather to a therapy wherein budesonide and formoterol were used for maintenance (D1) and formoterol was used alone for acute relief (D3, D14). Several documents emphasised the need to use as little medication as possible (D43, page S5; D47, page S5, last paragraph of section “Gaining control...”) or referred to avoiding overdosing with steroids (D1, page 2 middle paragraph). The concept of the invention was applicable to any dose within the therapeutic window (supported by D32a, page 750, right column, last paragraph to page 751). Being

able to use only one inhaler was just a very small advantage because in any case the patient only needed one for rescue. Even if wanting to give only one inhaler, the skilled person would have taken Ventide® which comprised salbutamol, much better known as a reliever than formoterol. Also budesonide did not stand out as a unique steroid in terms of a broader therapeutic window (D46, page 88, Figure 3-5b). The clinical advantage of the invention was not predictable from the prior art. Thus the present invention was of true clinical significance and based on very little motivation.

Auxiliary request 1 - Clarity

The feature of severity reduction, which came from page 4, lines 11 to 12, of the application, related to both number and severity of individual exacerbations. Comparison was to be made with a treatment consisting of the same maintenance therapy but a different symptomatic relief treatment, as was shown in D32. It was clear how the severity of exacerbations was to be determined, the concept having a general meaning which would be understood by the skilled person: D18, published in 1997, also used the same terminology. The claim linked the reduction of severity to "when needed" use and not to maintenance use. In the prior art there was no reliever that reduced exacerbation severity.

Auxiliary request 2 - Clarity

Once or twice daily further defined the as-needed treatment, providing an upper limit (a cap) for said therapy; it was not intended to be a regular symptomatic relief, and obviously the medicament was not to be taken in the absence of symptoms. There was

no other possible interpretation for a mind willing to understand, since the claim referred to regular treatment plus as-needed treatment. Claim 2 just covered one or two weeks, this being also a limiting feature. The dose was to be interpreted as the dose that was indeed given to the patient, i.e. the dose that reached the patient.

Auxiliary request 2a - Admission and clarity

This request was submitted to overcome objections under Article 123(2) EPC raised for the first time at the oral proceedings. It comprised only minor amendments which simplified the case, and should be accepted for procedural fairness. As regarded clarity, the same arguments as for auxiliary request 2 also applied.

Auxiliary requests 3, 4 and 5 - Clarity

The same arguments as for the previous requests also applied, *mutatis mutandis*, to these requests.

XV. The respondents' arguments, in so far as relevant for this decision, may be summarised as follows:

Admission of late-filed documents

Respondent IV requested that none of documents D38a, D49, D50 and D56, *inter alia*, be admitted into the proceedings. D38a was an attempt by the patentee to redefine the meaning of "rescue" medicine: this redefinition was however not a *prima facie* credible interpretation of D1, since it was not supported by any other documents, and the "morning dip" was not even mentioned in D1 or in the opposed patent. As regarded D49 and D50, their relevant content was already set out

in D1. D56 did not add to other documents on file, which already disclosed the role of short-acting β_2-agonists in the treatment of asthma.

Main request - Novelty

Respondent I endorsed respondent IV's submissions in writing as regards the meaning of "rescue"; this had a well-known meaning in the art, to be interpreted as identical to as-needed therapy. Indeed, the patent too used the term "rescue" in the same sense (paragraph [0012]) and the appellant had also given it this interpretation during examination. During appeal proceedings, the appellant had for the first time referred to "morning dip" and nocturnal asthma in the context of "rescue" interpretation, and in its latest letter it had stated that "rescue" referred to formoterol's rapid onset of action. All decisions on file however (opposition division and national court decisions) confirmed that "rescue" was equivalent to symptomatic relief when needed. Although D1 indeed disclosed sequential, separate and simultaneous administration, the effects disclosed in the disputed sentence implied that there had to be simultaneous administration; likewise, avoidance of two inhalers also implied that.

Respondent III referred also to the Dutch and Swedish national court decisions as confirming that rescue medicine was the same as symptomatic relief when needed. The appellant's definition for "rescue medicine" had changed with time, from as-needed medicine (during examination) to emergency treatment in hospital and further to treatment of "morning dip", but none of these alternative interpretations could be found anywhere else in the art. The patent also used

the term "rescue" to mean "as needed". D1 indeed disclosed use of the combination for both maintenance and symptomatic treatment (page 4, lines 6 to 12). The term "carrying" had no possible interpretation other than "physical carrying": if the patient was away for more than 12 hours, he/she would have to carry inhalers for both maintenance and as-needed therapy. D1 however taught that the patient only had to carry one inhaler, which could be used for both therapies. It was known in the art that formoterol could be used for both maintenance and rescue (D3, paragraph 3).

Respondent IV noted that the problem addressed by D1 was poor patient compliance with long-term prophylactic treatment (page 2, first full paragraph). D1 further taught that formoterol acted rapidly (page 2, line 21) and had a long-lasting action, while budesonide had very low systemic effects even at high inhaled doses (page 2, lines 29 to 33). On page 3, lines 8 to 13, D1 referred to the short-acting β_2-agonists as having drawbacks such as nocturnal waking; this was reduced by the use of formoterol. In the section "Outline of the invention", the greater efficiency and duration of bronchodilation action were compared with short-acting β_2-agonists: rapid onset of action was the additional feature over the combinations of D49 and D50. The passage about providing a rescue medicine had a standard meaning in the art which meant "as needed" to treat exacerbations. Avoiding the need to carry two inhalers was again an issue of compliance: the more inhalers, the worse the compliance. The only sensible interpretation in the context of D1 was that only the formoterol/budesonide inhaler had to be carried: asthma treatment being a dual therapy, when D1 disclosed the use of only one inhaler, then this inhaler had to serve both purposes (maintenance and acute therapy). The

disclosure of a twice-daily regime did not exclude rescue use in addition. The alternative interpretation of "rescue medicine" provided by the appellant had changed throughout the proceedings, from its accepted standard meaning to emergency medicine and then to prevention of "morning dip". All court decisions and the appealed decision came to the same conclusion as regarded "rescue". When D1 was published, maintenance therapy with long-acting β_2-agonists was standard (D43) and thus "morning dip" was an unusual problem: a patient did not really need to take rescue medication in the morning. Also the reference in D1 to "avoiding overdosing" would make no sense if only maintenance therapy was foreseen.

Main request - Inventive step

Respondent I endorsed respondent III's arguments. The skilled person was not a physician or doctor with no academic exposure, who would of course be extremely conservative, but rather an academic who would also develop new treatments.

Respondent III noted that the problem as formulated by the appellant was not to be found in the patent: evidence of clinical improvement had not been filed until ten years later and there was nothing in the patent that rendered the alleged effect plausible. Therefore the post-published data of D32/D32a and D33/D33a could not be used to redefine the technical problem. The technical problem was thus at the most an alternative. Even if it could be considered an improvement, it would be obvious. D1 at the very least disclosed the use of the combination for maintenance therapy and also disclosed its use for as-needed therapy. Even if it might not have disclosed the two

uses together, it would be obvious to try with reasonable expectation of success since D1 taught that it worked for both uses. There was no technical prejudice. Instead, D3, page 2, third paragraph, as well as D14, page 849, right column "Foradil - Posologie/Mode d'emploi - Traitement d'entretien et prophylaxie" taught that formoterol could be used for both rescue and maintenance. D1 disclosed that there was no risk of overdosing when administering β_2-agonists with steroids but instead the dose was the right one according to the asthma severity. Even if a further advantage was not expected, if the invention was obvious to carry out, it still lacked inventive step.

According to respondent IV, the distinguishing feature to the closest prior art D1 could be seen as the combination of a maintenance treatment with a rescue treatment. For the formulation of the technical problem, the benefits disclosed in the patent should be taken into account: a simpler approach with improved compliance (paragraph [0003]) and counteracting worsening of symptoms (paragraph [0012]). As regarded the alleged optimisation of steroid dose, the patent data did not show it and the problem was not addressed in the patent as filed; nor was the particular dose of the steroid a feature of claim 1. In fact, the patent provided no data at all; the problem could be considered as being plausibly solved only because of the known properties of formoterol and budesonide. The skilled person thus had to rely on common general knowledge to make the solution plausible, but the same common general knowledge also rendered the solution obvious. The invention was at the most a mere implementation of the suggestion of D1. D46 was not representative of the state of the art at the priority date: the prior art also included unapproved

treatments, research papers, and patent literature. The combination of long-acting β_2-agonists and steroids for acute asthma management was well established (D43, D46, D47); these documents also taught doubling the steroids in acute situations. D18 was a landmark study showing the efficacy of budesonide and formoterol, confirming D1 (Table 2). It was common general knowledge that formoterol had a rapid onset of action, so that it would be suitable for rescue use. The argument that the skilled person would not want to use excess steroid missed the point that the patent was about patients with poor compliance: for such patients the issue was not how to prevent them from taking too much steroid but rather how to get them to take enough.

Auxiliary request 1 - Clarity

Respondent IV argued that it was not clear what the basis for comparison was for the reduction of severity. It could also be assumed that the dose might be relevant. The term "severity" was also unclear in that it might relate to the total exacerbations or to each individual exacerbation. It was also not clear what severe as compared with e.g. moderate exacerbations were. If the patent relied on comparative tests to support functional features of the claim, then it should have provided the parameters together with controls and standards, or else clinical trials would be needed. As it was, the patent relied on subsequent assays to define functional features.

Respondents I and III endorsed the argumentation of respondent IV.

Auxiliary request 2 - Clarity

Respondent I endorsed the arguments of respondent IV.

Respondent III argued that it was not clear whether the doses in the claim related to the dose that the device ejected or to the dose that reached the patient. It was also not clear whether the claim was restricted to two weeks only and then never again or another period of two weeks right after the first. Moreover it was not apparent that the as-needed use in claim 1 was meant to be up to once or twice daily, as argued by the appellant.

Respondent IV argued that the doses feature was unclear, because it was not apparent whether these were metered doses or delivered doses. Moreover, a precise dose as in the claim was dependent on the type of inhaler. The as-needed use as in claim 1 was actually a redefinition of the regular use, and the limitation to treat exacerbations during one or two weeks in claim 2 was unclear.

Auxiliary request 2a - Admission and clarity

Respondent I endorsed the arguments of respondent IV.

Respondent III argued that, given that the appellant had already filed three separate sets of auxiliary requests, this new request should not be admitted. In fact, the appellant should have anticipated that the issues addressed by this request would be raised.

Respondent IV noted that it had already raised an objection in writing to the previous request, arguing that there was an unallowable intermediate generalisation from Example 5. It should thus have been apparent to the appellant that there was a discrepancy

between the disclosure in Example 5 and the wording of the claim.

As regarded clarity, respondents I, III and IV argued that the same objections raised against auxiliary request 2 applied, *mutatis mutandis*, to this request.

Auxiliary requests 3, 4 and 5 - Clarity

Respondents I, III and IV stated that their arguments in relation to the previous auxiliary requests applied also, *mutatis mutandis*, to auxiliary requests 3, 4 and 5.

XVI. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, in the alternative, that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1 or 2 filed with the letter of 27 July 2015, of auxiliary request 2a filed during the oral proceedings, or of auxiliary requests 3 to 5 filed with the letter of 27 July 2015.

Respondents I, III and IV requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. The oral proceedings before the board took place in the absence of respondent II who had been duly summoned but decided not to attend.

Under Article 15(3) RPBA the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case. Thus, for reasons of procedural economy, the board decided to continue the proceedings in the absence of respondent II in accordance with Rule 115(2) EPC.

The principle of the right to be heard pursuant to Article 113(1) EPC has been observed since that provision only affords the opportunity to be heard, and by choosing not to attend the oral proceedings a party gives up that opportunity.

3. Request for accelerated processing

The Finnish Market Court had asked for accelerated processing of the present appeal, in view of revocation and infringement actions concerning the patent in Finland. In accordance with the Notice from the Vice-President Directorate-General 3 concerning accelerated processing before the boards of appeal (OJ EPO 2008, 220), the case was accelerated and oral proceedings before the board were scheduled as soon as possible.

4. Admission of late-filed documents

4.1 Admission of new submissions during appeal proceedings is governed by the Rules of Procedure of the Boards of Appeal. According to Article 12(2) RPBA, the statement of the grounds of appeal and the reply thereto shall contain a party's complete case. Article 13(1) RPBA leaves it to the board's discretion to admit any amendment to a party's case after it has filed its grounds of appeal or reply thereto. This discretion is

to be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

4.2 Respondent IV raised objections against the admission of all documents which were filed by the appellant with a letter sent in response to the respondents' replies to the grounds of appeal. The appellant also objected against the documents which were filed by respondent IV as a reaction to the new claim requests filed by the appellant with the above-mentioned letter. Admission of each of these documents was discussed at oral proceedings. However, in view of the fact that of these documents only documents D38a, D49, D50 and D56 were finally relied upon by the parties, the board does not find it necessary to provide a decision concerning admission of the other documents, which in fact do not play a role in the substantive reasoning of the present decision.

4.3 Documents D38a, D49, D50 and D56 were all filed after the statement of the grounds of appeal and replies thereto. Their admission is thus governed by the principles of Article 13 RPBA. The board notes that these documents were filed as a reaction to the novelty objections raised by the respondents in their replies to the grounds of appeal. That they were not filed already with the statement of the grounds of appeal is because the decision of the opposition division on novelty was positive and thus not contested by the appellant: there had been no need for the appellant to address this issue in its statement of the grounds of appeal. Only with the respondents' replies did the issue become relevant again, and the appellant reacted accordingly.

Moreover, the board considers that none of these documents adds to the complexity of the case or creates a fresh case, but rather they are merely additional evidence to support the appellant's view of what was common general knowledge in the field at the publication date of D1 and at the priority date of the patent. Even D38a, which was filed as evidence supporting a further possible interpretation of D1, is not considered to change the factual framework of the proceedings, as argued by respondent IV. Instead, it merely serves to support the appellant's position, defended already before the opposition division, that the allegedly novelty-destroying disclosure of D1 in fact allowed different interpretations.

4.4 The board thus decided to admit documents D38a, D49, D50 and D56, as well as the related facts and submissions, into the proceedings (Article 13(1) RPBA).

5. Main request (claims as granted)

5.1 Article 100(c) EPC

Article 100(c) EPC was cited as a ground of opposition within the nine-month period stipulated by Article 99(1) EPC. The opposition division decided that the granted claims did not contain added matter within the meaning of Article 100(c) EPC. This part of the decision was not disputed by any of the parties and the board also sees no reason to pursue objections under Article 100(c) EPC against the main request.

5.2 Novelty

5.2.1 Document D1 is a patent application published in 1993, disclosing the use of a combination of formoterol and

budesonide for administration by inhalation in the treatment of asthma. The administration of the combination formoterol and budenoside may be simultaneous, sequential or separate (page 3, line 36 to page 4, line 3). D1 furthermore discloses regular (e.g. twice daily) asthma therapy with the combination formoterol/budesonide (e.g. page 4, lines 19 to 21; page 6, lines 22 to 27).

5.2.2 Under the heading "Outline of the Invention" (paragraph bridging pages 3 and 4), document D1 discloses that "[t]he present invention is based on the concept of a novel combination therapy whereby formoterol (...) and budesonide are administered **simultaneously**, sequentially or seperately [sic] by inhalation", emphasis added by the board. It then states that "[t]his combination has not only a greater efficiency and duration of bronchodilator action but (...) also has a rapid onset of action. This new feature is of utmost importance in order to establish a higher compliance for patients and it **provides a rescue medicine thereby avoiding the necessity for the patient of carrying two different inhalers**" (emphasis added). While these advantageous properties of the combination (greater efficiency and duration of bronchodilator action, rapid onset of action) are in fact the properties of formoterol, a long-acting β_2-agonist with rapid onset of action (D1, page 2 lines 14 to 27), it is however readily apparent that this last sentence, read in the context of the preceding sentences, relates to the combination formoterol/budesonide and not to one of the drugs in isolation. This last-mentioned sentence thus discloses that the combination formoterol/ budesonide serves to establish a higher therapy compliance and provides a rescue medicine. The statement that the need for two different inhalers is

avoided further confirms that the sentence relates to the combination, and in particular to the embodiment wherein the two active ingredients are administered simultaneously (i.e. in one inhaler). Moreover, although the expression "rescue medicine" does not exclude the therapy of nocturnal asthma, or of symptoms associated with the "morning dip" (expression used in document D38a), the board considers that the disclosure on page 4 of document D1 about the combination formoterol/budenoside as rescue medicine is made without further specifications and thus it also encompasses the option of using the composition containing both active ingredients for symptomatic relief as needed, as required in claim 1 of the main request.

5.2.3 However, the subject-matter of claim 1 of the main request is not anticipated by document D1 in view of the following. Claim 1 of the main request is directed to a second medical use, characterised by the use of the combination formoterol/budesonide, in admixture, for the treatment of asthma, wherein the treatment regime comprises both a maintenance therapy (treatment "on a regular basis") and a symptomatic therapy ("symptomatic relief, when needed"). Such a dual treatment regime is not disclosed in D1.

5.2.4 Document D1 discloses the use of the combination formoterol/budesonide for asthma treatment in general, and envisages a twice-daily administration regime. The generic disclosure in document D1 concerns the use of the combination for the treatment of respiratory disorder, such as asthma, without further specification of the treatment regime (e.g. page 1, lines 10 to 14; page 4, line 23 to page 6, line 3; claims). Only two passages in D1 refer to the dosing regime for the

combination therapy as being twice daily. The first is on page 4, lines 19 to 21, and relates to the treatment of asthma on a regular basis, twice daily, to avoid nocturnal asthma (which is a problem mentioned on page 3, lines 10 to 14 of D1). The second is the passage on page 6, lines 23 onwards, which is of a general nature and mentions a "twice-daily administration" and further defines recommended ranges for the doses of the two active drugs in the therapy of asthma (e.g. for mild, moderate or severe asthma). The passage on page 6 is not restricted to the administration of a composition simultaneously containing both active ingredients. In fact, it becomes clear from the previous paragraph on page 6, lines 17 to 20, that the ratio and dosage ranges defined may also apply to the separate administration of the two drugs in a sequential combination therapy.

5.2.5 Moreover, although document D1 teaches that the combination formoterol/budesonide provides a "rescue medicine", i.e. teaches that the combination can also be used for symptomatic relief, it does not specifically disclose a therapeutic regime consisting of both regular therapy together with symptomatic relief for a composition simultaneously containing formoterol and budenoside. The board thus comes to the conclusion that the treatment regime as claimed in claim 1 of the main request is not directly and unambiguously disclosed in D1, and this is, according to established case law, enough to render a second medical use claim notionally novel over the prior art (G 2/08, OJ EPO 2010, 456).

5.2.6 Finally, contrary to the respondents' submissions, it is not manifest that the passage on page 4, lines 6 to 10, inevitably relates to the dual therapy claimed in

claim 1 of the main request, by virtue of the fact that one single inhaler containing the combination formoterol/budenoside is carried. That is because the combination therapy for the treatment of asthma on a regular basis, as presented on page 4, includes simultaneous, sequential and separate inhalation of the two active ingredients. The statement concerning the possibility of the patient not having to carry a second inhaler has to be understood in that context as referring to the embodiment wherein both active ingredients are administered simultaneously as rescue medicine. However, page 4 of document D1 does not disclose that the rescue medicine for simultaneous administration (in one inhaler) of the two active ingredients is inevitably part of a specific dual therapy consisting of administration of the same admixture of two active ingredients, on a regular basis, for the chronic treatment of asthma **and**, as needed, for symptomatic therapy.

5.2.7 Consequently, in view of the reasons given above, claim 1 of the main request is considered to meet the requirements of Article 54(1) and (2) EPC.

5.3 Inventive step

5.3.1 The present patent (see paragraph [0003]) addresses the problem of under-treatment of asthmatic patients resulting from "[t]oo complicated therapy with different medications and devices", leading to "misunderstanding and communication problems between patient and doctor", and "poor compliance" with the therapy. It thus concludes that a "new and more simple approach to asthma treatment" could be of "tremendous help for many patients suffering from (...) asthma" and notes in this context that "[t]he combination of

budesonide and formoterol in the same device as suggested in (...) WO 93/11773 [D1 in the proceedings] and WO 98/15280 [D8] (...) offers a favorable pathway to improve today's asthma management with an excellent safety profile". However, it is further noted in the same paragraph that when using such a combination as taught in the prior art a second medication was still needed, for as-needed symptomatic relief, and this could "negatively affect the overall compliance of the patient." At paragraph [0012], the patent further states that "[t]he as needed use (...) will also minimize the difficulty of predicting which patients will be controlled on a low dose of inhaled steroid rather than increasing the steroid dose before adding a long-acting β_2-agonist. Under-treatment with inhaled glucocorticosteroids following a too low maintenance dose will be more or less 'self-corrected' by the rescue usage according to the present invention". Thus, the goal of the patent is to improve patient compliance with asthma treatment and, at the same time, to optimise steroid dosage in the sense that under-treatment with inhaled steroid is corrected on an individual basis.

5.3.2 Document D1, which discloses the combination therapy of formoterol and budesonide for the treatment of asthma, also recognises the problem of asthma being an "often poorly treated disease" (page 1, line 25) and further explains that "[t]he most common cause for poor control of asthma is poor compliance with the long-term management of chronic asthma, particularly with prophylactic treatments, such as inhaled steroids, which do not give immediate symptom relief. Patients will readily take β_2-agonist inhalers, since these provide rapid relief of symptoms, but often do not take prophylactic therapy, such as inhaled steroids,

regularly because there is no immediate symptomatic benefit" (page 2, lines 3 to 11). D1 aims also at improving compliance in asthma treatment, which should thus solve the problem of under-treatment with inhaled steroids. Therefore, document D1 represents the closest prior art.

5.3.3 The difference to the claimed subject-matter is, as discussed above, that document D1 does not disclose a dual treatment regime consisting of a treatment on a regular basis plus a treatment on an as-needed basis using the same admixture for the combination formoterol/budesonide. The objective technical problem in view of D1 lies in the provision of a therapy for asthma, with better compliance and optimisation of the inhaled steroid dosage for the patient.

5.3.4 The solution is the use of the admixture formoterol/budesonide in a dual treatment regime comprising both regular and as-needed treatment, as claimed. According to the patent, such a treatment regime permits not only better patient compliance but also patient-specific self-correction of the inhaled steroid dose (paragraph [0012]). Although the patent does not provide any experimental or clinical data concerning this treatment regime, the board considers that in the light of the teachings of the patent alone it is plausible that the problem is solved by the proposed solution. This is further confirmed by the post-published clinical trials in documents D32a and D33a, and by the corresponding data analysis presented in D32 and D33.

5.3.5 It thus remains to be established whether the skilled person, aiming at solving the above-mentioned technical problem and equipped with the knowledge of the prior

art, would arrive at the claimed solution in an obvious way.

5.3.6 At the priority date, it was state of the art to aim asthma therapy not only at controlling the symptoms but also at treating the underlying bronchial inflammation (patent, paragraph [0002]; D1, page 1, line 33 to page 2, line 1). It was also known that symptomatic control required bronchodilation therapy, usually with inhaled β_2-agonists with rapid onset of action such as salbutamol, which were administered as needed; treatment of the underlying inflammation was achieved by inhaled steroids, which however provided no immediate relief of symptoms. A widely recognised problem with asthma treatment was that while most patients would promptly take therapy for symptomatic relief, the same was not true for the regular asthma medication, i.e. the steroids aimed at controlling the underlying inflammation (D1, page 2, lines 3 to 11). This lack of compliance with the steroid therapy was due to the fact that the patients did not derive any immediate therapeutic benefit from it and thus were not motivated to pursue it. As a consequence, many patients were under-treated as regarded maintenance therapy with steroids and, due to their poorly controlled asthma, suffered more acute exacerbations.

5.3.7 To overcome the above problem, D1 provided the combination of formoterol, a β_2-agonist, with budesonide, a steroid, observing that higher patient compliance with the therapy was established due to the rapid onset of action of formoterol (which provides immediate relief). It is also to be noted that such a combination therapy with both β_2-agonists and steroids was known at the publication date of D1: e.g. the inhaler Ventide® (combination of the short-acting β_2-

agonist salbutamol and the steroid beclomethasone) of document D56. Also D1 refers to two patent documents (D49 and D50 in the proceedings) that disclose a further combination of beclomethasone and salmeterol, a long-acting β_2-agonist, which had the advantage over the salbutamol/beclomethasone combination that it had a longer action, thus requiring fewer daily administrations (see e.g. D49, page 1, lines 21 to 34). These combination therapies were used for regular maintenance therapy, providing at the same time bronchodilation and treatment of inflammation.

5.3.8 Formoterol was known to provide the advantages of long-acting β_2-agonists (namely long duration of action) together with those of short-acting β_2-agonists (rapid onset of action), making it suitable for both long-term and acute asthma treatment (D1, page 2, lines 21 to 27; D3, page 2, third paragraph; D14, page 849, right column "Posologie/Mode d'emploi: Traitement d'entretien et prophylaxie"). D1 clearly teaches the use of formoterol in combination with budesonide in order to increase patient compliance and thus, as a consequence, solve the problem of under-treatment with steroids. D1 does not disclose how the acute treatment of asthma is to be done, but it does teach that the combination formoterol/budesonide can also be used as a rescue medicine (page 4, lines 6 to 10).

5.3.9 The skilled person would thus consider either to use the established acute therapy with inhaled β_2-agonist bronchodilators (standard therapy) or to follow the teaching in document D1 that the budesonide/formoterol combination (in one inhaler) could also be used for rescue therapy. It would also be immediately clear to the skilled person that a standard acute therapy would have no effect whatsoever on the steroid maintenance

therapy, while the budesonide/formoterol combination would potentially have a two-fold impact on ensuring that the patient took the necessary inhaled steroid dosage: first, it would provide an additional steroid dose to the patient who apparently was in need of it; and second, by using the same inhaler for both maintenance and acute therapies, it would render asthma therapy less complicated, which would lead to better patient compliance. The skilled person, prompted by the teaching of D1 and on the basis of his common general knowledge about asthma treatment, would thus arrive at the solution to the invention without the need for inventive skill.

5.3.10 The appellant's arguments were mostly based on the concept that at the priority date of the contested patent inhaled steroids were considered to have therapeutic value only for maintenance, long-term asthma treatment, but not for symptomatic relief. In the appellant's view, the skilled person would not have adopted an acute therapy with inhaled steroids, because he knew that these would have no therapeutic value for the acute situation and thus their administration would amount to an unnecessary medication, with even a risk of steroid overdosage.

However, contrary to the appellant's arguments, the generally approved therapy protocols for asthma did foresee a role for steroids in the management of acute exacerbations. In fact, increasing the steroid doses for a limited period of time was recommended in the case of asthma exacerbations (e.g. D18, page 1410, right column, last sentence; D43, page S5 column "step 2"; D46, page 107, right column, 5th bullet point; D47, page S3, left column, third paragraph from bottom). While this increase in steroid load concerned the

maintenance therapy it was nevertheless in the context of acute symptomatic relief: the underlying idea was to administer more steroid to the patient who apparently needed it, which is the same underlying concept as in the patent. The skilled person would immediately appreciate that the same effect would be achieved whether the extra dose of steroid was added to the maintenance therapy or to the acute therapy.

5.3.11 The board also cannot accept the appellant's argument that the skilled person would not consider formoterol as the first choice among β_2-agonists for use for symptomatic relief, since its use was controversial and was not part of the generally accepted therapeutic recommendations; other β_2-agonists (namely short-acting β_2-agonists) were better known and routinely used at the time (as evidenced by the contemporaneous guidelines for asthma treatment, e.g. D46).

The board notes however that, as agreed by all parties, the skilled person is not a clinician treating asthma patients, who would of course strictly follow therapy guidelines (such as D46) without departing from them. Rather, the skilled person is an asthma specialist with both clinical and academic expertise, who is also involved in the development of new treatments. This skilled person would thus be open to new therapeutical alternatives which were supported by technical evidence. He would thus also take into consideration the teaching in documents D3 and D14, indicating that formoterol was, due to its rapid onset of action, also suitable for use in acute symptomatic relief. And he would also consider the above-mentioned teachings of D1 that the admixture formoterol/budesonide could be used as a rescue medicine.

5.3.12 It is furthermore noted that the fear of overdosing inhaled steroids does not apply in the context of the technical problem underlying the patent, which is the inverse problem, namely under-treatment with inhaled steroids. The limits between under-treatment and overdosing with inhaled steroids were not so close that there was a risk of rapidly moving from one situation to the other. Rather, inhaled steroids in general, and budesonide in particular, were known to have a large therapeutic window (D1, page 2, line 29 to page 3, line 3) and few side-effects. In fact, even D46 teaches that systemic steroids could be given in case of moderate to severe attacks in order to speed recovery and prevent recurrence of exacerbations (page 59, Table), although these were known to have significantly more side-effects than inhaled steroids (page 61, Table, column Potential Adverse Effects; also in the column Therapeutic Issues it is stated, in relation to inhaled steroids, that "[t]he potential but small risk of adverse events is well balanced by their efficacy"). The skilled person would thus have no reason to fear that overdosing could occur. Either the patient had no or very few acute exacerbations, in which case he would require no or infrequent rescue medication, and thus would administer no or a very limited extra load of steroids, or the patient had many acute exacerbations and would therefore inhale considerably more steroid when taking relief medication: in this latter case it would appear that the asthma was poorly controlled and thus it was therapeutically appropriate to increase the steroid load. In view of the rapid onset and long duration of action of formoterol, the patient would however in any case get an immediate, long-lasting relief, thus preventing him from taking more, unnecessary, medication.

5.3.13 The appellant further argued that D33/D33a showed that the treatment regime according to the invention had the additional advantage that a clinical improvement (i.e. fewer exacerbations) was achieved with lower steroid dosages in comparison to a treatment regime using the combination budesonide/formoterol for maintenance therapy and terbutaline (short-acting β_2-agonist) alone for rescue therapy. The board notes that if this effect is an extra advantage of the therapy, different from optimisation of steroid dosage inherent to the patient's dosage self-correction through the acute therapy, then it has not been disclosed in the application as filed and thus cannot lead to a reformulation of the technical problem. As such, since the technical problem remains the same, the proposed solution is still obvious for the reasons given above.

5.3.14 The subject-matter of claim 1 of the main request thus lacks inventive step (Article 56 EPC).

6. Auxiliary request 1

6.1 There were no objections from the respondents against the admission of this request into the proceedings. The board also had none.

6.2 Clarity

6.2.1 The sole claim of this request differs from claim 1 of the main request, besides the deletion of the term "prevention", by the addition of a functional feature from the description, which further characterises the "when-needed use" as being so that it "reduces the severity of asthma exacerbations".

6.2.2 This added feature renders the claim unclear: it is not apparent how a reduction of severity is to be defined, i.e. whether it relates to the number of crises or to the symptomatology of the crisis or to both, nor is it apparent what the basis for comparison is, e.g. whether it is with a treatment without symptomatic relief or with another symptomatic relief. The appellant's argument that the concept of "severity of exacerbations" was well known is not convincing in this context: in fact, document D18 does define "severe exacerbations" by reference to specific parameters (D18, page 1406, last sentence of left column overbridging to the right column) and evaluates the effects of the therapy on the rates of severe and mild exacerbations (page 1407, left column, last paragraph). It is thus clear in D18 that it is the frequency of exacerbations (mild and severe) which is measured. In the patent however, let alone in the present claim, this is not clear. Moreover, in one possible interpretation, this feature also appears redundant, since it is to expect that a "when-needed use", i.e. a symptomatic relief therapy, will do exactly that: treat the symptoms of the exacerbation and therefore reduce the severity of the crisis.

6.2.3 Auxiliary request 1 is thus not allowable for lack of compliance of with Article 84 EPC.

7. Auxiliary request 2

7.1 There were no objections concerning the admission of this request into the proceedings. The board had none either.

7.2 During oral proceedings, the respondents raised objections under Article 123(2) EPC. In view of the

conclusions reached for Article 84 EPC below, the board sees no need to give a decision on this issue.

7.3 Clarity

7.3.1 The feature introduced into claim 1, which concerns the use for symptomatic relief to treat sporadic breakthrough symptoms, wherein said treatment consists of once or twice daily administration, is unclear. It is not apparent how such a treatment is to be distinguished from maintenance treatment, since it indeed foresees treatment on a regular basis (once or twice daily); the feature is thus contradictory in itself. It is also not clear how such a treatment should be used for treating sporadic breakthroughs which by definition do not necessarily occur once or twice daily.

The board does not agree with the appellant's arguments that this feature is to be interpreted as referring to the maximum number of administrations foreseen for symptomatic relief treatment and that of course no such administration will take place in the absence of an exacerbation. There is in fact no reference to a maximum number of daily administrations in the claim, but rather the claim recites that the symptomatic relief consists of once- or twice-daily administration, thus leaving no room for a different interpretation.

7.3.2 As regards independent claim 2, it is not clear how the feature relative to the duration of the use for symptomatic relief is to be understood. The limitation to one or two weeks of use for symptomatic relief raises serious doubts as to whether said use is indeed only to take place during a maximum period of two weeks and then never again, or whether after said period a

new cycle starts, meaning that the feature is in fact not limiting at all.

Even following the appellant's arguments that the feature is indeed limiting, meaning that the use for symptomatic relief is only for two weeks, it would appear that, after those two weeks, the claim would also cover a therapy consisting of only maintenance therapy with the combination of the invention, the acute symptomatic relief therapy then being left open.

7.3.3 Consequently, auxiliary request 2 is not allowable since claims 1 and 2 lack clarity (Article 84 EPC).

8. Auxiliary request 2a

8.1 Admission

8.1.1 The respondents had objections against the admission of this request, which was filed at the oral proceedings before the board.

8.1.2 This request was submitted as a direct reaction to new objections under Article 123(2) EPC against auxiliary request 1, raised by the respondents for the first time at oral proceedings. The amendments were straightforward and did not add to the complexity of the case. Accordingly, the board decided to admit auxiliary request 2a into the proceedings (Article 13(1) and (3) RPBA).

8.2 Clarity

8.2.1 The features discussed above in relation to auxiliary request 2 are also present in auxiliary request 2a.

Hence, for the same reasons, claims 1 and 2 of this request likewise lack clarity (Article 84 EPC).

9. Auxiliary requests 3 and 4

9.1 Clarity

9.1.1 These two requests consist of only one claim each which, in the case of auxiliary request 3, is identical to claim 1 of auxiliary request 2, while in the case of auxiliary request 4 it is identical to claim 2 of auxiliary request 2. Thus, for the same reasons as those given above in relation to auxiliary request 2, auxiliary requests 3 and 4 likewise lack clarity (Article 84 EPC).

10. Auxiliary request 5

10.1 This request consists of only one claim, which corresponds to the claim of auxiliary request 4 with the further functional feature discussed for auxiliary request 1.

10.2 Thus, the reasons given above in relation to auxiliary requests 1 and 4 directly apply to this request, which also lacks clarity (Article 84 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

N. Maslin M. C. Ortega Plaza

Decision electronically authenticated