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Datasheet for the decision of 18 October 2007

Case Number: T 0794/05 - 3.3.02

Application Number: 92924683.3

Publication Number: 0613371

IPC: A61K 31/57

Language of the proceedings: EN

Title of invention:
New Combination of formoterol and budesonide

Patentee:
AstraZeneca AB

Opponents:
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Miat S.p.A.
Liconsa, Liberacion Controlada de Sustancias
Chiesi Farmaceutici S.p.A.
ZAMBON GROUP S.p.A.
Generics [UK] Limited
NORTON HEALTHCARE LTD

Headword:
Asthma - combination/ASTRAZENECA

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 123(2), 123(3), 56

Keyword:
"Amendements - added subject-matter (yes); Main request, second to fourth Auxiliary Request"
"Amendments - broadening of claims (yes); first Auxiliary Request"
"Inventive step (no) - obvious agglomeration of known features"

Decisions cited:
-

Catchword:
-

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Case Number: T 0794/05 **-** 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 18 October 2007

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 17 May 2005 concerning maintenance of European patent No. 0613371 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J.-P. Seitz

Summary of Facts and Submissions

I. This decision has been pronounced on 18 October 2007; therefore all citations of the EPC in the following text are to be read as EPC 1973.

II. European patent No. 613 371 based on application No. 92 924 683.3, filed in the EPO as WO 93/11773 and referring to the international patent application PCT/EP92/02826, was granted with 31 claims.

Independent claims 1, 13 and 25 as granted read as follows:

"1. A medical product comprising, together,
(i) formoterol or a physiologically acceptable salt thereof, or a solvate of said salt, or a solvate of formoterol; and
(ii) budesonide
as a combined preparation for administration by inhalation.

13. A pharmaceutical composition for administration by inhalation, which comprises, together
(i) formoterol or a physiologically acceptable salt thereof, or a solvate of the salt, or a solvate of formoterol; and
(ii) budesonide.

25. Use of
(i) formoterol, or a physiologically acceptable salt thereof, or a solvate of said salt, or a solvate of formoterol; and
(ii) budesonide,

in the manufacture of a combined preparation for administration by inhalation in the treatment of respiratory disorder."

With respect to the other claims as granted, the Board refers to the specification of the patent in suit.

III. Opposition was filed against the granted patent under Article 100(a), novelty and inventive step, (b) and (c) EPC.

The following documents were cited *inter alia* during the proceedings before the opposition division and the Board of appeal:

(3) EP-A-0 416 950

(10) "IMS Panel Daten zu Verordnungen von Foradil und Mitverordnungen von Corticoiden", Schweiz, April bis September 1991

(15) Respondent's letter of 12 March 1996 during the examination procedure, being part of document (15) and containing experimental data (pages 5 to 8 of the letter)

(17) Experimental data submitted by opponents 01, 05 and 07 with their notices of opposition, named by opponent 1:
"Study protocol and results of animal experiments by Yamanouchi Europe B.V. as comparative tests for 4 different combinations of the new long acting β_2-agonists formoterol and salmeterol with

budesonide, beclomethasone dipropionate (BDP) and fluticasone as examples for steroids"

(22) Maesen, F. et al, "Formoterol in the treatment of nocturnal asthma", CHEST 1990; 98: 866-870

(NH1) Barnes, P.J., "The Drug Therapy of Asthma: Directions for the 21st Century" in "AAS 23: New anti-asthma drugs"; Birkhäuser Verlag, Basel 1988, 293-313

(A21) Transcript of proceedings of the meeting of the Pulmonary-allergy drugs advisory committee: Food and Drug Administration, public meeting on 12-13 December 1991, Rockville, Maryland, Volume I, 1-356 and Volume II, 1-287

(A41) Noonan, M. et al, "Efficacy and safety of budesonide and formoterol in one pressurised metered-dose inhaler in adults and adolescents with moderate to severe asthma", Drugs 66(17) 2006, 2235-2254

IV. The opposition division held that, because of the deletion of claims 7 and 18 from the patent as granted, the set of claims of the first auxiliary request met the requirements of the convention (Article 102(3) EPC).

It first noted that the requirements of Articles 123(2) and 83 EPC were fulfilled.

Concerning Article 54 EPC, the opposition division was of the opinion that the invention was neither anticipated by the teachings of document (10) nor by

the teachings of document (22) or any other document cited during the proceedings. Finally none of these documents disclosed a joint administration of formoterol and budesonide.

The opposition division considered document (NH1) to be the closest state of the art. The subject-matter of the patent, being a combination of two compounds selected from two lists (each of these lists containing two compounds itself), with respect to (NH1), was new and inventive. The technical problem to be solved was to provide formoterol and budesonide in a form for combined use. The person skilled in the art would not have been prompted to carry out the selections and the combination, all the more so because of the speculative language of (NH1).

All other cited documents were less relevant than document (NH1).

V. The appellants (opponents 02, 03, 06 and 07) filed appeals against that decision and submitted grounds of appeal.

VI. Dated 31 July 2007, a communication was sent out expressing, in particular, the Board's concern with respect to Article 123(2) and (3) EPC and to the question of whether the teaching of the patent in suit met the provisions of clarity (Article 84 EPC).

VII. The respondent, by way of reply to the communication of the Board, submitted nine sets of claims substituting all previous claim requests.

The wording of claim 1 of the main request is:

"A pharmaceutical composition for administration by inhalation in the treatment of respiratory disorder, which composition comprises, together:
(i) formoterol fumarate dihydrate; and
(ii) budesonide."

In claim 1 of the first auxiliary request, the word "together" is missing:

"A pharmaceutical composition for administration by inhalation in the treatment of respiratory disorder, which composition comprises formoterol fumarate dihydrate and budesonide."

Claim 1 of the second auxiliary request reads:

"A pharmaceutical composition comprising
(i) formoterol fumarate dihydrate and
(ii) budesonide
as a combined preparation for simultaneous administration by inhalation in the treatment of respiratory disorder."

Claim 1 of the third auxiliary request refers to claim 25 as granted; it is drafted in the form of a second medical use claim comprising the proportion of the two ranges of administration of the drugs formoterol and budesonide as an additional feature for the medicament:

"Use of
(i) formoterol fumarate dihydrate and

(ii) budesonide,
in the manufacture of a medicament for combination therapy for simultaneous administration
of 6 to 100 μg formoterol and
50 to 4800 μg budesonide daily
by inhalation in the treatment of respiratory disorder."

In the fourth auxiliary request, with respect to the third auxiliary request, the ranges of administration of the drugs are restricted to

"6 to 48 μg formoterol and
100 to 1600 μg budesonide daily".

Claim 1 of the fifth auxiliary request refers to a mixture of the drugs; its wording is:

"A mixture of
(i) formoterol fumarate dihydrate and
(ii) budesonide,
which mixture contains in the range of
6 to 100 μg of formoterol per
50 to 4800 μg of budesonide,
for administration by inhalation in the treatment of respiratory disorder."

With respect to this claim 1 of the fifth auxiliary request, in claim 1 of the sixth and the seventh auxiliary requests the ranges of the two drugs' content in the mixture, characterising the claimed range of the proportion in which they are contained ("… μg formoterol **per** … μg budesonide), are restricted to the same

numerical values as in claim 1 of the fourth auxiliary request.

In the seventh auxiliary request, additionally, the dependent claims 2 to 6, still existing in the fifth and sixth auxiliary requests, are omitted.

The wording of the single claim of the eighth auxiliary request is:

"A dry powder inhaler containing an agglomerated, free-flowing, micronised mixture of
(i) formoterol fumarate dihydrate and
(ii) budesonide,
which mixture contains in the range of
6 to 48 μg of formoterol per
100 to 1600 μg of budesonide
for administration by inhalation in the treatment of respiratory disorder."

VIII. On 18 October 2007, oral proceedings took place before the Board in the presence of the representatives of the proprietor (respondent) and the representatives of the appellants (opponents 02, 03, 06 and 07).
Opponents 01, 04, and 05 are parties as of right; opponent 04 had duly informed the Board in a letter dated 4 September 2007 that it would not attend the oral proceedings.

IX. The appellants' submissions can be summarised as follows:

Because of the introduction or cancellation of the word "together" concerning in particular the main request

and the first auxiliary request respectively, there were still objections with respect to Article 123(2) and (3) EPC. The further requests did not meet these provisions of the EPC for similar reasons.

Additionally, the subject-matter of some of the respondent's requests lacked novelty, and finally inventive step was missing with respect to all of them. In document (22) a de facto co-administration of formoterol as a β_2-agonist and budesonide as a steroid had been conducted, otherwise there would have been no sense in the experiments at all. Additionally, the teaching of document (NH1) had to be taken seriously, since normally in such cases no clinical or other in vivo trials or even in vitro trials were necessary with respect to the disclosure of a valid teaching.

Finally, the respondent, with his letter of 12 March 1996 submitted during the examination procedure, had only provided experiments describing the advantages of the teaching of the patent in suit with respect to the single administration of formoterol or budesonide (part of document (15)). The state of the art, however, already referred to a co-administration of these drugs. The appellants in their turn had shown with their experiments (document (17)) that there was no difference in the co-administration of formoterol und budesonide with respect to other combinations of β_2-agonists and steroids, in particular concerning combinations recommended in document (NH1).

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

With respect to the main request and to the first to fourth auxiliary requests, the provisions of Article 123 EPC finally were fulfilled since, in the application and in the patent in suit, the terms "composition", "together", "combined" and "simultaneous" were used synonymously.

The claims of the fifth to eighth auxiliary requests were derived from the text of the description and did not extend the protection conferred to the claims of the patent as granted either.

The subject-matter of the claims as submitted was new with respect to documents (10) and (22), in particular since in both documents there was no definite statement that formoterol and budesonide were administered together.

With respect to inventive step, the closest prior art should not be document (NH1) in order to avoid effects of hindsight. Document (A21), in the view of the respondent, was the closest prior art even if it taught away from the subject-matter of the patent in suit.

XI. The appellants (opponents 02, 03, 06 and 07) requested that the decision under appeal be set aside and that the European patent No. 0 613 371 be revoked.

XII. The respondent (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of its main request or, alternatively, on the basis of either one of its eight

auxiliary requests, all filed with letter dated 17 September 2007.

Reasons for the Decision

1. The appeals are admissible.

2. *Admissibility of the requests and late-filed evidence*

The Board considers that, compared with the claims of the requests contained in the answer of the respondent to the grounds of appeal, the amendments are occasioned by the arguments of the appellants and the content of the communication set out in writing by the Board.

Accordingly, the requests fulfil the requirements of Rule 57a EPC and they are admitted into the procedure.

As a consequence, the pieces of evidence of all the parties submitted shortly before the present proceedings are regarded as occasioned by the discussion of the new requests and admitted into the proceedings.

3. *Requirements of Article 123(2) and (3) EPC as well as Articles 83 and 84 EPC*

3.1 Main request and first to fourth auxiliary requests

3.1.1 Claim 1 of the main request refers to a pharmaceutical composition … comprising **together**:
(i) **formoterol fumarate dihydrate**; and
(ii) budesonide (emphasis by the Board).

Starting from the pharmaceutical composition as disclosed in the application as filed (see claim 2 and page 4, lines 30 to 34), the term "together" is newly introduced into the requested claim 1.

This term "together" is only disclosed in another part of the application as filed, namely in its claim 1 and in the corresponding sentence on page 4, lines 23 to 28: "The present invention provides a **medicament** containing, **separately**, or **together**, (i) formoterol (**and/or a physiologically acceptable salt and/or solvate thereof**) and (ii) budesonide **for simultaneous, sequential or separate administration** by inhalation in the treatment of respiratory disorder." (emphasis by the Board).

Thus, the term "together", in the application as filed, is connected to

- a medicament, not a pharmaceutical composition,
- a particular form of the drug formoterol being different from formoterol fumarate dihydrate
- being contained separately or together,
- and a definition of multiple ways of administration as alternatives.

As far as the form of formoterol to be included in the pharmaceutical composition is concerned, there is a further specification on page 6, lines 5 to 15, of the application as filed. But it does not clearly and unambiguously refer to formoterol fumarate dihydrate either: "Formoterol is preferably used in the form of its fumarate salt and as a dihydrate" (lines 14 and 15). This specification leaves open what substance or salt would be the basis of the dihydrate, in particular

since many different salts are mentioned in this paragraph.

Therefore, in addition to the difference between the pharmaceutical composition (possibly including a kit of parts) claimed before the Board and a medicament in the application as filed, the term "together" is originally disclosed as an alternative to "separately" and in the context with "formoterol (and/or a physiologically acceptable salt and/or solvate thereof)" and "for simultaneous, sequential or separate administration". This context is not kept in claim 1 of the main request.

Under these circumstances, claim 1 of the main request contains an embodiment not individualised in the application as filed, this embodiment as an unallowable selection extending beyond the original content of this application (Article 123(2) EPC).

3.1.2 Claim 1 of the first auxiliary request concerns a pharmaceutical composition and therefore corresponds to claim 13 as granted. This claim 13 contains the term "together", but the term is removed in the requested claim 1.

As a consequence, in the requested claim 1 there is no condition remaining for characterising in which relationship the two drugs are comprised in the pharmaceutical composition, while such a condition in the form of the word "together" was present in the claim as granted.

Therefore, the scope of claim 1 of the first auxiliary request is broader than the scope of claim 13 as granted.

In assessing, whether the protection conferred by the patent in suit is extended by the amendments in claim 1 of the first auxiliary request, the question now has to be answered whether its scope as requested was contained within any of the other granted claims.

The product claims 14 to 24 as granted refer back to claim 13 and contain further features. Consequently, their scope is narrower than the scope of claim 13.

Claims 25 to 31 are use claims containing the features of the product claims as a basis. They therefore are narrower in scope per se.

Thus, only independent product claim 1 as granted remains to be considered; it refers to
a medical product comprising, together,
(i) formoterol …; and
(ii) budesonide
as a combined preparation ….

Since even this product claim 1 contains conditions for characterising the relationship of the two drugs to one another ("together" and "combined preparation") it is narrower in scope than claim 1 of the first auxiliary request.

Therefore, claim 1 of the first auxiliary request extends the protection conferred by the patent in suit (Article 123(3) EPC).

3.1.3 Claim 1 of the second auxiliary request contains the following features:
"content of formoterol fumarate dihydrate" and
"content of budesonide" as a
"combined preparation"

In particular, the feature "combined preparation" is disclosed in claim 3 of the application as filed and is to be found there in the same context as the features "content of formoterol fumarate dihydrate" and "together" in claim 1 of the main request. Again there is a connection to

- a particular form of the drug formoterol being different from formoterol fumarate dihydrate,
- and a particular definition of the methods of administration.

As a consequence, the arguments in section 3.1.1 of this decision apply respectively, and claim 1 of the second auxiliary request does not fulfil the requirements of Article 123(2) EPC either.

3.1.4 Claim 1 of each of the third and fourth auxiliary requests is drafted in the form of a second medical use claim. Both claims refer to the use of both drugs, namely formoterol fumarate dihydrate and budesonide. Therefore, they are to be derived from use claim 7 in the application as filed.

Again the same relation with respect to the features "content of formoterol fumarate dihydrate" and "together" in claim 1 of the main request is to be found, now concerning "content of formoterol fumarate

dihydrate" and "for combination therapy for simultaneous administration".

In claim 7 of the application as filed, as well as in the description, the "content of formoterol" was disclosed as "content of formoterol (and/or a physiologically acceptable salt and/or solvate thereof)" and combination therapy was disclosed in the following context: "for combination therapy for simultaneous, sequential or separate administration".

Consequently, because some of the originally disclosed variations are missing, claim 1 of the third and fourth auxiliary requests also contains an embodiment not individualised in the application as filed, this embodiment as an unallowable selection extending beyond the original content of this application (Article 123(2) EPC).

3.2 Fifth to eighth auxiliary request

Claim 1 of each of these requests is to be derived from page 7, lines 6 to 12, in combination with page 6, lines 22 to 27, of the application as filed and its original claim 2.

There, a mixture of formoterol fumarate dihydrate and budesonide is explicitly mentioned as being in accordance with the invention.

Since "mixture" is a more restricted term than "pharmaceutical composition" or "medicament for combination therapy", the scope of these claims is narrower than the scope of the granted patent.

Consequently, the provisions of Article 123(2) and (3) EPC are fulfilled.

Additionally, the Board is satisfied that the subject-matter of the fifth to eighth auxiliary request also fulfils the requirements of Articles 83 and 84 EPC.

4. *Novelty; fifth to eighth auxiliary request*

Since none of the documents cited during the proceedings explicitly discloses a mixture of formoterol and budesonide, the Board does not contest the novelty of the products claimed in these requests.

5. *Inventive step; fifth to eighth auxiliary request*

5.1 Fifth to seventh auxiliary request

5.1.1 The subject-matter of claim 1 of each of these requests concerns

a mixture of
(i) formoterol fumarate dihydrate and
(ii) budesonide
which mixture contains the drugs in a particular "range of their proportion" and which mixture is suitable "for administration by inhalation in the treatment of respiratory disorder" (see chapter VII. of this decision).

The claimed "range of their proportion" in the fifth auxiliary request is defined by the term "in the range of 6 to 100 μg formoterol per 50 to 4800 μg budesonide".

The effect of the use of the word "per" is that only a proportion of the drugs and no absolute values for their quantity are taught by the claim.

In the sixth and seventh auxiliary requests, there is a restriction to the range of 6 to 48 μg formoterol per 100 to 1600 μg budesonide.

Since the claimed mixture in all these requests has to be suitable "for administration by inhalation in the treatment of respiratory disorder", formoterol fumarate dihydrate is part of the mixture in its property of being a β_2-adrenoceptor agonist (or in short β_2-agonist acting as bronchodilator; see patent in suit, page 2, lines 25 to 31, together with page 2, lines 5 to 8) and budesonide in its property as a steroid (see patent in suit, page 2, lines 32 to 35 in combination with lines 20 to 24 on the same page). Both drugs are well known in the treatment of respiratory disorders and asthma which is a particular form of respiratory disorder (see patent in suit, page 2, lines 36 to 37 and lines 5 to 6). Thus, it was not disputed by the parties that for the feature of such a formulation to be suitable "for administration by inhalation in the treatment of respiratory disorder", it had to be suitable "for administration by inhalation in the treatment of asthma".

5.1.2 Document (NH1) represents the closest state of the art.

This document discloses on page 308, in the paragraph under the heading "Conclusions"

formulations comprising as a combination (see lines 11 and 12 of this paragraph)
(i) β_2-adrenoceptor agonists (see lines 3 and 12) and
(ii) steroids (see lines 9 to 12)
for the treatment of asthma (see lines 1 to 2).

While trying to characterise the development in the field of treating asthma in the near future, the author of (NH1) points out that only a few new drugs have appeared (line 2 of the conclusions), that the only imaginable improvement with β_2-agonists was a longer duration of action (lines 5 and 6) and that inhaled steroids were extremely effective anyhow as chronic treatment in asthma (lines 9 to 11). The individualised substances belonging to these statements are to be found on page 295 of (NH1) as formoterol and salmeterol (second paragraph on this page) cited as long-acting β_2-agonists and on page 303 as budesonide and beclomethasone cited as examples for the steroids (lines 1 to 5 of the first paragraph).

As to the relationship between the β_2-agonist drug and the steroid drug, their combination is required in document (NH1), for instance in the form of combined inhalers, "since they will improve the compliance of inhaled steroids (which is poor because of the lack of immediate bronchodilator effect)" (lines 11 to 15 of the conclusions).

Therefore, the specific teaching of document (NH1) is

to provide a combination of
(i) formoterol or salmeterol and
(ii) budesonide or beclomethasone

being suitable for administration by inhalation in the treatment of asthma, a respiratory disorder.

It has to be noted that this closest state of the art refers to a combination of one of the two mentioned β_2-agonists and one of the two mentioned steroids and not to any of these drugs alone.

The explanation of why the combination of the drugs is to be built to "improve the compliance of inhaled steroids" is given in brackets after the cited wording in document (NH1) and means, for the skilled person, and this is not disputed by the parties - with combined inhalers as an example - that the drugs have to be provided in a form that ensures that asthma patients keep taking their steroid in addition to the β_2-agonist, even when the rapid relief caused by the β_2-agonist makes the patient believe that he would not additionally need the steroid.

5.1.3 During the entire procedure before the Board and the opposition division, no comparative examples referring to such a combination of drugs were submitted that could show any advantage of the claimed mixture over other embodiments according to the teaching of document (NH1):

The experiments submitted by the respondent in document (15) show advantages of the mixture, but only in comparison with the single drugs.

Based on the same type of experiments, in document (17), the appellants on the contrary show that the mixtures of β_2-agonists and steroids

salmeterol - beclomethasone dipropionate,
formoterol fumarate - beclomethasone dipropionate and
salmeterol - fluticasone propionate
are **equivalent** to the claimed mixture
formoterol fumarate - budesonide.

Even in evidence submitted by the respondent during the appeal procedure, only equivalent results in the comparison of the administration of formoterol and budesonide as a mixture and alternatively as a joint medication are mentioned (see document (A41), "Results" and "Conclusions" paragraphs at the end of the abstract).

Thus, no amelioration or special effect with respect to the state of the art can be claimed by the respondent, and the technical problem underlying the patent in suit can only be seen in putting the teaching of document (NH1) into practice, namely
providing a particular combination of
(i) formoterol or salmeterol and
(ii) budesonide or beclomethasone
being suitable for administration by inhalation in the treatment of asthma, at least in the form of a combined inhaler for improving patient compliance.

5.1.4 The solution to this problem is the provision of one specific combination of a β_2-agonist and a steroid, selected from four possible combinations as a mixture in a particular range of their proportion.

5.1.5 Having regard to the examples of the patent in suit and in the absence of any counter-evidence provided by the

appellants, the Board is convinced that the problem has been plausibly solved.

5.1.6 The skilled person in the field of treating respiratory disorders like asthma is also aware of document (3).

This document, in its examples 5 to 11, refers to dry powder formulations, namely mixtures of the

(i) β_2-agonist salmeterol and the
(ii) steroid beclomethasone
for administration by inhalation in the treatment of respiratory disorders (see (3), examples 5 to 11 together with claim 1).

That means that one of the two β_2-agonists and one of the two steroids, mentioned in particular in document (NH1) for use in combination, are presented in document (3) as a mixture suitable for exactly the same purpose.

Under these circumstances, it was obvious to provide also the combination of each of the other two drugs mentioned, namely formoterol and budesonide, in the form of a mixture.

5.1.7 The fact that the mixture is claimed in particular proportions of the components cannot contribute to the acknowledgment of inventive step.

Since the intended use of the mixture is known and this use is the same as the use for which each component is known on its own (treatment of respiratory disorders),

it is merely routine work to find out the suitable proportions of the components in the mixture.

Moreover, the respondent did not claim any contribution of the proportions of the mixture to the assessment of inventive step.

5.1.8 Consequently, the Board can only conclude that the subject-matter of claim 1 of each of the fifth to seventh auxiliary requests does not involve an inventive step, as it merely amounts to providing the mixture of the other of each of the two pairs of drugs known from document (NH1) with respect to and in the manner known from document (D3).

5.2 Eighth auxiliary request

5.2.1 The subject-matter of the eighth auxiliary request concerns
a dry powder inhaler containing the mixture according to claim 1 of the seventh auxiliary request
in an agglomerated, free-flowing, micronised
form.

Since examples 5 to 11 of document (3) deal with "metered dose dry powder formulations", where the ingredients are micronised and filled into hard gelatine capsules or cartridges to be administered by an inhaler (see (3), page 6, lines 37 to 41), the additional features with the exception of the mixture being "agglomerated" are obvious in the light of the disclosure of documents (NH1) and (3). Therefore these features cannot provide for an inventive step either.

Finally, it was not disputed that the person skilled in the art was familiar with the feature "agglomerated" in the context of the subject-matter of the patent in suit and that this additional feature of the eighth auxiliary request could contribute nothing to the assessment of inventive step.

6. Under these circumstances, the arguments of the respondent cannot succeed.

6.1 The respondent argued that document (A21) should be regarded as the closest prior art.

A priori, the fact that a document is a mere transcript of a controversial discussion on a topic, and does not represent a clear technical teaching, disqualifies it from being the closest prior art document.

But also with respect to the teaching of the patent in suit and in view of the teaching of document (NH1) as discussed in this decision, document (A21) has to be ruled out. While (NH1) has the same objective as the patent in suit as far as patient compliance is concerned and while, in mentioning both of the drugs proposed in the patent in suit as a combined preparation for treatment of respiratory disorders, it has the most relevant technical features in common, document (A21) only concerns β_2-agonists in the treatment of asthma in a more abstract manner with little reference to steroids.

6.2 The respondent wanted to support the arguments in favour of an inventive step by the submission that, in view of the critical discussion on regular use of

β_2-agonists at the priority date of the patent in suit, the person skilled in the art would never have thought of a fixed combination of β_2-agonists and steroids. The need for flexible use of the β_2-agonist would have stopped him thinking of such a fixed combination with a drug that had to be taken by the patient at regular intervals.

In terms of the assessment of inventive step, these arguments amount to claiming a prejudice to the teaching of the patent in suit. The decision on such an indication in favour of inventive step, however, has to be based on a positive statement of a unanimous opinion of the skilled persons, held widely or universally.

The fact that a meeting of the Pulmonary-allergy drug advisory committee was held to discuss the topics written down in document (A21) per se, already indicates that there was no unanimous opinion and the documents existing in favour of a fixed combination of β_2-agonists and steroids, such as (NH1) and (3), confirm that there was no prejudice in terms of assessment of inventive step.

Therefore, these arguments of the respondent cannot succeed either.

7. Thus, the subject-matter of the main request and that of the second to fourth auxiliary requests does not meet the provisions of Article 123(2) EPC, the subject-matter of the first auxiliary request does not meet the provisions of Article 123(3) EPC and the subject-matter of the fifth to eighth auxiliary requests does not meet the requirements of Article 56 EPC respectively.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chairman:

A. Townend U. Oswald