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Datasheet for the decision of 13 March 2013

Case Number: T 1067/10 - 3.3.02

Application Number: 02006356.6

Publication Number: 1214937

IPC: A61K 31/445, A61P 17/00

Language of the proceedings: EN

Title of invention:
Terfenadine carboxylate and the treatment of dermal irritation

Patent Proprietor:
Sunovion Pharmaceuticals Inc.

Opponent:
Teva Pharmaceutical Industries Ltd.

Headword:
Terfenadine caboxylate and the treatment of dermal irritation/SUNOVION PHARMACEUTICALS

Relevant legal provisions:
EPC Art. 113(2), 104(1)
RPBA Art. 12, 13, 16

Keyword:
"Late-filed requests not admitted"
"No valid requests left"
"Apportionment of costs (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1067/10 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 13 March 2013

Appellant: (Patent Proprietor)	Sunovion Pharmaceuticals Inc. 84 Waterford Drive Marlborough, MA 01752 (US)
Representative:	Cowley, Catherine Mary Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Respondent: (Opponent)	Teva Pharmaceutical Industries Ltd. 5 Basel Street, P.O. Box 3190 Petah Tiqva 49131 (IL)
Representative:	Wong, Kit Yee D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 23 March 2010 revoking European patent No. 1214937 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

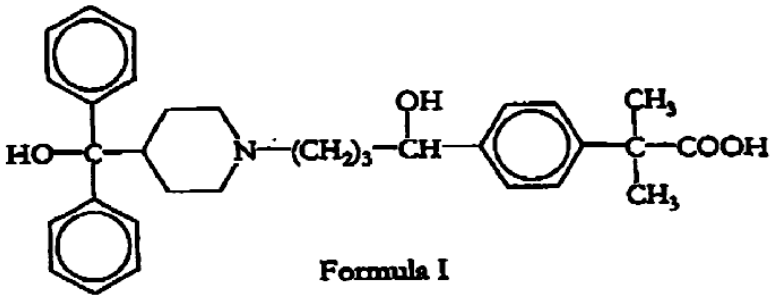
Chairman: U. Oswald
Members: M. C. Ortega Plaza
R. Cramer

Summary of Facts and Submissions

I. European patent No. 1 214 937, based on the European patent application No. 02006356.6 which was filed as a divisional application of application No. 97104837.6 (parent application), which was filed as a divisional application of application No. 93918584.9, which was filed as an international patent application published as WO 94/03170 (root application), was granted with 24 claims.

Claim 1 as granted read as follows:

"1. Use of a composition comprising a compound of formula I:

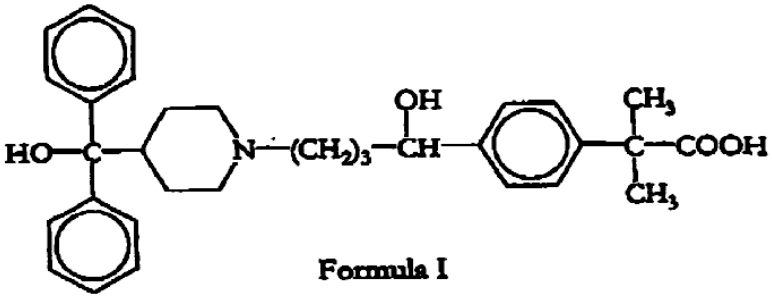


Formula I

or a pharmaceutically acceptable salt thereof, for the preparation of a medicament for use in providing symptomatic relief from dermal irritation associated with an allergic disorder, cough, cold or flu, wherein the induction of cardiac arrhythmia is avoided, said treatment comprising administering a therapeutically effective amount of a compound of formula I to a human patient whose hepatic function is not impaired".

Independent claim 16 as granted read as follows:

"16. A pharmaceutical composition in the form of an oral solid preparation comprising 20 to 200 mg of a pharmaceutically acceptable salt of a compound of formula I:

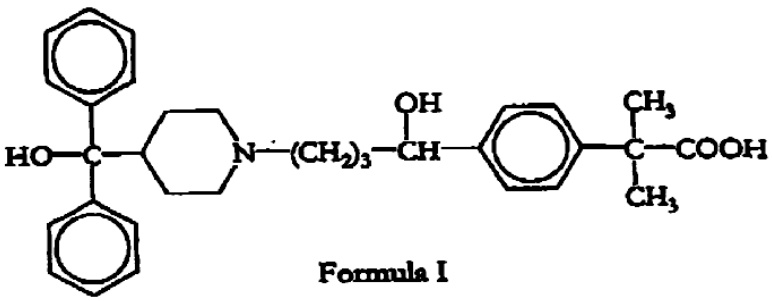


Formula I

and an inorganic acid selected from the group consisting of hydrochloric acid, hydrobromic acid, hydroiodic acid, sulphuric acid, and a pharmaceutically acceptable carrier or excipient, for use in treating dermal irritation, wherein the induction of cardiac arrhythmia is avoided".

Independent claim 23 as granted read as follows:

"23. A pharmaceutical composition in the form of an oral solid preparation comprising 20 to 200 mg of a pharmaceutically acceptable salt of a compound of formula I:

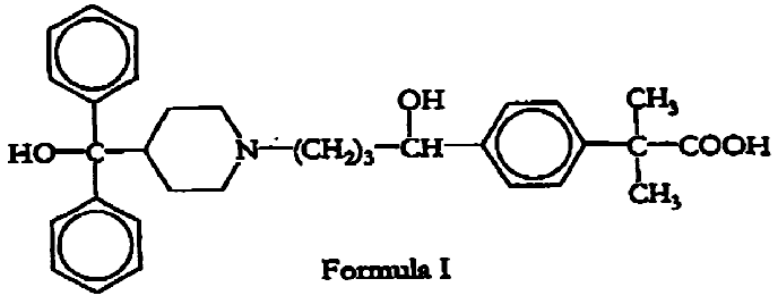


Formula I

and an inorganic acid selected from the groups consisting of hydrochloric acid, hydrobromic acid, sulphuric acid and phosphoric acid, and a pharmaceutically acceptable carrier or excipient".

Independent claim 24 as granted read as follows:

"24. Use of a pharmaceutically acceptable salt of a compound of formula I:



Formula I

and an inorganic acid selected from the group consisting of hydrochloric acid, hydrobromic acid, hydroiodic acid, sulphuric acid and phosphoric acid, for the preparation of a pharmaceutical composition for the treatment of dermal irritation wherein the induction of cardiac arrhythmia is avoided, wherein the pharmaceutical composition is in the form of an oral solid preparation comprising 20 to 200 mg of the pharmaceutically acceptable salt of the compound of formula I and a pharmaceutically acceptable carrier or excipient".

II. Opposition was filed and revocation of the patent in its entirety was requested in particular pursuant to Article 100(c) (the subject-matter of the patent extends beyond the content of the application, or

earlier application, as filed) and 100(a) EPC (lack of novelty and lack of inventive step).

III. The following document was cited *inter alia* in the opposition and appeal proceedings:

D1 US 4254129

IV. The present appeal lies from a decision of the opposition division revoking the patent (Article 101(2) and 101(3)(b) EPC).

V. The opposition division's decision is based on the set of claims as granted (main request) and on auxiliary requests 1 to 3 filed with letter dated 8 December 2009.

The opposition division considered that the grounds of opposition under Article 100(c) EPC prejudiced the maintenance of the patent as granted.

In particular, the amendment present in claim 1 as granted, which concerned the definition of the human patient to whom the medicament was to be administered as one "whose hepatic function is not impaired", introduced subject-matter which extended beyond the content of the application as filed, as well as of the parent application as filed and of the root application as filed.

Moreover, the opposition division also considered that granted claims 16 and 24 extended beyond the content of the earlier applications as filed since the medical conditions to be treated were not confined to an anti-histaminic treatment.

Additionally, the opposition division considered that auxiliary requests 1 to 3 failed for reasons analogous to those given for the main request.

VI. The patentee (appellant) filed an appeal against said decision, and grounds thereto. With its grounds of appeal the appellant filed several abstracts, as well as a main request which is identical to the set of claims as granted, and auxiliary requests 1 to 3.

Auxiliary request 1 differed from the set of claims as granted in that claims 16 and 24 had been amended by introduction of the following: "associated with an allergic disorder, cough, cold or flu", after the expression "dental irritation".

Auxiliary request 2 differed from the set of claims as granted in that claims 16 to 24 had been deleted.

Auxiliary request 3 differed from the set of claims as granted in that claims 12 and 16 to 24 had been deleted.

VII. The respondent filed counterarguments to the grounds of appeal with a letter dated 9 December 2010. It requested that the appeal be dismissed. It also requested that the present appeal be consolidated with appeal case T 2102/09.

VIII. The appellant filed a letter dated 3 March 2011 containing a reply to the respondent's counterarguments. In said letter it requested that the request for consolidation be refused. Moreover, it mentioned that it had requested "*referral of two points of law to the*

Enlarged Board of Appeal in instant proceedings" without specifying which points of law it meant or which questions it intended to propose. With said letter the appellant maintained the main request and the auxiliary requests 1 to 3 filed with the grounds of appeal. It also filed an additional document.

IX. The board sent a communication pursuant to Article 15(1) RPBA as an annex to the summons to oral proceedings.

In said communication the board expressed the opinion that it was disinclined to consolidate appeal cases T 1067/10 and T 2102/09, since the factual and legal framework were not necessarily identical in both cases.

The board expressed *inter alia* a preliminary opinion in relation to the grounds pursuant to Article 100(c) EPC. The board cited decision G 2/10, EPO OJ 2012, 376.

The board also expressed in said communication that since the mention of the grant of the patent was dated 30 May 2007, the patent in suit had been granted before the EPC 2000 entered into force (13 December 2007). Therefore, Article 54(5) EPC 2000 did not apply to the patent in suit and Article 54 EPC 1973 did not allow purpose-related product claims for second and further medical uses. As a consequence, claim 16 as granted manifestly lacked novelty *inter alia* vis-à-vis document D1.

X. With a letter dated 28 February 2013 the appellant filed a new main request and auxiliary requests 1 to 8. It also announced that the main request (set of claims

as granted) and the auxiliary requests previously on file were withdrawn.

XI. Oral proceedings took place on 13 March 2013.

XII. At the beginning of the oral proceedings the Chairman asked the parties to state their requests. In reply the appellant filed a new main request and five auxiliary requests (auxiliary requests 1 to 5) on the basis of which it requested maintenance of the patent in amended form. It also requested remittal to the department of first instance for further prosecution. Furthermore, it withdrew all the claim requests filed with its letter dated 28 February 2013.

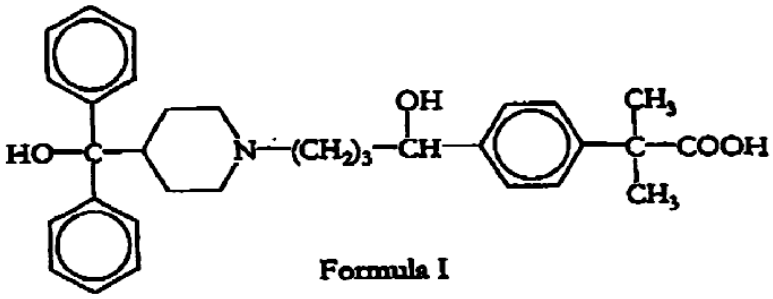
Just before closing the debate on the admissibility of the requests filed at the beginning of the oral proceedings, the appellant stated that it had a further auxiliary request, namely it stated that the set of claims as granted was its auxiliary request 6 (i.e. this last request is a request for maintenance of the patent as granted).

At the beginning of the oral proceedings the appellant also stated that it did not maintain the request for referral to the Enlarged Board of Appeal mentioned in the grounds of appeal (end of point 6) and in the letter dated 3 March 2011.

XIII. The main request filed at the oral proceedings contained three claims.

Claim 1 of the main request read as follows:

"1. A pharmaceutical composition in the form of an oral solid tablet or capsule containing a dose of 30 mg, 60 mg or 90 mg of a pharmaceutically acceptable salt of a compound of formula I:

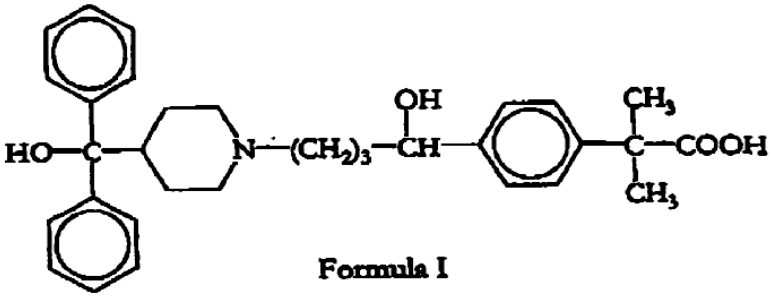


Formula I

and an inorganic acid selected from the group consisting of hydrochloric acid, hydrobromic acid, hydroiodic acid, sulphuric acid and phosphoric acid, and a pharmaceutically acceptable carrier or excipient, for use in an anti-histaminic treatment of dermal irritation associated with an allergic disorder, cough, cold or flu in a human patient, wherein the induction of cardiac arrhythmia is avoided".

Independent claim 2 of the main request read as follows:

"2. A pharmaceutical composition in the form of an oral solid tablet or capsule containing a dose of 30 mg, 60 mg or 90 mg of a pharmaceutically acceptable salt of a compound of formula I:

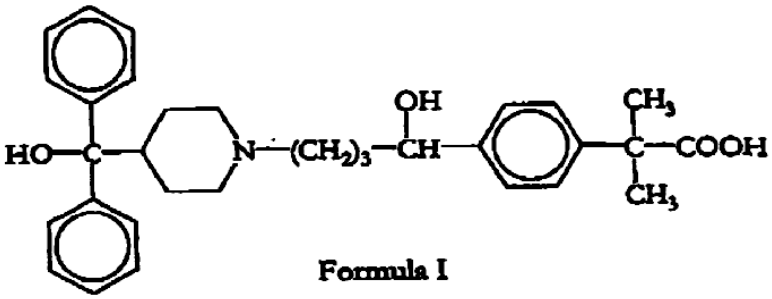


Formula I

and an inorganic acid selected from the group consisting of hydrochloric acid, hydrobromic acid, hydroiodic acid, sulphuric acid and phosphoric acid, and a pharmaceutically acceptable carrier or excipient".

Independent claim 3 of the main request read as follows:

"3. Use of a pharmaceutically acceptable salt of a compound of formula I:



Formula I

and an inorganic acid selected from the group consisting of hydrochloric acid, hydrobromic acid, hydroiodic acid, sulphuric acid and phosphoric acid, for the preparation of a pharmaceutical composition for use in an anti-histaminic treatment of dermal irritation associated with an allergic disorder, cough, cold or flu in a human patient, wherein the induction of cardiac arrhythmia is avoided, wherein the pharmaceutical composition is in the form of an oral solid preparation comprising 20 to 200 mg of the

pharmaceutically acceptable salt of the compound of formula I and a pharmaceutically acceptable carrier or excipient".

As regards auxiliary request 1 filed at the oral proceedings, independent claims 1 and 2 are identical to independent claims 1 and 2 of the main request filed at the oral proceedings. Claim 3 of auxiliary request 1 differs from claim 3 of the main request in that the expression "an oral solid preparation comprising 20 to 200 mg" after "is in the form of" has been replaced by the following: "an oral solid tablet or capsule containing a dose of 30 mg, 60 mg or 90 mg".

Auxiliary request 2 filed at the oral proceedings contains one single claim only, which is identical to independent claim 2 of the main request filed at the oral proceedings.

Auxiliary request 3 filed at the oral proceedings contains one single claim only, which differs from independent claim 2 of the main request and claim 1 of auxiliary request 2 both filed at the oral proceedings in that in contains the following wording: ", for use in an anti-histaminic treatment of a human patient" after the word "excipient".

Auxiliary request 4 filed at the oral proceedings contains one single claim only, which differs from claim 1 of auxiliary request 3 filed at the oral proceedings in that it contains the following wording: ", wherein the induction of cardiac arrhythmia is avoided" after the expression "human patient".

Auxiliary request 5 filed at the oral proceedings contains one single claim only, which is identical to claim 1 of the main request filed at the oral proceedings.

XIV. At the oral proceedings the respondent maintained its request that the appeal be dismissed.
It no longer asked for consolidation of appeal cases T 1067/10 and T 2102/09 at the oral proceedings, since the appeal case T 2102/09 had in fact already been dealt with by the board of appeal and concluded.
Moreover, the respondent requested apportionment of costs at the oral proceedings for the first time.

XV. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows.

Submission of the new requests was justified by the outcome of the appeal proceedings in T 2102/09, in which the "disclaimer" was considered not to be allowable. The decision in T 2102/09 had been announced at the oral proceedings which took place on 11 March 2013.

The new main request found its basis in the main request filed with the letter dated 28 February 2013, in which the following amendments had been made: deletion of claims 1 to 14, introduction of a small amendment in claims 1 and 3, namely the expression "in a human patient" had been added.

Auxiliary request 1 was derived from auxiliary request 2 filed with the letter dated 28 February 2013, with the inclusion of the expression "in a human patient" in

claims 1 and 3 and the deletion of claim 1. Auxiliary request 2 was based on auxiliary request 3 filed with the letter dated 28 February 2013. Auxiliary request 3 was based on auxiliary request 4 filed with the letter dated 28 February 2013. Auxiliary request 4 was based on auxiliary request 5 filed with the letter dated 28 February 2013. Auxiliary request 5 was based on claim 15 of the main request filed with the letter dated 28 February 2013 with the inclusion of the expression "in a human patient".

The appellant submitted that it considered that the main request filed with the letter dated 28 February 2013 was admissible and that the main request filed at the oral proceedings related to deletion of claims in relation to that previous main request, and that it contained only minor amendments which were easy to handle. Moreover, regardless of the outcome of T 2102/09, it was to be expected that the patentee would delete the claims with the "disclaimer" since the set of claims as granted contained separate independent claims, some of them without the mentioned "disclaimer". It was then a normal procedural step to delete some of the claims as granted. The respondent could not have been taken by surprise by the new main request.

Claim 1 of the main request resulted from a combination of claims 16 and 17 as granted and it included the requirement that the treatment be an anti-histaminic treatment as a restriction in relation to the dermal irritation of claim 16 as granted. Moreover, it was specified in claim 1 that the dermal irritation was "associated with an allergic disorder, cough, cold or flu" and that the treatment concerned a human patient.

The combination of claims 16 and 17 had taken place in response to the comments in paragraph 9 of the communication of the board of appeal sent as an annex to the summons. In said communication it was said that claim 16 as granted manifestly lacked novelty. The specification of the amounts had overcome the novelty objection. The amendment concerning the specification of the treatment as anti-histaminic treatment was in direct reply to the board's objection in point 3 of said board's communication. The amendment concerning the specification "associated with an allergic disorder, cough, cold or flu" was already present in claim 16 of auxiliary request 1 filed with the grounds of appeal. This had been done in response to the findings in the opposition division's decision in relation to Articles 123(2) and 76(1) EPC. The opposition division had indicated that with such a specification the treatment was inherently an "anti-histaminic treatment".

All the amendments introduced in the main request simplified the case. The specification of the patient as a human patient was in line with the content of the description of the application and root application as filed. It was introduced to ensure that the claim did not contain added subject-matter.

As regards claim 2 of the main request filed at the oral proceedings, the core of the claim corresponded to independent claim 23 as granted in which the form of the oral solid preparation, as well as the dose, had been narrowed down. The features found their basis in the description as originally filed. The reasons for their introduction were the same as those given in relation to claim 1, in particular since the comment in relation to novelty in paragraph 9 of the board's

communication directly applied to granted claim 23 as well. As regards claim 3 of the main request filed at the oral proceedings, it was derived from claim 24 as granted, in which the treatment had been specified as anti-histaminic treatment and the dermal irritation had been specified as "associated with an allergic disorder, cough, cold or flu". Additionally the patient was defined as a human patient. All these specifications were introduced in claim 3 for the reasons analogous to those given in connection with claims 1 and 2. The features concerning the form of the oral solid preparation and the amounts or doses could not have taken the respondent by surprise since these features were already dealt with in relation to dependent claim 17 in the opposition division's decision (page 15, second paragraph). These amendments had not been introduced into the claims previously, because it had been clear at the oral proceedings before the opposition division that they were considered to relate to unallowable added matter.

Since the claims with the "disclaimer" were potentially contentious they had been deleted. The same applied to the deletion of dependent claims. Certain boards of appeal admitted sets of claims in which deletions of claims were undertaken.

In claim 1 of the main request filed at the oral proceedings the expression "solid" was retained since it was present in claim 16 as granted. The amendments did not contravene the requirements of Article 123(3) EPC since the specification of the treatment as "an anti-histaminic" treatment concerned a restriction or limitation from the previously claimed scope. A *cachet*

was not included but the embodiments were equally individualised. The further reason for the change of language "containing a dose…" instead of "providing a unit dosage…" as in granted claim 17 was to keep as close as possible to the description in the application and root application as filed in order to pre-empt objections under Article 76(1) and 123(2) EPC. There was no shift of invention. The respondent should have been prepared to react to amended claims. The claims filed at the oral proceedings were very similar to those filed with the letter dated 28 February 2013, which had been filed as a direct reply to the board's communication.

Claims 1 and 2 in auxiliary request 1 were already in the main request also filed at the oral proceedings. Claim 3 had been amended by restricting the dosage form and the dose. The reasons are analogous to those given for the main request, i.e. addressing possible novelty and Article 123(2), 76(1) EPC objections.

Auxiliary request 2 had only one single claim (as claim 2 of the main request), which simplified the appeal.

Auxiliary request 3 had only one single claim, which was based on claim 2 of the main request filed at the oral proceedings, incorporating the feature "for use in an anti-histaminic treatment". This was intended as a first medical use claim in accordance with Article 54(5) EPC 1973 and concerned the broadest definition of the initially disclosed invention.

Auxiliary request 4 incorporated the passages relating to the avoidance of cardiac arrhythmia in order to prevent an objection of added subject-matter under Articles 123(2), 76(1) EPC.

Auxiliary request 5 contained only claim 1 of the main request filed at the oral proceedings.

As regards auxiliary request 6 which was filed shortly before the closing of the debate on the admissibility of the requests filed at the beginning of the oral proceedings, the appellant stated that in its understanding there was some case law indicating that the set of claims as granted may be submitted as a final request.

XVI. The respondent's arguments, as far as relevant for the present decision, may be summarised as follows.

The respondent submitted at the oral proceedings that the request for apportionment of costs was made since the case had gone on for many years, during which the appellant had not filed any amended requests other than those filed with the grounds of appeal. The appellant had maintained the requests filed with the grounds of appeal even with the appellant's letter dated 3 March 2011, where some counterarguments to the respondent's response to the grounds of appeal had been submitted. The appellant had changed the nature of the appeal with the requests filed at the beginning of the oral proceedings, taking the respondent by surprise. This filing of the new requests concerned an abuse of procedure which justified the request for apportionment of costs. Moreover, the filing of the new requests at

the beginning of the oral proceedings could not be justified in the light of the outcome of another case for which no consolidation had been made. The discussion on the admissibility of the sets of claims filed with the letter dated 28 February 2013 had never taken place. The filing of the new sets of claims amounted to an unjustified situation of a fresh case by deletion of all claims with the so-called "disclaimer" at such a late stage of the proceedings.

The appellant's submission that all the amendments were reasonably to be expected was unfair. The board should provide for fair proceedings. This would no longer be the case if the newly filed requests were to be admitted. Article 12(2) RPBA made it clear that the parties had a duty to present a complete case with the grounds of appeal. This had not been the case in the present procedure as became evident from the appellant's submissions. Thus, there had been an abuse of procedure.

Sometimes in the proceedings a patentee may delete claims as granted. However, if in the present case the product claims were so important for the appellant it should have filed the amended product claims at opposition proceedings, or at the latest with the grounds of appeal. The opposition division had concluded that the claims containing the "disclaimer" were not allowable pursuant to Article 100(c) EPC. Therefore, there was a chance that the decision would be confirmed. The deletion of granted claims 1 to 15 undertaken in the main request filed at the oral proceedings completely changed the nature of the appeal case at such a very late stage of the proceedings.

The respondent also submitted that in its response to the grounds of appeal dated 9 December 2010 it had submitted arguments to support why granted claim 1 encompassed added subject-matter pursuant to Article 100(c) EPC in view of the presence of the specification "to a human patient whose hepatic function is not impaired". As regards granted claims 16 and 24 it had mentioned in said letter that the term "dermal irritation" independent from the term "an anti-histaminic treatment" involved added matter and that the appellant had not given any reasons to justify the contrary. Moreover, the respondent had also submitted in said letter that claims 16, 17, 23 and 24 as granted related to unallowable combinations of numerous selections and thus they were not allowable pursuant to Article 100(c) EPC.

However, for over two years the appellant had not taken the opportunity to modify its claims requests. There was no valid justification for waiting until the oral proceedings to do so. Moreover, the introduction of features from the description in the claims filed at the oral proceedings amounted to a new combination of features which could not have been expected as the facts on file stood before. The decision in appeal case T 2102/09 was not a unique decision in the matter of allowability of claims containing "disclaimers".

Additionally, the respondent stressed that the newly filed claim 1 did not relate to a mere combination of claims 16 and 17 as granted. In particular, the wording was different. The change in the wording of the new claim 1 of the main request filed at the oral

proceedings had completely changed the nature of the claim. Moreover, the introduced amendments were not *prima facie* allowable in relation to Article 123(2) and (3) EPC. In this context it referred to the lack of mention of the qualifying feature "symptomatic relief" from dermal irritation and to the specification of "an anti-histaminic treatment". Furthermore, the argument that claim 1 of the main request should be admitted since it derived from a combination of claims 16 and 17 as granted also failed, since claim 17 as granted contained added subject-matter pursuant to Article 100(c) EPC as expressed in the opposition division's decision and commented on in the respondent's letter dated 3 March 2011. Therefore, claim 1 of the main request was *prima facie* non-allowable. The same applied to claim 2.

The preliminary opinion of the board in relation to the "disclaimer" expressed in the board's communication sent as an annex to the summons did not concern the introduction of a new objection pursuant to Article 100(c) EPC by the board.

Additionally, the respondent further submitted that if every amendment was so clear and expectable it should have been made earlier. The appellant had had ample opportunity during opposition and appeal proceedings, but it had waited until the oral proceedings before the board. The particular combination of features in claim 1 of the main request filed at the oral proceedings was not present in any of the claims presented with the grounds of appeal.

There was no reason to expect the amendment concerning the specification of the dose amounts for the specific salts in claim 2 of the main request filed at the oral proceedings. In claim 3 of the main request the range 20 to 200 mg was retained.

The respondent also mentioned that the appellant had to discharge its burden to present a complete case as required by Article 12(2) RPBA and cited decision T 316/08 of 26 May 2010. The requests filed with the letter dated 28 February 2013 were also non-admissible.

The respondent also submitted that the arguments already submitted also applied *mutatis mutandis* to auxiliary requests 1 to 5 filed at the oral proceedings.

As regards auxiliary request 6 which had been filed shortly before the closing of the debate on the admissibility of the requests filed at the beginning of the oral proceedings, the respondent objected to the re-filing of such a request since it had been withdrawn with the letter dated 28 February 2013 and there was no justification for such a tactical procedure. Moreover, the set of claims as granted did not overcome any of the objections re Article 100(c) EPC. Thus, said request was *prima facie* non-allowable.

XVII. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request, or alternatively on the basis of one of auxiliary requests 1 to 5, all filed during the oral proceedings, or more alternatively that the patent be maintained as granted (auxiliary request 6) and that

the case be remitted to the department of first instance for further prosecution. It further requested that the request for apportionment of costs be refused.

The respondent (opponent) requested that the appeal be dismissed and requested apportionment of costs.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 *Admissibility of the claims requests filed at the beginning of the oral proceedings (main request and auxiliary requests 1 to 5)*

1.2.1 Article 12(2) RPBA stipulates that the statement of grounds of appeal shall contain an appellant's complete case, setting out clearly and concisely the reasons why the decision under appeal be reversed, amended or upheld, and should specify expressly all the facts, arguments and evidence relied on.

1.2.2 In the present case the appellant filed with the grounds of appeal dated 30 July 2010 a main request (set of claims as granted) and three auxiliary requests (auxiliary requests 1 to 3). In all the requests, use claim 1 was identical to claim 1 as granted and contained the so-called "disclaimer". According to the opposition division's findings such a claim was non-allowable for grounds pursuant to Article 100(c) EPC. Moreover, in the sets of claims of auxiliary requests 2

and 3 filed with the grounds of appeal, independent claims 16 to 24 as granted had been deleted, and in the set of claims of auxiliary request 1 filed with the grounds of appeal only claims 16 and 24 as granted were amended by introduction of the expression "associated with an allergic disorder, cough, cold or flu".

1.2.3 The appellant maintained all the requests filed with the grounds of appeal with its letter dated 3 March 2011 and chose not to file any new requests. This letter was filed after the respondent had filed a reply dated 9 December 2010 to the appellant's grounds of appeal in which it was clear that Article 100(c) EPC was still a contentious matter in relation to claims 1 (in particular in view of the presence of the so-called disclaimer), 16, 17, 23 and 24 as granted and that the respondent considered that none of these problems were fully addressed by the requests on file.

1.2.4 While Article 12(1)(c) RPBA provides that appeal proceedings shall be based on, in addition to the grounds of appeal and reply, any communication sent by the board and any answer thereto, this does not mean that the appellant has an unlimited right to file amended sets of claims as a reply to a board's communication, or that any set of claims filed after a board's communication expressing a preliminary opinion has been issued will automatically be admitted into the proceedings.

1.2.5 Article 13(1) RPBA provides that any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion, and that discretion shall 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.
Additionally, the right of both parties for fairness of the proceedings and equity has to be considered in *inter partes* appeal proceedings.

Article 13(3) RPBA provides that amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings.

1.2.6 At the beginning of the oral proceedings the appellant made it clear that it withdrew the claims requests filed with its letter dated 28 February 2013. Thus, the discussion on their admissibility, and the decision to admit or refuse their admission, never took place. Therefore, an assessment of the admissibility of the requests filed at the beginning of the oral proceedings cannot be based on the false assumption that the requests filed with the letter dated 28 February 2013 would have been admitted into the proceedings.

1.2.7 Leaving aside the question whether or not deletion of the independent use claim (claim 1 as granted) containing the so-called "disclaimer" is to be seen at such a late stage of the proceedings as an admissible procedural step, it cannot be ignored that each set of claims (main request and auxiliary requests 1 to 5) filed at the beginning of the oral proceedings contains at least one independent claim which has been reworded and which is different from any of the amended claims

of auxiliary request 1 filed with the grounds of appeal (the other sets of claims filed with the grounds of appeal did not contain redrafted claims).

It has to be stressed that, contrary to the appellant's allegations, none of the sets of claims filed at the beginning of the oral proceedings (main request and auxiliary requests 1 to 5) relates to a set of claims merely differing from the set of claims as granted in that some claims had been deleted. Moreover, the product claims are not derived from a mere combination of dependent granted claims but have been redrafted and contain new wordings of features. Thus, it cannot be said that the amendments could have been expected and were clear and simple to handle.

1.2.8 The board's communication sent as an annex to the summons expressed a preliminary opinion of the board based on the sets of claims filed with the grounds of appeal and maintained with the appellant's letter dated 3 March 2011. Said communication did not contain any direction of the board within the meaning of Article 12(1)(c) RPBA to file further sets of claims with amended product claims. Apart from the fact that the respondent had already, with its grounds of opposition dated 29 February 2008 (page 25, point 7.7), raised an objection of lack of novelty against claim 16 as granted in view of document D1, the preliminary opinion expressed in point 9 of the board's communication sent as an annex to the grounds of appeal does not justify the late filing of amended sets of claims because the objection of lack of novelty of the product claims had been already overcome by deletion of the product claims in the sets of claims of auxiliary

requests 2 and 3 filed with the grounds of appeal and maintained with the appellant's letter dated 3 March 2011. Therefore, the board's communication cannot serve as a valid justification for the admission of the requests filed at the beginning of the oral proceedings (main request and auxiliary requests 1 to 5).

Additionally, the board is convinced that the appellant had had ample opportunity to file amended sets of claims during opposition and appeal proceedings and did not need to wait for the board's preliminary opinion in order to react to the findings of the opposition division, or to address matters clearly contentious as the facts on file stood long before the board's communication was sent to the parties.

1.2.9 Moreover, the amendments introduced in claims 1 and 2 of the main request originate from the description, and thus they open new and complex issues for discussion at such a very late stage of the proceedings, in particular in relation to the requirements of Articles 123(2) and 76(1) EPC owing to new combinations of specific features. Moreover, the specification of the solid oral form together with the particular definitions of the doses for the pharmaceutical composition now claimed represents a shift of the invention in relation to the assessment of novelty vis-à-vis document D1, which cannot be justified at such a very late stage of the proceedings. Additionally, the board cannot see that there is any objective justification for the late introduction in claim 1 of the main request of the amendment concerning the definition of the patient as a "human patient". In particular, it cannot be seen that this amendment

addresses any objection recently raised on the appeal file.

Therefore the main request is not admissible.

1.2.10 The reasons given above for the main request also apply *mutatis mutandis* to auxiliary request 1 since claims 1 and 2 are identical to claims 1 and 2 of the main request. Additionally, use claim 3, which originates from granted claim 24, has been reworded by allegedly incorporating features from the description and thus it opens new and complex issues for discussion at such a late stage of the proceedings.

Therefore auxiliary request 1 is not admissible.

1.2.11 The reasons given above for the main request also apply *mutatis mutandis* to auxiliary request 2 since claim 1 is identical to claim 2 of the main request.

Therefore auxiliary request 2 is not admissible.

1.2.12 Claim 1 of auxiliary request 3 in addition to its new wording, which is similar to that of claim 2 of the main request, incorporates an additional feature concerning the treatment as a purpose. This amounts to a complete fresh case in relation to the product claim which has been defended by the appellant as a first medical use claim for the anti-histaminic treatment of particular dosage forms and doses. This procedural step is inadmissible at such a very late stage of the proceedings since it creates a completely fresh case for the claimed invention in relation to novelty and inventive step. The filing of such a request completely

changes the nature of the appeal and takes the other party by surprise at such a late stage in the proceedings. Additionally, the wording of claim 1 opens new and complex issues in relation to the allowability of amendments under Articles 123 and 76(1) EPC.

Therefore auxiliary request 3 is not admissible.

1.2.13 The admission of auxiliary request 4 fails for reasons analogous to those given above for auxiliary request 3 in view of the fact that both claims 1 share a similar wording. Additionally, claim 1 contains further features which require further assessment for the first time in relation to their allowability under Articles 123 and 76(1) EPC.

Therefore auxiliary request 4 is not admissible.

1.2.14 Claim 1 of auxiliary request 5 is identical to claim 1 of the main request. Therefore, the reasons given above in relation to the presence of the reworded claim 1 in the main request apply *mutatis mutandis* to auxiliary request 5.

Therefore auxiliary request 5 is not admissible.

1.2.15 Consequently, the sets of claims filed at the beginning of the oral proceedings (main request and auxiliary requests 1 to 5) are not admitted into the proceedings.

1.3 *Auxiliary request 6*

As the Chairman was about to close the debate on the admission of the claims requests filed at the beginning

of the oral proceedings, the appellant announced that it wished to file a further auxiliary request (auxiliary request 6), namely the set of claims as granted was its final request.

However, this procedural step cannot be found to be admissible since it amounts to an unallowable delaying tactic in view of the fact that the appellant had already withdrawn the set of claims as granted with its letter dated 28 February 2013. It has to be stressed that the opposition division had revoked the patent in suit, *inter alia* because the granted claims contained added subject-matter pursuant to Article 100(c) EPC. Moreover, it was evident from the content of the file, and in particular from the preliminary opinion expressed by the board in the communication sent as an annex to the grounds of appeal, that, as the facts on file stood, it was not to be expected that the set of claims as granted would be considered to overcome all the objections on file pursuant to Article 100(c) and 100(a) EPC. The filing of auxiliary request 6 at such a stage of the proceedings cannot be seen as a valid means to redress the opposition division's decision. It simply does not fulfil the requirement of being *prima facie* allowable.

Additionally, the re-filing of the set of claims as granted was not accompanied by any justification other than that other boards allegedly occasionally admit the set of claims as granted as a patentee's final request. However, the present board has to stress that the admission of requests into the proceedings has to be decided in the light of the particular circumstances of each case. As already said, the appellant had

explicitly withdrawn the set of claims as granted in the present case. The argument of being the patentee's last chance in view of the non-admission of the main request and auxiliary requests 1 to 5 cannot be accepted since, as already mentioned in this decision, the appellant had had ample opportunity to file amended sets of claims at an earlier stage in the proceedings and did not need to wait until the oral proceedings to do so.

Therefore, auxiliary request 6 is not admitted into the proceedings.

1.4 Article 113(2) stipulates that the instances of the EPO shall examine and decide upon a European patent only in the text submitted to it, or agreed, by the proprietor of the patent. Since none of the appellant's claims requests has been admitted into the proceedings there is no basis for a patent to be maintained and thus the appeal has to be dismissed.

2. *Request for apportionment of costs*

The respondent requested an apportionment of costs in view of the fact that the appellant filed new requests on the day of oral proceedings, thereby withdrawing the requests it had filed on 28 February 2013. According to the respondent this was an abuse of procedure and it had wasted time studying requests that were no longer maintained.

According to Article 16(1) RPBA the board may, subject to Article 104(1) EPC, order a party to pay some or all of another party's costs, where a party has e.g.

incurred costs due to an amendment to a party's case pursuant to Article 13 RPBA (Article 16(1)(a) RPBA) or an abuse of procedure (Article 16(1)(e) RPBA). Only costs necessarily and reasonably incurred may be ordered (Article 16(2) RPBA). Moreover, the apportionment of costs must be equitable (Article 104(1) EPC).

However, the respondent has not incurred any additional unexpected costs due to the late change of the appellant's case. The respondent did not have to develop a new line of argumentation, as it already considered the requests filed on 28 February 2013 to be inadmissible. The oral proceedings were not substantially delayed either.

Consequently, the request for apportionment of costs is refused.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The request for apportionment of costs is refused.

The Registrar: The Chairman:

N. Maslin U. Oswald