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Datasheet for the decision of 11 March 2013

Case Number: T 2102/09 - 3.3.02

Application Number: 97104837.6

Publication Number: 815860

IPC: A61K 31/445

Language of the proceedings: EN

Title of invention:
Terfenadine carboxylate and the treatment of allergic disorders

Patent Proprietor:
Sunovion Pharmaceuticals Inc.

Opponents:
Teva Pharmaceutical Industries Ltd.
Hexal AG

Headword:
Terfenadine carboxylate and the treatment of allergic disorders/SUNOVION PHARMACEUTICALS

Relevant legal provisions:
EPC Art. 100(c), 123(2), 76(1)
RPBA Art. 12, 13

Keyword:
"Admissibility of auxiliary requests 3 and 4 (yes), auxiliary requests 1, 2, 5 to 7 (no); main request and auxiliary requests 3 and 4: added subject-matter (yes)"

Decisions cited:
G 0001/03, G 0002/03, G 0002/10

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 2102/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 11 March 2013

Appellant: (Patent Proprietor)	Sunovion Pharmaceuticals Inc. 84 Waterford Drive Marlborough, MA 01752 (US)
Representative:	Jump, Timothy John Simon Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Respondent I: (Opponent 1)	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)
Respondent II: (Opponent 2)	Hexal AG Industriestrasse 25 D-83607 Holzkirchen (DE)
Representative:	Hamm, Volker Maiwald Patentanwalts GmbH Jungfernstieg 38 D-20354 Hamburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 18 September 2009 revoking European patent No. 815860 pursuant to Article 101(2) EPC.**

Composition of the Board:

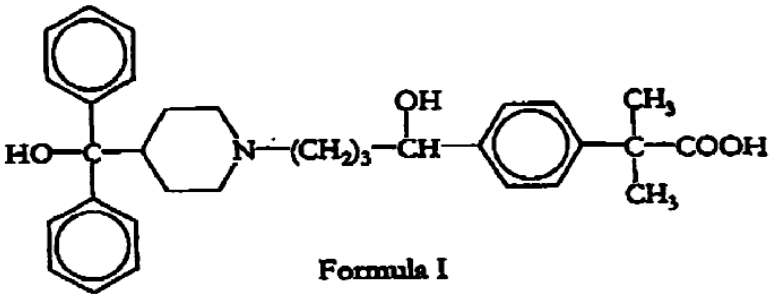
Chairman: U. Oswald
Members: M. C. Ortega Plaza
R. Cramer

Summary of Facts and Submissions

I. European patent No. 0 815 860, based on European patent application No. 97104837.6, was filed as a divisional application of application No. 93918584.9 filed as an international patent application published as WO 94/03170 (root application), and was granted with 15 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 manufacture of a medicament for use in an anti-histaminic treatment in which 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."

II. Oppositions were 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). Opponent O1 also filed insufficiency of disclosure as ground for opposition (Article 100(b) EPC).

III. The documents cited *inter alia* in the opposition and appeal proceedings included the following:

D1 US 4254129
D2 WO 93/23047

D53 Monthly index of medical specialities (Mims), UK, issue of May 1992 (Anti-allergic drugs)

D54B Goodman and Gilman, The Pharmacological Basis of Therapeutics, sixth edition, 1980, pages 609-646

D55 A. Goodman and Gilman, The Pharmacological Basis of Therapeutics, seventh edition, 1985, pages 302-321

D56 J.T. Barbey et al., Proceedings of a Symposium, American Journal of Rhinology, 1999, vol. 13, No. 3, 235-243

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

V. The opposition division's decision was based on the main (and sole) request, which was the set of claims as granted.

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

It considered that since claim 1 as granted contained a disclaimer "*which had not been expressed in the application as originally filed*", the criteria set out in the Enlarged Board of Appeal decisions G 01/03, OJ EPO, 2004, 413 and G 02/03, OJ EPO, 2004, 428 applied. It was of the opinion that the amendment in claim 1 as granted, concerning the definition of the human patient to which 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.

Additionally, the opposition division expressed the opinion that the subject-matter in claims 1 to 8 and 13 to 16 as granted lacked novelty in view of documents D1 and D2 (the European application deriving from the PCT application published as WO 93/23047).

VI. The patentee (appellant) lodged an appeal against said decision, and filed grounds thereto. With its grounds of appeal the appellant filed documents D54B, D55 and D56, together with auxiliary requests 1 to 4 (as working version and as clean version).

VII. Respondents O1 and O2 filed counter-arguments to the grounds of appeal.

VIII. The appellant filed a letter dated 17 December 2010 in reply to the respondents' counter-arguments.

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

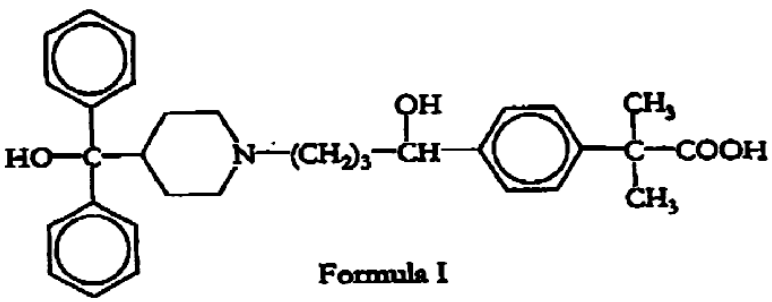
In said communication the board expressed *inter alia* a preliminary opinion in relation to the assessment of the grounds of opposition under Article 100(c) and 100(a) EPC (novelty). In said communication the board pointed out that the examination of added matter had to be made using the principles developed in the jurisprudence of the boards of appeal. Within this context the board cited the Enlarged Board of Appeal decision G 02/10, OJ EPO, 2012, 376, to show that the requirements of Articles 123(2) and 76(1) EPC applied also to claims containing a disclaimer.

X. With a letter dated 28 February 2013 the appellant filed seven auxiliary requests, i.e. auxiliary requests 1 to 7.

Auxiliary request 1 contains one single claim which is identical to claim 1 as granted.

Claim 1 of auxiliary request 2 reads as follows:

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

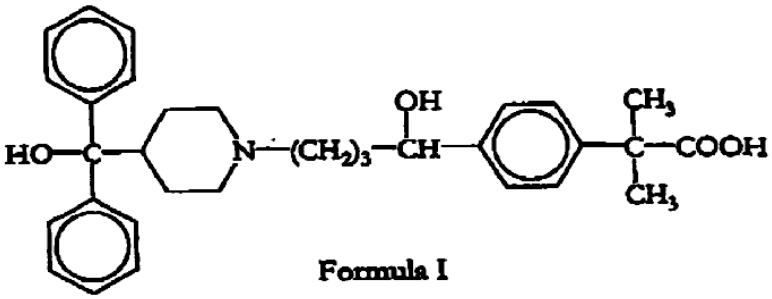


Formula I

or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for use in an anti-histaminic treatment **for providing symptomatic relief from sneezing, rhinorrhea or lacrimation associated with an allergic disorder, cough, cold or flu**, in which 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" (emphasis added).

Claim 1 of auxiliary request 3 reads as follows:

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

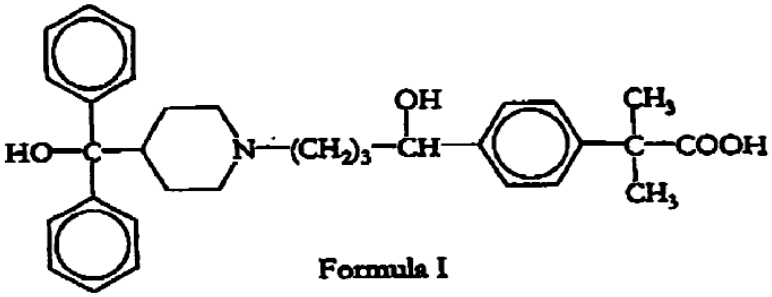


Formula I

or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for use in an anti-histaminic treatment **of allergic rhinitis, solar urticaria or symptomatic dermographism**, in which 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" (emphasis added).

Claim 1 of auxiliary request 4 reads as follows:

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

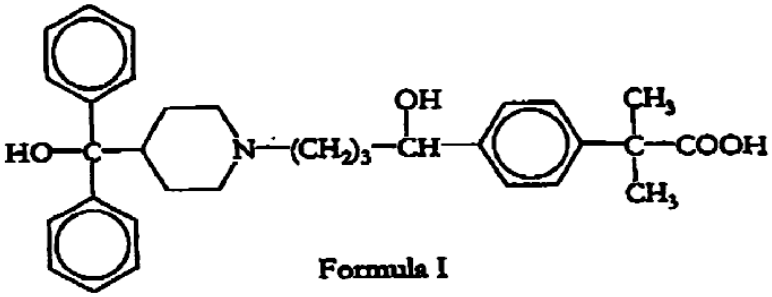


Formula I

or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for use in an anti-histaminic treatment **of allergic rhinitis**, in which 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" (emphasis added).

Claim 1 of auxiliary request 5 reads as follows:

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

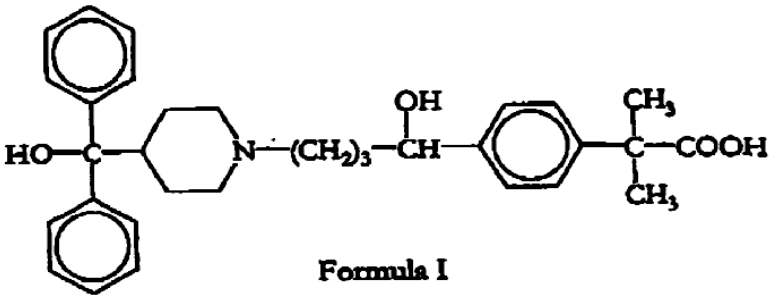


Formula I

or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for use in an anti-histaminic treatment **for providing symptomatic relief from sneezing, rhinorrhea or lacrimation associated with an allergic disorder, cough, cold or flu**, in which the induction of cardiac arrhythmia is avoided, said treatment comprising administering a compound of formula I **in an amount of 20-200 mg/day** to a human patient whose hepatic function is not impaired" (emphasis added).

Claim 1 of auxiliary request 6 reads as follows:

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



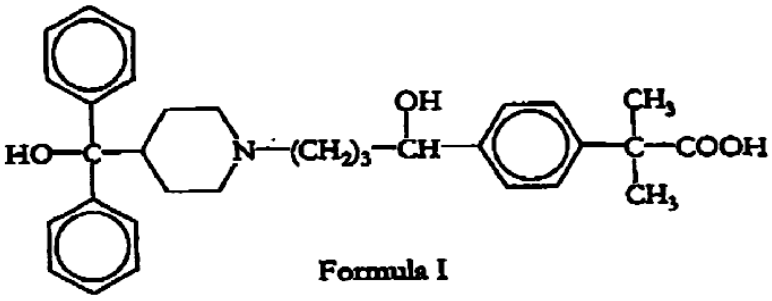
Formula I

or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for use in an anti-histaminic treatment **for providing symptomatic relief from sneezing, rhinorrhea or lacrimation associated with an allergic disorder, cough, cold or flu**, in which 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, **wherein the composition is a tablet or capsule containing 30 mg, 60 mg or 90 mg dose of the compound of formula I, or**

pharmaceutically acceptable salt thereof" (emphasis added).

Claim 1 of auxiliary request 7 reads as follows:

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



Formula I

or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for use in an anti-histaminic treatment in which 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, **wherein the composition further comprises a therapeutically effective amount of a decongestant"** (emphasis added).

XI. Oral proceedings took place on 11 March 2013. During the oral proceedings the board decided to admit into the proceedings auxiliary requests 3 and 4 and not to admit into the proceedings auxiliary requests 1, 2 and 5 to 7, all filed with the letter dated 28 February 2013.

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

(a) *Admissibility of the auxiliary requests filed with the letter dated 28 February 2013*

Auxiliary requests 1 to 7 had been filed in reply to objections raised in the board's communication sent as an annex to the summons. They should be admitted into the proceeding since they did not raise any new issues and the amendments were clear and easy to understand. Some of the requests were the same as previous requests filed in response to the opposition division's decision. Auxiliary request 1 contained only one single claim which was identical to claim 1 as granted; the dependent claims had been deleted in order to overcome possible objections pursuant to Article 100(c) EPC. The amendments in claim 1 of auxiliary request 2 narrowed the scope of the claim in order to overcome novelty and possible inventive step objections. The request derived from the previous auxiliary request 1, with further restrictions. The amendments addressed objections under Article 123(2) EPC and avoidance of possible double patenting with the deletion of "dermal irritation". Auxiliary requests 3 and 4 were identical to auxiliary requests 2 and 4, respectively, which had been filed with the grounds of appeal. These requests, which had long been on file, had been filed to overcome novelty objections. Auxiliary request 5 contained one single claim in order to avoid possible attacks under Article 123(2) EPC. The amendment concerning the treatment was similar to that of auxiliary request 2. Moreover, the specifications of the amounts of the drug per day addressed potential lack of novelty objections. The amounts appeared in claims 4 and 5 as granted. The amendments were simple to understand and did not raise

new issues. Auxiliary request 6 also contained a single claim. The amendment concerning the treatment was similar to that of auxiliary request 2. Moreover, the specification of the dosage form was made in order to address novelty issues. These amendments were not difficult to understand. Auxiliary request 7 contained one single claim which incorporated the decongestant, as was the case of claim 11 as granted. The amendment was easy to understand.

The appellant further stressed that the amendments in the auxiliary requests filed with the letter dated 28 February 2013 could not have taken the respondents by surprise since the claims were the same as or very similar to those filed with the grounds of appeal.

Moreover, the appellant argued that during the opposition proceedings it had been of the opinion that the set of claims as granted was allowable. Only when reading the reasons in the opposition division's decision had it become aware of the problems in relation to Article 100(c) EPC. When the application was undergoing prosecution the case law had been more generous in relation to admissibility of disclaimers. The case law in relation to disclaimers had changed through the years. This justified the filing of the auxiliary requests with the grounds of appeal. It did not make sense to file auxiliary requests before knowing the reasons why the opposition division considered that the disclaimer was not allowable under Article 100(c) EPC.

(b) *Main request (set of claims as granted)*

The appellant submitted that claim 1 as granted found it basis in the root application as filed. The requirements of Articles 123(2) and 76(1) EPC were met. In particular, terfenadine carboxylic acid was disclosed in the root application to be useful in an anti-histaminic treatment (of a human patient) which did not induce significant cardiac arrhythmia (page 11, lines 9-21). Terfenadine carboxylic acid (terfenadine carboxylate) was disclosed as the most preferred active compound on page 15, lines 9-10, of the root application as filed. Furthermore, page 16, first paragraph, of the root application as filed provided an allowable basis for the use claim in Swiss-type form. The appellant acknowledged, however, that there was no *verbatim* basis in the root application as filed for the disclaimer in claim 1 as granted concerning the phrase "*to a human patient whose hepatic function is not impaired*".

In its communication sent as an annex to the summons to oral proceedings the board had cited the Enlarged Board of Appeal decision G 2/10. In point 4.5.1 of the reasons, the disclosure test was explained, namely that "*after the amendment the skilled person may not be presented with new technical information*". Thus, according to decision G 2/10, the skilled person should not be presented with technical information which he would not derive directly and unambiguously from the application as filed, using common general knowledge. At the end of point 4.5.2 of the reasons, decision G 2/10 stipulated that "*the point of reference for assessing an amended claim for its compatibility with*

Article 123(2) EPC is the subject-matter which the claim contains after the amendment. In other words, it is the subject-matter remaining in the claim after the amendment". In point 4.5.4 of the reasons, decision G 2/10 stressed the need for technical assessment of the case under consideration requiring an assessment of the overall circumstances of the individual case and that "*the test to be applied is whether the skilled person would, using common general knowledge, regard the remaining claimed subject-matter as explicitly or implicitly, but directly and unambiguously, disclosed in the application as filed*". This test had to be performed regardless of whether the disclaimer was a "disclosed" or an "undisclosed" disclaimer. The subject-matter remaining in claim 1 after the introduction of the amendment concerned the treatment of the hepatically non-impaired population, i.e. the "normal" population. Therefore, the skilled person would immediately understand from the content of the root application as filed that the compound of formula I would be administered to patients with non-impaired hepatic function. This was knowledge by default which was directly and unambiguously derivable from the root application as filed. The particular recommendations given for patients with impaired hepatic function (page 20, lines 21-22, of the root application as filed) implied that the "normal" population also received the anti-histaminic treatment disclosed in the root application. Therefore, the amendment did not add new subject-matter. The discussion about the content of documents D1 and D2 was irrelevant since the claim as granted did not extend to subject-matter undisclosed in the root application as filed.

The appellant also referred to Enlarged Board of Appeal decision G 1/93, OJ EPO 1994, 541, which expressed the following in relation to the problem of added subject-matter: "*With regard to Article 123(2) EPC, the underlying idea is clearly that an applicant shall not be allowed to improve his position by adding subject-matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application*". The amendment under dispute did not confer on the patentee an unwarranted advantage since the anti-histaminic treatment reflected the normal situation, i.e. it addressed the "normal" population, and thus, the amendment would never provide inventive step over the prior art. Nor did the disclaimer result in defining a new patient group in the claim, because all human patients without hepatic impairment were members of the group of human patients in general. The hepatically impaired patients corresponded to an abnormal population of patients to be treated since the skilled person knew that the drug was metabolised through the liver. Moreover, document D2 set a definition for hepatic impairment as one "*which inhibits the normal liver function*". This was what the skilled person would understand. In this context the appellant referred to document D53. When asked by the board about the case when a patient was temporarily hepatically impaired, the appellant again cited document D53 and added that it was well known to the skilled person what hepatic impairment was. The appellant submitted that document D53, which was an extract from the monthly index of medical specialities published in the UK, was aimed at

general practitioners (GPs) and served as background information for their prescriptions of drugs. The appellant pointed to page 236, Triludan^{R}, which contained Terfenadine as active drug, in particular "S/P: **Hepatic impairment**, QT prolongation" (emphasis added). Thus, "hepatic impairment" was a well known term commonly used in the field which did not require further explanations. As a result, it would also be known to the skilled person what a non-impaired liver function was. The appellant further submitted that respondent O1 had contended that "hepatically impaired" had a special meaning in relation to terfenadine, However, if this was the case the skilled person would know what was meant. In fact the only special meaning for "hepatic impairment" was the general meaning reflected in document D2.

The appellant stated at the oral proceedings that if the findings in decision G 2/10 were considered not to be applicable to the present case, then an alternative route of argumentation in relation to the Enlarged Board of Appeal decisions G 1/03 and G 2/03 had been developed. The appellant referred to its written submissions during appeal proceedings. With its grounds of appeal the appellant had argued that the amendment concerning the disclaimer "*to a human patient whose hepatic function is not impaired*" had been introduced during prosecution of the application in order to restore novelty over D2. The phrase "*to a human patient whose hepatic function is not impaired*" did not disclaim more than necessary since the disclosure of D2 which formed part of the state of the art under Article 54(3) EPC was restricted to the use of terfenadine carboxylate as an anti-histaminic for

treating hepatically impaired persons. Claims 8 to 22 in D2, some of which covered the use of terfenadine carboxylate for treating non-hepatically impaired patients, had been added upon filing the application D2. The treatment of non-hepatically impaired patients had no basis in either of the two priority documents.

Additionally, the disclaimer present in claim 1 as granted did not provide a technical contribution to the claimed invention. There was no breach of the criteria set out in Enlarged Board of Appeal decisions G 1/03 and G 2/03. Additionally, document D1 did not provide a direct and unambiguous disclosure of an anti-histaminic treatment in any human patient group. Therefore, the disclaimer did not serve to render the subject-matter claimed novel over document D1.

Moreover, the appellant stressed that its main line of argumentation was that decision G 2/10 reflected all circumstances underlying the investigation of added subject-matter after introduction of a disclaimer (G 2/10, point 2.1 of the reasons). Decision G 2/10 had shown that the application of the criteria set out in decision G 1/03 was not the relevant test for assessing whether the subject-matter remaining in the claim after the introduction of the disclaimer was disclosed in the application as filed (G 2/10, end of point 1 and point 2.1 of the reasons). The reasons for the introduction were irrelevant, what mattered was whether the remaining subject-matter was directly and unambiguously disclosed in the application as filed.

Additionally, decision G 1/03 made it very clear that a disclaimer for excluding a conflicting application

under Article 54(3) EPC was allowable. Such a disclaimer excluding subject-matter only for legal reasons did not infringe Article 123(2) EPC (G 1/03 point 2.1, in particular 2.1.3, of the reasons). The disclaimer in claim 1 as granted actually removed what was disclosed in the conflicting application D2 and had a right to the priority dates. Document D2 disclosed the anti-histaminic treatment using terfenadine carboxylate for hepatically impaired patients (page 2, second and third paragraphs, pages 4 and 5). This was the content of D2 which had a right to the priority dates. The subject-matter in claims 8 to 22 relating to the treatment of non-impaired patients was not covered by the priority documents and thus was not part of the prior art under Article 54(3) EPC. The passages quoted by the respondents, such as the second paragraph on page 4 of D2, should be read within the context of document D2, which concerned hepatically impaired patients. Although document D2 cited document D1 as disclosing that terfenadine carboxylate was an anti-histaminic agent (page 1, last paragraph), such a reading of the disclosure in document D1 was questionable. In particular, document D1 disclosed the substituted piperidine derivatives to be useful as antihistamines, antiallergy agents, and bronchodilators (column 1, first paragraph, lines 29-31). Terfenadine carboxylate was disclosed in column 3 and example 3. Further, in column 5, D1 suggested that the compounds were useful as antihistamines, antiallergy agents and bronchodilators. However, the skilled person would know that not all compounds would have all the activities. Moreover, the test disclosed in column 6 of document D1 mentioned that terfenadine carboxylate attained a significant reduction in histamine-induced isolated

guinea pig ileal muscle contraction. However, the ability to oppose histamine-induced guinea pig ileal muscle contraction *in vitro* was not sole indicator of an anti-histaminic activity and many substances which were not histamine (H_1) receptor antagonists would prevent histamine-induced contraction in this test, such as salbutamol and other beta-adrenoceptor antagonists, theophylline and other phosphodiesterase inhibitors. A reduction of histamine in the test mentioned in document D1 did not mean that the compound was inevitably a blocker of histaminic receptors. Additionally, the appellant cited document D54B and stated that the skilled person would have thought that the compounds in document D1 were either anti-histaminic or bronchodilators, but not both at the same time. Moreover, contrary to the statement in document D2, document D1 did not disclose any oral activity for terfenadine carboxylate. Additionally, the amendment did not imply any unwarranted advantage over document D1 since it concerned administration to the normal population.

As regards respondent O1's comment that page 8, lines 23-25 of the root application did not mention hepatic impairment, the appellant stated that the skilled person would also make use of his common general knowledge.

The appellant added in relation to document D2 that the fact that claims directed to the treatment of non-hepatically impaired patients were introduced when the international application was filed was an indication that the applicant of D2 thought that document D1 did not disclose that feature. D1 did not directly and

unambiguously disclose that terfenadine carboxylate was an anti-histaminic agent useful for an anti-histaminic treatment. Moreover, document D54B referred on page 623 to H_1-blocking agents, but document D1 did not teach whether terfenadine carboxylate was a H_1-blocking agent. The appellant further stated that its root application disclosed for the first time the use of terfenadine carboxylate in an anti-histaminic treatment for the normal population.

(c) *Auxiliary requests 3 and 4 (Articles 100(c), 123(2), 76(1) EPC)*

The basis for the amendment "of allergic rhinitis, solar urticaria or symptomatic dermographism" in claim 1 of auxiliary request 3 was to be found on page 13, lines 1 to 3, page 11, line 6 and page 19, lines 4-6. The claim had been narrowed down to more preferred embodiments which had been individualised in the root application as filed. The arguments submitted for the main request applied *mutatis mutandis* to the rest of the claim. The new features did not change the situation in relation to the allowability of the disclaimer, since the non-hepatically impaired patients were disclosed in the root application as filed.
The appellant submitted that analogous reasons applied to claim 1 of auxiliary request 4, in which the limitation to "allergic rhinitis" concerned the most preferred embodiment (page 13 of root application as filed).

XIII. Respondent O1's arguments, as far as relevant for the present decision, may be summarised as follows.

(a) *Admissibility of the auxiliary requests filed with the letter dated 28 February 2013*

Respondent O1 objected to the "extremely late" filing of these auxiliary requests, namely more than five years after oppositions had been filed. During opposition proceedings the patent proprietor had not filed any auxiliary request, in order to force a remittal to the department of first instance as result of the appeal proceedings. Such a procedural strategy should not be allowed, it was an abuse of procedure. Therefore, the auxiliary requests which were identical to those filed with the grounds of appeal should not be admitted (Article 12 RPBA).

Additionally, the auxiliary requests which were filed for the first time with the letter dated 28 February 2013 should not be admitted into the proceedings since they had been filed less than one month before the oral proceedings and opened new issues (Article 13 RPBA). The appellant had known about the issues pursuant to Articles 100(c) and 123(2) EPC for a long time and had not needed to wait until a board's communication was issued in order to amend the claims. The amended claims included lists of specific ailments, so these amendments opened new substantive issues. It was not reasonable to expect the respondents to deal with the substantive amendments introduced in the newly filed sets of claims. Deletion of ailments within a given list was not a simple thing, since it had to be investigated whether unallowable selections had taken place. Moreover, combinations of the treatment of certain disorders with certain dosages or dosage forms opened new issues under Article 123(2) EPC.

Respondent O1 submitted that the opposition division had already cited Enlarged Board of Appeal decisions G 1/03 and G 2/03 in the communication sent with the summons to oral proceedings. However, the patentee had not filed any amended sets of claims in preparation for the oral proceedings before the opposition division. Respondent O1 further submitted that the minutes of the oral proceedings before the opposition division indicated that, after the announcement that the set of claims as granted failed on grounds pursuant to Article 100(c) EPC, the patentee had been asked whether or not it wished to submit any further requests. The patentee had replied that it did not.

(b) *Main request (set of claims as granted)*

Respondent O1 referred to its written submissions during opposition and appeal proceedings. It submitted in particular that claim 1 as granted contained the phrase "*to a human patient whose hepatic function is not impaired*" which had been added as a disclaimer during prosecution of the application, in order to distinguish the patient group from those in document D2. However, the disclaimer in claim 1 as granted was insufficient to establish novelty over document D2. The disclosure in document D2 was broader than what had been excluded in claim 1. Document D2 contained a summary of the content of document D1 (*inter alia* page 1, lines 20-23, page 3, lines 29-34). Document D2 acknowledged that terfenadine carboxylic acid was known as an anti-histaminic agent (*inter alia*, page 4, lines 8-10). In terms of the general teaching in document D2 there was no difference between hepatically impaired

and hepatically not impaired patients. The claims in document D2 for which priority was validly claimed were restricted to hepatically impaired patients, to distinguish the claimed subject-matter from what had been known in document D1. However, the teaching in document D2 was not restricted to what was claimed. Therefore, the disclaimer in claim 1 as granted was inadmissible. In fact, the actual meaning of the disclaimer was unclear since nowhere in the patent was it explained what was meant by the expression "*a human patient whose hepatic function is not impaired*". One had to turn to document D2, page 4, lines 18-25, to find a definition of an "hepatically impaired patient". The disclaimer took the opposite direction, requiring that the hepatic function was not impaired. Therefore, the meaning in the disclaimer was not necessarily the same. Additionally, the root application of the patent in suit recommended that children, patients aged over 65 years and those with impaired renal or hepatic function initially received low doses (page 20, lines 20-22). However, it was not clear whether the meaning of "impaired hepatic function" given in this passage of the root application was the same as in the disclaimer in granted claim 1. In particular, the question arose whether patients who might have an impaired hepatic function owing to alcohol consumption were encompassed by granted claim 1. The anti-histaminic treatment which was acknowledged in document D2 to be known from document D1 concerned doses within a range of 1-50 mg, 1 to 4 times per day.

The disclaimer in claim 1 as granted was further inadmissible since it affected the technical contribution of the subject-matter claimed not only in

relation to document D2, which formed part of the prior art under Article 54(3) EPC, but also in relation to document D1 which was state of the art under Article 54(2) EPC. Therefore, granted claim 1 contained added subject-matter within the meaning of Article 100(c) EPC.

Additionally, respondent O1 argued that the Enlarged Board of Appeal decision G 2/10 concerned a different situation, namely one in which the disclaimed subject-matter was disclosed in the application as filed. The disclaimed subject-matter was not an embodiment of the invention and there was no basis in the root application as filed for excluding the group concerning hepatically impaired patients. Moreover, since the disclaimer had been introduced in view of existing prior art it had to be the assessed whether or not it made a technical contribution. The disclaimer was not admissible under the criteria set out in decisions G 1/03 and G 2/03. Moreover, the expression "hepatic impairment" had a special meaning depending on the specific scenario. The appellant had used a general term concerning a specific drug, terfenadine, within another context, terfenadine carboxylate, introducing new technical information into the claim. Document D2 had been very specific when defining "hepatic impairment". The amendment in claim 1 as granted concerned unallowable added subject-matter since it did not exclude the content of D2 itself. The amendment followed a purpose in respect of the prior art which could not be ignored. The subject-matter claimed in claim 1 as granted related to an unallowable selection of the subject-matter initially disclosed which concerned the anti-histaminic treatment of all patients

without making any distinction. The only exception was that for some patients a lower dose was recommended. Additionally, respondent O1 summarised its position in relation to the disclaimer by saying that it had objected to its meaning, its basis in the root application as filed, and the argument that it fulfilled the function for which it had been introduced.

Respondent O1 further argued that the expression "hepatically impaired" had different meanings depending on the situation. Hepatic impairment in document D2 related to very specific situations which had also to do with terfenadine and the cardiac events experienced in the patients. This was partly reflected on page 8, last paragraph, of the root application. However, there was no mention of hepatic impairment in this paragraph of the root application. The mention on page 20, line 22, of impaired hepatic function was made within a different context. Therefore, the disclaimer was an undisclosed disclaimer and decisions G 1/03 and G 2/03 were relevant. Respondent O1 also argued that the appellant's argumentation that the disclaimer was admissible since it excluded the subject-matter of a conflicting application under Article 54(3) EPC was not correct. In particular, the disclaimer was not appropriate since the subject-matter claimed was not disclosed for the first time in the patent in suit. All passages cited from D2 concerning the teaching that terfenadine carboxylate had an anti-histaminic activity were covered by the priority. The content of these passages could not be separated from the patient subgroups since anti-histaminic activity was not dependent on liver impairment. Document D2 disclosed that terfenadine carboxylate was histamine H_1-receptor

antagonist on page 4, lines 7-10, without depending on document D1. Thus, the appellant's argument that some compounds in document D1 had anti-histaminic activity and some did not was irrelevant. Moreover, document D54B disclosed on page 623 the pharmacological properties of H_1-blocking agents and stated that their activity was predictable from interaction with H_1-receptors. Moreover, on page 624, D54B mentioned the guinea pig ileum model as well known. Consequently, document D1 was certainly novelty-destroying and document D2 was novelty-destroying with or without the disclaimer.

(c) *Auxiliary requests 3 and 4 (Articles 100(c), 123(2), 76(1) EPC)*

The arguments submitted for the main request applied *mutatis mutandis* to auxiliary requests 3 and 4. Additionally, document D2 referred explicitly to "seasonal allergic rhinitis" (page 4).

XIV. Respondent's O2 arguments, as far as relevant for the present decision, may be summarised as follows:

(a) *Admissibility of the auxiliary requests filed with the letter dated 28 February 2013*

Respondent O2 agreed with respondent O1 that the auxiliary requests filed with the letter dated 28 February 2013 should not be admitted into the proceedings. In particular, the auxiliary requests had been filed too late and opened new complex issues in relation to Article 123(2) EPC.

(b) *Main request (set of claims as granted)*

Respondent O2 referred to its written submissions in the appeal proceedings and stated that it endorsed respondent's O1 arguments in relation to the grounds of opposition pursuant to Article 100(c) EPC and claim 1 of the main request.

Moreover, respondent O2 questioned whether the patients whose hepatic function was not impaired were "normal" patients. When determining whether a hepatic function was impaired certain parameters were to be measured. Therefore, the question arose as to whether or not patients under liver stress fell within the definition. Document D53 was not useful since it did not establish the common general knowledge in relation to the disputed term. The disclaimer was not admissible, since it did not suffice to establish novelty and it did not fulfil the requirements of Article 123(2) (and Article 76(1)) EPC.

(c) *Auxiliary requests 3 and 4 (Articles 100(c), 123(2), 76(1) EPC)*

Respondent O2 did not add any comments in relation to auxiliary requests 3 and 4.

XV. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or alternatively that the patent be maintained in amended form on the basis of one of the auxiliary requests 1 to 7 filed with the letter of 28 February 2013, and that the case

be remitted to the department of first instance for further prosecution.

The respondents (opponents) requested that the appeal be dismissed.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 *Admissibility of auxiliary requests 3 and 4 filed with the letter dated 28 February 2013*

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 should be reversed, amended or upheld, and should specify expressly all the facts, arguments and evidence relied on.

1.2.2 With the grounds of appeal (dated 28 January 2010) the appellant maintained as main request the set of claims as granted, challenging with arguments the reasons given in the opposition division's decision. Additionally, it filed with the grounds of appeal four auxiliary requests (auxiliary requests 1 to 4). The filing of these four auxiliary requests with the grounds of appeal is in principle an admissible procedural step since it relates to an admissible precautionary measure in case the board of appeal upheld the opposition division's decision. Moreover,

the detailed and complete reasons why the opposition division considered claim 1 of the set of claims as granted not to be allowable pursuant to Article 100(c) EPC were known to the parties when receiving the written decision. Thus, the appellant filed the auxiliary requests with its grounds of appeal trying to remedy the situation.

The appellant replaced auxiliary requests 1 to 4 filed with its grounds of appeal with auxiliary requests 1 to 7 filed with its letter dated 28 February 2013.

In view of the fact that the sets of claims of auxiliary requests 3 and 4 filed with the letter of 28 February 2013 are identical to auxiliary requests 2 and 4 filed with the grounds of appeal, respectively, they are admitted into the proceedings (Article 12 RPBA). Their re-filing only represents a clarification of their ranking in relation to those auxiliary requests filed for the first time with the letter of 28 February 2013.

1.3 *Admissibility of auxiliary requests 1, 2 and 5 to 7 filed with the letter dated 28 February 2013*

1.3.1 The sets of claims of auxiliary requests 1, 2 and 5 to 7 were filed for the first time with the letter dated 28 February 2013.

1.3.2 While Article 12(1)(c) RPBA provides that appeal proceedings are 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 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.

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, in *inter partes* appeal proceedings the right of both parties to fair proceedings and equitable treatment has to be considered.

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.

1.3.3 The board's communication sent as an annex to the summons expressed *inter alia* its preliminary opinion in relation to the grounds pursuant to Article 100(c) EPC and claim 1 as granted. The communication also contained a preliminary opinion in relation to novelty of the subject-matter in claim 1 as granted. 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. In fact, the appellant had already filed four auxiliary requests with its grounds

of appeal, as a reaction to the reasons in the opposition division's decision concerning Articles 100(c) and 100(a) EPC (lack of novelty).

The board's communication did not contain any comment concerning the dependent claims of the main request.

1.3.4 Therefore, the late filing of auxiliary request 1, in which all dependent claims as granted have been deleted, cannot be justified as a direct reply to the board's communication. Additionally, auxiliary request 1 maintains claim 1 as granted. Therefore, the filing of auxiliary request 1 is also not justified by the board's observations in relation to claim 1 as granted.

Consequently, auxiliary request 1 filed with the letter dated 28 February 2013 is not admitted into the proceedings (Articles 12 and 13 RPBA).

1.3.5 Claim 1 of auxiliary request 2 contains an amended wording in relation to the definition of the ailments to be treated. This amended wording opens at a very late stage in the proceedings, new and complex issues in assessing the Swiss-type claim, in particular in relation to Articles 123(2) and 76(1) EPC.

The appellant justified the filing of auxiliary request 2 as an attempt to avoid possible problems of double patenting. However, the argumentation of possible double patenting in relation to identical subject-matter already claimed in patent EP-B1-1214937 (which derives from European application 0200635.6 which was filed as a divisional application of application 97104837.6, i.e. the application from which

derives the patent in suit in the present appeal proceedings) had been made by respondent O1 in its letter dated 03 June 2010 and responded to by the appellant with its letter dated 17 December 2010. Therefore, the appellant could have filed auxiliary request 2 earlier in the appeal proceedings. The board's communication sent as an annex to the summons merely drew the parties' attention to such an issue when considering the admissibility of the auxiliary requests.

Consequently, auxiliary request 2 filed with the letter of 28 February 2013 is not admitted into the proceedings (Article 13 RPBA).

1.3.6 Claim 1 (single claim) of auxiliary request 5 has been amended in relation to the choice of ailments to be treated together with the specification of a range for the daily dose. This amended claim does not arise from the direct incorporation of granted claim 5 since the definition of the treatment does not correspond identically to any of the granted claims 1 to 4. Therefore, amended claim 1 of auxiliary request 5 opens up new and complex issues at a late stage in the proceedings, in particular in relation to Articles 123(2) and 76(1) EPC.

The appellant justified its filing as a fair attempt to reply to lack of novelty objections. However, the opposition division's decision contains detailed reasons against the novelty of the subject-matter of the granted claims 1 to 8 and 13 to 15 and the respondents had pursued the objections of lack of novelty vis-à-vis documents D1 and D2 in their

responses to the appellant's grounds of appeal. Therefore, the appellant could have filed auxiliary request 5 earlier, it did not need to wait until the board had sent an invitation with the summons to oral proceedings mentioning document D1 as novelty-destroying for granted claim 1.

Consequently, auxiliary request 5 filed with the letter dated 28 February 2013 is not admitted into the proceedings (Article 13 RPBA).

1.3.7 Claim 1 of auxiliary request 6 has been amended in relation to the choice of ailments to be treated together with the choice of the dosage form and doses. The amendments corresponding to the dosage form and doses incorporate at a late stage in the proceedings features from the description in order to allegedly overcome novelty objections. Claim 1 is in fact a new reworded use claim relating to a shift of the invention which is unjustified at such a late stage in the proceedings since the problems concerning lack of novelty had long been known to the appellant.

Consequently, auxiliary request 6 filed with the letter of 28 February 2013 is not admitted into the proceedings (Article 13 RPBA).

1.3.8 Claim 1 of auxiliary request 7 represents an amendment to the party's case which is unjustified at such a late stage in the proceedings (Article 13 RPBA). Claim 1 corresponds to claim 1 as granted into which claim 11 as granted has been incorporated. However, it was known to the appellant from the opposition division's decision that the opposition division did not consider

that the subject-matter of dependent claims 9 to 12 lacked novelty vis-à-vis documents D1 and D2. Therefore, such an amended claim could have been filed earlier in the proceedings. Additionally, claim 1 of auxiliary request 1 diverges from the amendments introduced in the auxiliary requests previously on file and thus takes the other parties to the proceedings by surprise.

Consequently, auxiliary request 7 filed with the letter of 28 February 2013 is not admitted into the proceedings (Article 13 RPBA).

2. *Main request (Article 100(c) EPC)*

2.1 The patent in suit, European patent No. 0815860, was granted on European application No. 97104837.6 which is a divisional application of European application No. 93918584.9 (EP 0701443), based on the international application published as WO 94/03170 (root application as filed).

As reflected in Article 100(c) EPC, opposition may be filed on the grounds that "*the subject-matter of the European patent extends beyond the content of the application as filed, or, if the patent was granted as a divisional application … beyond the content of the earlier application as filed*".

2.2 Claim 1 as granted relates to a second or further medical use claim in the Swiss-type form which relates to the use of a composition comprising a compound of formula I (terfenadine carboxylic acid) or a pharmaceutically acceptable salt thereof. The medical indication is defined as "*anti-histaminic treatment in*

which 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***" (emphasis added).

2.3 The feature concerning the definition of the patient as "a human patient whose hepatic function is not impaired" was introduced during the prosecution of the application as an attempt to establish novelty over European application No. 93909249.0 (EP 0639976) deriving from international application D2 (WO 93/23047) which is state of the art within the meaning of Article 54(3) EPC 1973 by virtue of Article 158 EPC 1973 (only as far as the relevant subject-matter in D2 is entitled to one, or both, of the claimed priority dates).

2.4 The root application as filed does not contain any general definition of the patients to be treated by administration of one of the compounds depicted by formula I on page 11 of the root application as filed, *inter alia* terfenadine carboxylic acid (Z is COOH) or a pharmaceutically salt thereof. The only reference to some of the patients to be treated can be found on page 20 of the root application in connection with the recommendation for adjusting the initial low doses to individual doses after titration based on individual responses or blood levels. The passage reads as follows: "It is further recommended that children, patients aged over 65 years, and those with **impaired** renal or **hepatic function** initially receive low doses, and that they then be titrated based on **individual**(s) response(s) or blood level(s)" (emphasis added). Thus, from this

passage it can be inferred that the treatment disclosed in the root application as filed generally encompasses different sorts of patients, extending beyond those specific patients for which specific recommendations are given. However, the root application as filed does not contain a basis for individualising the treatment according to claim 1 as granted.

In fact, the general practitioner has to take into consideration the age and the general state of each individual patient before deciding about the prescription of a particular treatment. Moreover, as acknowledged in the root application as filed, the general practitioner may have to adjust the dose to a particular individual patient by means of titration based on parameters which are individually determined. However, the knowledge that the general practitioner is able to assess, making use of the tools he commonly uses in the exercise of his duties, whether or not the general state of a patient makes him vulnerable to health risks when undergoing a certain treatment does not allow the conclusion that the root application as filed discloses in a direct and unambiguous manner the specific anti-histaminic treatment in which induction of arrhythmia is avoided for a group of patients whose hepatic function is not impaired. In particular, there is no mention in the root application as filed of any standard test for establishing the parameters to determine hepatic impairment. Moreover, there is an essential difference between the situation in which a general practitioner making use of his general skills evaluates how far a patient is at risk, because his hepatic function is impaired, in order to adjust the administration modus, dosage form, dose and dosage

regime to that particular patient, and the generic teaching in a patent application necessary for determining a particular group of patients as a functional limitation of a certain anti-histaminic treatment so that the induction of cardiac arrhythmia is avoided.

Additionally, even considering that the skilled person would use his common general knowledge, this common general knowledge has to be established, when disputed, by means of general background art. The general background art cited by the appellant is the monthly index of medical specialities D53 which relates to a well known pharmaceutical-prescribing reference work in the UK aimed *inter alia* at general practitioners. The particular passage cited by the appellant concerns a medicament, Triludan^{R}, which is classified in D53 among the "Anti-allergic drugs" and contains an anti-histaminic drug, namely terfenadine, in three alternative dosage forms. Under the special precautions ("S/P") for Triludan^{R} can be read: "Hepatic impairment, QT prolongation".

First of all, it is questionable that the expression "patient with hepatic impairment" can be used as a synonym for "patient whose hepatic function is impaired" since some patients with hepatic impairment preserve hepatic function, at least to a certain degree. Secondly, the appreciation of whether or not, and to which degree, a patient suffers from hepatic impairment or has an impaired hepatic function is a question of a case-by-case evaluation involving not only qualitative but also quantitative tests to determine the severity of the liver disease or liver impairment. None of these

tests has been referred to in the root application as filed. Nor does the root application as filed contain either a definition of the term "impaired hepatic function" or a reference to a prior-art document in this respect. The general knowledge reflected in document D53 is that risk assessment is recommended in relation to the liver, as well as to the heart, when prescribing any of the three options listed for the medicament Triludan^{R} containing terfenadine. However, D53 does not disclose any teaching as to how to assess hepatic impairment, or which are the limits to be set in relation to a human patient's hepatic function, in order to determine that the patient is eligible for, or has to be excluded from, a certain anti-histaminic treatment. Therefore, even considering for the sake of argument that a human patient whose hepatic function is not impaired is to be identified by default, the group of human patients whose hepatic function is impaired is not sufficiently identified in the root application as filed to allow singling out of the treatment defined in granted claim 1.

Therefore, claim 1 as granted includes technical information which is not directly and unambiguously disclosed in the root application as filed.

In relation to the understanding of what is "hepatic impairment" and what is not, the appellant also referred to document D2, which is at the origins of the introduction of the disputed amendment.

Document D2 defines that a "hepatically impaired patient is a patient having impaired liver function due to disease, such as alcoholic cirrhosis or hepatitis,

or due to administration of a drug, such as ketokonazole, erythromycin or troleandomycin, which inhibits normal liver metabolic function. In the hepatically impaired patient, terfenadine is not metabolized at the normal rate to terfenadine acid metabolite" (page 4, lines 18-25). However, this definition of hepatically impaired patients and, by default of hepatically not impaired patients, is not part of the disclosure of the root application as filed and document D2 is not a document forming part of the general knowledge of the skilled person at the effective date of filing of the patent in suit. Moreover, document D2 establishes a causal link between the impaired liver function and specific diseases, or treatments with specific drugs. By contrast, claim 1 as granted defines a human patient group which includes patients whose hepatic function is not impaired. Thus, it is questionable whether or not the hepatic function of the patients who are to undergo the anti-histaminic treatment with terfenadine carboxylate according to claim 1 as granted may be temporarily inhibited, since a normal liver metabolic function may be temporarily inhibited by moderate or severe alcohol consumption, or by some other drug, or substance intake affecting liver metabolism. Furthermore, the definition of hepatic impairment in document D2 is made relative to the administration of **terfenadine** in a certain dose since terfenadine undergoes extensive first-pass metabolism, in particular to its active metabolite, terfenadine carboxylic acid (document D2, page 1, lines 15-17). Document D2 further states: "When administered **terfenadine at the recommended dosage**, a hepatically impaired patient will experience increased levels of terfenadine in the blood and decreased levels of the

acid metabolite over that expected with the non-hepatically impaired patient. Increased blood levels of terfenadine in turn may cause diseases in the action potential and in various membrane currents of cardiac cells which may trigger cardiac events of QT prolongation and/or ventricular tachycardia". Thus, the definition of the term "hepatic impairment" in document D2, and by default of non-impairment, has a qualitative and quantitative meaning which is not reflected in claim 1 as granted.

Therefore, the definition of the hepatic function of the human patient to be treated according to claim 1 as granted cannot be separated from the claimed anti-histaminic treatment in which induction of cardiac arrhythmia is avoided by administration of terfenadine carboxylate, since the Swiss-type form claim necessarily establishes a functional link between the patients eligible for the treatment and the medical treatment itself. This technical information is not directly and unambiguously derivable from the root application as filed.

Consequently, already for the reasons given above claim 1 as granted fails since its subject-matter extends beyond the content of the earlier application (root application) as filed (Article 100(c) EPC).

2.5 Furthermore, Enlarged Board of Appeal decision G 1/03 states the following in point 2.1.3 of the reasons: "*For the interpretation of Article 123(2) EPC, it may be concluded from the foregoing (point 2.1.1) that the purpose of a disclaimer excluding a conflicting application is merely to take account of the fact that*

different applicants are entitled to patents in respect of different aspects of inventive subject-matter and not to change the given technical teaching. The disclaimer splits the invention as a whole in two parts: in respect of the identical part, it preserves the rights of the first applicant; for the rest, disclosed for the first time in the later application, it attributes the right to the second applicant. This approach restricts the effects of Article 54(3) EPC to resolving the problem of double patenting.

Such a disclaimer, only excluding subject-matter for legal reasons, is required to give effect to Article 54(3) EPC and has no bearing on the technical information in the application. It is, therefore, not in contradiction to Article 123(2) EPC. Applied in this sense, the term disclaimer is justified also in its literal meaning. An invention comprising different specific embodiments or groups thereof has been disclosed in the application as filed, a part of which is excluded from the requested protection, i.e. no longer claimed. The remaining subject-matter is not modified by the disclaimer".

However, the findings just quoted require that the conflicting application under Article 54(3) EPC does not disclose the same invention but **only overlaps** with the second application which contains **subject-matter not covered by the disclosure** of the first application (G 1/03, point 2.1.1 of the reasons, paragraph bridging pages 430-431). In the present case the **disclosure** of the conflicting application D2 (which is covered by the priority documents) is not restricted to the claims for which the appellant has acknowledged that they are

covered by the priority documents (namely, claims 1 to 7). Document D2 discloses that the compounds of formula (1), *inter alia* terfenadine carboxylate, are useful as "*anti-histamine H_1-receptor antagonists and as such provide relief of symtoms associated with histamine-mediated diseases and conditions such as seasonal allergic rhinitis, urticaria, and the like*" (page 4, lines 7-10). This teaching is not restricted to the use in the treatment of hepatically impaired patients; it also encompasses the use in the treatment of hepatically not impaired patients, which have been defined by the appellant as "normal" patients. Moreover, it is immaterial for the assessment of the disclosure in document D2 whether this passage is factually reflected by the content in document D1 or derives from the technical knowledge of the authors of document D2.

Additionally, the passage on page 2, lines 16 to 20 of D2, which states that the patients with impaired hepatic function do not experience cardiac events of QT prolongation and/or ventricular tachycardia when receiving terfenadine carboxylate, has to be understood in the light of the disclosure on page 4, which has been already commented on. In particular, in the light of the disclosure in document D2, the avoidance of cardiac events of QT prolongation and ventricular arrhythmia is inherent to the use of terfenadine carboxylate (active metabolite of terfenadine) instead of terfenadine (which undergoes extensive first-pass metabolism). Document D2 discloses that in the patients with hepatic impairment who have been administered terfenadine, "*significant concentrations of unchanged terfenadine can be detected with the rate of acid metabolite formation being decreased. In subjects with*

normal hepatic function, unchanged terfenadine plasma concentrations have not been detected. Recently, it has been found that patients with impaired hepatic function (alcohol cirrhosis, hepatitis), or on ketokonazole or troleandomycin therapy, or having conditions leading to QT prolongation (e.g., hypokalemia, congenital QT syndrome), may experience cardiac events of QT prolongation and/or ventricular tachycardia at the recommended dose of terfenadine" (page 2, first paragraph).

Therefore, the amendment in claim 1 as granted is insufficient to establish novelty over document D2 and thus, does not fulfil the criteria set out in decision G 1/03.

Additionally, Enlarged Board of Appeal decision G 2/10 expressed the following: "*It can thus be stated that neither decision G 1/93 nor decision G 1/03 intended to modify the general definition of the requirements of Article 123(2) EPC established in opinion G 3/89 and decision G 11/91, which definition has become the generally accepted, one could also say the "gold" standard, for assessing any amendment for its compliance with Article 123(2) EPC*" (last paragraph of point 4.3 of the reasons).

Applying the "gold" standard to the subject-matter in claim 1 as granted, the board has come to the conclusion for the reasons given in paragraph 2.4 above that the skilled person is presented after the amendment with new technical information which he would not derive directly and unambiguously, using common general knowledge, from the application as filed.

2.6 Consequently, the main request fails since it extends beyond the content of the earlier application as filed (Article 100(c) EPC).

3. *Auxiliary requests 3 and 4*

3.1 Each claim 1 of auxiliary requests 3 and 4 specifies treatment of "*a human patient whose hepatic function is not impaired*". Therefore, the reasons given above for claim 1 of the main request apply *mutatis mutandis* to each claim 1 of auxiliary requests 3 and 4.
Additionally, the specification of the ailments to be treated does not help, since it includes in both cases allergic rhinitis, but document D2 explicitly mentions seasonal allergic rhinitis on page 4, second paragraph.

Therefore, auxiliary requests 3 and 4 fail since they extend beyond the content of the earlier application (root application) as filed (Articles 100(c) and 76(1) EPC).

4. In view of the fact that all the claim requests which are admitted into the proceedings fail on grounds pursuant to Article 100(c) EPC there is no need to discuss the request for remittal to the department of first instance for further prosecution since it was dependent on the board finding any of the claim requests allowable under Articles 123(2) and 76(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

N. Maslin U. Oswald