

ET1129.97-010150017

DECISIONS OF THE BOARDS OF APPEAL

Decision of Technical Board of Appeal 3.3.1 dated 26 October 2000

T 1129/97 - 3.3.1

(Translation)

Composition of the board:

Chairman: A. J. Nuss

Members: P. P. Bracke

J. P. B. Seitz

**Applicant: CENTRE INTERNATIONAL DE RECHERCHES DERMATOLOGIQUES
GALDERMA (CIRD GALDERMA)**

Headword: benzimidazole derivatives/GALDERMA

Article: 69(1), 84 EPC

Keyword: "Clarity of claims" - "Interpretation of terms"

Headnote

"Explicit disclosure of the exact meaning of the term "lower alkyl" in the description alone and not in the claims is not sufficient per se for the claims to meet the clarity requirement."

Summary of facts and submissions

I. European patent application No. 92 911 098.9 (publication number 0 643 701), corresponding to the international application with the publication number WO 92/21663, was refused by decision of 7 July 1997 for lack of clarity (Article 84 EPC).

The examining division held that the claims which were the subject of the decision did not meet the clarity requirement because they included the terms "lower alkyl" and "lower fluoroalkyl". It based its refusal on the principle set out in decision T 337/95 (OJ EPO 1996, 628), which states that the term "lower alkyl" is ambiguous.

The set of claims on which the examining division based its decision had been submitted by letter of 27 December 1996 and consisted of 15 claims for the designated countries other than ES and GR, 14 claims for ES and 15 claims for GR.

Claim 1 for the designated countries other than ES and GR read as follows:

"Benzimidazole derivatives, characterised in that they correspond to the following general formula:

in which:

R₁ and R₂

atom, a

an OR₄

fluoroalk

halogen

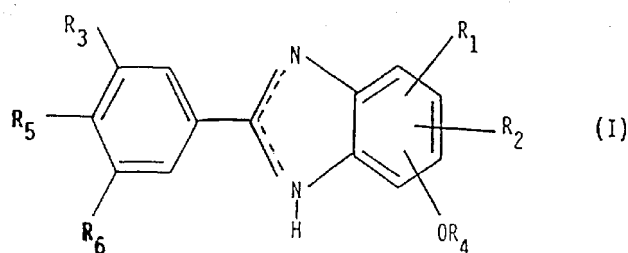
a hydrogen atom, a **lower alkyl** radical, a halogen, a hydroxyl or a lower alkoxy radical having from 1 to 6 carbon atoms,

R₄ represents a hydrogen atom, a **lower alkyl** radical, a benzyl radical, or a -CO-R₇, PO₃H or SO₃H radical or an amino acid residue,

R₇ represents a **lower alkyl** radical, a lower alkoxy radical having from 1 to 6 carbon atoms, the -(CH₂)_n-COOH radical, n = 1 to 6, or the -Nr'r'' radical,

r' and r'' representing a hydrogen atom, a **lower alkyl** radical, or r' and r'' taken

together form, with the nitrogen atom, a 5- or 6-membered heterocycle selected from



represent a hydrogen

lower alkyl radical,

radical, a **lower**

yl radical or a

atom, R₃ represents

the group consisting of the piperidino, morpholino, pyrrolidino and piperazino radicals, optionally substituted in position 4 by a **lower alkyl** radical, R₅ and R₆ represent, in one case, an OR₈ radical and, in the other, a mono- or polycyclic cycloalkyl radical having from 5 to 12 carbon atoms, linked to the phenyl ring via a tertiary carbon;

R₈ represents a hydrogen atom, a **lower alkyl** radical, an acyl radical having from 2 to 7 carbon atoms, a benzyl radical optionally substituted by one or a number of halogen atoms or the benzoyl radical,

and the salts of the said compounds obtained by addition of a pharmaceutically acceptable acid or base" (emphasis added by the board).

II. The appellants (applicant) filed an appeal against this decision and submitted one set of claims as a first auxiliary request by letter of 31 October 1997 and two sets of claims as second and third auxiliary requests by letter of 9 June 2000, and by fax of 5 September 2000 submitted corrected wordings for claim 3 for ES and GR according to the third auxiliary request.

Following a communication from the board of appeal, the appellants withdrew the first auxiliary request.

The wording of the claims according to the second auxiliary request differed from the wording in the main request in that the terms "lower alkyl radical" and "lower fluoroalkyl radical" (see the emphasised words in the claim cited in paragraph I) were replaced by "alkyl radical having from 1 to 6 carbon atoms" and "fluoroalkyl radical having from 1 to 6 carbon atoms" respectively.

The wording of the claims according to the third auxiliary request differed from the wording in the main request in that the terms "lower alkyl radical" and "lower fluoroalkyl radical" (see the emphasised words in the claim cited in paragraph I) were replaced by "alkyl radical having from 1 to 6 carbon atoms" and "fluoroalkyl radical having from 1 to 6 carbon atoms and from 1 to 5 fluorine atoms" respectively.

III. The third auxiliary request consisted of 15 claims for the designated countries other than ES and GR; 14 claims for ES; and 15 claims for GR.

The independent claims for all designated countries other than ES and GR according to the third auxiliary request read:

"1. Benzimidazole derivatives, characterised in that they correspond to the following general formula:

in which:

R₁ and R₂

hydrogen

radical

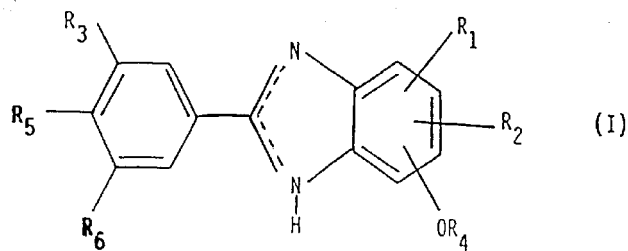
carbon

radical, a

having from 1 to 6 carbon atoms and from 1 to 5 fluorine atoms or a halogen atom,

R₃ represents a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**,

a halogen, a hydroxyl or a lower alkoxy radical having from 1 to 6 carbon atoms,



represent a

atom, **an alkyl**

having from 1 to 6

atoms, an OR₄

fluoroalkyl radical

R_4 represents a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**, a benzyl radical, or a $-CO-R_7$, PO_3H or SO_3H radical or an amino acid residue,

R_7 represents an **alkyl radical having from 1 to 6 carbon atoms**, a lower alkoxy radical having from 1 to 6 carbon atoms, the $-(CH_2)_n-COOH$ radical, $n = 1$ to 6, or the $-Nr'r''$ radical,

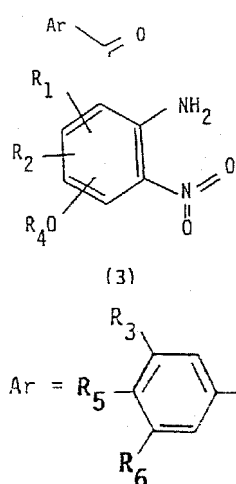
r' and r'' representing a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**, or r' and r'' taken together form, with the nitrogen atom, a 5- or 6-membered heterocycle selected from the group consisting of the piperidino, morpholino, pyrrolidino or piperazino radicals, optionally substituted in position 4 by an **alkyl radical having from 1 to 6 carbon atoms**,

R_5 and R_6 represent, in one case, an OR_8 radical and, in the other, a mono- or polycyclic cycloalkyl radical having from 5 to 12 carbon atoms, linked to the phenyl ring via a tertiary carbon;

R_8 represents a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**, an acyl radical having from 2 to 7 carbon atoms, a benzyl radical optionally substituted by one or a number of halogen atoms or the benzoyl radical, and the salts of the said compounds obtained by addition of a pharmaceutically acceptable acid or base" (emphasis added by the board).

"10. Process for the preparation of the compounds of formula (I) according to any of claims 1 to 9 and of their salts, wherein an aromatic carboxylic acid derivative of the formula:

is reacted with
in which R_1 ,
claim 1,
 Q represents
 Ar represents
the reaction
intermediate
cyclised by
a reagent
phosphorus



an orthonitroaniline of the formula:

R_2 and R_4 have the meanings given in

a hydroxy function or a chlorine atom and the radical:

having been carried out in the pyridine, the compound obtained is reduced, then heating in a solvent and in the presence of chosen from paratoluenesulphonic acid or oxychloride and, if desired, the salts of

said compounds of formula I are obtained by addition of a pharmaceutically acceptable acid or base."

"11. Pharmaceutical composition, characterised in that it contains, in a vehicle suitable for administration enterally, parenterally, topically or ocularly, at least one compound of formula (I) according to any of claims 1 to 9."

"13. Use of a compound according to any of claims 1 to 9, for the preparation of a pharmaceutical composition intended for the treatment or the prevention of inflammatory and/or immuno-allergic conditions."

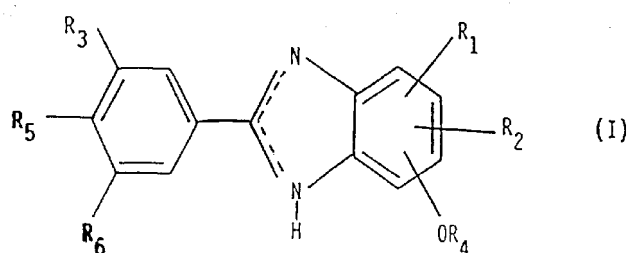
"14. Cosmetic composition intended to prevent unhealthy skin appearance, characterised in that it contains, in a suitable cosmetic vehicle, at least one compound as defined in any of claims 1 to 9."

The independent claims for ES according to the third auxiliary request read:

"1. Process for the preparation of benzimidazole derivatives of the general formula:

in which:

R₁ and R₂
atom, an
from 1 to
OR₄
radical



represent a hydrogen
alkyl radical having
6 carbon atoms, an
radical, a **fluoroalkyl**
having from 1 to 6

carbon atoms and from 1 to 5 fluorine atoms or a halogen atom,

R₃ represents a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**, a halogen, a hydroxyl or a lower alkoxy radical having from 1 to 6 carbon atoms,

R₄ represents a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**, a benzyl radical, or a -CO-R₇, PO₃H or SO₃H radical or an amino acid residue,

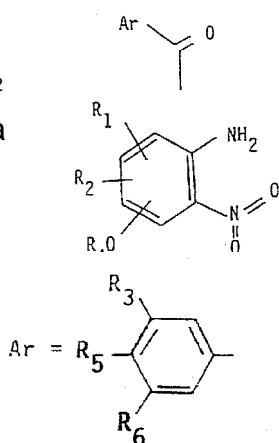
R₇ represents an **alkyl radical having from 1 to 6 carbon atoms**, a lower alkoxy radical having from 1 to 6 carbon atoms, the -(CH₂)_n-COOH radical, n = 1 to 6, or the -Nr'r" radical

r' and r'' representing a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**, or r' and r'' taken together form, with the nitrogen atom, a 5- or 6-membered heterocycle selected from the group consisting of the piperidino, morpholino, pyrrolidino and piperazino radicals, optionally substituted in position 4 by an **alkyl radical having from 1 to 6 carbon atoms**,

R₅ and R₆ represent, in one case, an OR₈ radical and, in the other, a mono- or polycyclic cycloalkyl radical having from 5 to 12 carbon atoms, linked to the phenyl ring via a tertiary carbon;

R₈ represents a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**, an acyl radical having from 2 to 7 carbon atoms, a benzyl radical optionally substituted by one or a number of halogen atoms or the benzoyl radical, and the salts of the said compounds, in which an aromatic carboxylic acid derivative of the formula:

is reacted with
in which R₁, R₂
Q represents a
represents the
the
pyridine,
reduced,
the
paratoluen
and, if



an orthonitroaniline of the formula:

and R₄ are defined as above,

hydroxy function or a chlorine atom and Ar
radical:

reaction having been carried out in the
the intermediate compound obtained is

then cyclised by heating in a solvent and in

presence of a reagent chosen from

esulphonic acid or phosphorus oxychloride

desired, the salts of said compounds of

formula I are obtained by addition of a pharmaceutically acceptable acid or base" (emphasis added by the board).

"10. Process for the preparation of a pharmaceutical composition, characterised in that at least one compound obtainable according to the process of any of claims 1 to 9 is mixed with a vehicle suitable for administration enterally, parenterally, topically or ocularly."

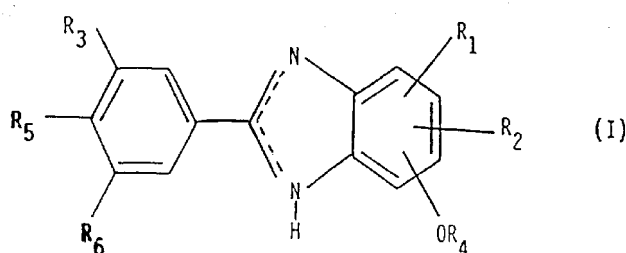
"13. Cosmetic composition intended to prevent unhealthy skin appearance, characterised in that it contains, in a suitable cosmetic vehicle, at least one compound obtainable according to the process of any of claims 1 to 9."

The independent claims for GR according to the third auxiliary request read:

"1. Benzimidazole derivatives, characterised in that they correspond to the following general formula:

in which:

R₁ and
hydroge
radical
carbon
radical,



R₂ represent a
n atom, an **alkyl**
having from 1 to 6
atoms, an OR₄
a **fluoroalkyl** radical

having from 1 to 6 carbon atoms and from 1 to 5 fluorine atoms or a halogen atom,

R₃ represents a hydrogen atom, an **alkyl** radical **having from 1 to 6 carbon atoms**, a halogen, a hydroxyl or a lower alkoxy radical having from 1 to 6 carbon atoms,

R₄ represents a hydrogen atom, an **alkyl** radical **having from 1 to 6 carbon atoms**, a benzyl radical, or a -CO-R₇, PO₃H or SO₃H radical or an amino acid residue,

R₇ represents an **alkyl** radical **having from 1 to 6 carbon atoms**, a lower alkoxy radical having from 1 to 6 carbon atoms, the -(CH₂)_n-COOH radical, n = 1 to 6, or the -Nr'r'' radical

r' and r'' representing a hydrogen atom, an **alkyl** radical **having from 1 to 6 carbon atoms**, or r' and r'' taken together form, with the nitrogen atom, a 5- or 6-membered heterocycle selected from the group consisting of the piperidino, morpholino, pyrrolidino and piperazino radicals, optionally substituted in position 4 by an **alkyl** radical **having from 1 to 6 carbon atoms**,

R₅ and R₆ represent, in one case, an OR₈ radical and, in the other, a mono- or polycyclic cycloalkyl radical having from 5 to 12 carbon atoms, linked to the phenyl ring via a tertiary carbon;

R_8 represents a hydrogen atom, an **alkyl radical having from 1 to 6 carbon atoms**, an acyl radical having from 2 to 7 carbon atoms, a benzyl radical optionally substituted by one or a number of halogen atoms or the benzoyl radical, and the salts of the said compounds obtained by the addition of a pharmaceutically acceptable acid or base" (emphasis added by the board).

"10. Process for the preparation of the compounds of formula (I) according to any of claims 1 to 9 and of their salts, wherein an aromatic carboxylic acid derivative of the formula:

is reacted

in which R_1 ,

1,

Q represents

represents

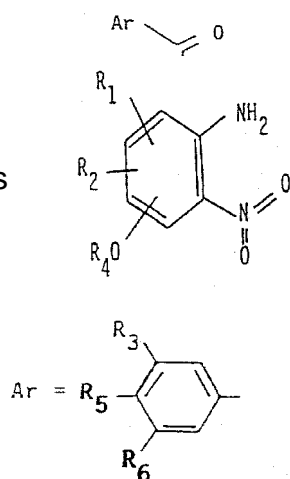
the

pyridine,

reduced,

the

paratolu



with an ortho-nitroaniline of the formula:

R_2 and R_4 have the meanings given in claim

a hydroxy function or a chlorine atom and Ar the radical:

reaction having been carried out in the

the intermediate compound obtained is

then cyclised by heating in a solvent and in

presence of a reagent chosen from

enesulphonic acid or phosphorus oxychloride

and, if desired, the salts of said compounds of formula I are obtained by addition of a pharmaceutically acceptable acid or base."

"11. Process for the preparation of a pharmaceutical composition, characterised in that at least one compound as defined in any of claims 1 to 9 is mixed with a vehicle suitable for administration enterally, parenterally, topically or ocularly."

"14. Cosmetic composition intended to prevent unhealthy skin appearance, characterised in that it contains, in a suitable cosmetic vehicle, at least one compound as defined in any of claims 1 to 9."

IV. The appellants argued that in their case the expressions "lower alkyl" and "lower fluoroalkyl" were precisely defined in the description, whereas the description in the

case which resulted in decision T 337/95 did not contain any precise definition of the expression "lower alkyl" which featured in the claims. Hence the principle established in T 337/95 was not applicable to the present case.

Furthermore, in T 238/88 (OJ EPO 1992, 709) the feature "alkyl" had been deemed to be neither imprecise nor ambiguous, so the appellants found it difficult to believe that this same feature "lower alkyl" could make the scope of the claim unclear.

V. The appellants request that the patent be granted

- on the basis of the set of claims which was the subject of the contested decision (main request)

- on the basis of the set of claims submitted by letter of 31 October 1997 as the second auxiliary request, or

- on the basis of the set of claims submitted by letter of 31 October 1997 as the third auxiliary request, including corrected claims 3 for ES and GR as submitted by fax of 5 September 2000.

Reasons for the decision

1. The appeal is formally correct and is admissible.

2. Main request

2.1 Article 84 EPC stipulates that the claims defining the matter for which protection is sought must be clear. Given that claim 1 relates to benzimidazole derivatives characterised by a general formula (I), for the clarity requirement to be met the group of compounds according to claim 1 must be defined in such a way that the skilled person can unambiguously distinguish the chemical compounds which belong to the claimed group from those which do not.

The issue here is whether the terms "lower alkyl" and "lower fluoroalkyl" in claim 1 define a set of radicals clearly and precisely enough for this distinction to be made.

2.1.1 It is not disputed that the term "lower alkyl" does not have a well-recognised meaning in the art of organic chemistry, given that it offers no certainty as to the

maximum number of carbon atoms in the alkyl group, as already stated in decision T 337/95 (Reasons 2.8).

However, in the case which resulted in decision T 337/95, there was no definition of the term "lower alkyl" in the description, which thus offered no conclusive teaching as to the number of carbon atoms there may be in a "lower alkyl" group.

By contrast, in the present case it was in fact stated on page 2 of the description, lines 31 and 32 and 35 to 37, that "Lower alkyl radical must be understood to mean a linear or branched radical having from 1 to 6 carbon atoms" and that "Lower fluoroalkyl radical must be understood to mean a radical having from 1 to 6 carbon atoms and from 1 to 5 fluorine atoms, such as the trifluoromethyl radical". Thus here, unlike in decision T 337/95 (Reasons 2.9.3), what essentially needs to be decided is whether, in order to meet the requirements of Article 84 EPC, it is necessary and sufficient for the skilled person to be able to resolve any lack of clarity in claim 1 *per se* by referring to the description which supports it.

2.1.2 The clarity requirement of Article 84 EPC in fact relates only to the claims, and consequently, as the EPO's boards of appeal have consistently ruled, it demands that these be **clear per se** for a person skilled in the art with general knowledge of the technical field in question, without the need to refer to the description of the patent in suit (see T 2/80 OJ EPO 1981, 431, Reasons 2). Thus the meaning of the wording of a claim must be fully evident from the actual terms of that claim, such that it is sufficient in itself to provide useful protection and is therefore unambiguous.

In the present case, the term "lower alkyl" appearing in claim 1 is not sufficiently precise for a skilled person to be able, immediately and unequivocally, to determine the maximum number of carbon atoms that a lower alkyl group may contain and hence unambiguously to distinguish the chemical compounds which belong to the claimed group from those which do not.

2.1.3 Explicit disclosure of the exact meaning of the term "lower alkyl" in the description alone and not in claim 1 is not sufficient *per se* for that claim to meet the clarity requirement.

Article 69(1) EPC certainly states that the description is to be used to interpret the claims. However, Article 69 EPC is only concerned with the extent of protection conferred **whenever that extent is to be determined**, particularly for third parties, and not with defining the matter for which protection is sought by means of a claim, as stipulated in Article 84 EPC. The appellants cannot, therefore, rely on the disclosure in the description under Article 69 EPC to avoid meeting the requirements of Article 84 EPC, without which the primary requirement of self-sufficiency would not be met and interpretation of the protection conferred would be left to chance.

2.1.4 The appellants also refer to decision T 860/93, OJ EPO 1995, 47, in which the board found that recourse could be had to the description to **determine** whether the claims were clear.

However, the issue in that decision is not whether the disclosure in the description can be used to clarify a term in a claim. Moreover, in point 5.5 of the Reasons in T 860/93 the board expressly ruled that it was not possible to refer to the description to render the meaning of a claim clear.

2.1.5 Given that the expression "lower alkyl" in organic chemistry does not have a generally accepted meaning in terms of the maximum number of carbon atoms, the board concludes that claim 1 according to the main request does not meet the clarity requirement of Article 84 EPC.

2.1.6 Since the appellants have cited the earlier decision T 238/88, the board considers it worthwhile recalling the finding in that case. There, the feature "alkyl" appeared in the definition of the substituents of the claimed compounds, and the board held that the term "alkyl" undoubtedly related to a current technical term used in chemistry which was neither imprecise nor ambiguous.

However, the issue in the present case is not so much whether the term "alkyl" is clear, but whether the term "**lower** alkyl" is in itself sufficiently clear that a skilled person can unambiguously distinguish the compounds which belong to the claimed group from those which do not. Although the term "alkyl" relates to a current technical term used in chemistry, the problem is with the qualifier "**lower**". This having no generally accepted meaning in terms of the maximum number of carbon atoms, a skilled person reading only the claim is unable to distinguish the compounds which belong to the claimed group from those which do not.

2.1.7 The appellants further could not see why the expressions "lower alkyl" and "lower fluoroalkyl" did not meet the clarity requirement whereas the expressions "amino acid residue" and "a mono- or polycyclic cycloalkyl radical having from 5 to 12 carbon atoms, linked to the phenyl ring via a tertiary carbon" were not equally open to the same objection.

Although use of the latter two expressions means that the wording of the claims covers a very large number of radicals, a skilled person can easily distinguish the compounds which are claimed from those which are not, since the two expressions identify very precise groups of radicals. The board therefore sees no reason to object to any lack of clarity in these terms.

2.1.8 The appellants have further drawn the board's attention to the fact that since decision T 337/95 the EPO has continued to grant patents with main claims featuring the expression "lower alkyl".

This board however is competent to rule only on the present appeal proceedings, relating to the examining division's decision to refuse the patent application in suit; it does not have the power to pronounce, in general terms going beyond its remit, on the allowability of the wording of claims in other patent applications. That would entail setting an authoritative precedent and would therefore be *ultra petita*.

2.1.9 The appellants further contend that Article 84 EPC merely requires a claim to be clear, which does not necessarily mean that it is precise.

This argument cannot stand, as it flies in the face of the terms of that article's first line, which establishes the purpose of a claim, namely to define the protection conferred by the patent as a monopoly right. To fulfil this purpose it is obviously necessary, albeit implicitly, for the wording of the claim to be without ambiguity so that its interpretation is not left to chance, and for it to be precise, yet concise.

Ruling otherwise would mean denying third parties a reasonable degree of certainty as to the extent of the protection conferred.

Article 69(1) EPC says the same, stipulating that the extent of the protection conferred by the patent is to be determined by the terms of the claims, which **nevertheless** (as a concession) may be interpreted in the light of the description.

Taken together, these two provisions show that the practice of using an ambiguous and therefore imprecise term in the wording of a claim, and relying for its interpretation on an implicit but essential reference to the description, must remain prohibited. The principle of the self-sufficiency of the claim must be retained.

2.2 Moreover, the Article 84 EPC requirement for the claims to be supported by the description means that the subject-matter of the claim must be drawn from the description and that it is not acceptable to claim something which is not described.

The EPO appeal boards have consistently ruled that the Article 84 EPC requirement for the claims to be supported by the description merely reflects a general legal principle that **the extent of the patent monopoly**, as defined by the claims, must correspond to **the technical contribution** to the art. This means that the definitions in the claims must essentially correspond to the scope of the invention as disclosed in the description; and consequently, a technical feature which is described and highlighted in the description as being an essential feature of the invention must

necessarily be part of the independent claims defining that invention (see decision T 409/91, OJ EPO 1994, 653, Reasons 3.3).

2.2.1 In the present case, given that the description alone says that "Lower fluoroalkyl radical must be understood to mean a radical having from 1 to 6 carbon atoms and from 1 to 5 fluorine atoms, such as the trifluoromethyl radical" (see page 2, last paragraph) and that the rest of the description gives no other details, the description cannot be used to support (or justify) a claim referring to lower fluoroalkyl radicals having from 1 to 6 carbon atoms and more than five fluorine atoms.

2.2.2 The appellants have also argued that the number of fluorine atoms is very easy to calculate in the case of a fluoroalkyl radical having from 1 to 6 carbon atoms, as there can only be between 1 and 13 fluorine atoms. As the claims must be seen in their context, ie in the light of what is disclosed in the description (in the present case namely the passage reading "Lower fluoroalkyl radical **must be understood to mean** a radical having from 1 to 6 carbon atoms and from 1 to 5 fluorine atoms, such as the trifluoromethyl radical" (emphasis added by the board)), the appellants conclude that this expression must, in the light of the description, be taken to imply: "must be understood, **in particular (or notably)**, to mean ...".

2.2.3 The board cannot accept this argument, given that there is no indication anywhere in the description that radicals R_1 and R_2 can represent alkyl radicals having more than five fluorine atoms, and therefore a skilled person reading the description is forced to conclude that an essential feature is that the lower fluoroalkyl radicals do not contain more than five fluorine atoms.

2.2.4 The board likewise concludes that claim 1 as worded is not clearly supported by the description, in contravention of Article 84 EPC.

2.3 Consequently, the main request does not meet the Article 84 EPC requirements of clarity and support by the description.

3. *Second auxiliary request*

Given that the wording of the claims according to the second auxiliary request still retains the expression "fluoroalkyl radical having from 1 to 6 carbon atoms", this set of claims likewise does not meet the Article 84 EPC requirement of support by the description (see Reasons 2.2 above).

4. *Third auxiliary request*

4.1 Amendments

As the amendments to the wording of the claims according to the third auxiliary request are the result of incorporating the proper meanings of the terms "lower alkyl" and "lower fluoroalkyl" appearing on page 2, lines 31 and 32 and 35 to 37, of the application as filed, these amendments are not in breach of Article 123(2) EPC.

4.2 Article 84 EPC

The effect of the amendments thus made to the wording of the claims according to the third auxiliary request is to remove the objections as to clarity and support by the description raised by the examining division.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to grant a patent on the basis of the set of claims submitted by letter of 31 October 1997 and entitled "Third auxiliary request", with the corrected claims 3 for ES and GR as submitted by fax of 5 September 2000.

