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D E C I S I O N
of 30 August 2001

Case Number: T 0056/97 - 3.3.2

Application Number: 84114906.5

Publication Number: 0154009

IPC: A61K 31/54

Language of the proceedings: EN

Title of invention:
Use of a thiazide diuretic for the manufacture of a non-diuretic antihypertensive medicament

Patentee:
Euro-Celtique S. A.

Opponent:
TAKEDA CHEMICAL INDUSTRIES, LTD

Headword:
"Thiazide diuretics"/EURO-CELTIQUE

Relevant legal provisions:
EPC Art. 52(4), 54, 56, 84, 113, 123(2), (3)

Keyword:
"Main request first and fourth auxiliary requests, novelty (no);"
"Second auxiliary request, contravention of Article 123(2) EPC;"
"Third auxiliary request, not acceptable under the terms of Articles 84, 123(2) and (3) EPC"

Decisions cited:
G 0005/83, G 0004/92, G 0001/93, T 0317/95, T 0934/97

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0056/97 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 30 August 2001

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 22 November 1996 concerning maintenance of European patent No. 0 154 009 in amended form.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: G. F. E. Rampold
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No. 0 154 009 was granted to the appellant/proprietor pursuant to European patent application No. 84 114 906 5. Claim 1 read as follows:

"Use of a thiazide diuretic having a predetermined diuretic effective dose for the manufacture of a non-diuretic anti-hypertensive composition comprising a unit dosage amount of the thiazide diuretic insufficient to achieve effective diuresis, but sufficient to achieve anti-hypertension, said amount being within the range of 7-25% by weight of the predetermined diuretic effective dose;" dependent claims 2 to 11 claimed specific elaborations of that use.

II. The appellant/opponent filed notice of opposition requesting full revocation of the patent for exclusion from patentability, lack of novelty and inventive step (Articles 52(4), 54, 56 and 100(a) EPC); for insufficiency of disclosure (Articles 83 and 100(b) EPC); and for added subject-matter Articles 123(2) and 100(c) EPC). The relevant citations are:

(1) US-A-4 139 633

(2) Europ. J. Clin. Pharmacol. 10, 1976, 177-182

(5) DE-A-3 027 392

(6) Europ. J. Clin. Pharmacol. 8, 1975, 393-401

(7) British Medical Journal, Vol. 283, 1983, 1535-1538

(8) The Lancet, November 9 1963, 996-970

(9) A. Lennart *et al*, Abstract No. 12, First European Meeting on Hypertension, Milan, Italy, 29th May - 1st June 1983.

III. In an interlocutory decision posted on 22 November 1996, the opposition division refused the proprietor's main request that the opposition be rejected and its auxiliary requests filed in the written proceedings, but maintained the patent on the basis of claims 1 to 9 filed as "amended new first auxiliary request" during oral proceedings, with claim 1 amended by addition of the following disclaimers at its end:

"Use of a thiazide diuretic <.....> effective dose, ***excepting a unit dosage amount of 12.5 or more mg hydrochlorothiazide in a composition for twice-daily application, and excepting a unit dosage amount of 0.25 or more mg cyclopenthiazide in a composition for thrice-daily application."***

Dependent claim 3 was adapted to the disclaimers in amended claim 1 ("hydrochlorothiazide 1.75 - ***under 12.5 mg"***; cyclopenthiazide 0.07 - ***under 0.25 mg"***) and claims 10 and 11 were deleted.

IV. The opposition division held that the claims were correctly drafted in the "second (further) medical use" format in accordance with decision G 5/83; that the claimed subject-matter was thus not excluded from patentability under Article 52(4) EPC; that the amended claims complied with Article 123(2) and (3) EPC; and

that the opponent's arguments as to insufficiency of disclosure under Article 100(b) EPC and added subject-matter under Article 100(c) EPC did not succeed.

The opposition division found novelty since the claims related to a new therapeutic application of known diuretic compounds, but held that claim 1 as granted was uninventive because certain variants of the claimed invention did not, as against certain disclosures in (6) and (8), solve the actual problem of providing, by the use of a thiazide diuretic, antihypertensive action without effective diuresis. As to the auxiliary request filed during oral proceedings (see paragraph III *supra*), the opposition division concurred with the proprietor that it was admissible under the provisions of Article 100(b) and 83 EPC to exclude, by way of the disclaimers in claims 1 and 3, those variants of the claimed invention incapable of being performed. It found that the remaining subject-matter in the claims involved an inventive step.

V/A. Both parties appealed. In addition to its **main request** that the decision under appeal be set aside and the patent be maintained unamended, the appellant/proprietor filed together with its grounds of appeal four auxiliary requests.

V/B. In its **present first auxiliary request** claims 1 and 3 correspond to claims 1 and 3 upheld by the opposition division (see paragraph III above) and claims 2 and 4 to 11 to those as granted, the **second disclaimer** at the end of claim 1 differing as follows:

"and excepting a unit dosage amount of 0.25 or more mg cyclopenthiazide in a composition for ***twice-daily***

application."

V/C. The **second auxiliary request** consists of claims 1 to 11 in the third auxiliary request, filed on 5 September 1996 during the first-instance opposition and corresponding to the granted claims (see paragraph I above), with the following added at the end of claim 1:

"Use of a thiazide diuretic <.....> effective dose, ***said thiazide diuretic being provided in the form of a salt, an adsorbate salt or a complex, preserving the non-polarized, free-acid, liquid-soluble form of the thiazide diuretic in the gastrointestinal tract."***

V/D. The **third auxiliary request** consists of claims 1 to 11 in the fourth auxiliary request, filed on 5 September 1996 during the first-instance opposition and corresponding to the granted claims(see paragraph I above), with the following added at the end of claim 1:

"Use of a thiazide diuretic <.....> effective dose, ***and a mixed cation-anion-resin-thiazide adsorbate salt, or, a hydroxymetal thiazide salt, or, a calcium disodium thiazide edate salt or disodium thiazide edetate salt, or, a hydroxyalkylcellulose thiazide complex or carboxymethylcellulose thiazide complex, or, the povidone thiazide complex, or, the povidone thiazide molecular complex, or, an amiloride-thiazide salt."***

V/E. The **fourth auxiliary request** consists of claims 1 to 9 upheld by the opposition division (see paragraph III above).

VI. At oral proceedings before the board on 30 August 2001, the appellant/opponent was represented. The duly summoned appellant/proprietor informed the board in advance that it would not attend the hearing.

VII. The principal arguments relied on by the appellant/proprietor in its grounds of appeal and in its further written submissions were:

Claim 1 as granted related to use of a thiazide diuretic for the manufacture of a simultaneously anti-hypertensive and non-diuretic composition for which it was necessary to determine first the diuretic effective dose of the particular thiazide diuretic used and then the dose which corresponded to an amount within the range of 7-25% by weight of that diuretic effective dose. Within this range a unit dosage amount had to be chosen insufficient to achieve effective diuresis, but sufficient to achieve anti-hypertension. The ranges of the unit dosage amounts given for the 11 different thiazide diuretics listed in dependent claim 3 were selected on the basis of their respective predetermined diuretic effective dose. It was thus clear that the claims as granted related to a second medical use as recognised in decision G 5/83 and that such claims were not, contrary to the appellant/opponent's assertions, excluded from patentability under the terms of Article 52(4) EPC.

It was correct that the unit dosage amount of 12.5 mg hydrochlorothiazide (hereinafter "HCT") in a composition for twice daily application disclosed in citation (6) and the unit dosage amount of 0.25 mg cyclopenthiazide in a composition for thrice daily application disclosed in citation (8) fell within the

dosage ranges given for these two thiazide diuretics in dependent claim 3. The opposition division was, however, wrong to conclude from those disclosures that claim 1 as granted was either non-inventive, because it included certain variants of the claimed invention which did not solve the actual problem underlying the patent in suit, or contravened Article 83 EPC, because certain variants of the claimed invention were incapable of being performed.

Both citations (6) and (8) were unclear as to the actual effects achieved by using the particular thiazide diuretics in the unit dosage amounts mentioned above. In any case, the cited prior art merely referred to the response of patients to a specific dose range in a very specific test protocol. This did not, however, permit the conclusions that claim 1 did not solve the problem or was obvious nor that the invention was generally incapable of being performed. Although it was well-known that many well-established and successful medicaments failed to exert the desired effect in single individual cases, this did not impair the general usefulness and acceptance of such medicaments. The usefulness of thiazide diuretics for the indicated therapeutic purpose over the whole range claimed was thus in the present case beyond doubt. Maintenance of the patent as granted was accordingly justified.

VIII. The appellant/opponent's submissions in writing and during the oral proceedings can be summarised as follows:

The alleged invention's actual teaching consisted in an instruction to doctors to use a reduced amount of a thiazide diuretic, known to provide both diuresis and

antihypertensive action, in order to achieve only one effect, namely the antihypertensive. This was thus a therapy practised on the human body and accordingly excluded from patentability under Article 52(4) EPC.

Since the "diuretic effective dose" was neither disclosed nor defined in the patent in suit, the disclosure of the invention was insufficient. The disclosure did not enable its addressee to establish the actual dosage to be used nor whether or not the dosage actually used was covered by the claims.

The ranges of the unit dosage amounts given for the 11 different thiazide diuretics listed in dependent claim 3 of all requests extended beyond the content of the application as filed and thus contravened Article 123(2) EPC. The broad generalisation in claim 1 of the second auxiliary request from the specific disclosure of the invention in the application as filed was similarly not adequately supported and contrary to Article 123(2) EPC.

The wording of the claims did not exclude the use of a thiazide diuretic in combination with another antihypertensive agent.

Even if claim 1 was construed as excluding the use of an additional antihypertensive agent, the disclosure of citations (1), (6) and (8) was prejudicial to the novelty of the claims upheld by the opposition divisions. All cited references described the antihypertensive activity of certain thiazide diuretics in unit dosage amounts explicitly referred to in Example 1 of the patent in suit as insufficient to achieve effective diuresis. If claim 1 was correctly

interpreted as including the option of using an additional antihypertensive agent, citations (2), (5), (7) and (9) also prejudiced novelty.

In the first-instance opposition proceedings, the chairman declared that none of the main, first or second auxiliary requests involved an inventive step. Nevertheless, the opposition division upheld under Article 56 EPC claims which differed from those requests only by the insertion of an additional disclaimer. However, according to the consistent case law of the boards of appeal, there was no basis in the EPC for the substantiation of inventive step by disclaimers.

IX. The appellant/proprietor requested in writing that the decision under appeal be set aside and that (as main request) the patent be maintained as granted, or alternatively according to either its first auxiliary request filed on 24 March 1997, or its second or third auxiliary requests (corresponding to the third and fourth auxiliary requests filed on 5 September 1996); or (as fourth auxiliary request) that the decision under appeal be maintained.

The appellant/opponent requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. The appeal is admissible.

Main request (see paragraph V/A supra)

2. As appears from paragraph I above, claim 1 is in the conventional "second (further) medical use" format. In spite of that particular form of the claim ("Swiss type claim"), the board has difficulties in accepting the opposition division's conclusions and the appellant/proprietor's submissions that the features of claim 1 do in fact reflect a new therapeutic application from which novelty for the claimed use of commonly known thiazide diuretics can be derived in accordance with the principles recognised in decision G 5/83 (OJ EPO 1985, 64) and that, accordingly, claim 1 relates to a second (further) medical use for such diuretics.

If one concludes that claim 1 does not teach a second (further) medical use, then the question arises, whether or not the claimed use has to be considered as a method referred to in Article 54(2) EPC.

2.1 It is generally understood that the concept of "therapy" or "therapeutic application" includes treatment of a particular illness or disease with a specified chemical substance or composition in a specified human or animal subject in need of such treatment. As is acknowledged in the patent in suit (see especially page 2, lines 19 to 26) and is, moreover, clearly derivable from the state of the art cited in the present proceedings (see the citations referred to in paragraph II above), thiazide diuretics are among the most commonly used therapeutically active substances in the treatment of hypertension by oral administration of the active substance to patients or other human or animal subjects suffering from the

symptoms and complaints of hypertension. Claim 1 of the patent in suit teaches the use of thiazide diuretics for precisely that therapeutic application or purpose. In the patent in suit the therapeutic substances used, ie thiazide diuretics, the disease to be treated or the ailment to be cured, ie hypertension, the method of application of the active substance, ie oral administration in the form of tablets or capsules or liquid preparations (see patent specification, page 10, line 44 to page 11, line 6), and the category of patients to be treated or cured, are all exactly the same as in the cited prior art. Additionally, claim 1 specifies in broad functional terms - ie "a unit dosage amount of the thiazide diuretic insufficient to achieve effective diuresis, but sufficient to achieve anti-hypertension, said amount being within the range of 7 to 25% by weight of the predetermined effective dose"- the unit dosage amount or, differently expressed, the prescribed dosage regimen to be used for the known therapeutic application of thiazide diuretics.

2.2 The opposition division concluded in the impugned decision (see paragraph 2 d) of its Reasons) that the specification of the above-mentioned unit dosage amount or the prescribed dosage regimen in claim 1 was not disclosed in the prior art and that this justified acknowledgment of novelty in terms of a second or further medical use of thiazide diuretics for their otherwise known therapeutic application. Although the board finds that even the particular unit dosage amount specified in claim 1 is not novel (for the reasons in points 3 to 3.3 below), those conclusions of the opposition division prompt the board nevertheless to explain why it differs from the opposition division on

the question of novelty.

2.3 The alleged invention is based on the finding or discovery that, by orally administering thiazide diuretics in a certain prescribed dosage regimen or low unit dosage amount, antihypertensive activity can be achieved in patients without inducing effective diuresis. Thus, all that has been discovered is that, if thiazide diuretics are administered in sufficiently low dosage units, their diuretic effect will be to a certain extent less (see "insufficient to achieve **effective** diuresis") or even possibly absent, while the antihypertensive activity remains. Even assuming in the appellant/proprietor's favour that this was not known in the state of the art, it could only be regarded, in the board's judgment, as an additional item of knowledge about the known therapeutic application of thiazide diuretics for the treatment of hypertension to alleviate or cure the symptoms and complaints of hypertension in an human or animal subject in need of it, but could not in itself confer novelty on this known therapeutic application. For the acknowledgment of novelty, such a finding or discovery would be required to lead to a specified **new therapeutic application or purpose.** That not being the case here, the board fails to see how claim 1 could, even making the assumption above, be construed as relating to a second or further medical use. The board therefore cannot agree with the opposition division's view that the patent in suit claims an invention that is new in terms of Article 54 EPC as understood in decision G 5/83 (*loc. cit.*) or any of the other decisions in the substantial body of case law which has been developed by the boards of appeal in this respect (see eg "Case Law of the Boards of Appeal of the European Patent

Office", 3rd edition, 1998, I. C. 6.2, pp 98-103).

2.4 The above considerations lead necessarily to the question whether or not claim 1 is compatible with Article 52(4) EPC. That article does not exclude medicaments and their preparation from being patentable, but has the purpose of ensuring that the actual use, by practitioners, of methods of medical treatment when treating patients should not be subject to restraint or restriction by patent monopolies. The Enlarged Board stated in decision G 5/83 (*loc. cit.*, see especially Reasons, point 22) that the intention of Article 52(4) EPC is to free from restraint non-commercial and non-industrial medical and veterinary activities. Hence, in the present case the decisive question is whether claim 1 concerns a method of treatment as opposed to what is available for treatment.

2.5 To decide this question the board has to consider the features that effectively contribute to the core of the alleged invention as claimed. These features concern the administration of known medicaments, ie thiazide diuretics, in a particular prescribed dosage regimen or a particular unit dosage amount for the known treatment of hypertension without simultaneously inducing effective diuresis. They reflect in fact the discovery that a specifically chosen treatment regimen, which requires predetermination by doctors of the diuretic effective dosage range in relation to each particular thiazide diuretic used (see Example 1), provides the

desired result. The specific amount of the thiazide diuretic to be administered is then conventionally selected by the doctor, as is the time and schedule of administration (see Example 1: the unit dose is administered in from 4 to 8 consecutive hourly doses, once or twice daily).

However, determination of the best individual treatment schedule, in particular the prescribing and modification of drug dosage regimens used for administering a particular medicament, so as to comply with the specific needs of a patient and to achieve the desired result of the treatment in an individual patient, calls first and foremost for the exercise by a medical practitioner of his professional skill in curing, preventing or alleviating the symptoms of suffering and illness. Such activities are typical of the non-commercial and non-industrial medical activities which Article 52(4) EPC intends should remain free from restraint. Against that background, the board has difficulty in seeing claim 1 as more than an unsuccessful attempt to obtain protection for a method of therapeutic treatment of the human or animal body by couching it in the form of a "Swiss type claim" (see also decision T 317/95 of 26 February 1999, not published in OJ EPO).

2.6 Since the appellant/proprietor's main request must in any case fail for the reasons set out below, no final decision on the above issues is necessary in the present case.

3. The appellant/proprietor itself submitted in its grounds of appeal (see page 3, 2nd full paragraph), *inter alia*, that "the numerical values in dependent

claim 3 were determined, when the invention was made, on the basis of the predetermined diuretic effective doses for the respective thiazide diuretics, as then known to the patentee". The patent in suit states in the last full paragraph on page 9 that "the pharmaceutically acceptable non-diuretic anti-hypertensive unit dosage compositions are prepared to contain a sufficient quantity of selected thiazide active ingredient to provide not less than 7% by weight and not more than 25% by weight of the predetermined diuretic effective dose of the selected thiazide diuretic. It will be observed that when the thiazide content falls below 7% of the diuretic dose for the particular thiazide compound selected, then the desired antihypertensive action will not be realised. When the unit dose of the thiazide compound is greater than 25% of the diuretic dose for the thiazide compound selected, then diuresis and certain of the adverse properties associated with diuresis will occur to detract from the overall advantages of the present invention".

3.1 Certain unit dosage amounts or prescribed dosage regimens, which fall within the ranges explicitly envisaged in Example 1 and claim 3 of the patent in suit, for example those for the administration of HCT and cyclopenthiazide, were already used in the state of the art for the treatment of hypertension by oral administration of the aforementioned diuretics either alone [see eg citations (1), (6),(8)] or in combination with other antihypertensive agents [see eg citations (2), (5), (7), (9)].

3.2 The wording of claim 1 ("<...> a non-diuretic anti-hypertensive composition, **comprising** a unit dosage

amount of the thiazide diuretic <...>") leaves no doubt that protection is sought for the use of thiazide diuretics either alone or in combination with other antihypertensive agents in the treatment of hypertension.

3.3 For example, citation (9) discloses, *inter alia*, the use of compositions comprising a unit dosage amount of 6.25 mg HCT in combination with either 10 mg or 40 mg of the angiotensin converting enzyme inhibitor enalapril for the treatment of patients with mild or moderate hypertension by once a day oral administration. In this respect, citation (9) states that a much lower dosage of thiazide [eg 6.25 mg] than the ones routinely given are effective in the treatment of mild to moderately severe hypertension, at least in combination with enalapril, and that such treatment is remarkably well tolerated.

The unit dosage amount or prescribed dosage regimen of 6.25 mg HCT in (9) falls within the preferred range of the unit dosage amount specified for the claimed use of HCT in claim 3 and corresponds to 25% by weight of the lower limit of the range of the predetermined diuretic effective dose of HCT (see Example 1 on page 34 of the application as filed and Example 1 on page 11 of the patent as granted). This disclosure in the state of the art is therefore prejudicial to the novelty of claim 3. Since claim 3 depends on claim 1 and, moreover, in view of the observations in point 3 above, claim 1 necessarily includes the subject-matter of dependent claim 3, the subject-matter of claim 1 therefore lacks novelty over citation (9).

3.4 The main request is accordingly not acceptable under

the terms of Article 100(a) in conjunction with Articles 52(1) and 54(1) and (2) EPC. In these circumstances, there is no need for the board to comment on the other objections brought forward by the appellant/opponent to the allowability of that request.

First auxiliary request (see paragraph V/B above), Fourth auxiliary request (see paragraph V/E above)

4. While the above considerations relate to the subject-matter of claims 1 and 3 of the main request, the same conclusions also apply to the subject-matter of claims 1 and 3 of the first and the fourth auxiliary requests. Those claims differ from the corresponding claims in the main request only by the respective disclaimers introduced either during the opposition proceedings (in the case of the fourth auxiliary request) or the subsequent appeal proceedings (in the case of the first auxiliary request).

4.1 Though an insertion of an exclusion in claims in the form of a disclaimer may in certain cases be acceptable, this is always an exceptional step. According to the established case law of the boards of appeal - see, as an example only, decision T 934/97 of 6 June 2001, not published in OJ EPO and the numerous references to other relevant decisions of the boards of appeal cited therein - introduction of a disclaimer is only acceptable if all the requirements derived from Article 123(2) EPC are strictly met.

These requirements are based on the legal principle underlying Article 123(2) EPC, namely that an applicant is not allowed to improve his position, by adding subject-matter not disclosed in the application as

filed or removing subject-matter from the application as filed, so as to give him an unwarranted advantage over, or damage the legal security of, third parties relying on the content of the original application (see decision G 1/93, OJ EPO 1994, especially Reasons, point 9).

4.2 In view of the foregoing, the board observes that none of the disclaimers allowed in the request upheld by the opposition division (in the present fourth auxiliary request), and likewise none of the disclaimers introduced by the claims of the first auxiliary request at the appeal stage meet any of the requirements referred to in the above-mentioned decisions. However, even if, in the appellant/proprietor's favour, the disclaimers were assumed to be allowable, the disclosure of citation (9) would not thereby be excluded and it would remain prejudicial to the novelty of claims 1 and 3 of both requests for the reasons given above for the lack of novelty of the main request. Both the first and fourth auxiliary requests must thus fail for the same reasons as the main request.

Second auxiliary request (see paragraph V/C above)

5. The further limitation of the thiazide diuretic in claim 1 as being "provided in the form of a salt, an adsorbate salt or a complex, preserving the non-polarized, free-acid, liquid-soluble form of the thiazide diuretic in the gastrointestinal tract", could

be considered, in the board's judgment, as acceptable in view of the disclosure from page 18, 2nd full paragraph, to page 23, first full paragraph, of the application as filed, if it was adequately supported by the originally filed documents.

5.1 However, the functional feature, which the board considers as an indispensable element of the claim for justifying the proposed amendment to claim 1 under the terms of Article 123(2) EPC, reads in claim 1 "preserving the non-polarized, free-acid, **liquid**-soluble form of the thiazide diuretic in the gastrointestinal tract", as opposed to the corresponding disclosure in the application as filed (see page 19, lines 3-5) reading "to preserve the non-polarized, free-acid, **lipid**-soluble form of the thiazide diuretic in the gastrointestinal tract". The terminology "lipid-soluble form" or "lipid soluble" is used throughout the entire disclosure in the application as filed.

5.2 In the absence of any evidence to the contrary, it appears clear from the disclosure of the claimed invention referred to above that a salt, an adsorbate salt or a complex of the thiazide diuretic capable of preserving its **lipid**-soluble form in the gastrointestinal tract - such as eg the thiazide compound in the form of its insoluble basic hydroxy metal salt (see page 20 of the application as filed) or in the form of the other highly specific salts and complexes referred to in the paragraph bridging pages 28 and 29 - are necessarily distinctly different in their technical properties and qualities and in their functionality from a salt, an adsorbate salt or a complex of the thiazide diuretic capable of preserving

its **liquid**-soluble form in the gastrointestinal tract. In sharp contrast to the salts referred to in the patent in suit preserving the lipid-soluble form of the thiazide diuretic, a salt preserving the liquid-soluble form would apparently include water-soluble salts such as a simple sodium salt of thiazide diuretics for the use claimed in the patent in suit. This does not form part of the disclosure of the invention in the application as filed.

5.3 Since the appellant/proprietor did not file a request for correction, even though the second auxiliary request was filed together with the grounds of appeal, as long ago as 24 March 1997, ie more than 4 years before the date of the oral proceedings which both the proprietor and the opponent requested, the board must conclude that the amendment to claim 1 in the second auxiliary request lacks adequate support in the application as filed and, consequently, that the claim as amended contravenes Article 123(2) EPC. The second auxiliary request is therefore also not acceptable.

Third auxiliary request (see paragraph V/D above)

6. According to the disclosure in the paragraph bridging pages 28 and 29 of the application as filed, the desired effects of the claimed invention can be achieved by the administration of:

(a) from 7% to 25% of the diuretic effective dose of the selected thiazide compound (see claim 1 of the main request), **or** (b) a mixed cation-anion-resin-thiazide adsorbate salt, or, (c) a hydroxymetal thiazide salt, or, (d) a calcium disodium thiazide edate salt or disodium thiazide edetate salt, or, (e) a

hydroxyalkylcellulose thiazide complex or carboxymethylcellulose thiazide complex, or, (f) the povidone thiazide molecular complex, or, (g) a beta-adregenic receptor blocking amine thiazide salt, or (h) an amiloride-thiazide salt.

6.1 In view of that passage it is far from clear what protection is sought by claim 1 of the third auxiliary request which reads:

"Use of a thiazide diuretic <.....>said amount being within the range of 7-25% by weight of the predetermined diuretic effective dose, **and** a mixed cation-anion-resin-thiazide adsorbate salt, or any of the options referred to above, (c), or (d), or (e), or (f), or (h)."

6.2 If understandable at all, claim 1 could, in the board's opinion, only be understood as requiring the simultaneous use of from 7% to 25% of the effective dose of the selected thiazide compound **and** a mixed cation-anion-resin-thiazide adsorbate salt of an unidentified thiazide compound in an unidentified unit dosage amount or any of the other forms (c), or (d), or (e), or (f), or (h) of an unidentified thiazide compound in an unidentified unit dosage amount for the claimed purpose. Such a claim is entirely unsupported by the disclosure in the description of the application as filed contrary to Articles 84 and 123(2) EPC and, moreover, extends the scope of protection conferred by the claims as granted contrary to Article 123(3) EPC. The third auxiliary request must therefore also fail.

Procedural Matters

7. The Enlarged Board of Appeal has interpreted the provisions of Article 113(1) EPC concerning the right to be heard as meaning that a decision against a party which has been duly summoned but which fails to appear at oral proceedings may not be based on facts put forward for the first time during those oral proceedings (see decision G 4/92, OJ EPO 1994, 149, Conclusion 1). Notwithstanding this, in its decision the Enlarged Board of Appeal clearly viewed the possibility of holding hearings in a party's absence, as provided for in Rule 71(2) EPC, in relation to the need for proper administration of justice, in the interests of which no party should be able to delay the issue of a decision by failing to appear at oral proceedings (see especially point 4 of the reasons). This can only mean that parties to the proceedings must expect that, on the basis of the established and plainly relevant facts, any decision may go against them.

As regards new arguments, the requirements of Article 113(1) EPC have been satisfied even if a party who has chosen not to appear consequently did not have the opportunity to comment on them during oral proceedings, insofar as such new arguments do not change the grounds on which the decision is based. In principle, new arguments do not constitute new grounds or evidence, but are reasons based on the facts and evidence which have already been put forward (see especially point 10 of the reasons).

7.1 The board's decision to revoke the patent in suit is based entirely on grounds, facts and evidence which were already known to the appellant/proprietor from the first-instance opposition proceedings and which were

again brought to its attention by the appellant/opponent's written submissions during the appeal proceedings. By electing not to attend the oral proceedings - which it had itself requested - the appellant/proprietor only denied itself the opportunity to present or amplify its own arguments and/or further challenge the arguments of the appellant/opponent, or the reasons for the decision under appeal.

7.2 The board is therefore of the opinion that, in the circumstances of the present case, its decision to revoke the patent in suit conforms with the conclusions of the Enlarged Board of Appeal in decision G 4/92 and does not contravene the appellant's procedural rights as laid down in Article 113(1) EPC, in spite of its elected absence from the oral proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Townend P. A. M. Lançon