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D E C I S I O N
of 24 February 2000

Case Number: T 0867/95 - 3.3.4

Application Number: 85901895.4

Publication Number: 0180597

IPC: A61K 45/06

Language of the proceedings: EN

Title of invention:
Cough/cold mixtures comprising non-steroidal anti-inflammatory drugs

Patentee:
RICHARDSON-VICKS, INC.

Opponents:
SmithKline Beecham Plc
Reckitt & Colman Products Limited
The Wellcome Foundation Limited
Dr. Karl Thomae GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"All requests; inventive step (no); obvious combination - synergistic effect not disclosed in the application as filed"

Decisions cited:
T 0184/92, T 0268/89

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0867/95 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 24 February 2000

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 23 August 1995 revoking European patent No. 0 180 597 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: L. Galligani
Members: R. E. Gramaglia
W. Moser

Summary of Facts and Submissions

I. European patent No. 0 180 597, based on European patent application No. 85 901 895.4, was granted on the basis of 18 claims for all designated Contracting States except AT (hereafter: non-AT States) and 34 claims for the Contracting State AT.

II. Six notices of opposition were filed. Revocation of the patent in its entirety was requested on the grounds of lack of novelty, lack of inventive step (Articles 52, 54, 56 and 100(a) EPC) and insufficiency of disclosure (Articles 83 and 100(b) EPC). Two opponents later withdrew their oppositions.

III. The Opposition Division found that the claims of the main request submitted on 3 November 1994 and those of auxiliary requests "A" to "D" submitted on 20 June 1994 did not meet the requirements of Article 56 EPC and thus revoked the patent.

IV. The following documents are referred to in the present decision:

Schedule "A": A list of the ingredients present in various cough/cold preparations available on the UK market in 1982;

The "KG-S" papers:

(1) Hayakawa H. et al. English translation of Japanese Pharmacology and Therapeutics, Vol. 8, No.2 (1980);

(2) Nakagawa K. et al., English

translation of The Clinical Report, Vol. 13(1) (1979);

(P1) Restorative Sciences, page 1455 (Annex III to the decision under appeal; a post-published document filed by the patentee on 20 June 1995);

(P2) Ferreira S.H. et al., Prostaglandins, Vol. 18, No. 2, pages 179-190 (1979);

(P10) Loh L. et al., J. Neurology, Neurosurgery and Psychiatry, Vol. 41, pages 664-671 (1978)

(P11) Lewis T., Pain, The Macmilland Press Ltd, pages vii, 24-27, 140-141 (reprint 1981).

(P12) Panush R.S., Arthritis Rheum., Vol. 19, No. 5, pages 907-917 (1976);

(P13) Fitzpatrick F.A. et al., Prostaglandins, Vol. 12, No. 6, pages 1037-1051 (1976);

(P14) Robinson D.R. et al., Prostanglandins and Medicine, Vol. 1, pages 461-477 (1978);

(P15) Espey L.L. et al., Fertility and Sterility, Vol. 38, No. 2, pages 238-247 (1982);

(IV-1) Lee K.Y. et al., The Lancet,

pages 1110-1111 (May 1979);

(IV-2) Kailis S.G., Australian J. Pharmacy, pages 145-149 (March 1980);

(IV-3) New York State Journal of Medicine, page 1269 (July 1980);

(IV-4) The Lancet, page 839 (April 1982);

(VI-K/24) Federal Register, Food and Drug Administration, pages 38312-38424 (9 September 1976);

(PH1) to (PH4) The Pharmakon Tests: tests of algesia using mice carried out in 1991-1992 by the Pharmakon Research Inc. and submitted to Analgesic associates, Larchmont, New York US;

(UPJ) The Upjon Tests: clinical trials carried out in 1990 by the Upjohn Company on human patients;

(JJ) The Johnson & Johnson Tests: tests of algesia using mice carried out in November 1992 by Johnson & Johnson, filed on 13 April 1995 in annex to Prof. Meredith's witness statement;

(N) The Pharmacist's Guide: "Nurofen" (1983);

(M) Stacher G. et al., Eur. J. Clin. Pharmacol., Vol. 21, pages 485-490

(1982).

V. The appellant (patentee) lodged an appeal against this decision and submitted a statement setting out the grounds of appeal together with a new auxiliary request "D" on 21 December 1995.

VI. Respondents I, II, III and IV (opponents 01, 03, 04 and 05) filed counterarguments.

VII. The parties were summoned to oral proceedings. In reply to this invitation, respondents I and IV informed the board that they would not attend oral proceedings. During oral proceedings, which took place on 24 February 2000, the appellant, while maintaining the main request, changed the auxiliary requests on file as follows: the set of claims version "C" was made the first auxiliary request, the set of claims version "D" was made the second auxiliary request and a new third auxiliary request was filed. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the following documents:

(a) main request: claims 1 to 6 for all designated Contracting States except AT and claims 1 to 10 for the Contracting State AT, filed on 3 November 1994; or

(b) 1st auxiliary request: set of claims version "C", i.e. claims 1 to 4 for all designated Contracting States except AT and claims 1 to 6 for the

Contracting State AT, filed on 20 June 1995; or

(c) 2nd auxiliary request: set of claims version "D", i.e. claims 1 to 4 for all designated Contracting States except AT and claims 1 to 6 for the Contracting State AT, filed on 21 December 1995; or

(d) 3rd auxiliary request: claim 1 for all designated Contracting States except AT and claim 1 for the Contracting State AT, submitted during oral proceedings.

Respondents I to IV requested that the appeal be dismissed.

VIII. Claim 1 of the **main request** for the non-AT States and for AT read as follows:

"1. A pharmaceutical composition of matter for use in the treatment of cough, cold-like and/or flu symptoms in a mammalian organism, and adapted for unit dosage oral administration, said composition comprising (i) at least one non-narcotic analgesic constituent which is a non-steroidal anti-inflammatory drug (NSAID) which is a propionic acid derivative or a pharmaceutically acceptable salt thereof, in combinatory admixture with (ii) at least one sympathomimetic decongestant selected from pseudoephedrine, phenylpropanolamine or phenylephrine or a pharmaceutically acceptable salt thereof."

Claim 1 of the **first auxiliary request** (version "C") for the non-AT States and for AT read as follows:

"1. A pharmaceutical composition of matter for use in the treatment of cough, cold-like and/or flu symptoms in a mammalian organism, and adapted for unit dosage oral administration, said composition comprising (i) 100-200 mg ibuprofen or a pharmaceutically acceptable salt thereof, in combinatory admixture with (ii) 30 mg pseudoephedrine or a pharmaceutically acceptable salt thereof."

Claim 1 of the **second auxiliary request** (version "D") for the non-AT States and for AT read as follows:

"1. A pharmaceutical composition of matter for use in the treatment of cough, cold-like and/or flu symptoms in a mammalian organism, and adapted for unit dosage oral administration, said composition comprising (i) 200 mg ibuprofen or a pharmaceutically acceptable salt thereof, in combinatory admixture with (ii) 30 mg pseudoephedrine or a pharmaceutically acceptable salt thereof."

The sole claim of **the third auxiliary request** for the non-AT States and for AT read as follows:

"1. A pharmaceutical composition of matter for use in the treatment of cough, cold-like and/or flu symptoms in a mammalian organism, and adapted for unit dosage oral administration, said composition comprising (i) 125-500 mg naproxen or a pharmaceutically acceptable salt thereof, in combinatory admixture with (ii) at least one sympathomimetic decongestant selected from 60-120 mg pseudoephedrine or a pharmaceutically acceptable salt thereof."

IX. In support of the inventive step of the claims of all

requests, the appellant submitted essentially the following arguments:

- The closest prior art was represented by "Schedule A", a list of the ingredients present in various cough/cold preparations available on the market in 1982 and comprising the "old" NSAIDs paracetamol or aspirin together with sympathomimetic decongestants. Alternatively, the closest prior art could be taken as being the "KG-S papers" disclosing the propionic acid NSAID ibuprofen combined with an anti-histamine. Regardless of which starting point was chosen as closest prior art, there was no incentive in modifying the compositions of "Schedule A" or the "KG-S papers" to arrive at the claimed compositions comprising a propionic acid NSAID with a sympathomimetic amine (SAM).

- Rather, the skilled person would have avoided the claimed combination because there was expectation of hypertensive crisis (see documents (IV-1) to (IV-4) and (P1)). Moreover, before the priority date of the patent in suit, there was expectation that SAMs were likely to reduce or destroy the analgesic effect of analgesic drugs, thus leading to hyperalgesia (pain increase). Documents (P11), (P10) and (P2) taught that pain could be mediated through the sympathetic nervous system. Document (P2) also showed that NSAIDs were not able to counteract the hyperalgesic effect of SAMs.

- One could not simply replace the new propionic acid NSAIDs for aspirin or paracetamol in the old compositions of "Schedule A" because the mechanism

of action of the new ingredients was, in the light of the small amount of information available, substantially different from that of the old ingredients (see documents (P12) to (P15)). The skilled person would thus have been discouraged from replacing an old analgesic such a paracetamol or aspirin with a new propionic acid NSAID in a cough/cold combination product.

- The known disadvantages of combination drugs, like eg the fact that combination products could mask underlying secondary infections or comprise components with different pharmacokinetics, would have discouraged the skilled person from making the claimed combinations.

- The claimed combinations were expected to be refused by the Regulatory Authorities unless a special additional benefit such as synergy could be demonstrated.

- Therefore, the skilled person would not have gone into the direction of the claimed combinations and could not have expected that substantial benefits, including synergism, would have been obtained. The patent taught synergy between the ingredients of the claimed compositions (analgesia synergy). Experimental test reports (PH1) to (PH4),(UPJ) and (JJ) further confirmed this.

X. Respondents I to IV essentially submitted the following arguments:

- It would have been obvious to replace aspirin or paracetamol with propionic acid NSAIDs in the

known compositions of "Schedule A" having regard to the known advantages achieved by the latter such as enhanced anti-pyretic and anti-inflammatory activity and lower incidence of untoward side effects (eg, gastrointestinal ulcerations experienced with aspirin and hepatic toxicity caused by paracetamol). This was even more true since ibuprofen was reclassified in the latter part of 1983, so that instead of being available as a Prescription Only Medicine, it became available as an Over The Counter (OTC) medicine to be sold without a prescription.

- The documents cited by the appellant for showing an expectation of hypertensive crisis related to the combination of indomethacin (an acetic acid NSAID) with phenylpropanolamine. No general teaching could be drawn from these documents that combinations based on a propionic acid NSAID and a SAM were expected to induce hyperalgesia.

- Failure to prevent hyperalgesia caused by local administration of isoprenaline (different from the claimed SAMs) using indomethacin (an acetic acid NSAID) could not be interpreted as being the same as saying that the combination of a propionic acid NSAID and a SAM decongestant selected from pseudoephedrine, phenylephedrine and propanolamine given orally would have increased pain.

- The different mode of action of the newly available NSAIDs would have encouraged rather than dissuaded the skilled person from substituting eg ibuprofen for paracetamol.

- The available experimental test reports did not show that there was synergism with the claimed combinations. Synergy was not disclosed in the patent application as filed, and thus the appellant could not rely in support for inventive step on an alleged synergism submitted 8 years after the filing date of the application. Even if a synergistic effect occurred, this was a mere bonus following from doing what was obvious.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. The only point at issue in these appeal proceedings is the inventive step. In respect of this issue, the "KG-S papers" have also been held as the closest prior art in alternative to "Schedule A". The "KG-S papers" relate to clinical investigations on the use of "KG-S" tablets comprising the propionic acid NSAID ibuprofen in combination with an anti-histamine in the treatment of the cold syndrome. The only difference between the claimed composition and the formulation of the "KG-S" tablets lies in that a sympathomimetic decongestant such as pseudoephedrine is further added to the "KG-S" tablets or, alternatively, the anti-histamine is replaced with a sympathomimetic decongestant.

3. Schedule A is a list of 24 cough/cold combination products available on the UK market in 1982. Some products comprise the "old" NSAIDs paracetamol or aspirin and one sympathomimetic decongestant selected

from pseudoephedrine, phenylpropanolamine or phenylephrine. The only difference between the claimed compositions and the formulations of Schedule A is that the "old" NSAIDs paracetamol or aspirin of Schedule A are replaced by the "newer" propionic acid NSAIDs such as ibuprofen and naproxen in the claimed compositions.

4. Although both Schedule A and the KG-S papers are equally promising starting points for arriving at the claimed subject-matter, Schedule A is, in the board's judgement, closer prior art than the KG-S papers. This is because the composition disclosed by the KG-S papers (analgesic/anti-inflammatory agent + anti-histamine) is, as a whole, pharmacologically more remote from the claimed combination (analgesic/anti-inflammatory agent + sympathomimetic decongestant) than the composition of Schedule A (analgesic/anti-inflammatory agent + sympathomimetic decongestant).

5. Within the framework of the problem-solution approach normally adopted by the boards to evaluate the inventive step, the problem the patent in suit seeks to solve vis-à-vis Schedule A is to provide further pharmaceutical compositions for use in the treatment of cough, cold-like and/or flu symptoms comprising an analgesic/anti-inflammatory agent and a sympathomimetic decongestant. Compositions comprising the "newer" propionic acid NSAIDs in admixture with at least one sympathomimetic decongestant is the proposed solution.

6. It has to be established whether or not the above solution, ie the replacement of the "newer" propionic acid NSAIDs for aspirin or paracetamol in the compositions of Schedule A follows in an obvious manner from the prior art.

7. The board observes that the "new" NSAIDs such as ibuprofen have been known since the seventies to be superior vis-à-vis aspirin or paracetamol. It was known, as acknowledged in the application as filed on page 1, line 30 to page 2, line 8, that they exhibited an enhanced anti-pyretic and anti-inflammatory activity with lower incidence of untoward side effects, eg, gastro-intestinal ulcerations experienced with aspirin and hepatic toxicity caused by paracetamol (acetaminophen). It must be concluded that there was a strong incentive in effecting the replacement referred to in point 3 supra, in view of the known advantages that such replacement would have achieved. The board is thus left with the task of establishing whether or not the reasons adduced by the appellant (dealt with under points 8 to 12 infra) were so strong as to discourage the skilled person from effecting the claimed combination of a propionic acid NSAID with a sympathomimetic amine.

8. The appellant refers to documents (IV-1) to (IV-4) and (P1) in support of the view that the skilled person would have avoided the claimed combination because there was expectation of hypertensive crisis. However, as regards documents (IV-1) to (IV-4), the board observes that these documents are concerned with adverse reactions which occur with a combination of indomethacin with phenylpropanolamine. Indomethacin is a member of a different class of analgesic drug (acetic acid NSAID) and exhibits a different structure from that of the propionic acid NSAIDs stated in the claims at issue. The skilled person thus could not extrapolate from document (IV-1) that hypertensive crisis had also to be expected by administration to a patient of the claimed compositions. In conclusion, no general

teaching can be drawn from these documents that the claimed combinations based on a propionic acid NSAID and a SAM were expected to induce hyperalgesia. As for document (P1), it has to be disregarded because of its publication after the priority date of the patent in suit.

9. The appellant also argues that the skilled person would have expected hyperalgesic effects (pain increase) to occur with the claimed combination. The board, however, notes that documents (P11), (P10) and (P2) are concerned with investigations wherein the sympathetic nerve supply is blocked at peripheral regions. These studies are thus not predictive of the effects of SAMs given orally. Further, while it is true that document (P2) shows that indomethacin fails to prevent hyperalgesia caused by isoprenaline, it has to be noted that indomethacin is an acetic acid NSAID (ie a NSAID **different** from the propionic acid NSAIDs stated in the claims at issue) and that isoprenaline is a SAM **different** from the SAMs stated in the claims at issue, and which is, moreover, administered **locally**. Therefore, a general conclusion could not be drawn by the skilled person that the combination of a propionic acid NSAID and a SAM decongestant selected from pseudoephedrine, phenylephrine and propanolamine given **orally** would have increased pain.

10. It is argued by the appellant that since the mode of action of the "new" NSAIDs is significantly different from that of the "old" ingredient aspirin or paracetamol, substitution of the former for the latter requires caution. The skilled person was thus discouraged from replacing eg paracetamol or aspirin with a "new" propionic acid NSAID in a cough/cold

combination product. In the board's judgement, apart from the fact that the "new" NSAIDs such as ibuprofen have been known since the seventies, there was at the priority date of the patent in suit strong evidence of superiority of these new aspirin-like NSAIDs vis-à-vis aspirin or paracetamol. The skilled person would have attributed these superior properties to the somewhat different mode of action of the drugs and would have been encouraged rather than dissuaded from substituting eg ibuprofen for paracetamol.

11. The appellant's line of argument that the known disadvantages of combination drugs would have discouraged the skilled person from making the claimed combinations, is also not convincing. This is because combination drug products for use in the treatment of coughs, colds and flu had been available for many years before the priority date of the patent in suit (see eg Schedule A).

12. As for the appellant's proposition that potential difficulties associated with obtaining regulatory approval were a deterrent to the skilled person from making the claimed combinations, the board disagrees thereto. Questions of regulatory approval are not considered to be a concern of the "skilled person" defined as one or more persons selected from pharmacists, formulators, pharmacologists and/or clinicians, namely (a) person(s) skilled in the art of making drug combinations, who is/are occupied with the sole technical problem of providing further pharmaceutical compositions in alternative to the known ones.

13. Therefore, the above facts invoked by the appellant

were not able to divert the skilled person from replacing the "newer" propionic acid NSAIDs for aspirin or paracetamol in the compositions of Schedule A. The claimed pharmaceutical compositions comprising a known propionic acid NSAID and a known SAM decongestant selected from pseudoephedrine, phenylpropanolamine and phenylephrine thus represent an obvious solution to the problem underlying the patent in suit and do not involve an inventive step.

14. In support of the contention that the claimed compositions are not obvious, the appellant invokes synergy and argues that the skilled person could not have expected that the claimed compositions would have exhibited synergy (analgesia synergy), as can be derived from the patent in suit and from later experimental test reports (PH1) to (PH4), (UPJ) and (JJ). In the board's view, this newly invoked technical effect has the consequence that the technical progress achieved in the claimed subject-matter of the application as filed against the prior art would need to be more ambitiously restated as being not merely the provision of pharmaceutical compositions in alternative to the products listed in Schedule A, but the provision of compositions which display a synergistic effect. The established case law allows restatement of the problem on the basis of objective criteria. According to decision T 184/82 (OJ EPO, 1984, 261), "regarding the effect of the invention", reformulation of the problem can be allowed "provided the skilled man could recognise the same as implied in or related to the problem initially suggested".

15. This is in line with decision T 268/89 (OJ EPO, 1994, 50), according to which it is not permissible to draw

on knowledge acquired only after the date of filing or priority in identifying the problem. It would indeed be unfair for later acquired knowledge to be used to justify a restricted claim. It has thus to be established whether or not the application as filed actually addressed the issue of synergism of compositions comprising a propionic acid NSAID and a sympathomimetic amine (SAM) decongestant, as the appellant maintains.

16. The appellant relies on a statement on page 12, lines 1 to 7 of the application as filed: "Among such Table 1 antihistamines, sympathomimetics, cough suppressant-antitussives and expectorants, in combination with a non-steroidal anti-inflammatory drug, applicants have already demonstrated a synergistically enhanced analgesic and anti-inflammatory response in a mammalian organism, as shown in Example 1", for arguing that the patent teaches "general synergy", and thus synergy also for the claimed compositions comprising a propionic acid NSAID and a sympathomimetic amine (SAM) decongestant.

17. The board, however, is of the opinion that the above passage merely relates to synergy found between ibuprofen and diphenylhydramine of Example 1, ie a combination outside the scope of the claims of the patent in suit because diphenylhydramine is an anti-histamine rather than a SAM decongestant. As regards the possible interpretation of this passage as teaching "general synergy", as the appellant maintains, it has to be noted that Table 1 referred to in this passage relates to 14 antihistamines, sympathomimetics, cough suppressant-antitussives and expectorants. The "non-steroidal anti-inflammatory drug" referred to in this

passage are the following 18 compounds: ibuprofen, naproxen, flurbiprofen, fenoprofen, ketoprofen, suprofen, tolmetin sodium, zomepirac, sulindac, indomethacin, mefenamic acid, meclofenamate sodium, diflunisal, flufenisal, piroxicam, sudoxicam and isoxicam (see page 6, lines 14 to 28), giving rise to 14 x 18 = 258 possible binary combinations. If the board interpreted the above passage as teaching "general synergy", this would imply that **each** of the 258 possible binary combinations contemplated by the application as filed (eg meclofenamate sodium/cyproheptadine or suprofen/ potassium guaiacolsulfonate) **must** exhibit synergy: not only is this not credible, but it is also in contradiction with the appellant's argument that synergy is unpredictable, and that for this reason the claimed compositions are not obvious. Thus, as the application as filed did not address the issue of a synergistic effect in relation to compositions comprising a propionic acid NSAID and a sympathomimetic amine (SAM) decongestant at all, neither an alleged surprising synergy nor later experimental test reports (PH1) to (PH4),(UPJ) and (JJ) can be invoked as a factor in support of inventive step of otherwise obvious combinations of components.

18. Under these circumstances, the appellant's main request is not allowable as the subject-matter of the claims does not meet the requirements of Article 56 EPC.

First auxiliary request (version "C")

19. The first auxiliary request (version "C") differs from the main request in that the claimed composition should comprise 100-200 mg ibuprofen and 30 mg pseudoephedrine. However, the conclusions arrived at by

the board under point 18 supra in respect of the main request are not affected by the restriction of the propionic acid NSAID and the sympathomimetic amine (SAM) decongestant to these individual compounds and the statement of weight ranges which are common in the art (see document (N): 200 mg ibuprofen and document (VI-K/24), page 38403, left-hand column: 30 mg pseudoephedrine). Therefore, under these circumstances, also the appellant's first auxiliary request is not allowable as the subject-matter of the claims does not meet the requirements of Article 56 EPC.

20. It is noted in passing that while the range for ibuprofen and pharmaceutically acceptable salts thereof of 100-200 mg in claim 1 finds a basis on page 7, line 15 of the application as filed, the figure of 30 mg in Table I of the application as filed relates to tablets or capsules of pseudoephedrine hydrochloride available on the market rather than to the unit dosage which is 60-120 mg (see Table I). Thus, while the range 60-120 mg is in the "reservoir" constituted by the application as filed, the figure of 30 mg cannot be taken out of its context of the list of preparations (elixirs, capsules, tablets) available on the shelves of a pharmacy. But the doubts which arise as to whether or not claim 1 of the first auxiliary request meets the requirements of Article 123(2) EPC need not be considered in view of the preceding negative conclusion regarding the issue of the inventive step.

Second auxiliary request (version "D")

21. The second auxiliary request (version "D") differs from the main request in that the claimed compositions should comprise 200 mg ibuprofen and 30 mg

pseudoephedrine. However, the conclusions arrived at by the board under point 18 supra in respect of the main request are not affected by the further restriction of the propionic acid NSAID and the sympathomimetic amine (SAM) decongestant to these individual compounds and the statement of their usual weights (see paragraph 19 supra). Therefore, under these circumstances, the appellant's second auxiliary request is also not allowable as the subject-matter of the claims does not meet the requirements of Article 56 EPC.

22. The considerations relating to Article 123 (2) EPC made in point 20 supra also apply to claim 1 of the second auxiliary request since it comprises the figure of 30 mg.

Third auxiliary request

23. The third auxiliary request differs from the main request in that the claimed composition should comprise 125-500 mg naproxen and 60-120 mg pseudoephedrine. However, the conclusions arrived at by the board under point 18 supra in respect of the main request are not affected by the restriction of the propionic acid NSAID and the sympathomimetic amine (SAM) decongestant to these individual compounds and the statement of their usual weight ranges (see document (M), page 489, right-hand column: 275 mg naproxen and document (VI-K/24), page 38403, left-hand column: 60-360 mg pseudoephedrine). Therefore, under these circumstances, also the appellant's third auxiliary request is not allowable as the subject-matter of the claims does not meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

U. Bultmann L. Galligani