

Veröffentlichung im Amtsblatt	Ja/Nein
Publication in the Official Journal	Yes/No
Publication au Journal Officiel	Oui/Non



Aktenzeichen / Case Number / N° du recours : T 261/87 - 3.3.1

Anmeldenummer / Filing No / N° de la demande : 79 300 364.1

Veröffentlichungs-Nr. / Publication No / N° de la publication : 0 015 334

Bezeichnung der Erfindung: Carminative preparations containing peppermint oil
Title of invention: or its active components
Titre de l'invention :

Klassifikation / Classification / Classement : A61K 9/52

ENTSCHEIDUNG / DECISION

vom / of / du 16 December 1988

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent /
Titulaire du brevet : J.B. Tillott Ltd.

Einsprechender / Opponent / Opposant : Rödler GmbH
Dr. Madaus & Co.

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Articles 54, 56

Schlagwort / Keyword / Mot clé : "Novelty (affirmative) - Per-se product claims
for novel dosage forms of known
pharmaceutically active ingredient"
"Inventive step (affirmative) - novel dosage
form following logically from unobvious
indication"

Leitsatz / Headnote / Sommaire

Europäisches
Patentamt

European Patent
Office

Office européen
des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours



Case Number : T 261/87 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 16 December 1988

Appellant :
(Opponent 01)

Rödler GmbH
Mölsheimer Strasse 36
D-6521 Flörsheim bei Worms

Representative :

von Kreisler, Alek
Patentanwälte Von Kreisler-Schönwald-Fues-Keller
Selting-Werner
Deichmannhaus am Hauptbahnhof
D-5000 Köln 1

Appellant :
(Opponent 02)

Dr. Madaus & Co.
Postfach 91 05 55
D-5000 Köln 91

Representative :

Riedl, Peter
Reitstötter, Kinzebach & Partner Patentanwälte
Sternwartstrasse 4
Postfach 86 06 49
D-8000 München 86

Respondent :
(Proprietor of the patent)

J.B. TILLOTT LIMITED
25 Harley Street
London W1N 2BR
GB

Representative :

Burford, Anthony Frederick
W.H. Beck, Greener & Co.
7 Stone Buildings
Lincoln's Inn
London WC2A 3SZ
GB

Decision under appeal :

Decision of the Opposition Division of the European
Patent Office dated 3 February 1987, posted on
15 May 1987, rejecting the opposition filed against
European patent No. 0 015 334 pursuant to
Article 102(2) EPC.

Composition of the Board :

Chairman : K. Jahn
Members : F. Antony
 W. Moser

Summary of Facts and Submissions

- I. European patent application No. 79 300 364.1, which had been filed on 9 March 1979, was granted as European patent No. 15 334 on 19 May 1982, with five claims, of which the only independent one, Claim 1, reads as follows:

"An enterically coated hard gelatin capsule containing a pharmacologically active ingredient characterised in that said ingredient is peppermint oil in an amount of 0.05 ml to 0.5 ml per capsule."

- II. The Appellants (Opponents) filed notices of opposition against the patent, by duly confirmed telex of 18 February 1983 and by letter received on 19 February 1983, respectively, requesting complete revocation, for alleged lack of inventive step over five cited documents, especially:

- (1) Taschen-Rezeptierbuch von Pharmakon und H. Rödler KG, 192-193 (1978).

Besides, one Appellant (briefly referred to as "Madaus") alleged prior public use by way of a product designated "JHP-Rödler Kapseln".

- III. Further documents were later submitted to the Opposition Division, some by the Appellants, some by the Respondent (patent proprietor), inter alia:

- (3) Rote Liste 1976, Präparat 28114B;
(8) Package insert "JHP Rödler" Kapseln (1981);
(10) Letter from ABDA dated 11 February 1983;

- (11) Bild-Zeitung of 19 November 1981;
- (12) Commercial leaflet "JHP Rödler Kapseln" (1981);
- (13) Documents filed in support of the corresponding USA patent application, comprising in particular:
 - (13a) Greenberger et al. "Drug Treatment of Gastrointestinal Disorders" (1978), 195-198, and
 - (13b) Thesis by Brian K. Evans, "Physical and Biological Properties of Carminatives" (1980), 198;
- (16) Data Sheet "Rowachol Capsules" (1984); and
- (18) Encyclopedia of Common Natural Ingredients" (1980), 231.

IV. In a decision orally announced on 3 February 1987 and posted on 15 May 1987, the Opposition Division rejected the oppositions. It was held that the subject-matter of the patent-in-suit was both novel and inventive. The novelty followed from the fact that the "old" JHP Rödler capsules (which had been sold prior to the application date) were non-enterically coated soft gelatin capsules, and the Rowachol capsules were soft gelatin capsules containing an oil which was not peppermint oil. The latter capsules represented the closest prior art and were for a use other than the treatment of irritable colon - or bowel - syndrome (i.c.s). For such treatment, drugs of very different nature had been previously recommended, with no incentive in the entire prior art as to the use of peppermint oil. It was only after the application date that, as evidenced by (8) and (12), the "new" JHP Rödler capsules, containing peppermint oil in enterically coated capsules, had come to

the market and were described in the literature, with reference to the inventors of the patent-in-suit as originators.

- V. Notices of appeal against the decision of the Opposition Division were filed by the Appellants on 3 and 9 July 1987, respectively, and the appeal fees duly paid. Statements of grounds were submitted on 11 and 24 September 1987, respectively. In these Statements and in later submissions, the Appellants attacked the claims of the patent-in-suit as allegedly unclear. They contested their novelty in view of what they considered an excessive interpretation of the claimed scope by the Respondent, but have admitted during oral proceedings held on 16 December 1988 that there was "formal" novelty in view of the feature of "hard" gelatin capsules in Claim 1. They further took the position that the alleged invention related to a further pharmaceutical use of a known ingredient, which is why a per-se product claim was not admissible. They criticized lack of evidence for any advantages of peppermint oil over other essential oils, and of hard over - allegedly equivalent - soft gelatin capsules. They seek to introduce into the proceedings new documents, showing that the enteric use of peppermint oil against i.c.s. was obvious, in particular

(19) Römpps Chemie-Lexikon, 7th edition (1974), catchword "Pfefferminzöle";

(24) A Systematic Treatise on Materia Medica and Therapeutics (1907),

a literature reference first cited by the Respondent at the pre-grant examination stage; and

- (26) Hornbostel et al. "Innere Medizin in Praxis und Klinik", 2nd edition, vol. IV (1978), 15.155-15.157.

They request that the decision under appeal be set aside and the patent be revoked.

- VI. The Respondent contests the implied assertion that the problem underlying the patent in suit was how to make JHP capsules gastric-juice-resistant and intestine-soluble; in his view, the problem was how to treat i.c.s. It being unknown that JHP could be of possible help, and there being no reason why the known uses thereof should require administration to the intestine and not to the stomach, there was no incentive to modify the capsules accordingly. The literature on the "new" JHP Rödler capsules (i.e. those introduced after the application date of the patent in suit) correctly presented these as a surprising new possibility to treat i.c.s. Further, having regard to the absence of any effective treatment of i.c.s., to the long known use of peppermint oil as a carminative, and to its ready availability, it could not have been obvious to use it for such treatment. As to the Rowachol capsules, these did not contain peppermint oil and served a different purpose, thus they could not render use of the former for the treatment of i.c.s. obvious.

The Respondent requests to dismiss the appeals.

- VII. Besides, in a letter dated 16 July 1987, on which neither of the Appellants has commented, the Respondent requested certain corrections in the Decision under appeal and in the minutes of the oral proceedings held before the Opposition Division on 3 February 1987.

Reasons for the Decision

1. The appeals comply with Articles 106 to 108 and Rule 64 EPC; they are thus admissible.
2. As lack of clarity (Article 84 EPC) is not a ground for opposition (Article 100 EPC) and the claims as granted were not amended during opposition proceedings, there is, in view of Rule 66(1) EPC, no legal basis for the Board to consider the respective objection. It is observed, however, that the literal wording of the claims as they stand, is quite clear in that such wording relates to enterically coated hard gelatin capsules containing an active ingredient which is peppermint oil. In other words, the capsules may additionally contain other inactive components, but the active ingredient contained therein is peppermint oil substantially free from other active ingredients.
3. Under the aspect of the purpose which the invention seeks to achieve, i.e. combatting i.c.s., the Board takes the position that the closest state of the art is not represented by known capsules whose outer material and filling are more or less similar to what the invention teaches, but which were designed to combat different ailments - such as disclosed in (1) or (3), but rather by compositions and methods previously recommended for the treatment of i.c.s. - Thus (13a) and (26) are to be considered the closest prior art.
 - 3.1 In (13a) the chapter dealing with i.c.s. (referred to as "irritable bowel syndrome") commences on page 195. In the section "Treatment" beginning on page 196, anticholinergics are mentioned in the first place. After a brief discussion of the arguments speaking in favour of, and the problems connected with anticholinergic

therapy, the second paragraph of the said section starts with the statement that "Synthetic anticholinergics have been used widely in treating (i.c.s.), but their effectiveness has not been established". Next (page 198), "psychotropic agents" and "other agents" (viz. laxatives and simethicone) are likewise mentioned as possibilities, though with little encouragement.

- 3.2. A similar picture is gained from (26), where the section "Therapie" (page 15.157) commences to read (translation): "The most important therapeutic measure for i.c.s. is a thorough examination of the patient convincing him of the 'non-organic' character or the functional nature of his condition. This will generally require a time-consuming dialogue pointing to the connection between psyche and intestinal function ...". In the sentence bridging the two columns on page 15.157 it is stated that "in addition to simple psychotherapeutic measures including autogenic training, sedatives, psychopharmaceuticals and anticholinergics, taken singly or in combination, may be therapeutically valuable".
4. Expressed in blunt terms, what follows from the two preceding sub-paragraphs is, that no fully satisfactory treatment of i.c.s. existed. This is confirmed by the statements of (12) - no prior art - referred to below in greater detail. Against this background, the problem to be solved by the invention may be seen in proposing means for the effective treatment of i.c.s.
5. As solution to this problem, the patent-in-suit recommends enterically coated hard gelatin capsules containing as pharmacologically active ingredient peppermint oil in a quantitative range from 0.05 to 0.5 ml per capsule. That this simple measure does indeed

solve the problem is credible in view of the undisputed passage of column 3, line 55, to column 4, line 27, of the specification as granted.

6. As to novelty:

6.1. The closest prior art as defined in sub-section 4.1 above relates to entirely different compositions. As against these, the claimed capsule is clearly and without dispute novel.

6.2. Document (1) relates to capsules containing peppermint oil ("spezialbehandeltes japanisches Pfefferminzöl" mentioned on page 193, lines 5 to 4 from the bottom). That this oil, obtained from *Mentha arvensis* and also referred to as JHP oil (abbreviated term for "Japanisches Heilpflanzen-Öl"), is indeed a peppermint oil follows likewise from (19), which defines peppermint oils as essential oils obtained from leaves etc. of various *Mentha* species and goes on stating that, while the pharmacopoeias of most countries approve only oils from *Mentha piperita*, the equivalent oils of *Mentha arvensis* (cornmint) are also used. "JHP oil" is obtained from *Mentha arvensis*; see (8) - no prior art - lines 5 to 6.

Document (1) is silent on whether the capsules are made of hard or of soft gelatin (or of what else), and on whether or not they are enterically coated. The indications mentioned in (1) would rather suggest absence of such coating, but would in no case allow a positive conclusion to the existence thereof, this being sufficient for the finding that the claimed capsules are novel over (1) in that they are enterically coated. Besides, it follows from (10) that sales of the products referred to in (1) were discontinued around early 1980

and resumed in autumn 1981, now - according to (8), which is of course not part of the prior art - with the added indication of i.c.s. ("Reizcolon" mentioned under "Anwendungsgebiete") and enterically coated (reference to "magensaftresistente Kapseln ..." in the heading). This confirms the conclusion that, prior to the recognition of utility against i.c.s., there was no enteric coating provided simply because there was no good reason to provide such.

6.3. The product disclosed in (3) contains a specific mixture of various terpenoid compounds in enterically coated capsules (see the term "Kps. (dünndarmlösl.)" = enterically coated capsule, after "Zus.:" = composition). However, the mixture not only contains two components, viz. camphene and borneol, which are not normally found in peppermint oil; more importantly, it lacks one of the typical constituents of peppermint oil, viz. menthyl acetate (cf. (18), page 231, first paragraph of section "Chemical Composition"). (The argument of one of the Appellants that the menthol content given in an analysis will often comprise esters such as menthyl acetate "calculated as menthol" cannot be accepted; see (13b), last three lines, where "esters calculated as menthyl acetate" are differentiated as against "free alcohols calculated as menthol".) Therefore, this mixture does not represent peppermint oil, which alone is sufficient to make the claimed capsule novel over (3). Besides, it follows from (16) - no prior publication - that the product of (3) consists of soft gelatin capsules.

6.4. Summarizing, while it is non-controversial that the claimed product differs from both, the products of (1) and of (3), in that it consists of hard gelatin capsules, this is not the only difference; rather, the

capsules of (1) are not enterically coated, and those of (3) do not contain peppermint oil.

- 6.5. The documents (8), (11), (12), (13b) and (16) cannot affect novelty, because they were published after the application date of the patent-in-suit.
- 6.6. The subject-matter of Claim 1 is thus novel.
7. Novelty of Claim 1 having been established, the further objection of one of the Appellants according to which the claims of the patent in suit should have been held in those terms allowed by the Decision of the Enlarged Board Gr 05/83 ("Second medical indication/Eisai", OJ EPO 1985, 64) must fail. The Board has already held allowable, in its Decision T 289/84 of 10 November 1986 (not published in the OJ EPO, but referred to, e.g., in Schulte "Patentgesetz", 4th edition, page 33, footnote 513i), a product claim for a therapeutic product novel by way of its form of application, in spite of the active ingredient contained therein being known.

In applying this principle to the present case, the claimed product as a whole - i.e. peppermint oil in enterically coated capsules - being novel (see section 6 above), Articles 52 and 54 EPC do not preclude protection by a per-se product claim.

8. It remains to be investigated whether or not it was obvious for the notional person skilled in the art confronted with the problem defined in section 5 above, to solve the said problem by providing the claimed capsules.
- 8.1. Clearly and without dispute, the documents considered to constitute the closest prior art - (13a) and (26) - do

not in themselves give any hint to treat i.c.s. by administering peppermint oil; for, the therapy recommended in these documents utilises entirely different drugs or methods.

- 8.2. It is true that components of mint plants have for a very long time been used in treating and alleviating various ailments of the human organism. In particular, peppermint oil in encapsulated form has previously been administered to the digestive tract for a number of purposes.
- 8.2.1. So for instance, (1) describes capsules - without mention to enteric coating; cf. sub-section 6.2 above - containing peppermint oil for a number of very different indications reaching from their use as a choleric or carminative to the treatment of menopausal disorders. However, there is no suggestion in (1) to use these capsules in connection with i.c.s., nor could the mention of digestion-related (e.g. carminative) uses be construed as pointing in the appropriate direction, given the absence of an enteric coating which is an obvious prerequisite for the treatment of local problems in the colon.
- 8.2.2. Document (3), mentioning (systemic) treatment with an encapsulated mixture of oils different from peppermint oil, of various conditions originating from anomalies of the gall, could likewise provide no incentive to the skilled person to use such capsules against i.c.s., not to speak of using against i.c.s. capsules containing specifically peppermint oil.
- 8.2.3. The very old document (24) - which deals with the therapeutic use of peppermint and its constituents such as peppermint oil against symptoms often connected with

i.c.s., such as flatulent colic, spasmodic pain in the bowels, griping and diarrhea, side by side with entirely different conditions such as nervous headache and gonorrhoea (see page 340, section "Specific Symptomatology") - is considered irrelevant as a possible pointer for the skilled person towards the specific use of encapsulated peppermint oil against the notoriously difficult-to-treat ailment i.c.s. (cf. sub-sections 4.2 to 4.4 above). If anything, (24) shows that the state of the art existing 70 years earlier came pretty close to making the invention, but did not actually make it, and meanwhile the development trend turned away from peppermint oil and went into an entirely different direction.

- 8.2.4. The remaining documents are either even more remote or have been published after the application date of the patent-in-suit - the latter applies to (8), (10), (11), (12), (13b), (16) and (18) - and can therefore not be cited to question existence of an inventive step. On the contrary, however, especially (12) can serve to support the unobviousness of the claimed proposal: This document, to which particular weight can be given because it originates from one of the Appellants, refers to the experiments of three British scientists two of whom are the inventors of the patent-in-suit, and states that the opinion that i.c.s. was very difficult to treat successfully "must now be corrected" (page 1, right-hand column, penultimate paragraph). In the framed paragraph further up in the same column, this document speaks of "surprising new possibilities" which Rödler's enterically coated capsules containing "JHP" (referred to as "peppermint oil" in (1)) are offering for the treatment of i.c.s. and related disorders. This praise by experts in the field is also reflected in the brief article headed "Wenn's im Magen rumpelt ..." in (11) and

supported by the undisputed fact that one of the inventors got a scientific award for this contribution to pharmaceutical practice (Respondent's letter dated 22 February 1988, page 5, lines 12 to 9 from the bottom).

- 8.2.5. In summary, the Board is satisfied that the various known uses for peppermint oil in human therapy did not constitute an incentive for the skilled person to provide enterically coated capsules containing peppermint oil for the treatment of i.c.s.
- 8.3. This being so, it is immaterial whether hard gelatin capsules in the context of the patent-in-suit have any advantage over - equally novel - enterically coated soft gelatin capsules containing peppermint oil, or whether peppermint oil is in any way better than other essential oils. Technical advance is not a separate requirement for patentability under the EPC; so once the claimed proposal is novel and, in the light of the problem to be solved, involves an inventive step (as has been shown above), it is not necessary for the Respondent to prove that his capsules are superior to, say, those described in (3) when these would be used for the purpose disclosed in the patent-in-suit. Accordingly, Claim 1 is held patentable.
9. Claims 2 to 5 relate to preferred embodiments of the subject-matter of Claim 1; hence they are also patentable.
10. The requests of the Respondent's letter dated 16 July 1987 cannot be considered by this Board, which is only concerned with the matter under appeal. Any corrections of errors found appropriate would have to be made by the instance who made such errors (if any), i.e. by the

Opposition Division; subject to Rule 89 EPC insofar as any errors in the decision, and subject to their recollection of the oral proceedings on 3 February 1987 insofar as the minutes thereof are concerned.

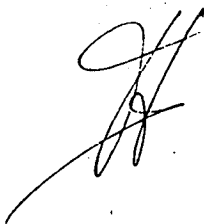
As such recollection will be the less perfect, the later a request for correction is considered, it is desirable to deliver minutes of oral proceedings to the parties with minimal delay, and equally for a party seeking corrections to submit the respective request promptly upon receipt of the minutes.

Order

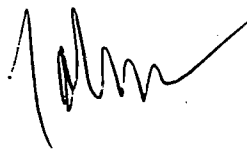
For these reasons, it is decided that:

The appeals are dismissed.

The Registrar



The Chairman



00696



22.2.89