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19

Aktenzeichen / Case Number / N<sup>o</sup> du recours : T 255/85

Anmeldenummer / Filing No / N<sup>o</sup> de la demande : 79 301 935.7

Veröffentlichungs-Nr. / Publication No / N<sup>o</sup> de la publication : 0 009 913

Bezeichnung der Erfindung: Antacid composition, method of its manufacture and  
Title of invention: fondant mix comprising an antacid compound  
Titre de l'invention :

Klassifikation / Classification / Classement : A 61 K 9/00

**ENTSCHEIDUNG / DECISION**  
vom / of / du 16 July 1987

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent /  
Titulaire du brevet : Beecham Group PLC

Einsprechender / Opponent / Opposant : Gödecke AG

Stichwort / Headword / Référence : Antacid composition/Beecham

EPO / EPC / CBE Article 56

Kennwort / Keyword / Mot clé : "Inventive step" - "Discouragement in the prior art".

Leitsatz / Headnote / Sommaire



Case Number : T 255/85

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.1  
of 16 July 1987

**Appellant :**  
(Opponent) Gödecke AG  
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**Representative :**

**Respondent :**  
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**Representative :**  
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**Decision under appeal :** Decision of Opposition Division of the European  
Patent Office dated 7 August 1985 rejecting  
the opposition filed against European patent  
No. 0 009 913 pursuant to Article 102(2) EPC.

**Composition of the Board :**

**Chairman :** K. Jahn  
**Member :** R. Andrews  
**Member :** G. D. Paterson

## Summary of Facts and Submissions

- I. The mention of the grant of the patent No. 0 009 913 in respect of European patent application No. 79 301 935.7, filed on 19 September 1979 and claiming priority of 21 September 1978 from a prior application in the United Kingdom, was announced on 8 June 1983 (cf. Bulletin 83/23) on the basis of 10 claims for the Contracting States BE, CH, DE, FR, IT, NL and SE and 10 claims for the Contracting State GB. Claim 1 for the first mentioned Contracting States reads as follows:

"A shaped antacid composition comprising a finely divided solid antacid compound dispersed in a fondant confectionery base which comprises a two phase system of solid sugar particles and a dissolved sugar liquid base".

Claim 9 for these Contracting States relates to an antacid mix comprising a finely divided solid antacid compound in combination with a fondant confectionery base as defined above.

Claims 1 and 9 for the Contracting State GB correspond to Claims 1 and 9 for the other Contracting States except for the proviso that the confectionery base is substantially free of dispersed fat material.

- II. On 5 March 1984 the Appellant filed a notice of opposition requesting the revocation of the patent on the grounds that the subject-matter of the patent was not patentable because it belonged to the state of the art according to Articles 54 and 56 EPC. The opposition was supported by the following documents:

- (1) US-A- 1 122 294
- (2) US-A- 3 642 535

- (3) Brockhaus Encyklopädie, 1968, page 400
- (4) US-A- 2 926 121
- (5) FR-M- 6 167
- (6) US-A- 1 502 207

III. The Opposition Division rejected the opposition by a decision dated 7 August 1985 on the basis that the subject-matter of the patent was novel in the light of the disclosure in documents (5) and (2). Document (5) discloses tablets comprising an antacid material and hydrated dextrose containing 8.5 to 9.2% by weight of water or hydrated lactose containing 1.8 to 5.2% by weight of water and document (2) teaches that fondant sugar size crystals are particularly suitable for the preparation of tablets. Furthermore the Opposition Division considered that documents (2) and (5) were not relevant for the assessment of the inventive step since they were not concerned with the technical problem underlying the disputed patent of providing antacid compositions with improved taste and "mouth-feel". With respect to document (1) the Opposition Division reached the conclusion that the term "fondant" used in this document did not clearly refer to the present two-phase confectionery base and, in any case, since the disclosure was restricted to fatty oils, would not lead the skilled person to the solution of the present problem. Document (4) was considered to teach away from the present invention since it disclosed that attempts to incorporate alumina gel (a solid antacid) in usual candy-making ingredients, such as sucrose and sorbitol, were unsatisfactory.

IV. A notice of appeal was lodged by the Opponent against this decision on 9 October 1985 with payment of the appropriate fee. In a statement of grounds filed on 4 December 1985 the Appellant argued that the skilled person must assume that

the term "fondant" in document (1) refers to a composition consisting of sugar and water. Furthermore it was known from document (5) to mask the unpleasant taste of antacids by using certain sugar bases. Thus it would be obvious to investigate suitability for the formulation of antacids of sugar forms that are known and usual for tablet formulations. To demonstrate that it is usual in the pharmaceutical field to use fondant for tablet formulations the Appellant has referred to the medicament "Contradol-N" as disclosed in the Rote Liste 1974. The Appellant has also expressed the opinion that if generally known fondant confectionery bases do not solve the problem underlying the disputed patent, the claims should be restricted accordingly.

- V. The Respondent has contended that the mere admixture of solid antacid with solid sugar material in a compressible tablet as disclosed in document (5) would not solve the problem underlying the patent-in-suit since discrete solid particles of antacid would be released in the mouth to produce the undesirable "gritty" or "chalky" texture. The Respondent has taken the view that the expression "fondant-pastille" used in connection with the medicament "Contradol-N" is applied to indicate that the medicament melts in the mouth. However, there are many sugar based formulations which could melt in the mouth but which would not provide the advantages of the present invention.
- VI. In the oral proceedings held on 16 July 1987 the Appellant restated his previous arguments with respect to inventive step having regard to the disclosure in documents (4) and (5). The Appellant also referred to US-A- 3 439 089 (7), which was cited in the European Search Report, in order to demonstrate that the problem of grittiness in medicated candy-like formulation is well-known in the art. The Respondent contended that the only prior art document

related to candy-like formulations containing antacids is document (4) and maintained that the disclosure of this document did not render it obvious to use a fondant confectionery base in combination with finely divided solid antacids.

VII. The Appellant requested that the decision under appeal be set aside and that the patent be revoked. The Respondent requested that the appeal be dismissed and the European patent be maintained in amended form on the basis of Claims 1 to 10 of both sets of claims as granted with the proviso that the expression "free of protective colloidal structure round the antacid" be inserted after the word "compound" in Claims 1, 9 and 10 of each set of claims. Alternatively, as an auxiliary request, the Respondent requested that the patent be maintained in amended form on the basis of claims which differ from the claims of the main request in that the word "aluminium" is inserted into Claims 1, 9 and 10 of each set of claims between the words "solid" and "antacid".

#### **Reasons for the Decision**

1. The Appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. There are no formal objections to any of the versions of the present claims. The proviso inserted in Claims 1, 9 and 10 in accordance with the Respondent's main request serves to more clearly distinguish the claimed subject-matter from the disclosure in document (4). The restriction to a finely divided solid aluminium antacid in accordance with the auxiliary request finds support on page 2, lines 33 and 34 of the published patent application (cf. also page 2, lines 43 and 44 of the printed patent specification).

3. The patent-in-suit relates to shaped antacid compositions comprising finely divided antacid compounds dispersed in a fondant confectionery base which comprises a two phase system of solid sugar particles and dissolved sugar liquid phase. Shaped antacid compositions, for example in the form of tablets, are naturally well-known and it is equally well-known that, due to their gritty or chalky texture, the taste and mouth-feel of these conventional antacid compositions has been found to be unpleasant. Furthermore the use of sugar-based products to mask the unpleasant taste of orally administered medicaments, including antacids, is part of the common general knowledge of the skilled person in this art. This common general knowledge is reflected, for example, in documents (1), (4) and (5). Document (1) discloses the use of a fondant confectionery base to render solid preparations of fatty oils, such as cod-liver oil, sweet and palatable. Document (4) relates to therapeutic candy-like products, for example in the form of marshmallows or gum drops, containing alumina gel, which are both pleasant in taste and attractive in appearance. Finally document (5) describes antacid tablets which melt in the mouth containing dextrose hydrate or lactose hydrate.

3.1. In the light of this common general knowledge the problem underlying the patent-in-suit in accordance with the main request is to be seen in providing further palatable shaped antacid compositions.

According to the patent-in-suit this problem is solved by dispersing finely divided solid antacid compounds in a confectionery fondant base. In view of the Examples in the patent-in-suit the Board is satisfied that this technical problem is plausibly solved.

- 3.2. After examination of the cited documents the Board has concluded that this technical teaching is not disclosed in any of them and the claimed subject matter is, therefore, novel. Since novelty is not disputed it is not necessary to consider this matter in detail.
4. It still remains to be examined whether the requirement of inventive step is met by the claimed subject-matter in accordance with the Respondent's main request.

Bearing in mind that antacid compositions should be palatable it would readily occur to the skilled person to investigate the incorporation of finely divided solid antacids into normal sugar-based products. From his common general knowledge he would be aware that there are eight principal types of sugar-based products, viz. hard candy, caramel or toffee nougat or nougatine, fondant, fudge, jellies, marshmallows, and gums or pastilles. It would be a matter of routine experimentation to incorporate a finely divided solid antacid compound into all these well-known sugar-based products. In the course of this routine work the skilled person would arrive at the proposed solution according to the disputed patent in accordance with the Respondent's main request. Therefore the Board considers that the subject-matter of Claims 1, 9 and 10 in accordance with the Respondent's main request does not involve an inventive step. Dependent Claims 2 to 8, which relate to preferred embodiments of the compositions according to Claim 1 do not contain any independent inventive features and are also unpatentable.



In contrast to the Opposition Division the Board does not consider that document (4) teaches away from the general concept of incorporating finely divided solid antacid compounds into sugar-based products. A proper reading of this document reveals that difficulties are only to be expected in the preparation of therapeutic candies containing alumina gel (cf. Column 1, lines 53 to 64).

- 4.1. In the light of this prior document (4) the problem underlying the patent-in-suit in accordance with the Respondent's auxiliary request is to be seen in providing further shaped candy-like antacid compositions containing aluminium antacid compounds. The solution to this problem is to disperse the aluminium antacid compound in a fondant confectionery base as defined above.

From Examples 1 to 4 and 6 of the disputed patent the Board is satisfied that this technical problem is credibly solved.

- 4.2. The novelty of the solution of the technical problem in accordance with the Respondent's auxiliary request follows from the conclusion that the solution to the more general technical problem in accordance with the main request was not disclosed in any of the cited prior art documents (cf. paragraph 3.2).
- 4.3. Document (4) discloses therapeutic candy-like products containing fully hydrated alumina gel as the antacid compound. However it was found that normal candy making ingredients did not produce a satisfactory candy or an effective antacid product (cf. Column 1, lines 53 to 64). In order to obtain a candy-like product in which the necessary degree of hydration of the alumina gel was maintained and in which the acid consuming capacity of the alumina gel and the speed with which it neutralises acid was not appreciably

reduced, it was essential to provide a hydrated protective colloidal layer around the aluminium hydroxide (cf. Column 2, lines 31 to 34 and lines 42 to 48). From the disclosure of this prior art document a skilled person would conclude that in order to incorporate an alumina antacid compound in a sugar-base product it is essential to use a protective colloid and a particular sequence of combining the various ingredients of the compositions (cf. Column 1, line 69 to Column 2, line 6).

Thus the teaching of this document represents a very clear warning to the skilled person that any attempt to incorporate an alumina antacid compound in a sugar-base product would fail in the absence of a protective colloidal material and would serve to actively discourage the skilled person from investigating the incorporation of alumina antacid compounds into sugar-based products. The Board is of the opinion that the question to be asked is not whether the skilled person could have used a fondant confectionery base to produce a candy-like product containing an alumina antacid compound but whether he would have done so in the expectation of obtaining a satisfactory product in the light of the teaching in document (4) (cf. T 2/83, OJ 6/84, page 265, particularly point 7 on page 270).

In the Board's view none of the cited prior art documents gives any indication that the solution to the technical problem of providing candy-like products containing alumina antacid compounds lay in dispersing the finely divided solid compound in a fondant confectionary base.

- 4.4. Document (5) relates to antacid tablets with improved disintegration properties comprising a hydrated dextrose containing 8.5 to 9.2% by weight of water or a hydrated lactose containing 1.8 to 5.2% by weight of water as the disintegrating agent (cf. left-hand column of page 1, lines

1 to 4 and the Summary). The use of these two specific sugars to produce conventional antacid tablets which are smooth and pleasant in the mouth (cf. 3rd to 5th lines from the bottom of the right-hand column of page 1 and the Table on page 2) would not provide an incentive to the skilled person to ignore the clear warning in document (4) with regard to the incorporation of alumina antacid compounds into usual sugar-based products, such as a fondant confectionery base.

- 4.5. Document (7), which was referred to by the Appellant during the course of the oral proceedings, relates to medicated lozenges which are free of grittiness (cf. column 2 lines 11 and 12). In the absence of any reference to alumina antacid compounds this document would not be of any assistance to the skilled person in his search for the solution to the present technical problem.
- 4.6. Since during the oral proceedings neither the parties nor the Board referred to any of the other less relevant documents cited during the opposition or appeal proceedings, any discussion of them is superfluous.
- 4.7. It is therefore concluded that the subject-matter of Claims 1, 9 and 10 of both set of claims in accordance with the Respondent's auxiliary request involves an inventive step. Dependent Claims 2 to 8 of both sets of claims are allowable in view of the patentability of their respective Claim 1.

#### **Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside .

2. The case is remitted to the first instance with the order to maintain the patent in amended form on the basis of the Claims in accordance with the auxiliary request and the description to be amended accordingly.

The Registrar

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The Chairman

A handwritten signature in black ink, appearing to be the name 'H. Linn' written in a cursive, flowing style.