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Anmeldenummer / Filing No / N<sup>o</sup> de la demande : 80 303 773.8

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Bezeichnung der Erfindung: Improved gamma-sorbitol polymorph and uses thereof  
Title of invention:  
Titre de l'invention :

Klassifikation / Classification / Classement : C07C 31/26

**ENTSCHEIDUNG / DECISION**  
vom / of / du 29 August 1990

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent /  
Titulaire du brevet : ICI Americas Inc.

Einsprechender / Opponent / Opposant : CPC Europe Limited

Stichwort / Headword / Référence : Gamma-sorbitol/ICI

EPÜ / EPC / CBE Articles 54, 83 and 99(1) and Rule 55(c)

Schlagwort / Keyword / Mot clé : "Sufficiency of disclosure (yes)"  
"Novelty (confirmed) - not an inevitable result  
of prior art process"  
"Function of communications in inter-parte  
proceedings"

Leitsatz / Headnote / Sommaire



Case Number : T 173/89 - 3.3.1

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.1  
of 29 August 1990

**Appellant :**  
(Opponent)

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**Decision under appeal :**

Interlocutory decision of the Opposition Division of  
the European Patent Office dated 24 January 1989  
concerning maintenance of European Patent  
No. 0 032 288 in amended form.

**Composition of the Board :**

**Chairman :** K.J.A. Jahn

**Members :** R.W. Andrews

J. Stephens-Ofner

## Summary of Facts and Submissions

- I. European patent No. 0 032 288 in respect of European patent application No. 80 303 773.8, which was filed on 24 October 1980, was granted with ten claims on 14 March 1984 (cf. Bulletin 84/11).
  
- II. On 14 December 1984 a notice of opposition was filed requesting the revocation of the patent on the grounds that its subject-matter lacked novelty and inventive step and that it did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person. The opposition was supported, inter alia, by the following document:
  - (1) US-A-3 973 041.
  
- III. In a communication dated 22 August 1986, the Opposition Division, in commenting on the pleaded ground of anticipation, drew attention to a lack of supporting evidence.
  
- IV. By an interlocutory decision dated 24 January 1989, the Opposition Division maintained the patent in amended form on the basis of Claims 1 to 8 submitted during the oral proceedings held on 21 January 1987.

The Opposition Division held that the disclosure of the disputed patent was sufficient since it disclosed two processes in detail by which the claimed product may be obtained.

The Opposition Division also held that the subject-matter of the amended Claim 1 was novel since the process specifically disclosed in document (1) was different from

the one exemplified in the patent in suit and that the physical parameters of the claimed gamma-sorbitol were different from the corresponding data for the product disclosed in this document.

The Opposition Division considered that the claimed subject-matter involved an inventive step since, in the absence of any teaching in document (1) with respect to the tableting properties of the gamma-sorbitol disclosed therein, it was not obvious that gamma-sorbitol with improved tableting properties could be prepared.

- V. An appeal was filed against this decision on 10 March 1989 with payment of the prescribed fee.

In his Statement of Grounds of Appeal filed on 24 May 1989 and during the oral proceedings held on 29 August 1990, the Appellant contended that Claim 1 was open to objection under Article 84 EPC insofar as features (e) and (f) were concerned. The Appellant also argued that, although the claims were not restricted to the use of gamma-sorbitol for the manufacture of tablets, parameters (c) and (d) of Claim 1 were only of any benefit in this context. Moreover, the use of these parameters would place a manufacturer who uses gamma-sorbitol obtained by the prior art method for the production of chewing gum at a serious disadvantage with regard to the question of infringement.

The Appellant also maintained that the disputed patent failed to disclose the specific process conditions which have to be employed to yield the claimed product. In support of this ground he argued that, since the general process described in the disputed patent was anticipated by the detailed disclosure of document (1), it was incumbent upon the Patentee to teach the skilled person how he must work differently from document (1) to obtain the claimed

product rather than the one disclosed in that document and, following the decision T 226/85, to give guidance and information on what to do in case of failure to obtain the desired product. Furthermore, the Appellant contended that there was no indication in the disputed patent of the criticality of process variables, such as rotational speed, feed temperature or feed rate, with respect to the nature of the product produced.

The Appellant also alleged that the claimed gamma-sorbitol polymorph was not novel since it is the inevitable product of the process disclosed in document (1) as shown by the submitted experimental evidence. According to the Appellant, this experimental evidence also demonstrated that random differences in shaft rotation speeds and feed rates between the example of document (1) and those of the patent in suit were of no technical significance. The Appellant further contended that document (1) discloses a product which has a melting point in the range 96° to 101°C, as opposed to a product having a melting range of 96° to 101°C.

- VI. The Respondent argued that the Appellant has failed to prove, unequivocally, that the claimed gamma-sorbitol polymorph is the inevitable result of the process disclosed in document (1), since none of the Appellant's experiments were carried out under exactly the same process conditions as those disclosed in document (1). Moreover, the Respondent considered that the large variations in the process parameters in the Appellant's experiments would have masked any effects that slight variations in these parameters might have had on the properties of the gamma-sorbitol obtained.

The Respondent also contended that, in view of the fact that the heats of fusion of the products of the Examples of the disputed patent were determined by differential scanning calorimetry (DSC), it was clear that the melting points were also measured by this method.

The Respondent further maintained that it was not necessary to know the heat of fusion of 100% crystalline gamma-sorbitol since a comparison with the DSC thermograms of the products obtained by repeating Examples I and II of the disputed patent would indicate whether the material was the desired gamma-sorbitol polymorph.

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 that the patent be maintained on the basis of the documents filed during oral proceedings. Claim 1 of these documents reads as follows:-

"A modified gamma-sorbitol polymorph having improved tableting properties characterized in that the modified gamma-sorbitol has:

- (a) a disrupted and loose crystal structure visible on a scanning electron microscope at 2000x power;
- (b) a surface area value for a -20/+60 mesh powder of the polymorph of at least about 1.0 square meter per gram;
- (c) a compression value of about 3.82 mm or less, said compression value being the thickness in millimeters of a round, flat, bevelled edge tablet which is 15.9 mm (5/8 inch) in diameter and which is formed under

2.9 tonnes (3.2 U.S. tons) pressure on a 1.00 + 0.05 gram charge consisting of 99.5% by weight of a -20/+60 mesh powder of the polymorph and 0.5% by weight of magnesium stearate;

(d) a Strong Cobb Arner hardness value of at least about 22 kilograms for the round tablet of paragraph (c);

(e) a gamma-sorbitol crystal content of about 100% by weight; and

(f) a melting point of 100 to 101°C.

Independent Claims 5 and 8 relate to confectionery and pharmaceutical compositions respectively comprising the modified gamma-sorbitol polymorph of Claim 1.

VIII. At the conclusion of oral proceedings the Board's decision was announced.

#### Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. The notice of opposition was filed on 14 December 1984. Amongst other matters, it alleged lack of novelty on the ground that the process of prior document (1) would inevitably produce the claimed product. This fact was merely asserted, but was in no way supported by evidence of the kind required by Rule 55(c) EPC.

In the communication dated 22 August 1986, i.e. nearly two years after the filing of the notice of opposition, the Opposition Division stated as follows (paragraph 3.8):

"Opponent, who is contesting the novelty of the subject-matter of the claims of EP-B1-32 288 has the burden of proof in this respect. This holds especially in the present situation, where two separate indicators (melting point and new process of production) support the novelty of the products concerned. It is not sufficient for such a purpose to rely solely on assumptions and theoretical considerations (cf. e.g. the explanations in respect to the heat diffusion). It is necessary to provide data which show that the products of D1 (working example), and examples 1 and 2 of EP-B1-32 288 are identical ...". This passage of the communication constitutes a clear invitation to the Opponent to improve his case in a particular respect, namely by providing evidence, omitted from his notice of opposition, contrary to Rule 55(c), of identity between the products of the opposed patent and the products obtained by carrying out the process described in prior document (1).

The Board is aware that Article 114(1) EPC confers a certain measure of inquisitorial function upon the instances of the European Patent Office, as well as on the Boards of Appeal, because it states (English version) that: "in proceedings before it the European Patent Office shall examine (emphasis added) the facts on its own motion". By contrast, the German and French texts of this passage are by no means so peremptory. Furthermore, the Board is also mindful of the purpose of Article 114(2), which allows the European Patent Office to disregard facts or evidence which "are not submitted in due time" - a requirement that finds expression with equal force in all the three languages.

Article 99(1) EPC and Rule 55(c) EPC, clearly lay down that the due time for filing evidence in opposition cases is at the date of filing the notice of opposition. In addition, the "General Principles for Opposition Procedure in the



EPO" (OJ EPO 1989, 417) give further guidance in relation to the time and manner in which the parties' cases in opposition proceedings should be presented. Thus, in paragraph 2, it is stated: "The EPO's aim remains to establish as rapidly as possible, in the interests of both the public and the parties to the opposition proceedings, whether or not the patent may be maintained given the Opponent's submissions. It seeks to achieve this by means of a speedy and streamlined procedure ..." (emphasis added). Paragraph 8 goes on to state "Under Rule 55(c), the notice of opposition must contain an "indication" of the facts, evidence and arguments in support of the grounds of opposition. This requirement is to be interpreted as meaning that the notice of opposition must at least indicate clearly to the proprietor the case he has to answer ..." (emphasis added). Paragraph 13, in dealing with facts and evidence not submitted in due time, lays down: "In order to expedite proceedings, parties should in principle submit all facts, evidence and requests at the beginning of the procedure. Where this is not possible, the facts, evidence or requests must be submitted at the earliest opportunity. If relevant facts or evidence are submitted by a party only at a late stage of the proceedings without a very good reason and, if as a consequence, unnecessary costs are incurred by another party, this will be taken into account in apportionment of costs ...". Thus the underlying principle, clearly recognised and implemented by the Boards of Appeal, e.g. in T 117/86, OJ EPO 1989, 401; as well as in T 182/89 (to be published, headnote published in OJ EPO 8/1990), is one of early and complete presentation of the parties' case, as opposed to the piecemeal and tardy introduction of their arguments and evidence. It is this jurisprudence, together with the express wording of Article 114(2) EPC, that sets the legal limit upon the inquisitorial power of the instances of the European Patent Office, as well as of the

Boards of Appeal, which power, therefore, should not be interpreted as extending to the carrying out of a roving inquiry into the facts alleged and the evidence adduced, even at a late stage in the proceedings, in an attempt to establish (as far as possible) the "absolute truth" in relation to a matter at issue. It should also be remembered that in opposition proceedings, the degree of the burden of proof is one of balance of probability (Zeolites, T 219/83, OJ EPO 1986, 211), as opposed to some greater degree of proof, e.g. proof beyond reasonable doubt.

Lastly, all instances of the European Patent Office and, in particular, the Boards of Appeal, are required to abide by the principle of judicial impartiality, and accordingly refrain, even when exercising their legitimate powers under Article 114 EPC as a whole, from giving one-sided assistance in inter partes matters.

In its above-mentioned communication of 22 August 1986 the Opposition Division quite plainly invited one party, namely the Opponent, to improve its novelty-attack by filing evidence of a certain type, which the Opponent then duly proceeded to do. In the Board's opinion, the expression of preliminary conclusions in communications in inter partes proceedings is, in itself, objectionable, unless their sole purpose is to clarify matters and/or to curtail the length and complexity of proceedings. It is a fortiori undesirable, and inconsistent with the above cited jurisprudence and General Principles, for communications in such cases to contain express or even implied invitations to one party to improve his case in a specific manner.

3. There are no formal objections to the present claims under Article 123 EPC. In particular, the present Claim 1 results from a combination of Claims 1 and 5 as filed and granted. Claims 2 to 8 correspond to original and granted Claims 2, 3 and 6 to 10 respectively.

- 3.1 With regard to the Appellant's objection to the characterisation of the modified gamma-sorbitol in Claim 1 in terms of its melting point, the Board is convinced that, in view of the use of DSC to determine the percentage of gamma crystal content of products obtained in Reference Example 1 and Examples I and II, the skilled person would automatically conclude that the melting point of the product is the melting peak temperature as determined in known manner by DSC.
- 3.2 The Board is also satisfied that the requirement that the crystal content of the modified gamma-sorbitol is about 100% by weight does not introduce any ambiguity into Claim 1 since a comparison of the DSC thermogram of the unknown product with that of a sample produced by accurately following the instruction set forth in Examples I and II of the patent in suit would enable the skilled person to establish the gamma crystal content of the product in question.
- 3.3 Therefore, the Board has no doubts that a skilled person in this particular area of chemistry would be in a position to decide whether a crystalline sorbitol possesses the physical properties set out in the present Claim 1 and fulfils the criteria in the tests defined therein.
- 3.4 Although it is true that parameters (c) and (d) are only of benefit to the tablet manufacturer, the claimed modified gamma sorbitol is stated to be less gritty than prior art products (cf. column 4, lines 11 to 21). This statement, which has not been challenged by the Appellant, clearly implies that the product claimed in the patent in suit would possess properties that would be of benefit to the chewing gum manufacturer.

Since the present product was not available to a manufacturer before the claimed priority date, the possible infringer would only have to consider whether his gamma sorbitol possessed the properties listed in the present Claim 1 only if he or his supplier changed their method of manufacturing gamma sorbitol. The listed parameters are in no way unusual and could be checked by any competent analytical laboratory.

4. Articles 83 and 100(b) EPC require that the invention is disclosed in a manner that is sufficiently clear and complete for it to be carried out by the skilled person.
- 4.1 According to the disputed patent, the modified crystalline gamma-sorbitol, which is the subject-matter of the present invention, is preferably produced by feeding molten sorbitol at a temperature of 96° to 97°C to a mixer in which the molten magma is simultaneously cooled and kneaded (cf. column 4, lines 22 to 30 and column 5, lines 10 to 36). In the examples commercially available, continuous mixers are used. For one of these mixers the length, nominal diameter, heat exchanger surface area, internal volume and nominal power are given (cf. the sentence bridging columns 5 and 6). The operating conditions for this mixture are specified in terms of the shaft rotation speed, blade tip speed, production rate of sorbitol and water jacket temperature (cf. Examples I and II). Additionally, it is disclosed that, apart from the introduction of preheated sparged air through a sintered metal tube inserted in the feed line, the mixer was closed to the atmosphere (cf. column 6, lines 11 to 17, column 7, lines 62 and 63 and column 8, lines 57 and 58).
- 4.2 Since none of the Appellant's experiments complied in every detail with Example I or II of the disputed patent, there is no evidence available to the Board from which it could

be inferred that the skilled person, who faithfully followed the instructions given in Examples I and II, would not obtain a modified crystalline gamma sorbitol falling within the terms of Claim 1. However, it was pointed out in paragraph 3 of the decision T 226/85 (cf. OJ 1988, 336), that for the disclosure of a patent to be considered sufficient not only must the exemplified specific embodiments be reproducible but so must any embodiment which falls within the ambit of the claim.

4.3 During the oral proceedings, the Respondent admitted that a certain amount of trial and error is necessary to establish suitable process conditions in the crystallisers to produce crystalline gamma sorbitol falling within the terms of Claim 1. However, in the present circumstances, the Board does not consider that the necessity of carrying out a certain number of test runs places an undue burden on the skilled person in the field of sorbitol chemistry or that such a skilled person would be required to exercise any inventive ingenuity to establish suitable process conditions given the information in the disputed patent as regards the type of mixer to be used, viz. continuous twin screw mixers which impart a high shearing force at low shaft speed (cf. column 4, lines 57 to 60).

4.4 It is also clear from the disclosure of the disputed patent that, in his investigations to establish sets of process conditions other than those exemplified, the skilled person would have to examine four main process variables, i.e. melt feed rate, shaft rotation speed, feed temperature and water jacket temperature. Using the process condition used in Reference Example 1 and Examples I and II as the starting point, the skilled person in the art of crystallisers would have no difficulty in devising a series of experiments to examine the effects of the individual process parameters, particularly since the possible

variations in the temperature throughout the system are restricted by the requirements that the feed must be molten and that the plastic magma consisting of molten sorbitol and gamma-sorbitol crystals has to be continuously discharged from the mixer. Additionally, the disputed patent teaches the possible use of the water jacket at less than full capacity at low feed rates (cf. Example II).

- 4.5 Therefore, in these circumstances, the Board is satisfied that the disclosure of the disputed patent is sufficient to enable the skilled person to put the invention into practice.
- 4.6 The above-mentioned decision T 226/85 also held that, although in certain circumstances a reasonable amount of trial and error is permissible, the skilled person must be lead directly towards success through the evaluation of initial failures in the light of adequate information in the patent specification or on the basis of his common general knowledge. Alternatively, in the case of random experiments, a statistical acceptable rate of success should be achieved (cf. paragraph 8).

The present case may be distinguished from this earlier case insofar as there is no evidence to support an allegation that the skilled person could not reproduce the invention by repeating the Examples of the disputed patent or that their successful repetition would be in any way fortuitous. Furthermore, in view of the Examples and information in the disputed patent, any trial and error would be of the informed type with a high expectation of success.

5. With regard to novelty, document (1) discloses, in general, that a gamma-sorbitol polymorph may be prepared by passing molten sorbitol at a temperature ranging from 90° to 126°C

through a water-cooled mixer wherein it is subjected to high speed, high shear mixing while simultaneously kneaded and cooled prior to extrusion onto a cooling surface (cf. column 1, lines 45 to 49). According to the detailed disclosure of this document, molten sorbitol at a temperature of 96.8°C is fed into a mixer similar to the one described in Reference Example 1 of the disputed patent at a feed rate of 22.7 kg/h (50 lbs/h). The mixer blades are rotated at 31 rpm and the water jacket temperature is 15°C. The sorbitol is obtained as a coarse single crystalline mass having a heat of fusion of 45.9 calories per gram and a melting point ranging from 96° to 101°C (cf. column 1, lines 51 to 65). According to Examples 2 and 3, chewing gum and bubble gum, respectively, are prepared using crystalline sorbitol containing 92% of the gamma polymorph.

- 5.1 During the opposition and appeal proceedings, the Appellant submitted the results of numerous experiments in which sorbitol was crystallised in a mixer similar to the one described in document (1) and the disputed patent. However, none of these experiments were carried out under the precise conditions disclosed in document (1). Therefore, it has not been demonstrated to the Board's satisfaction that a skilled person following the precise disclosure of document (1) would inevitably obtain a modified gamma-sorbitol having all the properties (a) to (f) referred to in the present Claim 1.

Although document (1) could be construed as disclosing a gamma-sorbitol having a melting point of 101°C, there is no disclosure in this document which would suggest that this product would fulfil requirements (a) to (e) of the present Claim 1. In fact, the inventor named in both document (1) and the patent in suit stated categorically that if the skilled person were to follow the teaching of document (1)

he would obtain a dense product. Thus, even if this dense product had a melting point of 100° or 101°C, it would not meet the requirements (a) to (d).

Therefore, in the Board's judgement, the subject-matter of present Claim 1 and that of the dependent Claims 2 to 4, which relate to preferred embodiments of the invention according to Claim 1, is novel in the light of the disclosure of document (1). The confectionery and pharmaceutical compositions, which form the subject-matter of Claims 5 to 8, are also novel, since they comprise the novel modified gamma sorbitol of Claim 1.

6. During the appeal proceedings, the Appellant did not pursue his objection that the subject-matter of the patent in suit did not involve an inventive step. Having considered this matter, the Board sees no reason to disagree with the Opposition Division's conclusion that, having regard to the teaching of document (1), the claimed subject-matter was inventive.

**Order**

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

1. The appeal is dismissed.
2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the documents filed during oral proceedings.

**The Registrar:**

  
M. Beer

**The Chairman:**

  
K.J.A. Jahn