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D E C I S I O N
of 9 October 2003

Case Number: T 1150/01 - 3.3.2

Application Number: 91914668.8

Publication Number: 0497985

IPC: A61K 47/38

Language of the proceedings: EN

Title of invention:
Coating base for pharmaceutical film and production thereof

Patentee:
Shin-Etsu Chemical Co., Ltd.

Opponents:
THE DOW CHEMICAL COMPANY
Clariant GmbH

Headword:
Base for film coating pharmaceuticals/SHIN-ETSU

Relevant legal provisions:
EPC Art. 54(1)(2), 56

Keyword:
"Main request: novelty of product-by-process claim (no): the claim encompasses known products"
"First auxiliary request: admissibility (no): too late filed"
"Second auxiliary request: novelty (yes): none of the cited documents discloses all the process features of the method claim"
"Inventive step (no): there is no evidence of an improvement achieved by the process features"

Decisions cited:
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Catchword:
-

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Case Number: T 1150/01 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 9 October 2003

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 24 August 2001 concerning maintenance of European patent No. 0497985 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: M. Ortega Plaza
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No 0 497 985 based on the application No. 91 914 668.8 (filed as international application WO 92/03167) was granted on the basis of 4 claims.

Independent claim 1 as granted read as follows:

"1. A base for film-coating pharmaceuticals comprising a cellulose ether having a low degree of polymerization obtainable by causticizing a pulp having a copper number of not more than 0.4 g/100 g, adding an etherifying agent to form a cellulose ether having a high degree of polymerization, then refining it with hot water, drying by heating to adjust the moisture content of the cellulose ether to 1 to 5% by weight, finely pulverizing the dried cellulose ether and depolymerizing the fine powder."

Independent claim 4 as granted read as follows:

"4. A method for preparing a base for film-coating pharmaceuticals comprising a cellulose ether having a low degree of polymerization obtained by causticizing a pulp having a copper number of not more than 0.4 g/100 g, adding an etherifying agent to form a cellulose ether having a high degree of polymerization, then refining it with hot water, drying by heating to adjust the moisture content of the cellulose ether to 1 to 5% by weight, finely pulverizing the dried cellulose ether and depolymerizing the fine powder."

II. The following documents *inter alia* were cited in the proceedings:

(1) IPPTA, Vol. 24, No 4, Dec. 1987, 67-73

(6) EP-A-0 210 917

(13) Ullmans Encyclopedia of Industrial Chemistry, Vol. A5, Verlag Chemie, Weinheim/New York, 1986, pages 461 to 468

III. Opposition was filed by two opponents and revocation of the patent in its entirety was requested pursuant to Article 100(a) EPC on the grounds of lack of novelty and lack of inventive step and to Article 100(b) EPC on the grounds of lack of sufficiency of disclosure.

IV. The appeal lies from an interlocutory decision of the opposition division maintaining the patent in amended form under Articles 102(3) and 106(3) EPC.

The opposition division considered that the amendments introduced in the main request (claims 1 and 4 filed with the letter of 13 October 1999, claims 2 and 3 as granted) met the requirements of Article 123(2) EPC, since the features introduced in claims 1 and 4 were based in the specification of the application as filed. It also considered that the amendments did not introduce a lack of clarity into the amended claims (Article 84 EPC).

The opposition division further considered that the disclosure of the patent in suit provided sufficient information to carry out the invention as claimed and hence the requirements of Article 83 EPC were met.

As regards the novelty of the subject-matter of independent claims 1 and 4, the opposition division took the view that no single piece of prior art cited during the opposition proceedings disclosed, in combination, all the features specified in the said claims.

Additionally, the opposition division considered the allegation of public prior use made by opponent I as insufficiently substantiated.

As regards inventive step, the opposition division considered that document (6) represented the closest prior art. It defined the technical problem as to provide cellulose ether bases for film coating pharmaceuticals having improved whiteness and a low degree of polymerisation. The opposition division considered that the problem was solved in the light of the examples.

The opposition division further considered that there was no clear indication in the prior art that cellulose pulps with a low copper number would be particularly suitable for the manufacture of cellulose ether bases for pharmaceutical coatings. The opposition division also stated that the skilled person could have contemplated using the features specified in the claims for making cellulose ether bases for coatings but would not have been able to recognise that using each of

these features would lead to cellulose ethers with improved whiteness.

V. The appellant (opponent II) lodged an appeal against that decision. In its grounds of appeal it pursued the issues relating to Article 123(2) EPC with respect to the specification of the pulverization conditions in the independent claims, as well as the issues relating to lack of novelty for the products defined as products-by-process and lack of inventive step for the products and the process claimed. It also filed with its grounds of appeal additional technical data.

VI. A communication of the Board was sent as annex to the summons for oral proceedings. The attention of the parties was drawn to the passages in the application as originally filed serving as basis for the amendment concerning the pulverizing step in the independent claims. The Board expressed its preliminary opinion that this amendment could be considered allowable. Moreover, the Board reminded the parties of the particularities relating to product-by-process claims.

VII. The appellant announced by its letter of 26 June 2003 that it would not attend the oral proceedings.

VIII. Opponent I, which is a party as of right, announced with its letter of 18 March 2003 that it did not intend to attend the oral proceedings.

IX. With its letter of 14 July 2003 the respondent (patentee) replied to the Board's communication with arguments in favour of the novelty of the product claim 1.

X. Oral proceedings were held before the Board on 9 October 2003.

The respondent maintained its main request as on file and filed two amended sets of claims, as auxiliary requests, during the oral proceedings.

Claim 1 of the main request read as follows:

"1. A base for film-coating pharmaceuticals comprising a cellulose ether having a low degree of polymerization obtainable by causticizing a pulp having a copper number of not more than 0.4 g/100 g, adding an etherifying agent to form a cellulose ether having a high degree of polymerization, then refining it with hot water, drying by heating **while maintaining the temperature of the cellulose ether to be dried in the range of 40 to 80° C and maintaining the inner surfaces of the drying apparatus at a temperature of not more than 100°C,** to adjust the moisture content of the cellulose ether to 1 to 5% by weight, finely pulverizing the dried cellulose ether **using an impact pulverizer for not more than one minute** and depolymerizing the fine powder." (*emphasis added by the Board*).

Claim 4 of the main request read as follows:

"4. A method for preparing a base for film-coating pharmaceuticals comprising a cellulose ether having a low degree of polymerization obtained by causticizing a pulp having a copper number of not more than 0.4 g/100 g, adding an etherifying agent to form a

cellulose ether having a high degree of polymerization, then refining it with hot water, drying by heating **while maintaining the temperature of the cellulose ether to be dried in the range of 40 to 80°C and maintaining the inner surfaces of the drying apparatus at a temperature of not more than 100°C,** to adjust the moisture content of the cellulose ether to 1 to 5% by weight, finely pulverizing the dried cellulose ether **using an impact pulverizer for not more than one minute** and depolymerizing the fine powder." (*emphasis added by the Board*).

Claim 1 of the first auxiliary request differed from claim 1 of the main request by the introduction of the following "**being free of impurities and having a viscosity as a 2% aqueous solution as determined at 20°C of not more than 20 cST"** (*emphasis added by the Board*), after the expression "cellulose ether having a low degree of polymerization".

The second auxiliary request contained one claim, which was identical to claim 4 of the main request.

XI. The respondent's argument relating to the admissibility of the auxiliary requests filed during the oral proceedings may be summarised as follows:

The first auxiliary request was filed in order to overcome the Board's objections with respect to a possible lack of novelty of the product claim. It was filed at such a late stage because the Board's communication (sent as annex to the summons for oral proceedings) was not sufficiently detailed. The scope of the amended product claim 1 was narrowed in the

first auxiliary request. Moreover, the modifications arose from a combination of claims (claim 2 was introduced into claim 1) and from the introduction of an expression taken from the description of the application as originally filed ("being free of impurities").

The respondent further argued that the description of the patent in suit was not too long, therefore this modification of the claim could have been expected.

The second auxiliary request merely concerned the deletion of the product claims.

The respondent's arguments with respect to novelty may be summarised as follows:

The product of claim 1 was directed to a base for film-coating pharmaceuticals comprising a cellulose ether having a low degree of polymerization and which was obtainable by specific process steps, which had an impact on the product structure and which made the product different from the known products. Basically, this was due to the avoidance of chromophoric groups such as carbonyl groups formed through the modification/oxidation of the cellulose ether, which sharply increase the yellow index of the cellulose ether and cannot be removed to a great extent. Moreover, the cellulose ethers may contain impurities which are not carbohydrates and which cannot be extracted in the etherification step. By conducting the process steps of claim 1, a cellulose ether free of impurities was obtained.

None of the prior art products had the degree of whiteness of the products according to claim 1.

In particular, document (6) disclosed products with a certain whiteness degree and stated specific yellow index values for the products. However, the products of the patent in suit showed lower yellow index values than the known products due to the specific process steps (the use as starting material of a pulp with a low copper number, the temperatures and the moisture content in the drying step, and the conditions used in the pulverization step).

The respondent also stated that harsh drying conditions or excessive pulverisation lead to degradation of the products.

Additionally, the respondent argued that the method claimed was clearly novel since none of the prior art documents disclosed all the process features in combination.

With respect to inventive step the respondent's arguments may be summarised as follows:

Document (6) was the closest prior art. The problem was to provide a method for preparing a base for film-coating pharmaceuticals comprising a cellulose ether with improved whiteness.

The problem had been plausibly solved over document (6) in view of the yellow index values shown by the experiment results given on table 2 of the patent.

Besides lower yellow index values than those of the products of document (6), the yellow index of the tablet coated with the cellulose ether according to the patent in suit was surprisingly low and stable over time.

The reaction conditions for the depolymerization were not defined in the claims, but the skilled person would not provide for depolymerization conditions affecting the yellowness of the products.

The solution was not obvious in the light of the cited prior art, since that gave no indication to modify the known processes by the features defined in the claims as the solution to the technical problem.

In particular, there was no indication in document (6) of the copper number of the cellulose pulp, of the temperature in the drying step or of the conditions to be used in the pulverization step.

The respondent stated that the copper number of the starting materials according to the invention was extremely low. In reply to the appellant's submissions, the respondent did not deny that cellulose pulps having such low copper number were commercially available at the time of the invention, but it contended that there was no incentive in the prior art to use such products for the claimed method.

There was no suggestion in the prior art to combine the three mentioned features in order to achieve products with an improved degree of whiteness.

The teaching of document (13) was very general and although this document disclosed a certain percentage of moisture to be maintained at the drying step, the document did not disclose any temperatures or the milling conditions. Furthermore, there was no specific mention in document (13) of the copper number of the starting materials.

Finally, the respondent stated that the claimed process avoided the need for bleaching.

XII. The appellant requested that the decision under appeal be set aside and that the European patent No. 0 497 985 be revoked.

The respondent requested (main request) that the appeal be dismissed and that the patent be maintained as amended by the decision under appeal or alternatively that the decision under appeal be set aside and that the patent be maintained in accordance with either the first or second auxiliary requests filed during the oral proceedings.

Reasons for the Decision

1.1 The appeal is admissible.

1.2 However, the admissibility of the two set of claims filed by the respondent during the oral proceedings before the Board has to be considered.

1.2.1 The respondent argued, in justification of the late filing of these requests, that they concerned an attempt to overcome objections raised by the Board against the novelty of the product claim.

1.2.2 The Board indeed called the parties' attention to the issue of novelty of the product claims (in view of their "product-by-process" nature) in the annex to the summons to the oral proceedings, which was sent on 18 of December 2002, i.e. about 10 months before the date of the oral proceedings.

The Board's communication said *inter alia*: "Hence, the question arising when assessing the novelty of the subject-matter of claim 1 is whether the process as defined in claim 1 confers physical characteristics imparting novelty to the product (cellulose ether) with respect to the cellulose ethers known in the art.".

The Board notes that the respondent replied in its letter of 14 July 2003 to the novelty objection raised in the Board's communication.

1.2.3 Therefore, the Board holds that the respondent had sufficient time and ample opportunities to provide further amended claims before the oral proceedings. If the respondent chose to file the new set of claims at such a late step, it risked facing an admissibility objection, all the more so as the requests were filed after the appellant had announced that it was not attending the oral proceedings.

1.2.4 Claim 1 of the first auxiliary request has been amended not only by incorporating claim 2 of the previous set of claims on file, but also by introducing a further feature from the description. The Board considers that the feature introduced from the description has an influence on the assessment of the patentability of the product claims which could not have been predicted from the written submissions.

1.2.5 In conclusion, the Board considers the first auxiliary request submitted during the oral proceedings to be inadmissible, since it was filed too late.

1.2.6 With respect to the second auxiliary request submitted during the oral proceedings the Board considers it to be admissible, since it merely relates to the deletion of the product claims. The only remaining claim in the second auxiliary request is the method claim (claim 4 of the main request already on file).

1.3 In the Board's communication sent as annex to the summons for oral proceedings the Board expressed a positive preliminary opinion in relation to the amendment objected to by the appellant under Article 123(2) EPC in its grounds of appeal. The appellant did not argue this further and the Board sees no reason to differ from its preliminary opinion.

Furthermore, the amended claims relate to restrictions of the claimed subject-matter in the granted version and meet the requirements of Article 123(3) EPC.

1.4 The appellant did not pursue during the appeal proceedings the opposition ground relating to Article 100(b) EPC and the Board sees no reason to differ in this respect from the conclusions of the opposition division.

2. *Main request*

2.1 Claim 1 relates to "a base for film-coating pharmaceuticals comprising a cellulose ether having a low degree of polymerization". Accordingly, claim 1 is directed to a product *per se*. Claim 1 further defines the cellulose ether having a low degree of polymerization by its production process and thus the cellulose ether is defined as a "product-by-process".

The expression "a base for film-coating pharmaceuticals" only adds, to the "cellulose ether" claimed, the condition of suitability linked to its use as a constituent of a base for film-coating pharmaceuticals.

2.1.1 Cellulose ethers having a low degree of polymerization, which are suitable as constituents of a base for film-coating pharmaceuticals are known, in particular from document (6) (page 1, first sentence, second paragraph, page 2 last paragraph, page 7, lines 3 to 10).

Moreover, the cellulose ethers having a low degree of polymerization and high whiteness disclosed in document (6) are prepared by depolymerization of a cellulose ether with a high degree of polymerization (page 4, lines 5, 6 and page 4, second paragraph).

2.1.2 It remains to assess whether the cellulose ether of claim 1 can be distinguished from those of the prior art, particularly from those of document (6), by the process steps mentioned in the claim.

2.1.3 It is to be noted that claim 1 defines the chemical transformations responsible for the structural characteristics of the product (mixture of products) obtained from the initial cellulose pulp only in very general terms such as "etherification", "depolymerization" and that the products of document (6) are also obtained by depolymerization of etherified cellulose.

2.1.4 The process features specified in the claim merely relate to work up conditions of intermediate steps. These work up conditions may have a certain influence in avoiding degradation of the intermediate products already obtained, but that influence is negligible as a characterizing feature for the final end products, since the claim remains silent with respect to the reaction conditions for the major chemical transformations which the products undergo.

2.1.5 Furthermore, the claim lacks any characterization of the obtained products apart from the expressions "cellulose ethers having a low degree of polymerization" (final product) or "cellulose ethers having a high degree of polymerization" (intermediate product).

2.1.6 Therefore, the Board can only conclude that claim 1 encompasses known cellulose ethers having a low degree of polymerization such as those disclosed in document (6).

2.1.7 With respect to the respondent's argument relating to an avoidance of chromophoric groups (such as carbonyl) in the end compounds and to the improved whiteness of the end products, the following has to be said: neither the degree of substitution (DS) nor the yellow index (YI) of the cellulose ethers (intermediate and final products) are defined in the claim.

Moreover, in view of the lack of specification in the claims of the main transformations "etherification" and "depolymerization", it remains open how many free OH groups remain in the compounds which undergo oxidation and lead to degradation products, *inter alia* during the depolymerization process.

Additionally, the term "depolymerization" alone encompasses both mild and more harsh conditions, e.g. with respect to the concentration of hydrogen chloride in the reaction medium. The impact on the yellowness of the end products has been shown in document (6) (page 5, lines 16 to 20).

Therefore, the alleged avoidance of reducing-type by-products such as those having carbonyl groups or avoidance of degradation in previous intermediate steps cannot serve to characterise the final end product claimed if the product is obtained under any chemically meaningful depolymerization conditions from a cellulose

ether broadly defined (without any indication of its YI or its DS), as having a high degree of polymerization.

2.1.8 Finally, an initial low copper number of the cellulose pulp used as starting material does not provide for the absence of degradation by-products in the final end products or for a high purity of the final end products, which mainly depend on the reaction conditions of several chemical transformations which the starting products have to undergo and which are not specified in the claims.

2.2 In conclusion, the main request fails to meet the requirements of Article 54(1) and (2) EPC.

3. *Second auxiliary request*

3.1 Claim 1 of the second auxiliary request relates to a "method for preparing a base for film-coating pharmaceuticals comprising a cellulose ether having a low degree of polymerization".

3.2 The method claimed in claim 1 of the second auxiliary request is novel, since none of the prior art documents cited in the opposition and appeal proceedings discloses all the process features appearing in the claim.

3.3 The closest prior art is document (6) which relates to a method for the preparation of a cellulose ether having a decreased degree of polymerization (low average molecular weight) and having high whiteness. The cellulose ether product obtained by the method of document (6) gives a 2% by weight aqueous solution

having a viscosity of 20 centipoises **or lower** (*emphasis added by the Board*) at 20°C (page 2, last paragraph, page 3, lines 1 to 10).

3.3.1 The cellulose ether products obtained in document (6) are useful "as a coating agent of solid medicament forms of which high whiteness is particularly desirable" (page 7, second paragraph).

3.3.2 The preparation of the cellulose ether having a decreased degree of polymerisation takes place according to document (6) by depolymerization of a broad variety of cellulose ethers with the condition that they have a high degree of polymerization (page 3, last paragraph, page 4, lines 1 to 7).

It is further disclosed on page 4, lines 7 to 10: "For example, the **starting** cellulose ether should give a 2% by weight aqueous solution having a viscosity of at least 20 centipoises up to several hundreds of centipoises at 20°C".

3.3.3 Moreover, the cellulose ether having a high degree of polymerization should be, as disclosed in document (6), in powder form, and have preferably a particle size distribution as fine as desired in order to facilitate the depolymerization reaction under the conditions disclosed in said document (page 4, lines 13 to 17).

3.3.4 Document (6) is silent about the specific origins or preparation of the cellulose ether having a high degree of polymerization which is used as starting material for the depolymerization. However, in view of the fact that the class of cellulose ethers mentioned at the

passage bridging pages 3 and 4 (alkyl and hydroxyalkyl celluloses such as methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyalkyl alkyl celluloses such as hydroxyethyl methyl cellulose, etc.) is very well known in the art, it can only be concluded that any commercially available products or products obtainable by conventional means are suitable as starting material, except those having impurities making them unsuitable for the pharmaceutical use (such as certain derivatives originating from recycling cellulose waste materials).

3.4 The respondent defined the problem underlying the patent in suit as to provide a method for preparing a base for film-coating pharmaceuticals comprising a cellulose ether with improved whiteness.

3.4.1 However, there is no evidence to demonstrate that the process features specified in the claim positively influence the whiteness of the end product independently from the physical and chemical transformations mentioned very broadly in the claim.

The data displayed in table 2 of the patent in suit, referred to by the respondent, cannot serve as a straight comparison with document (6), since the products treated and obtained are not comparable. All the examples in table 2 relate to the preparation of hydroxypropyl methyl cellulose products, whereas the specifically prepared products in document (6) are methyl cellulose and hydroxyethyl cellulose products.

3.4.2 Therefore, the alleged presence of an improvement with respect to the known products cannot serve as a basis for the technical problem solved by the invention.

3.5 In view of the above analysis, the Board is not satisfied that the problem defined by the respondent has been plausibly solved by the claimed invention.

3.6 Accordingly, the problem to be solved can only be seen as the provision of an alternative method for preparing a base for film-coating pharmaceuticals comprising a cellulose ether having a low degree of polymerization.

3.7 The problem is solved by the method features of claim 1 for the preparation of the cellulose ether, as fine powder, having a high degree of polymerization.

3.8 In the light of the examples and the description of the patent in suit, the Board is satisfied that this problem has been plausibly solved.

3.9 It remains to be investigated whether the proposed solution is obvious in the light of the prior art to the skilled person in the field, i.e. an organic chemist with practical knowledge of industrial pharmaceutical technology.

3.9.1 The skilled person starting from document (6) would apply his or her common general knowledge to the conventional preparation of the cellulose ether having a high degree of polymerization to be subject to depolymerization.

3.9.2 Document (13) is a well known encyclopaedia which discloses in its entry for cellulose ethers such a conventional method for preparing them.

The process as shown in Figure 2 of document (13) comprises the *inter alia* the following: treatment with aqueous NaOH of cellulose, etherification, neutralization, isolation of crude cellulose ether, purification by extraction of salts and by-products, optionally compounding and cross linking, drying and finally milling.

For the production of cellulose ethers with viscosities lower than 50 000 mPa s (2% aqueous solution, ambient temperature), the method consists of starting from a cellulose pulp almost free of lignin, **highly purified**, well-bleached, and with high á-contents (page 466, second paragraph of point 2.1 under the heading "Row Material"). The skilled person clearly recognises in this definition a cellulose pulp having a low copper number.

Causticizing, etherification and neutralization conditions are disclosed on pages 466 to 467 of document (13).

3.9.3 With respect to the workup, document (13) discloses a purification by means of washing with hot water (that means refining with hot water). This purification allows the elimination of by-products and degradation products (page 467, right column paragraph before the last).

Document (13) also discloses the drying of the product. In that context document (13) teaches: "**Overheating** or **prolonged drying** should be avoided because decreased solubility or **thermal degradation** of the product may occur. Therefore, cellulose ethers **should not be dried exhaustively**, and **1-10% of the water** should remain in the product." (*emphasis added by the Board*) (page 468, left column, second paragraph).

Document (13) further indicates that "The material is subsequently milled under mild conditions." (page 468, left column, third paragraph).

3.10 Consequently, the skilled person faced with completing and putting into practice the method disclosed in document (6) only needs common general knowledge as represented by document (13). It is indeed within the skilled person's common knowledge to find by routine experimentation the temperature for avoiding overheating or thermal degradation in the drying step and the pulverizer type (to be chosen among those commercially known) together with an adequate time for achieving mild milling of the cellulose ether having a high degree of polymerization.

3.10.1 In the absence of any evidence showing a specific effect related to the temperature used in the drying step, the reference to the process feature "drying by heating while maintaining the temperature of the cellulose ether to be dried in the range of 40 to 80°C and maintaining the inner surfaces of the drying apparatus at a temperature of not more than 100°C" can only be regarded as a **careful drying step**, for avoiding

overheating and thermal degradation as known from document (13).

3.10.2 Similarly, in the absence of any evidence showing a specific effect related to the use of an impact pulverizer **for not more than one minute**, such a process step only provides milling conditions for the fine powder preferably required by the depolymerization method disclosed in document (6).

In particular, it is to be noted that the claim merely states a maximum pulverization time and the use of an impact pulverizer in general, but it remains silent about the particle size of the powder.

In both examples 4 and 5, shown in table 2 of the patent in suit, the particle size of the pulverized cellulose ether is of the order of 50 µm.

However, such a specific particle size is not an inevitable result of using any impact pulverizer for not more than one minute and therefore does not limit the claimed subject-matter.

3.10.3 In conclusion, there is no evidence that the features specified in the claims for the work up conditions have any influence on the whiteness of the end products other than that achieved by the conventional methods for drying and milling disclosed in document (13).

3.10.4 With respect to the moisture content, it does not require further consideration by the skilled person, since the claimed moisture content of 1 to 5% fully

overlaps with the range 1 to 10% specifically disclosed in document (13) (page 468, left column).

3.10.5 Furthermore, document (6) indicates: "A commercially available product of cellulose ethers **usually contains from about 0.5 to about 2.5% by weight of moisture**"(*emphasis added by the Board*). This moisture content in the starting cellulose ether should be taken into calculation for adjusting the concentration of the solution of hydrogen chloride used as agent for the depolymerization (page 5, last sentence, page 6 first sentence).

3.11 Therefore, the Board concludes that the method claimed in claim 1 of the second auxiliary request lacks an inventive step since it relates to the obvious reproduction by the skilled person of the teaching of document (6) in the light of general knowledge (as shown by document (13)) and routine experimentation.

3.11.1 With respect to the respondent's argument that document (13) does not specify the copper number of the cellulose pulp to be treated, the following has to be considered.

It was undisputed by the parties that, the lower the copper number, the higher the purity of the cellulose pulp and that, the lower the copper number, the lower the amount of reducing-type by-products or degradation products possessing chromophoric groups such as carbonyl groups. This was known long before the priority date of the patent in suit (e.g. document (1), pages 69 to 70).

To use highly purified products is a standard aim in preparative organic chemistry for pharmaceutical uses. Hence, the skilled person when following the teaching of document (13, with a view to subsequent pharmaceutical use as disclosed in document (6), would have chosen the purest cellulose pulps available, i.e. those with the lowest copper number possible.

3.11.2 Finally, it was also undisputed by the respondent that cellulose pulps having a copper number of not more than 0.4 g/100 g were commercially available products at the priority date of the patent in suit.

3.11.3 Additionally, and contrary to the respondent's arguments, the method of claim 1 does not specify the direct use of a **wood** pulp in the causticizing and etherification.

In its broadest sense the expression "pulp" employed in the claim merely means "a soft, wet, shapeless mass of material".

Hence, the impregnation of a cellulose powder with a solvent or its pre-treatment with aqueous NaOH and consequent swelling, leaves the cellulose as pulp to be further treated with highly concentrated NaOH, i.e. the causticizing of a cellulose pulp takes place as in document (13) (page 466, right column, two last paragraphs).

3.11.4 Finally, the method claimed does not necessarily prevent bleaching, as stated by the respondent; it may prevent bleaching at a late stage if the depolymerization conditions chosen are those disclosed in document (6) (page 7, second paragraph).

3.12 Accordingly, the second auxiliary request is rejected for lack of inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Townend U. Oswald