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Datasheet for the decision of 14 January 2016

Case Number: T 1609/12 - 3.3.03

Application Number: 06735129.6

Publication Number: 1858970

IPC: C08L1/28, C08B11/08, C08B11/20, C08B15/00, C08L1/08, C09D101/28

Language of the proceedings: EN

Title of invention:

BLOCKY HYDROXYETHYLCELLULOSE, DERIVATIVES THEREOF, PROCESS OF MAKING, AND USES THEREOF

Patent Proprietor:

HERCULES INCORPORATED

Opponents:

THE DOW CHEMICAL CO.
AKZO NOBEL CHEMICALS INTERNATIONAL B.V.

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 83, 123(2)
RPBA Art. 13(1)

Keyword:

Late-filed arguments (Art. 123(2) EPC; Art. 83 EPC) - admitted (no)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0001/92, T 0595/90, T 0594/01, T 1789/09

Catchword:

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Case Number: T 1609/12 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 14 January 2016

Appellant: (Patent Proprietor)	HERCULES INCORPORATED Hercules Plaza, 1313 North Market Street Wilmington, DE 19894-0001 (US)
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Appellant: (Opponent 1)	THE DOW CHEMICAL CO. 2030 Dow Center Midland, Michigan 48674 (US)
Representative:	Goldener, Beatrice c/o Dow International Holdings S.A. Bachtobelstrasse 3 8810 Horgen (CH)
Appellant: (Opponent 2)	AKZO NOBEL CHEMICALS INTERNATIONAL B.V. Velperweg 76 6824 BM Arnhem (NL)
Representative:	van Deursen, Petrus Hubertus Akzo Nobel N.V. Intellectual Property Department Velperweg 76 6824 BM Amhem (NL)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 May 2012 concerning maintenance of the European Patent No. 1858970 in amended form.**

Composition of the Board:

Chairman	M. C. Gordon
Members:	O. Dury
	C. Brandt

Summary of Facts and Submissions

I. The appeals by both opponents and the patent proprietor lie against the decision of the opposition division maintaining European patent No. EP 1 858 970 in amended form.

II. Two oppositions to the patent were filed, in which revocation of the patent in its entirety was requested on the grounds of Art. 100(a) EPC (both lack of novelty and lack of inventive step) and Art. 100(b) EPC.

III. During the oral proceedings before the opposition division held on 15th February 2012 the patent proprietor submitted an auxiliary request 1 (24 claims), of which the relevant claims read as follows (in claim 1 additions as compared to claim 1 as originally filed are indicated in **bold**, deletions in ~~strikethrough~~):

"1. A composition comprising hydroxyethylcellulose (HEC) having hydroxyethyl groups that are non-uniformly distributed on the cellulose backbone, **which HEC is a non modified HEC that does not contain secondary substituents**, wherein the unsubstituted trimer ratio (U3R) **as measured using the method described in the section "Unsubstituted Trimer ratio (U3R) Determination"** is greater than 0.21 and the hydroxyethyl molar substitution is greater than ~~about~~ 1.3 and less than ~~about~~ 5.0."

"4. A slurry process for making the hydroxyethyl-cellulose composition of claim 1 comprising

A) mixing and reacting cellulose, water and a base reagent in an organic solvent for a sufficient time and

at a sufficient temperature in order to form a first base reagent cellulose mixture, wherein the water to anhydroglucose (AGU) molar ratio is in the range of 5 to 35 and (a) the base reagent to AGU molar ratio is greater than 1.6 or (b) the base reagent to AGU molar ratio is less than 0.4,

B) (i) when (a) is used from Step A, then sufficient acid is added in order to reduce the base reagent concentration to a base reagent to AGU molar ratio of no less than 0.6 to form a second base reagent cellulose mixture, or
(ii) when (b) is used from Step A, then sufficient ethylene oxide is added and reacted at a sufficient temperature and for a sufficient time to form a HEC product with a hydroxyethyl molar substitution of less than 1.3, followed by additional base reagent to adjust the base reagent to AGU molar ratio to greater than 1.0 to form a base reagent HEC mixture, and
C) then adding to the second base reagent cellulose mixture from B(i) or to the base reagent HEC cellulose mixture from B(ii) a sufficient amount of ethylene oxide and reacting at a sufficient temperature and for a sufficient time in order to form the final HEC composition."

"8. A composition comprising a) a functional system selected from the group consisting of personal care compositions, household care compositions, pharmaceutical compositions, building and construction compositions, emulsion polymerization compositions, oil field servicing fluid compositions, civil engineering servicing fluid compositions, paper coating compositions, paper making compositions, architectural coating compositions, industrial coating compositions, printing ink compositions, adhesive compositions, and

mineral processing and recovery compositions and b) a hydroxyethylcellulose (HEC) of claim 1."

Claims 2-3, 5-7 and 9-24 were dependent on claims 1, 4 and 8, respectively.

IV. In the decision under appeal reference was made, *inter alia*, to the following documents:

D1: Mass spectrometric analysis of cellulose ethers, P. Arisz, 1995, pages 9-17 and 78-91

D2: US 4 228 277

D8: Bermocoll Cellulose ethers, Akzo Nobel Surface Chemistry AB, CCD 2200

According to that decision, the patent was to be maintained in amended form on the basis of auxiliary request 1 filed during the oral proceedings on 15th February 2012, which was held to satisfy the requirements of Art. 83, 84, 123(2)(3) EPC, to be novel over *inter alia* D1 and to be inventive starting from D2 as closest prior art.

V. In its statement of grounds of appeal opponent 1 requested that the patent be revoked and filed

D16: Datasheet Cellosize QP 30000H hydroxyethylcellulose, Dow (1 page)

Reference was also made to

D17: Experimental report by P. Arisz, dated 12 April 2010, Hercules BV (6 pages)

which had been submitted by the patent proprietor during the opposition proceedings (letter of 18 May 2010).

Further arguments were submitted with letter of 27 November 2012, 6 August 2013, 4 June 2014 and 2 November 2015.

VI. In its statement of grounds of appeal opponent 2 requested that the patent be revoked. Further arguments were submitted with letter of 4 December 2012.

VII. In its statement of grounds of appeal the patent proprietor requested that the patent be maintained in amended form according to either a main request or an auxiliary request.

In its rejoinder to the opponents' statements of grounds of appeal dated 12 April 2013, the patent proprietor submitted an auxiliary request 2, which corresponded to auxiliary request 1 filed during the oral proceedings on 15th February 2012.

Further submissions were made with letter of 21 March 2014.

VIII. With a communication issued on 31 July 2015 in preparation for oral proceedings, the Board set out its preliminary view of the case.

IX. With a telefax of 11 December 2015 the patent proprietor filed a main request and auxiliary requests 1 to 5 in replacement of all the requests formerly pending, whereby auxiliary request 5 corresponded to auxiliary request 1 filed during the oral proceedings on 15th February 2012.

X. During the oral proceedings held on 14 January 2016 in the presence of all parties the sole request maintained

by the patent proprietor corresponded to auxiliary request 1 filed during the oral proceedings on 15th February 2012, on the basis of which the opposition division had decided that the patent could be maintained and corresponding to auxiliary request 5 submitted with the telefax of 11 December 2015. The patent proprietor withdrew an objection made in writing regarding the admissibility of D16.

XI. The opponents' arguments, as relevant for the present decision, may be summarised as follows:

a) During the oral proceedings before the Board the disclaimer of claim 1 "which HEC [...] does not contain secondary substituents" was objected to pursuant to Art. 123(2) EPC.

Sufficiency of disclosure

b) The information provided in the patent in suit in order to determine the isotope correction factors, which were required for determining the U3R parameter mentioned in claim 1, was inadequate and incomplete. In that respect, different methods were used in D17 and D1.

c) Not enough details were provided in the patent in suit in respect of the permethylation and/or the partial methanolysis reactions which were to be performed on the HEC before determining U3R.

d) Considering the large error margin of the U3R measurement shown in D17, the skilled person would not be able to determine whether he was working within or outside the scope of claim 1, which

amounted to a lack of sufficiency.

e) During the oral proceedings before the Board a new objection of lack of sufficiency was raised in respect of the feature of claim 1 "hydroxyethyl molar substitution".

Novelty

f) It was indicated in Table 2 of the patent in suit that the commercially available HEC "Cellosize QP 30000H" according to D16 had a U3R of 0.196. Taking into account that the error margin for the determination of U3R derived from D17 in respect of sample ADX 359 was larger than the difference between the U3R value of the product of D16 (0.196) and that indicated in operative claim 1 (0.21), the subject-matter of claim 1 was not distinguished from the product of D16. The situation was even more serious when considering the error margin for the U3R of both the product of D16 and the value indicated in operative claim 1 or when considering that the value of 0.21 according to claim 1 encompassed U3R values as low as 0.205 following the mathematical rounding rules.

Reference was also made to T 1789/09 and T 594/01.

g) Considering that the product of D16 was commercially available, reproducibility or whether this was an enabling disclosure were not issues.

Inventive step

h) The subject-matter of claim 1 only differed from either D1 or D16 as closest prior art in defining a new parameter for the HEC, namely U3R.

Since the range of U3R mentioned in operative claim 1 had not been shown to be related to any technical effect, it was purely arbitrary and could not provide an inventive step. It was in particular obvious to increase only slightly the U3R of an HEC according to D16 e.g. in view of the HECs according to D8, which were shown in opposition proceedings to have a U3R in the range of operative claim 1.

Furthermore the subject-matter claimed could be attained in an obvious manner merely by using sub-optimal experimental conditions as compared to those disclosed in D1 e.g. by preparing less homogeneous HECs. In particular, an HEC exhibiting a low degree of substitution would automatically fulfill the U3R requirement according to claim 1. In that respect, the process steps defined in the patent in suit to prepare the claimed HECs amounted to routine wet chemistry procedures.

XII. The patent proprietor's arguments, as relevant for the present decision, may be summarised as follows:

a) The objection pursuant to Art. 123(2) EPC (see section XI.(a), above) should not be admitted because it was late filed and took the patent proprietor by surprise.

Sufficiency of disclosure

b) The determination of the isotope correction factors, as illustrated e.g. in D17, was usual in the art and known to any scientist working in the field of MALDI-TOF-MS. It was based on the natural abundance of carbon isotopes and could be derived from the structures of the trimers given in Structure 1 of the application as filed. The skilled person could further derive the method used on the basis of the values of the correction factors indicated in the application as filed for trimers with n = 0 to 3. In opposition proceedings, opponent 2 had had no difficulty in determining U3R according to the patent in suit in respect of an objection of public prior use.

c) The question whether the skilled person knows if he is working within or outside the scope of the operative claim was an issue of clarity, not sufficiency. Since U3R was already present in the granted claims, such a clarity objection could not be raised at the opposition stage.

d) Taking into account that in D17 U3R was measured on two samples (1 and 2) of two batches (A and B) of two different products (ADX 358 and ADX 359) the error margin of the MALDI-TOF-MS method (matrix assisted laser desorption ionization - time of flight - mass spectrometer) used to determine U3R was not as large as alleged by the opponents. Besides, it should be taken into account that differences between A and B samples could be related to the heterogeneous process typically used to prepare HEC. Greater accuracy could be achieved by increasing the size of the

samples or the number of samples.

Novelty

e) Considering that there was no relationship demonstrated to exist between D1 and D16, in particular in respect of the process used to prepare the HEC, it was not appropriate to apply to the U3R value of a product according to D16 an error margin derived from D17 in respect of products investigated according to D1. Also, making assumptions about an error margin in respect of an experimental value of the prior art did not constitute a novelty destroying disclosure.

f) Accounting the error margin for both the experimental value in respect of D16 and for the value specified in claim 1 amounted to taking the error margin into account twice, which was incorrect.

g) Should it be considered that the product of D16 had a U3R according to claim 1, there was no evidence on file that the skilled person was in a position to reproduce the HEC according to D16 without undue burden. Under such circumstances, D16 did not constitute an enabling disclosure and novelty was given, as followed from G 1/92 (section 1.4).

Inventive step

h) The composition of claim 1 differed from those according to any of D1 or D16, which could both be considered to represent the closest prior art, in

that the HEC defined therein had a specific U3R value of greater than 0.21.

Although the problem to be solved could be that of providing a composition which is usable for making tablets having a hardness equal to or higher than those of the prior art, an inventive step was also to be acknowledged if the problem was formulated as the provision of an alternative over the closest prior art.

The examples of the patent in suit showed that HECs as defined in claim 1 could be prepared using a specific process according to e.g. operative claim 4.

It was explained in the patent in suit that U3R defined a specific substitution pattern on the HEC backbone, which was referred to as "blocky" HEC. There was no hint in the prior art cited, in particular not in D1 and D16, that the skilled person had ever sought to prepare such blocky HECs.

D8 did not disclose U3R values and dealt with modified HECs which were not according to the operative claims. Therefore, D8 would not have been combined with either D1 or D16, which both dealt with unmodified HECs.

Even if the skilled person had wished to prepare an HEC having a U3R according to claim 1, no known method of preparing such an HEC existed before the patent in suit. Reference was made to T 595/90.

Under such circumstances there was no motivation

in the cited prior art to solve the above problem according to the operative claims.

XIII. The patent proprietor requested that the patent be maintained in the form as upheld according to the contested decision i.e. according to the fifth auxiliary request filed with letter dated 11 December 2015.

Opponents 1 and 2 both requested that the decision under appeal be set aside and that the patent be revoked.

XIV. The Board announced its decision at the end of the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. In its statement of grounds of appeal, opponent 1 raised a clarity objection in respect of the feature "as measured using ... Determination". In that respect, the Board indicated in its communication sent in preparation of the oral proceedings that it was questionable if that objection was allowable in view of G 3/14. That opinion was neither contested in opponent 1's reply of 2nd November 2015 (although other clarity issues were addressed) nor by either of the opponents during the oral proceedings before the Board. The Board can therefore identify no reason to diverge from its preliminary opinion on this matter.

3. Art. 123(2) EPC

3.1 An objection in respect of the feature "which HEC is a non-modified HEC that does not contain secondary substituents" was raised for the first time during the oral proceedings before the Board.

3.2 In that respect it is noted that the operative request corresponds to the request allowed by the opposition division and that no objection pursuant to Art. 123(2) EPC had been raised during the opposition proceedings. That objection was also not raised in the statement of grounds of appeal of either opponent nor in any of their following submissions. Nor was it explained at any stage before the oral proceedings before the Board why the findings of the opposition division according to which the operative request satisfied the requirements of Art. 123(2) EPC would be wrong. The objection under Art. 123(2) EPC came therefore as a surprise at the oral proceedings. Under such circumstances, the requirements of Art. 12(2) RPBA, according to which the statement of grounds of appeal shall contain a party's complete case, are not fulfilled. Besides, the objection pursuant to Art. 123(2) EPC put forward at the oral proceedings constitutes a significant amendment of the opponents' case and admitting said objection at such a late stage of the proceedings would both be unfair to the patent proprietor and run counter the need for procedural economy. The argument submitted during the oral proceedings and according to which opponent 2's representative had to take over a colleague's case only one week before the oral proceedings cannot justify any derogation from the obligation of fairness toward the patent proprietor and/or the stipulations of the RPBA regarding procedural economy. For those reasons, that

objection was not admitted to the proceedings (Art. 13(1) RPBA).

4. Sufficiency of disclosure

4.1 In order to meet the requirements of Art. 83 EPC, an invention has to be disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person without undue burden on the basis of the information provided in the patent specification, which means in the present case, *inter alia*, to prepare a composition according to claim 1 and/or to carry out a process according to claim 4.

4.2 Parameter U3R

4.2.1 It was not disputed by the parties that U3R, specified in operative claim 1, is a novel parameter. On the contrary, this is explicitly stated in paragraph 29 of the application as filed. It is further indicated in paragraphs 14 and 15 of the application as filed, that that parameter (U3R) characterises the substitution pattern of the ethylene oxide groups on the cellulose backbone, whereby the feature of claim 1 according to which U3R is "greater than 0.21" imposes the requirement that a large fraction of the anhydroglucose units in the cellulose backbone are not substituted with ethylene oxide. Such HECs are further described in the application as filed as having a non-uniform or blocky substitution pattern, which is responsible for providing the HECs with "unique rheology that has not been noted prior to this invention" (paragraphs 7, 14, 15, 41 and 42.)

In view of the above, in order to prepare a composition according to claim 1, one has either to be able to

select appropriately an hydroxyethylcellulose having a suitable U3R of "greater than 0.21" as defined in claim 1 and/or to determine whether an hydroxyethylcellulose prepared according to a process according to claim 4 fulfills said U3R requirement e.g. in order to determine the reaction conditions to be used in step C) which are necessary to prepare an hydroxyethylcellulose as defined in claim 1.

Therefore, it has to be assessed whether or not the application as filed, which is the yardstick for sufficiency, provides sufficient information in order reliably to determine U3R.

4.2.2 Isotope correction factors

According to paragraph 35 and the last two sentences of paragraph 36 of the application as filed, U3R is measured using MALDI-TOF-MS with the application of correction factors, whereby "the background corrected monoisotopic mass peak intensities are multiplied by a correction factor that is calculated from the theoretical isotope composition of the trimers".

Although some correction factors are indicated in said paragraph 36, the complete list of factors was only provided during the opposition proceedings, namely in Table 3 of D17. However neither in the patent nor in D17 was the calculation or derivation of the correction factors explained. Therefore, the question arose whether or not the skilled person was in a position to determine those factors from the information provided in the application as filed or from general knowledge of the relevant technical field.

During the oral proceedings the patent proprietor

explained that the calculation of those correction factors was usual in the art and was made by determining the chemical formula of each trimer according to Structure 1 of the application as filed with varying n values (page 9; n being 0 or a natural integer) and taking into account the natural abundance of each isotope, as illustrated in Table 3 of D17. That argument is supported by the fact that Opponent 2 had no difficulty in determining U3R according to the patent in suit in respect of an objection of public prior use (section 3.2 of the notice of opposition; U3R determined "using the MALDI-TOF-MS measurement described in the patent in suit"). Besides, a similar correction procedure is also used e.g. in D1 (page 87, paragraphs before and after Equation (3)), which confirms that such a procedure is known. It is further credible that the skilled person could have derived the calculation method used and illustrated in Table 3 of D17 on the basis of the information provided in the application as filed, in particular from the disclosure of paragraphs 30 (Structure 1), 34, 35 (compounds 1 are measured as their sodium ion adducts; mass peaks of the first trimers), 36 (background correction, as also shown in Table 2 of D17; percentages and correction factors of the first trimers corresponding to structure 1) and 37 (U3R is the ratio of the unsubstituted trimer to the most abundance class of trimers as illustrated in Fig. 1 of the application as filed).

It is true that, apparently, a different calculation method was used in D1 (page 87). However, the opponents have neither shown that that method leads to significantly different results than that used in the application as filed (and in D17), nor that the alleged ambiguity in the calculation method is such as to amount to a lack of sufficiency i.e. that it would not

allow the skilled person to prepare a composition according to claim 1 or to carry out a process according to claim 4.

In view of the evidence on file, any ambiguity in respect of the calculation of the U3R value is of such nature that it affects only the question of determining whether or not a given product is within or outside the scope of the claims, which is a matter governed by Art. 84 EPC, not however Art. 83 EPC.

4.2.3 Derivatisation method

According to paragraphs 29-34 of the application as filed U3R is measured by first degrading the HEC polymer down to monomers and oligomers by partial methanolysis of permethylated hydroxyethylcellulose derivatives. Information regarding the permethylation reaction and the partial methanolysis is provided in paragraphs 32-33 and 34, respectively, of the application as filed.

In that respect, the opponents' objection according to which applying different conditions either for the permethylation and/or the partial methanolysis reactions would lead to significantly different results in terms of U3R, is not supported by any evidence. It was also not shown why the decision of the opposition division, according to which the requirements of Art. 83 EPC would be met for hydroxyethylcellulose according to operative claim 1, would be wrong.

Therefore, on the basis of the evidence on file, the opponents' objection did not convince.

4.2.4 Accuracy of the determination method

In the absence of any information provided by the parties in respect of the usual accuracy of the MALDI-TOF-MS determination method, the only source of information is to be found in D17, which was relied upon by the parties.

D17 deals with the determination of U3R according to the patent in suit of two products of D1, namely ADX358 and ADX359 of D17, which correspond to HEC 1.75 and HEC 1.73 of D1, respectively. In that respect, D1 further teaches that HEC 1.75 and HEC 1.73 are two different products corresponding to hydroxyethylcellulose made from cotton cellulose and with a substitution degree of 1.75 and 1.73, respectively (D1: page 80 final paragraph continuing on to page 81; page 81, first sentence of section 4.2.2). It was not disputed by the parties that HEC 1.73 and HEC 1.75 are two different products, which conclusion is also supported by the data provided in D1 (e.g. Table 4.3; Figs. 4.11 and 4.12).

It is further explained in D17 (page 2, first paragraph of the section "Experimental") that each of the HEC samples ADX 358 and ADX 359 was derivatised (see above section 4.2.3) in duplicate (samples A and B) and each of the derivatised samples was measured in duplicate (samples 1 and 2), which gives four measurements for each of ADX 358 and ADX 359 as reported in Table 4 of D17 as follows

Table 4. HE-MS and U3R values derived from the MALDI data listed in Table 2.

	ADX358 1A	ADX358 2A	ADX358 1B	ADX358 2B	ADX359 1A	ADX359 2A	ADX359 1B	ADX359 2B
HE-MS	2.28	2.27	2.33	2.36	2.28	2.07	2.29	2.21
U3R	0.189	0.181	0.159	0.160	0.168	0.186	0.131	0.141

Those data exhibit some variability, both between two duplicates of a given derivative of a specific product (compare e.g. ADX 359 1A and ADX 359 2A) and between two derivatives of the same product (compare e.g. both ADX 359 1A-2A with both ADX 359 1B-2B). However, it cannot be excluded from the evidence on file that the different results between two duplicates for a given derivative (e.g. ADX 359 1A and ADX 359 2A, which show the highest variability) is due to the non homogeneity in the hydroxyethyl substitution pattern within a given sample used as starting material (here, ADX 359) and/or is due to the derivatisation method used to modify those samples. In other words, there are no grounds for concluding that the observed variability is an indication of the degree of accuracy of the determination method.

In view of the above it can only be concluded that the opponents have not shown that the skilled person is not in a position to determine unambiguously U3R because of the lack of accuracy or reproducibility of the MALDI-TOF-MS method.

4.2.5 For those reasons the opponents' objections regarding a lack of sufficiency in respect of the U3R parameter are not persuasive.

4.3 Parameter "hydroxyethyl molar substitution"

An objection in respect of the feature "hydroxyethyl molar substitution" was raised for the first time during the oral proceedings before the Board.

Although the issue of the determination of the degree of molar substitution was already discussed in the first instance proceedings (contested decision:

page 14, point 5.4 of the reasons) it had not been pursued in any of the written submissions made during the appeal proceedings. Nor was it explained at any stage before the oral proceedings before the Board why the findings of the opposition division in that respect would be wrong. That objection under Art. 83 EPC came therefore as a surprise at the oral proceedings.

Under such circumstances, and for the same reasons as indicated in above section 3.2 in respect of the late filed objection pursuant Art. 123(2) EPC, that objection was not admitted to the proceedings (Art. 13(1) RPBA).

4.4 Consequently, the requirements of Art. 83 EPC are met.

5. Novelty

5.1 The sole novelty objection was raised against the operative product claims (1-3 and 8-24) in respect of the commercial product Cellosize QP30000H of D16, for which a U3R value of 0.196 is indicated in Table 2 of the patent in suit.

5.2 It was not contested by the patent proprietor that Cellosize QP30000H was commercially available before the priority of the patent in suit and that it had a hydroxyethyl molar substitution according to operative claim 1. Therefore, the question remaining to be answered is whether or not the subject-matter of operative claim 1 may be distinguished from the HEC Cellosize QP30000H having a U3R of 0.196.

Said value of 0.196, as is the case for any measurement made in quantitative analytical chemistry, cannot be dissociated from the margin of uncertainty attached to

the measurement. Therefore, the issue to be addressed is whether or not the skilled person is in a position to distinguish a HEC having a U3R of 0.196 as determined by MALDI-TOF-MS from a HEC having a U3R of "greater than 0.21" according to claim 1.

5.3 In that respect, it is noted that in the application as filed it was defined in original claim 1 that protection was sought for HEC having a U3R "greater than 0.21" and that Cellosize QP30000H with a U3R 0.196 was explicitly acknowledged in Table 2 as a comparative example i.e. not according to the invention as defined in the original claims. In view of that information, it is concluded that, at the time of filing the present application, it was held that the skilled person was in a position unambiguously to determine that Cellosize QP30000H did not satisfy the U3R requirement according to operative claim 1 i.e. it was technically possible to ascertain that a value of 0.196 as determined by MALDI-TOF-MS was not "greater than 0.21".

5.4 Applying the mathematical rounding rules for the U3R value disclosed in Table 2 of the application as filed (0.196) gives a value of 0.20 if only two digits are considered, as is done in claim 1 (which defines a U3R "greater than 0.21"). Therefore, that argument, even if it were to be considered to the opponents' benefit, cannot succeed, as already concluded by the opposition division (second paragraph of section 6.4 of the contested decision).

5.5 There is no evidence nor any data on file regarding the degree of heterogeneity in terms of U3R of any sample of Cellosize QP30000H. Therefore, it cannot be concluded, that the product mentioned in Table 2 of the patent in suit must have contained at least some HEC

having a U3R "greater than 0.21", as argued by the opponents.

5.6 As explained above (section 4.2.4), D17 deals with the determination of U3R according to the patent in suit on products of D1. No connection whatsoever was shown to exist between documents D1/D17 and D16, in particular regarding the structure of the HECs disclosed therein and/or their preparation process. Under such circumstances, it was not shown that any conclusion drawn from the data of D17 would mandatorily be relevant for any product Cellosize QP30000H according to D16, in particular not for that mentioned in Table 2 of the patent in suit. In particular, no reason was advanced by the opponents why a sample of Cellosize QP30000H should exhibit the same degree of variability in terms of U3R as the products analysed in D17.

Besides, the U3R value of 0.196 reported in Table 2 of the patent in suit for a specific sample of Cellosize QP30000H was indicated by the patent proprietor as being a single measurement value (letter of 21 March 2014, section 3.1). In that respect, even if, for the sake of argument, a standard deviation derived e.g. from D17 were to be applied to the specific experimental value of 0.196 this would only express a probability that the "true value" of U3R of Cellosize QP30000H lies between the average value +/- the standard deviation as explained in section 3.1 of the patent proprietor's submission of 21 March 2014. Such a probability does not, in the Board's mind, amount to a direct and unambiguous disclosure such as to deprive the claimed subject-matter of novelty.

In those circumstances, the opponents' objections relying on applying a measurement error derived from

D17 on the experimental value of 0.196 given in Table 2 of the patent in suit did not convince.

5.7 In view of the above, the issue whether or not D16 constitutes an enabling disclosure in the light of G 1/92 or not, as argued by the patent proprietor, is not relevant for the present decision.

5.8 Decision T 1789/09, which was relied upon by the opponents, concerned a determination method of a parameter which was open to personal judgment i.e. the results depended on the person who conducted the test. It was not shown that this was also the case for the determination of U3R according to operative claim 1. On the contrary, it is indicated in the application as filed (e.g. paragraphs 8, 15 and 29) and was consistently argued by the patent proprietor that U3R is a parameter characterising the chemical structure of the HEC being claimed i.e. it is an intrinsic property of the HEC. Said property is furthermore determined on the basis of an experimental procedure relying on MALDI-TOF-MS, which shows that that parameter is independent of the person conducting the test. Therefore, T 1789/09 is not pertinent to the present case.

5.9 The conclusion of T 594/01 was that the end of a range of values specified in a claim overlapped the margin of uncertainty inherently associated with the same experimental value disclosed in a prior art document. Such conclusion is not relevant for the present case since the U3R value of 0.21 delimiting the subject-matter according to operative claim 1 is not identical with the U3R value of 0.196, which was argued to be disclosed for Cellosize QP30000H. Therefore, also the findings of that decision are not pertinent to the

present case.

5.10 For those reasons it cannot be concluded from the evidence on file that D16 directly and unambiguously discloses a product that anticipates the subject-matter of claim 1. The same conclusion applies for the dependent claims 2-3 and for each of claims 8-24, which make reference to the HEC according to claim 1.

6. Inventive step

6.1 Closest prior art

6.1.1 According to paragraphs 6-7, the patent in suit aims at providing efficient hydroxyethylcellulose-based rheology modifiers. Further, it is indicated in paragraphs 69-72 and in granted claims 40-42 that those hydroxyethylcellulose based compounds are usable as excipient in pharmaceutical compositions in the form of e.g. tablets.

6.1.2 The parties considered either D1 or D16 as possible closest prior art. Each of those disclosures is related to unmodified HEC suitable as rheology modifiers. Although D1 is the only document disclosing the possible use of cellulose ethers in pharmaceuticals e.g. to control the release of medicine in pills and capsules (page 9, first paragraph), the Board is satisfied that either of D1 or D16 may be considered as suitable starting point for the assessment of the inventive step.

6.2 Problem to be solved in view of the closest prior art

Although the patent proprietor argued that the problem to be solved could reside in an improvement in terms of

tablet hardness as compared to the closest prior art, he also defended a line of argumentation based on the formulation of the problem to be solved as being to provide a mere alternative to either of D1 and D16. During the oral proceedings the Board came to the conclusion that, on the basis of the evidence on file, the improvement relied upon by the patent proprietor could not be acknowledged. However, in view of the outcome of the present decision, it is not necessary for the Board to address this line of argument of the patent proprietor. Therefore, the problem to be solved in view of the closest prior art considered hereinafter is that of providing further compositions comprising HEC and processes for making HECs in alternative to those of D1 or D16.

6.3 Solution

It was not contested by the parties that the subject-matter being claimed differed from either of D1 or D16 in that the HEC is characterised by a U3R of "greater than 0.21".

6.4 Success of the solution

It was not contested by the opponents, in particular during the oral proceedings before the Board, that the above technical problem was solved. Nor does the Board see any reason to take a different view, in particular upon consideration of the examples of the patent in suit.

6.5 Obviousness

6.5.1 The question has to be answered whether the skilled person desiring to solve the above identified problem

would, in view of the prior art, have modified the disclosure of the closest prior art in such a way as to arrive at the claimed subject matter.

6.5.2 As explained in e.g. paragraphs 8, 15 and 29, the patent in suit is directed to so-called "blocky" HECs having hydroxyethyl groups that are non-uniformly distributed on the cellulose backbone, i.e. wherein the ratio of unsubstituted anhydroglucose trimers to the most frequently occurring substituted anhydroglucose trimer, which ratio is defined as parameter U3R, should be greater than 0.21. Therefore, parameter U3R reflects a specific pattern of substitution of the cellulose backbone i.e. it is an intrinsic property of the polymer which characterises the product *per se*. Under such circumstances, it has to be clarified whether or not the skilled person would have had any motivation to envisage such products and if he would have found any hint in the prior art how to prepare such products.

6.5.3 In that respect, it was not shown by the opponents that any of the documents cited dealt with the specific pattern of substitution aimed at in the patent in suit, namely the preparation of blocky, non uniformly substituted HECs whereby the pattern of substitution is such that it is quantified or characterised by having a U3R of greater than 0.21.

On the contrary, D1 rather aims at providing HECs having a homogeneous substitution pattern (page 80, second full paragraph; pages 89-91: section "The MS distributions of the cellotrioses"; Figs. 4.11 and 4.12; section 4.2.4). It is also noted that it was not shown by the opponents that the structure of the polymers which gives rise to the "homogeneity" as

defined in D1 is in any way related to the structure of the blocky HECs of the patent in suit as characterised in terms of U3R. In particular, although Fig. 4.11 of D1 specifically describes the distribution of unsubstituted and substituted trimers in a similar way as was done in Fig. 1 of the patent in suit, it was not shown that D1 associated those results with the substitution pattern required by the operative claims, in particular the ratio of the molar fraction of unsubstituted trimers to the molar fraction of the most abundant class of hydroxyethyl substituted trimers, specified by means of the parameter U3R.

D16 is a product datasheet disclosing some typical properties and uses of Cellosize QP30000H. It contains neither a hint to U3R nor to any specific aspects related to homogeneity/heterogeneity of the hydroxyethyl groups distribution on the cellulose backbone.

D8, which was referred by the opponents, is only directed to substituted HECs (i.e. having secondary substituents in addition to the hydroxyethyl groups of the HEC according to operative claim 1). Therefore, it is questionable if the skilled person would have considered combining the teaching of D8 with that of D1 or D16, which both deal with unmodified HECs. Besides, D8 does not explicitly disclose "blocky" HECs or U3R. Also, even if it had been shown that such HECs implicitly had a U3R of greater than 0.21, as argued by the opponents, the combination of D8 with any of D1 and D16 would be based on hindsight, i.e. knowing the solution proposed by the patent in suit, which is not allowable.

Therefore, on the basis of the documents cited, the

skilled person would have had no motivation whatsoever to envisage a HEC product having the specific structure now being defined in claim 1 and quantified by the U3R parameter.

6.5.4 The question further arose if there would have been any known method for the manufacture of a non modified hydroxyethylcellulose characterised by having a U3R "greater than 0.21" according to operative claim 1. In that respect, the HECs according to claim 1 are prepared using a specific slurry process as defined in e.g. operative claim 4. Although it was argued by the opponents that said process amounted to "routine wet chemistry analytical procedures", it was not shown that such a process could be arrived at in a non-obvious manner e.g. starting from the process disclosed in D1 (D16 is silent in respect of any process feature). Besides, according to EPO case law, a product which could be envisaged as such with all characteristics determining its identity including its properties in use, i.e. an otherwise obvious entity, might nevertheless become non-obvious and claimable as such, if there was no known way or applicable (analogous) method in the art for making it and the claimed methods for its preparation were therefore the first to achieve this and do so in an inventive manner (Case Law of the Boards of Appeal of the EPO, 13. Ed., 2007, I.D.9.17). During the oral proceedings before the Board, the question was addressed regarding what the skilled person would have had to have done e.g. starting from the process taught in D1 in order to arrive at the subject-matter of operative claim 1. Opponent 1 was in particular of the opinion that such a product could have been obtained by using sub-optimal experimental conditions, i.e. ones that were not as ideal as those disclosed on page 80 of D1. However, no evidence in

that respect was provided. Besides, in doing so, the skilled person would have had to deviate considerably from the teaching of D1, both in terms of the process taught on said page 80 of D1 and of the aim of D1, which is to obtain HECs with a homogeneous distribution of hydroxyethyl groups on the cellulose backbone, as explained above. Also, preparing HECs having a very low substitution degree, as proposed by Opponent 1, not only goes against the teaching of D1, which is to prepare water soluble HECs i.e. having a sufficiently high degree of substitution (see e.g. first two paragraphs on page 80) but it would also lead to HECs which are not according to operative claim 1, which have to have a hydroxyethyl molar substitution of greater than 1.3 and less than 5.0.

In the present circumstances of the case and in the absence of any evidence that HECs as defined in operative claim 1 could be arrived at in an obvious manner from the teaching of the cited prior art, it is to be concluded that, even if the compositions according to operative claim 1 had been shown to have been envisageable, which was also not shown to be the case here (see section 6.5.3 above), it was not shown by the opponents that a method of manufacture thereof would have existed or been apparent to the skilled person in an obvious manner.

6.5.5 Therefore, the subject-matter of claims 1 and 4, as well as that of the claims depending thereon fulfills the requirements of Art. 56 EPC. The same conclusion is further also valid for the subject-matter of operative claims 8-24, which all refer to said claim 1.

7. The sole request of the patent proprietor being allowable, the opponents' appeals have to be dismissed.

Order

For these reasons it is decided that:

1. The appeals of opponent 1 and opponent 2 are dismissed.

2. The patent is to be maintained in the form as upheld according to the contested decision.

The Registrar: The Chairman:

B. ter Heijden M. C. Gordon

Decision electronically authenticated