Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 4 July 2019

Case Number: T 2469/17 - 3.3.07

Application Number: 12714149.7

Publication Number: 2694110

IPC: A61K47/36, A61K9/20

Language of the proceedings: EN

Title of invention:
NOVEL POLYSACCHARIDE DERIVATIVES AND DOSAGE FORMS

Patent Proprietor:
Dow Global Technologies LLC

Opponent:
Shin-Etsu Chemical Co., Ltd.

Headword:
Polysaccharide derivatives/ DOW

Relevant legal provisions:
EPC Art. 114(2), 54, 56
RPBA Art. 13(3)

Keyword:

Late-filed experimental evidence - admitted (no)
Late-filed request - admitted (yes)
Novelty - (yes)
Inventive step - (yes)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2469/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 4 July 2019

Appellant: (Patent Proprietor)	Dow Global Technologies LLC 2040 Dow Center Midland, MI 48674 (US)
Representative:	f & e patent Fleischer, Engels & Partner mbB, Patentanwälte Braunsberger Feld 29 51429 Bergisch Gladbach (DE)
Appellant: (Opponent)	Shin-Etsu Chemical Co., Ltd. 6-1, Ohtemachi 2-chome Chiyoda-ku Tokyo 100-0004 (JP)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 September 2017 concerning maintenance of the European Patent No. 2694110 in amended form.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	P. Schmitz

Summary of Facts and Submissions

I. European Patent 2 694 110 was opposed on the grounds that its subject-matter lacked novelty and inventive step and was insufficiently disclosed. The following documents were among those cited during the proceedings before the opposition division:

D1: US 2001/0025101
D2: EP 497 985
D5: DE 44 14 544

II. The appeals of the patent proprietor (appellant-patent proprietor) and of the opponent (appellant-opponent) are against the decision of the opposition division which found that the patent and the invention according to auxiliary request 1 met the requirements of the Convention. The decision was based on the main request filed on 27 June 2016 and on auxiliary request 1 filed during the oral proceedings held on 11 May 2017.

The opposition division found *inter alia* that claim 1 of the main request lacked novelty over example 13 of D1 and example 4 of D2. The subject-matter of auxiliary request 1 was considered to comply with the requirements of Article 123(2) and (3) EPC, novelty and sufficiency of disclosure. Further, it was not obvious over a combination of the closest prior art D5 with D1 or D2.

III. In the statement setting out the grounds of appeal sent on 4 January 2018 the appellant-patent proprietor requested that the decision of the opposition division be set aside and that the patent be maintained on the basis of the main request filed during the opposition proceedings on 27 June 2016. Auxiliary requests were

then filed by letters dated 9 May 2018, 3 June 2019 and 25 June 2019.

IV. In its statement setting out the grounds of appeal submitted on 15 January 2018 the appellant-opponent requested that the decision under appeal be set aside and the patent be revoked. The statement of grounds of appeal also contained experimental data relating to a polysaccharide derivative disclosed in D5.

V. Over the course of the appeal procedure the appellant-opponent submitted the following documents:

E-1: ACM pulverizers (English version)
G: Micromerics 1989, 33, 110-112
G-2: Partial English translation of document G

VI. In a communication pursuant to Article 15(1) RPBA issued on 6 May 2019, the Board indicated that it did not intend to admit the experiments included by the appellant-opponent in its statement setting out the grounds of appeal. As to the requirement of inventive step, it considered that this should be assessed starting from D5. It also observed that the data in Table 5 of the patent appeared to indicate that it was possible to reduce the tablet to tablet weight variation by using a polysaccharide according to the invention as excipient.

VII. During the oral proceedings held on 4 July 2019, the appellant-patent proprietor changed the ranking of its requests with the effect that the request filed on 3 June 2019 as auxiliary request 12 became the new main request.

Claim 1 of this request read as follows:

"1. A polysaccharide derivative having a median Equivalent Projected Circle Diameter (EQPC) of less than 140 micrometers and a particle size and shape distribution meeting B:
B. i) no more than 40 volume percent of the polysaccharide derivative particles are fine particles having a particle length LEFI of less than 40 micrometers and
ii) no more than 40 volume percent of the polysaccharide derivative particles are fibrous particles, and the sum of the fine particles and the fibrous particles does not exceed 50 volume percent."

VIII. The arguments of the appellant-opponent can be summarised as follows:

(a) Admittance of the experiments included by the appellant-opponent in its statement of grounds of appeal

These experiments were *prima facie* relevant since they demonstrated that the polysaccharide disclosed in example 1 of D5 anticipated the subject-matter of the request considered by the opposition division to meet the requirements of the EPC. They could not be filed earlier since this request was only submitted during the oral proceedings before the opposition division.

(b) Admittance of the main request (former auxiliary request 12)

This request should not be admitted into the appeal proceedings as it was filed at a very late stage and only one month before the oral proceedings.

(c) Novelty

The repetition made by the appellant-opponent of example 13 of D1 and example 4 of D2 supported the conclusion that the subject-matter of claim 1 was not novel over these documents. The modifications of the procedures disclosed in these examples had no impact on the nature of the products obtained. The values for the viscosity and bulk density of the product obtained by the appellant-opponent in repeating example 13 of D1 were not identical to the values disclosed in D1. The difference was negligible however. The process conditions, which were not explicitly disclosed in D2, were selected for the repetition experiment based on an evaluation of what the skilled person would have done. There was at least a strong presumption that the product of example 13 of D1 and the product of example 4 of D2 had the same features as the polysaccharides defined in claim 1 of the main request. Under these circumstances the appellant-patent proprietor had the burden of proving that claim 1 was novel over the examples of D1 and D2.

(d) Inventive step

Document D5 was the closest prior art. The polysaccharide of claim 1 of the main request differed from the polysaccharide included in the composition of example 1 of D5 only in parameter B, i.e. a feature defining the particle size and shape distribution of the polysaccharide. The patent proprietor did not compare its product with that of D5. The technical problem was therefore the provision of an alternative polysaccharide derivative. D1 disclosed polysaccharides with high bulk density and good flowability. Similar

products were disclosed in D2. The skilled person would have arrived at the subject-matter of claim 1 by combining the teaching of D5 with the one of D1 or D2.

IX. The arguments of the appellant-patent proprietor can be summarised as follows:

(a) Admittance of the experiments included by the appellant-opponent in its statement of grounds of appeal

The experimental data included in the statement of grounds of appeal of the appellant-opponent were based on the repetition of an example of D5. This document was a patent application of the appellant-opponent and was filed with the notice of opposition. The product tested originated from the appellant-opponent itself and the specific sample used for the tests was produced in 2008 and had been stored since then. As a consequence, there was no reason why this evidence was withheld in proceedings before the opposition division and submitted only in appeal proceedings. Hence, the experimental data were not to be admitted into the appeal proceedings.

(b) Admittance of the main request (former auxiliary request 12)

The subject-matter of claim 1 of this request was based on one of the alternative groups of polysaccharides covered by the previous requests. This request was admissible since the filing of the latter did not raise any new issues.

(c) Novelty

The product obtained by the appellant-opponent in repeating example 13 of D1 was not the same product actually disclosed in this document since it had a different bulk density and viscosity. With regard to the repetition of example 4 of D2, it was noted that this document did not mention the pulverizing conditions. These were very important for determining the particle size and particle shape distribution of the polysaccharide. It was clear from document E-1 that several versions of the ACM pulverizer used in D2 were available. Certain operative conditions, such as the rotating speed, had an impact on the particle size. D2 did not provide any information in this regard. Furthermore, G-2 suggested using an ACM-60 pulverizer for cellulose material. The appellant-opponent used an ACM-10 instead. Thus, the experiment of the appellant-opponent was not evidence that example 4 of D2 anticipated claim 1.

(d) Inventive step

The polysaccharide of claim 1 differed from the polysaccharide used in example 1 of D5 in the particle size and shape distribution (parameter B). The results disclosed in Table 5 of the patent showed that by using of the polysaccharides of claim 1 it was possible to produce dosage forms with a more consistent average weight. None of the prior art documents suggested that this improvement could be obtained by the provision of the polysaccharides of claim 1.

X. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on

3 June 2019 as auxiliary request 12, or on the basis of of one of auxiliary requests 13 to 22 filed on 25 June 2019. The appellant-patent proprietor further requested that the experimental data contained in the appellant-opponent's statement setting out the grounds of appeal not be admitted into the appeal proceedings.

XI. The appellant-opponent requested that the decision under appeal be set aside and the patent be revoked. It further requested that the main request, filed on 3 June 2019 as auxiliary request 12, not be admitted into the appeal proceedings.

Reasons for the Decision

1. Admissibility of the experiments included by the appellant-opponent in its statement setting out the grounds of appeal

1.1 The scope of the experiments included by the appellant-opponent in its statement setting out the grounds of appeal (pages 9 and 10) is to demonstrate that the hydroxypropyl methyl cellulose (HPMC) used in example 1 of D5 is a polysaccharide as defined in the pending requests. The appellant-opponent explains that these experiments are in response to the decision of the opposition division to consider that the then pending auxiliary request 1 met the requirements of the EPC. They could not be submitted earlier since this request was only filed by the appellant-patent proprietor during the oral proceedings before the opposition division.

1.2 The Board notes that claim 1 of the request maintained by the opposition division corresponds to claim 9 of

the patent as granted. Document D5 is a patent application of the appellant-opponent that was cited with the notice of opposition. The appellant-opponent is also the producer of the specific HPMC used in example 1 of this document (HPMC 60SH-4000) and tested in the experiments included with the statement of grounds of appeal.

1.3 Irrespective of whether these experiments should have been submitted earlier as maintained by the appellant-patent proprietor, the Board considers that they are not admissible into the appeal proceedings because they are not *prima facie* relevant (Article 114(2) EPC).

Indeed, the data included in the statement setting out the grounds of appeal of the appellant-opponent relate to experiments carried out using a sample of the product HPMC 60SH-4000 which was produced in 2008. In the Board's view, there is no evidence that the HPMC 60SH-4000 produced in 2008 is exactly the same product described in D5 (filing date: 1994). Moreover, the experiments were made in 2017. It is therefore doubtful whether the relevant properties of the HPMC (i.e. flowability and amount of fine and fibrous particles) remained unchanged during the period 2008-2017. Thus, no conclusion can be drawn as to the features of the HPMC used in example 1 of D5 on the basis of the experiments made by the appellant-opponent.

1.4 Hence, the experiments in question are not admitted into the appeal proceedings.

Main request (filed on 3 June 2019 as auxiliary request 12)

2. Admissibility

2.1 In its statement setting out the grounds of appeal the appellant-patent proprietor defended its case on the basis of the main request filed during the opposition proceedings on 27 June 2016. Claim 1 of this request concerned a polysaccharide characterised *inter alia* by the requirement of having a particle size and shape distribution that meet conditions A or B or both. Hence, the claim covered three groups of polysaccharides, namely (i) polysaccharides meeting condition A, (ii) polysaccharides meeting conditions A and B and (iii) polysaccharides meeting condition B.

2.2 Claim 1 of the current main request differs from claim 1 of the main request filed on 27 June 2016 in that it is limited to polysaccharides meeting condition B, i.e. to polysaccharides defined as group (iii) in the previous paragraph.

Accordingly, the filing of the current main request neither increases the difficulty of the case nor does it introduce new issues, since it relates to subject-matter that was already included in a request filed during the proceedings before the opposition division. Hence the Board in exercising its discretion under Article 13(1) RPBA decides to admit into the appeal proceedings the main request, filed on 3 June 2019 as auxiliary request 12.

3. Article 123(2) EPC and sufficiency of disclosure

3.1 The appellant-opponent did not raise any objections under Article 123(2) EPC or with regard to the

requirement of sufficiency of disclosure. The Board sees no need to do this on its own motion.

4. Novelty

4.1 The appellant-opponent has reproduced example 13 of D1 and example 4 of D2 to show that the products obtained in these examples anticipates claim 1 of the main request.

As also discussed in the decision under appeal, by repeating the procedures of D1 and D2, the appellant-opponent made some modifications to the procedures disclosed in the prior art, for instance different apparatus have been used. In other cases the appellant-opponent had to select some experimental conditions in the absence of information in the prior art document.

The opposition division considered that these deviations from the disclosure of D1 and D2 had no relevant impact on the product obtained.

4.1.1 However, the Board notes with regard to the reproduction of example 13 of D1, that the product obtained by the appellant-opponent does not have the same value of bulk density and viscosity reported in D1 for the product of example 13. The differences are not negligible since for the bulk density it is around 14% (309 kg/m^3 in the experiment of the appellant-opponent vs 360 kg/m^3 in D1) whereas for the viscosity it is around 7% (14200 mPa.s in the experiment of the appellant-opponent vs 13300 in D1). The opposition division observed that the then pending claim 1 did not define the polysaccharides by referring to these parameters. Thus, in its view, the different values for

bulk density and viscosity did not imply that the product of D1 was not included in claim 1.

The current claim 1 also does not provide any limitation to the bulk density and viscosity of the polysaccharide. Nevertheless, the differences in bulk density and viscosity between the data of the appellant-opponent and the data of D1 indicate that the modifications made by the appellant-opponent when reproducing example 13 of D1 had an impact on the physical properties of the final product. In other words, the product obtained by the appellant-opponent is not the same product as the one disclosed in D1. The fact that the product obtained by the appellant-opponent is included in claim 1 is therefore immaterial.

In the appellant-opponent's view, its experiments would at least establish a strong presumption that the disclosure of example 13 of D1 anticipates claim 1. Under these circumstances the appellant-patent proprietor would have the burden of proving that claim 1 is novel. The Board does not share this position. Since the product prepared and tested by the appellant-opponent is different from the product of example 13 of D1, on the basis of the appellant-opponent's experiments there cannot be any presumption that the product of D1 is novelty-destroying.

4.1.2 Concerning the objection of lack of novelty over example 4 of D2, it is noted that this example provides very little information particularly with regard to the drying and pulverization process. Concerning the latter, D2 indicates that the pulverizer is an ACM pulverizer. It is clear however from Attachment-E1 that

several ACM pulverizers exist. Furthermore, this document indicates that "[a]djusting the rotating speed of the grinding rotor and the classifying rotor can easily control the product size" (page 2/11), "[c]hanging the air volume...can easily adjust the particle size" (page 4/11) and "[t]he ACM has numerous varieties of grinding and classifying parts, which allow the unit to produce a wide range of products". Example 4 however, not only fails to specify which specific ACM pulverizer has been used, but also does not mention important parameters, such as the rotating speeds and the air volume that determine the particle size of the final product. The process of example 4 also includes a depolymerization step after the pulverization. However, no indication is given as to the temperature at which this step is to be carried out and its duration.

4.1.3 In the Board's view, the disclosure of example 4 of D2 is unspecific and contains no univocal instruction for its repetition. It provides generic guidance that could be implemented in different ways. In its reproduction of example 4, the appellant-opponent, in the absence of detailed information, has been obliged to make a series of choices (e.g. the apparatus and the operative conditions). These are however not based on information disclosed in D2 but on a number of assumptions made by the appellant-opponent. At least the choice of using the ACM-10 pulverizer appears questionable with regard to the fact that Table 2 of G-2, which discloses some examples of applications of the ACM pulverizers, does not mention any polysaccharide as example of material for which the suggested ACM pulverizer is the ACM-10. It discloses however, that the polysaccharide CMC (carboxymethyl cellulose) can be pulverized by an ACM-60 pulverizer.

On the basis of these considerations the Board concludes that the product obtained by the appellant-opponent in its experiments is not a product which is directly and unambiguously disclosed in D2.

4.2 Therefore, claim 1 is novel over example 13 of D1 and example 4 of D2.

5. Inventive step

5.1 The patent in suit addresses the problem of providing polysaccharide derivatives which are useful as excipients in sustained release dosage forms, and which have an improved flowability ([0004]). As explained in paragraph [0002], the poor flowability of the excipient particles can cause problems in the manufacturing of tablets such as an increased variability of the tablets weight.

5.2 Closest prior art

5.2.1 The Board agrees with the parties and with the opposition division that document D5 represents the closest prior art. Example 1 of D5 describes the preparation of a matrix-tablet containing salicyamide as the active ingredient and HPMC as the component of the matrix. The specific HPMC used is the commercial product 60SH-4000.

The polysaccharide defined in the main request differs from the product 60SH-4000 in the amounts of fine and fibrous particles defined by feature B) of claim 1.

5.3 Technical problem

5.3.1 Table 5 of the patent provides data on the average tablet weight (ATW) and hardness (H) for tablets according to claim 1 (examples 13 to 15) and for comparative tablets (examples A and B). Table 5 also discloses the standard deviations of the ATW and H values.

In the appellant-opponent's view, the results disclosed in Table 5 would not be relevant for the definition of the technical problem since they do not relate to a comparison of the tablets of claim 1 with the tablet of example 1 of D5.

5.3.2 The tablets of examples A and B contain HPMC of CR or DC grade whereas the tablets of examples 13 to 15 contain HPMC having the features of claim 1. These different types of HPMC have substantially the same degree of substitution and viscosity (see paragraphs [0046], [0050] and [0051]). However, as shown in Table 2 of the patent, the amounts of fine and fibrous particles of the HPMC used for the tablets of examples A and B do not fulfil the conditions set out in claim 1 of the main request. The other ingredients contained in the tablets are identical (paragraph [0056]).

Hence, although the patent does not compare the tablets of claim 1 with the one of example 1 of D5, it still provides a comparison that makes it possible to assess the effects due to the amounts of fine and fibrous particles which represent the distinguishing features over the closest prior art.

5.3.3 The data presented in Table 5 show that the standard deviation of the ATW is significantly lower for tablets

containing the polysaccharide of claim 1 than for the comparative tablets. Thus, these data indicate that it is possible to reduce the tablet to tablet weight variation by using a polysaccharide according to claim 1 as excipient.

Thus, on the basis of the experimental results disclosed in Table 5 of the patent, the technical problem is the provision of a polysaccharide that makes it possible to prepare tablets with a more uniform tablet weight.

5.4 Obviousness

5.4.1 The appellant-opponent argued that documents D1 and D2 suggest replacing the polysaccharide of the tablet of example 1 of D5 with a polysaccharide according to claim 1.

5.4.2 This conclusion is not convincing. Neither D1 nor D2 discloses a polysaccharide having the features defined in claim 1. Furthermore, there is no indication in any of these documents to use the polysaccharides disclosed therein as excipients for sustained release tablets and there is no mention of the problem of reducing the variability of tablet weight.

5.5 For the above reasons the Board concludes that the subject-matter of the main request meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the set of claims of the main request (filed on 3 June 2019 as auxiliary request 12) and a description to be adapted thereto.

The Registrar: The Chairman:

B. Atienza Vivancos J. Riolo

Decision electronically authenticated