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**Datasheet for the decision
of 14 April 2016**

Case Number: T 1544/13 - 3.3.07

Application Number: 02727944.7

Publication Number: 1404300

IPC: A61K9/14, A61K9/16

Language of the proceedings: EN

Title of invention:

PHARMACEUTICAL COMPOSITIONS OF DISPERSIONS OF DRUGS AND
NEUTRAL POLYMERS

Patent Proprietor:

BEND RESEARCH, INC.

Opponent:

Wibbelmann, Jobst, Wuesthoff & Wuesthoff Patent- und
Rechtsanwälte

Relevant legal provisions:

EPC Art. 56, 100(a), 107
EPC R. 101

Keyword:

Admissibility of appeal - entitlement to appeal
Inventive step - (no)



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent
Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89
2399-4465

Case Number: T 1544/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 14 April 2016

Appellant: Wibbelmann, Jobst
(Opponent) Wuesthoff & Wuesthoff
Patent- und Rechtsanwälte
Schweigerstrasse 2
81541 München (DE)

Representative: von Hellfeld, Axel
Wuesthoff & Wuesthoff
Patentanwälte PartG mbB
Schweigerstrasse 2
81541 München (DE)

Respondent: BEND RESEARCH, INC.
(Patent Proprietor) 64550 Research Road
Bend, OR 97701-8599 (US)

Representative: Adam, Holger
Kraus & Weisert
Patentanwälte PartGmbH
Thomas-Wimmer-Ring 15
80539 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 27 May 2013
rejecting the opposition filed against European
patent No. 1404300 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman J. Riolo
Members: D. Semino
 D. T. Keeling

Summary of Facts and Submissions

I. European Patent No. 1 404 300 was granted on the basis of 9 claims, independent claim 1 reading as follows:

"1. A pharmaceutical composition comprising a solid amorphous dispersion of

(i) an acid-sensitive drug, that is, a drug which when administered to an acidic solution having a pH of from 1-4 decreases in concentration by at least 1% within 24 hours of administration;

(ii) a neutral concentration-enhancing dispersion polymer, that is, a polymer wherein the number of acidic groups covalently attached to said polymer is less than 0.05 milliequivalents per gram of said polymer; and
(iii) optionally, an excipient selected from the group consisting of a base and a buffer;

characterised in that

(a) said dispersion is substantially homogeneous and is formed by spray-drying;

(b) said drug in the absence of said polymer has a minimum solubility in aqueous solution of less than 1 mg/ml at any pH of from about 1 to 8; and

(c) said polymer is cellulosic and is selected from HPMC;

wherein when said composition comprises a second concentration-enhancing polymer then said dispersion is substantially free of said second polymer, and wherein said composition provides improved chemical stability relative to a control composition comprised of either an equivalent quantity of a dispersion of said drug and an acidic polymer or of an equivalent quantity of a dispersion of said drug and said neutral polymer but free from said base and said buffer."

II. A notice of opposition was filed in which revocation of the patent in its entirety was requested. The notice included form 2300 with an attached letter. In the notice under the item "Opponent - Name" was written "Dr. Jobst Wibbelmann, Wuesthoff & Wuesthoff, Patent- und Rechtsanwälte". In the attached letter under the heading "Opponent" was written "Wuesthoff & Wuesthoff, Patent- und Rechtsanwälte".

III. During opposition proceedings, the following documents *inter alia* were cited:

D2: EP-A-1 027 886

D3: Experimental Study - Comparison of HPMC vs PVP Dispersions

IV. The decision of the opposition division rejecting the opposition was announced at the oral proceedings on 18 April 2013. In the written decision it was indicated that the notice of opposition had been filed by "Wuesthoff & Wuesthoff, Patent- und Rechtsanwälte".

With regard to inventive step, the decision can be summarised as follows:

The subject-matter of granted claim 1 differed from the disclosure in D2, which was the closest prior art, in the selection of acid-sensitive drugs, the selection of HPMC (hydroxypropyl methylcellulose) and the functional definition relating to improved chemical stability over a control composition. The problem solved was the provision of alternative stable drug dispersion compositions of acid-sensitive and low-soluble drugs in dispersion polymers. The results in D3 showed that the use of HPMC resulted in physically stable compositions and nothing more was needed to support the formulation

of the problem as an alternative. The solution of using HPMC as a dispersion polymer without mixing it with a concentration-enhancing polymer was not obvious over D2 itself, which disclosed other polymers which could be used alone and HPMC only in combination with a concentration-enhancing polymer.

- V. The opponent (appellant) lodged an appeal against that decision in the name and on behalf of "Wuesthoff & Wuesthoff, Patent- und Rechtsanwälte", contesting the findings of the opposition division *inter alia* on the issue of inventive step.

- VI. With the reply to the statement setting out the grounds of appeal the patent proprietor (respondent) contested the admissibility of the appeal and filed arguments relating to the objections of the appellant.

- VII. In a communication sent in preparation of oral proceedings, the Board summarised the points to be dealt with, and provided *inter alia* a preliminary view on admissibility concluding that it could "see no justification for rejecting the appeal as inadmissible" (points 1 to 1.2) and on inventive step noting that "the tests in D3 do not refer to a specific disclosure of D2 and appear to address an issue (advantages of HPMC over PVP) which is not derivable from the application as filed" (point 6.3).

- VIII. Oral proceedings were held on 14 April 2016.

- IX. The arguments of the appellant, as far as relevant to the present decision, can be summarised as follows:

Admissibility of the appeal

- a) The question whether "Wuesthoff & Wuesthoff, Patent- und Rechtsanwälte" was a party to the proceedings adversely affected by the decision could only be answered on the basis of the decision, which clearly identified the same party as the one which filed the appeal. Moreover, the fact that the appellant was identical with the party identified in the decision clearly showed the intention to file an admissible appeal in the name of the true party concerned. The indication of "Wuesthoff & Wuesthoff, Patent- und Rechtsanwälte" as the opponent was consistent throughout the proceedings and never contested during opposition, so that the admissibility of the appeal on the basis of the indication of the same party as the appellant could not be called into question.

Patent as granted - inventive step

- b) The composition of claim 1 differed from those disclosed in D2 as the closest prior art in the selection of acid-sensitive drugs, the selection of HPMC and the functional definition relative to the improved chemical stability, whereby the functional feature was automatically achieved when using HPCM as stabilising polymer. The data in D3 were not suitable for demonstrating an unexpected effect for the combination of acid-sensitive drugs and HPMC, as PVP was not suitable for a proper comparison. The problem was therefore the provision of an alternative to the explicitly described solid amorphous dispersions of D2. The solution was not inventive over document D2 itself which disclosed some acid-sensitive drugs and the use of

HPMC as stabilising polymer. While it was true that D2 disclosed the use of HPMC only in combination with a second polymer, it mentioned that it was preferred to form a dispersion with only the drug and a stabilising polymer (such as HPMC) and then mix the second polymer (a concentration-enhancing polymer) to the already formed dispersion. This resulted in a composition falling under claim 1, which specified that, "when said composition comprises a second concentration-enhancing polymer then said dispersion is substantially free of said second polymer". Therefore, the composition of claim 1 did not involve an inventive step.

- X. The arguments of the respondent, insofar as relevant to the present decision, can be summarised as follows:

Admissibility of the appeal

- a) The appeal was not admissible as the appellant defined in the notice of appeal was a legal entity ("Wuesthoff & Wuesthoff, Patent- und Rechtsanwälte"), which was not a party to the proceedings. The opponent was "Dr. Jobst Wibbelmann" as indicated in form 2300 which constituted the notice of opposition. The indication "Wuesthoff & Wuesthoff, Patent- und Rechtsanwälte" was clearly part of the address of the opponent, even if it appeared in the box relating to the name. The identity of the opponent could not be changed by a different indication in the letter accompanying form 2300, or by an erroneous indication in the decision under appeal. The question whether the name of the appellant could be corrected was not relevant, as no request for correction was filed. What was crucial is that

the appeal was neither filed, nor intended to be filed, in the name of the opponent.

Patent as granted - inventive step

- b) The composition of claim 1 differed from the disclosure of D2, which was the closest prior art, in that D2 did not relate to acid-sensitive drugs, did not suggest to choose HPMC and did not mention improved chemical stability. Document D3 demonstrated an unexpected effect related to the use of HPMC, as it could not be expected that it affected the chemical stability of an acid-sensitive drug less than PVP. Since D2 did not consider acid-sensitive drugs, the problem was the provision of concentration-enhanced dispersions for acid-sensitive drugs. Out of the two embodiments of D2, only the second one disclosed HPMC, however only in combination with a second polymer. Therefore, it did not suggest the use of HPMC alone to obtain the advantages shown. Only with hindsight could the skilled person pick acid-sensitive drugs and combine them with HPMC as a single polymer. For these reasons, the composition of claim 1 involved an inventive step.

- XI. The appellant requested that the decision under appeal be set aside and the patent be revoked.
- XII. The respondent requested that the appeal be rejected as inadmissible or that the appeal be dismissed.

Reasons for the Decision

Admissibility of the appeal

1. The respondent raised an objection of inadmissibility in its reply to the statement setting out the grounds of appeal. It submits that the appeal is inadmissible because it was not filed by a party to the proceedings before the opposition division, as required by Article 107 EPC. It argues that the notice of opposition was filed by Dr Jobst Wibbelmann in his own name, whereas the notice of appeal was filed in the name of the firm for which Dr Wibbelmann works, i.e. Wuesthoff & Wuesthoff Patent- und Rechtsanwälte.
- 1.1 In fact a certain amount of confusion about the identity of the opponent was created when the notice of opposition was filed because different persons were referred to in the notice of opposition *stricto sensu* (Form 2300) and in the attached letter containing the grounds of opposition (see point II, above).
- 1.2 The respondent did not at any stage challenge the admissibility of the opposition on the ground that the identity of the opponent was not clear; it argues, on the contrary, that there is no doubt about the identity of the opponent, since the opposition was filed in the name of Dr Wibbelmann in person, and that an appeal cannot be filed by Wuesthoff & Wuesthoff Patent- und Rechtsanwälte because that firm was not a party to the proceedings before the Opposition Division. The argument is that the appeal should be rejected as inadmissible under Rule 101(1) EPC for non-compliance with Article 107 EPC.

- 1.3 The Board has concluded that it cannot uphold the respondent's request for the appeal to be rejected as inadmissible, since it cannot be established that the firm "Wuesthoff & Wuesthoff Patent- und Rechtsanwälte", in whose name the appeal was filed, was not a party to the proceedings before the opposition division within the meaning of Article 107 EPC.
- 1.4 At the beginning of the 16-page document entitled "OPPOSITION - FACTS AND ARGUMENTS", which was filed together with EPO form 2300 entitled "Notice of opposition to a European patent", the opponent was identified as "Wuesthoff & Wuesthoff Patent- und Rechtsanwälte". In so far as there was any confusion about the identity of the opponent, as a result of the slightly different information appearing on page 1 of the official "Notice of opposition" form, where the opponent was referred to as "Dr Jobst Wibbelmann, Wuesthoff & Wuesthoff Patent- und Rechtsanwälte", that could at most be characterized as a failure to comply with Rule 76(2)(a) EPC, which requires the notice of opposition to contain particulars of the opponent. Such a deficiency could have been remedied under Rule 77(2) EPC if the opposition division had brought it to the attention of Dr Wibbelmann and the firm "Wuesthoff & Wuesthoff Patent- und Rechtsanwälte" and requested them to remedy it within a specified period. However, no such deficiency was raised by the opposition division, which proceeded to identify the opponent as "Wuesthoff & Wuesthoff Patent- und Rechtsanwälte" in the decision under appeal. In the light of that circumstance it is entirely logical that the appeal was filed in the name of Wuesthoff & Wuesthoff Patent- und Rechtsanwälte and the view cannot be taken that that firm cannot be treated as a party to the proceedings under Article 107 EPC.

Patent as granted - inventive step

2. Both parties argued on inventive step starting from document D2 as the closest prior art. The Board has no reason to take a different approach.
- 2.1 Document D2 discloses compositions comprising a solid dispersion of a low-solubility drug and at least one polymer, in which at least a major portion of said drug once dispersed in said dispersion is amorphous (claim 1). The preferred method for making the dispersion is by "solvent processing" which consists of dissolution of the drug and one or more polymers in a common solvent followed by removal of the solvent, typically by spray-drying (paragraphs [0069] and [0070]). A large number of drugs may be used in the compositions (paragraph [0066]).
- 2.2 A specific embodiment of D2 discloses compositions containing a mixture of polymers, namely a stabilising polymer and a concentration-enhancing polymer (paragraph [0075]). As examples of suitable stabilising polymers a list of cellulose based polymers is given, including HPMC (paragraph [0077]). With regard to the presence of the concentration-enhancing polymer in the composition, D2 discloses that, in order to obtain the best compromise between stability and bioavailability, the dispersion is formed with only the drug and the stabilising polymer and then the concentration-enhancing polymer is dry- or wet-mixed with the dispersion or otherwise added to the dosage form (paragraph [0078]).
- 2.3 As to the disclosure of document D2, it was not contested that in view of the preferred method of making the dispersion which corresponds to the method of

preparation in the patent (cf. paragraphs [0071]-[0077] in the patent with paragraphs [0069]-[0074] in D2) the solid dispersions of D2 are amorphous and homogeneous. It was also not contested that, while the drugs used in D2 are only referred to as being low-solubility drugs and the issue of acid-sensitivity is not mentioned therein, some of the listed drugs (e.g. famotidine and erythromycin, see paragraph [0066]) are also acid-sensitive. The Board has to reason to diverge from this undisputed reading of D2.

- 2.4 Considering the specific embodiment of D2 with a stabilising polymer in the dispersion and a concentration-enhancing polymer mixed with the dispersion as the one closest to the claimed composition and therefore as the starting point for the analysis of inventive step, the composition of claim 1 differs therefrom in that it contains an acid-sensitive drug and HPMC in combination. While the individual features are present in D2 (see analysis above), their combination is not disclosed therein. As to the stability condition in granted claim 1 ("improved chemical stability relative to a control composition"), it is not disclosed as such in D2, even if the first polymer present in the dispersion is defined as a stabilising polymer.
- 2.5 No data are available to provide a comparison with the compositions disclosed in the relevant embodiment of document D2. Indeed, the only available comparative data are those of D3, which concerns a comparison of HPMC and PVP dispersions where one or the other polymer is used alone in the solid dispersion. Such a comparison has no bearing on the analysis of inventive step starting from the relevant embodiment of D2, as it does not show whether the choice of HPMC among the possible stabilising polymers disclosed in the embodiment in

combination with an acid-sensitive drug brings any advantage or improvement over the other possible options. In this respect it is relevant to note not only that the compositions of the relevant embodiment of D2 contain a stabilising polymer in the dispersion and a concentration-enhancing polymer mixed with the dispersion, while the compositions in D3 have a single polymer in the dispersion, but also that PVP does not appear in the list of stabilising polymers of that embodiment (see paragraph [0077] of D2 and point 2.2, above), but only as a possible concentration-enhancing polymer to be used in addition (paragraph [0081] of D2).

- 2.6 In the absence of proven effects, improvements or advantages over the relevant compositions of document D2, the problem solved is to be formulated as the provision of a further composition.
- 2.7 As outlined above, document D2 itself discloses all the features of granted claim 1, although not an acid-sensitive drug and HPMC as dispersion polymer in combination. However, the skilled person, looking for further compositions, would equally consider all options within the disclosure in D2, including this combination, as possible solutions to the posed problem without exercising any inventive activity. As the problem is the provision of a further composition, no hint to the specific combination is necessary. In this respect it is worthwhile noting that any different approach would make inventive any arbitrary choice within the disclosure of the document, which is not acceptable.
- 2.8 With regard to the stability condition in granted claim 1 ("wherein said composition provides improved chemical stability relative to a control composition comprised of either an equivalent quantity of a

dispersion of said drug and an acidic polymer or of an equivalent quantity of a dispersion of said drug and said neutral polymer but free from said base and said buffer"), the Board considers that it is automatically fulfilled when HPMC is used as a stabilising polymer. In this respect, there is no reason, nor any argument on the side of the respondent (who maintained that it is the specific choice of the polymer to confer stability) to conclude otherwise.

2.9 As to the arguments of the respondent that, contrary to what is claimed, HPMC is disclosed in the relevant embodiment of D2 only in combination with a second polymer and that D2 does not suggest the use of HPMC alone, it is noted that claim 1 includes the condition that "when said composition comprises a second concentration-enhancing polymer then said dispersion is substantially free of said second polymer". The presence of a second polymer is therefore not excluded in claim 1, but, on the contrary, it is foreseen, as long as the second polymer is not part of the dispersion. This is exactly what takes place in the relevant embodiment of D2, where the dispersion is formed with the drug and the first polymer (a stabilising polymer such as HPMC) and the second polymer (the concentration-enhancing polymer) is mixed with the dispersion already formed (paragraph [0078] of D2, see also point 2.2, above). In view of this correspondence between the teaching of D2 and what is covered by the claim, the arguments of the respondent have no bearing on the conclusion reached above.

2.10 For these reasons, the composition of claim 1 does not involve an inventive step.

Conclusion

3. As lack of inventive step is found for the patent as granted and no other request is present on file, it is not necessary for the Board to decide on any other issue and the patent is to be revoked.

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:



S. Fabiani

J. Riolo

Decision electronically authenticated