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**D E C I S I O N
of 18 May 2004**

Case Number: T 0412/00 - 3.3.2
Application Number: 92300406.3
Publication Number: 0551700
IPC: A61K 9/28
Language of the proceedings: EN

Title of invention:

Film coatings and film coating compositions based on
cellulosic polymers and lactose

Patentee:

BPSI Holdings, Inc., et al

Opponents:

SOCIETE D'EXPLOITATION DE PRODUITS POUR L'INDUSTRIE CHIMIQUE,
S.E.P.P.I.C
Roche Diagnostics GmbH

Headword:

Film coatings/BPSI

Relevant legal provisions:

EPC Art. 54, 84, 100(a),(b), 123(2),(3)

Keyword:

"Amended claims according to the appellant's main request -
compliance with the formal requirements of Article 84,
123(2)(3) EPC: yes"

"Novelty: yes"

"Agreement of the parties with the board's findings; requests
for oral proceedings withdrawn; remittal of the case to the
department of the first instance for further prosecution"

Decisions cited:

T 0925/98

Catchword:

-



Case Number: T 0412/00 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 18 May 2004

Appellant: BPSI Holdings, Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 21 February 2000
revoking European patent No. 0551700 pursuant
to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: G. F. E. Rampold
P. Mühlens

Summary of Facts and Submissions

I. This appeal is against the decision of the opposition division posted on 21 February 2000 to revoke European patent No. 0 551 700 ("the patent") entitled "Film coatings and film coating compositions based on cellulosic polymers and lactose". The Patent was granted to the appellant/proprietor with 38 claims on the basis of European patent application No. 92 300 406.3. The independent claims of the patent as granted read as follows:

- "1. A dry film coating composition for use in pharmaceuticals, food, confectionery forms, agricultural seeds, and the like, comprising a cellulosic polymer in an amount from 11% to 56% by weight of the composition, and lactose.

12. A method of coating substrates such as pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising:
mixing a cellulosic polymer and lactose into water to form an aqueous coating suspension, the cellulosic polymer forming from 11% to 56% by weight of the non-water ingredients;
spraying the coating suspension onto the substrates to form a film coating on the substrates; and
drying the film coating on said substrates.

14. A method of making a dry film coating composition for use in coating pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising

mixing a cellulosic polymer and lactose together to form a dry film coating composition, the cellulosic polymer forming from 11% to 56% by weight of the composition, preferably from 20% to 30%.

16. A method of making a dry film coating composition for use in coating pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising mixing a cellulosic polymer and lactose into water to form an aqueous coating suspension, the cellulosic polymer forming from 11% to 56% by weight of the non-water ingredients, preferably from 20% to 30%, and spray granulating the aqueous coating suspension to form a dry film coating composition.

 28. An aqueous coating suspension for coating substrates such as pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising a mixture of a cellulosic polymer, lactose, and water, the cellulosic polymer forming from 11% to 56% by weight of the non-water ingredients."
- II. Oppositions to the patent were originally filed by two parties - opponent 01 (respondent) and former opponent 02 which both sought revocation in full on the grounds of lack of novelty and inventive step (Articles 54, 56 and 100(a) EPC).

III. In the course of prosecution of the case before the opposition division, eighteen documents were relied upon by the parties. Of these documents, the following are referred to in the present decision (the numbering used by the opposition division is adhered to):

(11) JP Kokai Publication No. 51-123 815, date of publication: 28 October 1976 (English translation)

(12) JP Kokai Publication No. 49-133 515, date of publication: 21 December 1974 (English translation)

IV. The proprietor/appellant filed on 26 November 1999 an amended set of 23 claims forming its "First Auxiliary Request". In these claims, claims 1 and 10 as granted were combined and the other independent claims had a similar limitation introduced. This meant that claim 11 as granted was drafted in "First Auxiliary Request" as an independent claim, new claim 10. The independent claims of the "First Auxiliary Request" before the opposition division read as follows:

"1. A dry film coating composition for use in film coating pharmaceuticals, food, confectionery forms, agricultural seeds, and the like, comprising
a cellulosic polymer in an amount from 11% to 56% by weight of the composition, and
lactose in an amount from 11% to 56% by weight of the composition.

10. A dry film coating composition for use in film coating pharmaceuticals, food, confectionery

forms, agricultural seeds, and the like, formed from 40% by weight cellulosic polymer and 60% by weight lactose.

11. A method of coating substrates such as pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising:
mixing a cellulosic polymer and lactose into water to form an aqueous coating suspension, the cellulosic polymer forming from 11% to 56% by weight of the non-water ingredients and the lactose forming from 11% to 56% by weight of the non-water ingredients;
spraying the coating suspension onto the substrates to form a film coating on the substrates; and
drying the film coating on said substrates.

13. A method of making a dry film coating composition for use in coating pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising
mixing a cellulosic polymer and lactose together to form a dry film coating composition, the cellulosic polymer forming from 11% to 56% by weight of the composition, preferably from 20% to 30%, and the lactose forming from 11% to 56% by weight of the composition.

15. A method of making a dry film coating composition for use in coating pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising

mixing a cellulosic polymer and lactose into water to form an aqueous coating suspension, the cellulosic polymer forming from 11% to 56% by weight of the non-water ingredients, preferably from 20% to 30%, and the lactose forming from 11% to 56% by weight of the non-water ingredients, and spray granulating the aqueous coating suspension to form a dry film coating composition."

- V. The opposition division revoked the patent at the end of the oral proceedings pursuant to Article 102(1) EPC. The stated ground for the revocation was that the subject-matter of claim 12 of the main request and likewise claim 11 of the "First Auxiliary Request" lacked novelty over the disclosure of citation (12).
- VI. In its reasons for the decision, the opposition division found that citation (12) disclosed in the paragraph bridging pages 3/8 and 4/8 a method of coating tablets characterised by using as the coating material an aqueous suspension containing a mixture of hydroxypropylmethyl cellulose or hydroxypropyl cellulose and a saccharide at a weight ratio of 1:1. In the second paragraph on page 4/8 of (12) it was specified that the saccharide component might be selected from a range of six different saccharide compounds, including lactose. The coating method of (12) also included the step of spraying the suspension onto the tablets at elevated temperature in order to reduce the coating time and to form a dry film coating on said tablets.

As pointed out by the opposition division in the impugned decision, the patent proprietor/appellant did

not question the fact that the above-mentioned disclosures in citation (12) formed part of the state of the art, but disputed categorically that the presence of the cellulosic polymer in **an amount of from 11% to 56% by weight based on the non-water ingredients** was also directly and unambiguously derivable from the prior art of citation (11) or (12). The opposition division did not share this view. It considered that the reference in (12) to an aqueous coating suspension consisting of a cellulosic polymer and lactose at a weight ratio of 1:1 inevitably led the skilled reader to the conclusion that each of the two components was present in the coating suspension in a proportion of 50% by weight based on the non-water ingredients, since the wording "consisting of" excluded, in the opposition division's opinion, the presence of other components in the mixture. Although it was correct that, according to the disclosure on page 6/8 of citation (12), "if desired, a colorant usually used in colouring may be added" to the coating suspension, the opposition division emphasised that the addition of any further non-water ingredients to the aqueous coating suspension was disclosed in (12) as an entirely optional measure. Moreover, when looking into the examples of (12) the skilled reader would have immediately recognised that any of the optional ingredients, if present at all, was used in very small amounts, making sure that the proportion of the cellulosic polymer would not fall below the lower limit of 11% by weight specified in claim 12.

As regards the "First Auxiliary Request", the opposition division considered that the additional feature in claim 11 stipulating that lactose be present

in an amount from 11% to 56% by weight of the non-water ingredients was likewise already disclosed in (12) by the reference to the use of the cellulosic polymer and lactose in the coating composition at a weight ratio of 1:1.

In paragraph 4 of the decision under appeal, the opposition division indicated clearly that it did not consider, apart from citation (12), any of the further pieces of evidence submitted by the parties to the opposition proceedings and that it also did not consider, apart from the lack of novelty of claim 12 and claim 11 of the "First Auxiliary Request" over citation (12), any other grounds of opposition invoked by the opponents.

- VII. Together with the statement setting out the grounds of appeal filed on 23 June 2000, the appellant submitted a main request and auxiliary requests 1 to 12. The main request was identical to that in the decision under appeal, i.e. it consisted of claims 1 to 38 as granted. The claims of the auxiliary requests recited various further limitations.
- VIII. The respondent filed observations in reply supporting its request for the appeal to be dismissed with its letter of 4 January 2001.
- IX. In accordance with the requests of the appellant and the respondent, the board with communication of 10 November 2003 summoned the parties to oral proceedings, scheduled to take place on 18 May 2004.

X. In a letter dated 10 December 2003, former opponent 02 withdrew the opposition.

XI. In advance of the hearing before the board, the appellant submitted with its letter of 16 April 2004 an amended main request (also designated 13th Auxiliary Request) and three new auxiliary requests (designated 14th, 15th and 16th Auxiliary Requests) to replace all previous requests. The independent claims of the current main request read as follows with the amendments compared to the corresponding claims as granted (i.e. limitation of the absolute amounts of cellulosic polymer to the **range of "from 11% to 30% by weight** of the composition or the non-water ingredients") indicated in bold italic letters:

"1. A dry film coating composition for use in pharmaceuticals, food, confectionery forms, agricultural seeds, and the like, comprising a cellulosic polymer in an amount from 11% to **30%** by weight of the composition, and lactose.

11. A method of coating substrates such as pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising:
mixing a cellulosic polymer and lactose into water to form an aqueous coating suspension, the cellulosic polymer forming from 11% to **30%** by weight of the non-water ingredients;
spraying the coating suspension onto the substrates to form a film coating on the substrates; and
drying the film coating on said substrates.

13. A method of making a dry film coating composition for use in coating pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising mixing a cellulosic polymer and lactose together to form a dry film coating composition, the cellulosic polymer forming from 11% to **30%** by weight of the composition.

 16. A method of making a dry film coating composition for use in coating pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising mixing a cellulosic polymer and lactose into water to form an aqueous coating suspension, the cellulosic polymer forming from 11% to **30%** by weight of the non-water ingredients, and spray granulating the aqueous coating suspension to form a dry film coating composition.

 28. An aqueous coating suspension for coating substrates such as pharmaceutical tablets, food and confectionery forms, agricultural seeds, comprising a mixture of cellulosic polymer, lactose, and water, the cellulosic polymer forming from 11% to **30%** by weight of the non-water ingredients."
- XII. In a communication dated 10 May 2004, the rapporteur indicated to the parties that, according to his preliminary, non-binding opinion, amended claims 1 to 37 of the appellant's main request appeared to satisfy

the formal requirements of Articles 84, 123(2) and (3) EPC and to be novel within the meaning of Article 54(1) EPC over the prior art of citations (11) and (12), in view of the limitation of the absolute amounts of cellulosic polymer in the broadest claim to the claimed range of 11% to 30% by weight of the composition or the non-water ingredients.

The rapporteur also informed the parties that the board would see no necessity for the hearing to decide this case if they were to agree that the board allows the appeal on the basis of the appellant's main request and issues a decision with the following Order: The decision under appeal is set aside and the case is remitted to the department of first instance for further prosecution.

XIII. In reply to the above communication, the respondent and the appellant agreed that claims 1 to 37, according to the appellant's main request of 16 April 2004, meet the formal requirements of Articles 84, 123(2) and (3) EPC and that the subject-matter of these claims is novel over the prior art of citations (11) and (12). Both withdrew their request for oral proceedings, in the event that the board would allow the appellant's main request and issue a decision containing the Order set forth in XII above.

XIV. The board, by a communication of 13 May 2004, informed the representatives of the parties that the oral proceedings due to take place on Tuesday, 18 May 2004 had been cancelled.

Reasons for the Decision

1. The appeal is admissible.

Admissibility of the appellant's main request

2. The board considers that the appellant's current main request should be admitted into the proceedings. Although this request was filed late in the appeal proceedings - by a letter of the appellant on 16 April 2004, about one month before the date originally fixed for the oral proceedings - it was a response to the respondent's arguments developed during the written appeal proceedings. That said, those arguments were filed by the respondent over three years previously, with the respondent's letter of 4 November 2001, and the board does not condone such lateness *per se*.

However, in the present case the skilled reader would have recognised that the sole amendment to the claims of the appellant's current main request in comparison with the claims as granted consists of a limitation of the percentage of the cellulosic polymer to the range of from 11% to 30% by weight of the dry composition or the non-water ingredients (see XI above). Coupled with the fact that the respondent had nearly one month in which to study the case and to consider and prepare arguments in reply to the appellant's late filed main request, the board exercises its discretion in favour of the appellant and admits the main request into the proceedings.

- 2.1 The amendments to the claims of the current main request can fairly be said to be occasioned by grounds

for opposition specified in Article 100(a) EPC and to constitute a *bona fide* attempt on the part of the appellant to overcome the respondent's objections to lack of novelty and inventive step in the opposition and appeal statements. The proposed amendments to the granted patent are thus also admissible under the terms of Rule 57a EPC.

Allowability of the amended claims

3. The amendments to the claims of the appellant's main request before the board can be found in the application for the patent as originally filed; and the scope of the claims has not been extended by the amendments made to the claims as granted.
 - 3.1 Support for the proposed limitation of the percentage by weight of cellulosic polymer can be found in the application as filed on page 4, lines 4 to 11, where it is disclosed: *"The quantity of the cellulosic polymer is within the range of about 11% to about 56% by weight of the dry film coating composition and of the non-water ingredients of the aqueous coating suspension. A range of about 20% to 30% of the dry film coating composition and of the non-water ingredients of the aqueous coating suspension is preferred."*
 - 3.2 In decision T 925/98 of 13 March 2001 (see Case Law of the Boards of Appeal, 4th edition, 2001, III.A.3.3, page 220) the board stated that, in the case of a disclosure of both a **general range** and a **preferred range**, a combination of the preferred disclosed narrower range and one of the part-ranges lying within the disclosed overall range on either side of the

narrower range was unequivocally derivable from the original disclosure of the patent in suit. Thus, claiming a range of cellulosic polymer of from 11% to 30% by weight of the dry film coating composition and of the non-water ingredients of the aqueous coating suspension does not, in the present case, contravene Article 123(2) EPC and represents a major limitation of the scope of the claims as granted. Accordingly the claims now under consideration also meet the requirements of Article 123(3) EPC.

3.3 Although an objection under Article 84 EPC cannot in itself be a ground for opposition under Article 100 EPC, the board accepts that such an objection could be raised during opposition or opposition appeal proceedings if amendments made in those proceedings emphasised a problem of clarity. In the present case, however, the board sees no reason to call into question the clarity of the amended claims.

3.4 Since both the respondent and the appellant agreed with the opinion expressed in the board's communication of 10 May 2004 that claims 1 to 37 according to the appellant's current main request (Auxiliary Request 13) of 16 April 2004 meet all formal requirements of Articles 84, 123(2) and (3) EPC, there is no need for further detailed substantiation of this matter.

Novelty over citations (11) and (12)

4. In its communication of 10 May 2004, the board communicated its opinion to the parties that the subject-matter of claims 1 to 37 according to the appellant's current main request meets the requirement

of novelty within the meaning of Article 54(1) EPC over the prior art of citations (11) and (12), by virtue of the limitation of the proportion of cellulosic polymer to the range of from 11% to 30% by weight of the dry film coating composition and of the non-water ingredients of the aqueous coating suspension. Since this fact has not been disputed, any more detailed comments on the novelty over (11) and (12) would be superfluous.

Auxiliary requests

5. Since the main request is allowable, there is no need to examine the auxiliary requests.

Remittal to the department of first instance

6. Under Article 111(1) EPC, following initial examination of the appeal, the board has the discretionary power to remit the case to the first instance for further prosecution. The department of first instance is then required to take its own further decision on the merits of the case, without the board having given any ruling on the outcome to be expected. The purpose of referral back to the first instance department is to afford that instance the opportunity to consider and decide independently on the issues previously not dealt with. Thus, the board hereby remits this case to the department of first instance in order to give that instance the opportunity to examine, in the light of the cited documents and pieces of evidence **in their entirety**, whether or not any of the grounds for opposition invoked by the opponents, i.e. lack of

novelty **and** inventive step, prejudices the maintenance of the European patent.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:

A. Townend

U. Oswald