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D E C I S I O N
of 28 March 2001

Case Number: T 0081/98 - 3.3.2

Application Number: 93301442.5

Publication Number: 0587264

IPC: A61K 31/35

Language of the proceedings: EN

Title of invention:
Aqueous pharmaceutical formulations of sodium cromoglycate

Patentee:
FISONS plc

Opponent:
Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH

Headword:
Pharmaceutical formulations/FISONS

Relevant legal provisions:
EPC Art. 54

Keyword:
"Novelty: no - claimed range anticipated by an individualised value of the prior art"
"Late filed requests: no - contrary to a direction of the Board"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0081/98 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 28 March 2001

Appellant: (Proprietor of the patent)
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Respondent: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 27 November 1997 revoking European patent No. 0 587 264 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
C. Rennie-Smith

Summary of Facts and Submissions

I. European Patent No. 0 587 264 based on application No. 93 301 442.5 was granted on the basis of 10 claims.

Independent claims 1 and 10 as granted read as follows:

"1. A pharmaceutical formulation comprising a substantially clear aqueous solution characterised in that it has a viscosity of less than 10 mPa.s and contains 3.5 to 5% w/v of 1,3-bis(2-carboxychromon-5-yloxy)-propan-2-ol, or a pharmaceutically acceptable salt thereof, as active ingredient and glycerol, the concentration of ions of metals of groups IIA, IB, IIB and IVB of the periodic table or of transition metals being less than 20 ppm.

10. A pharmaceutical pack comprising a formulation according to any one of the claims 1 to 8, containing from 10 to 35 mg of active ingredient in unit dosage form.".

II. Opposition was filed against the granted patent by the respondent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step.

The following document was cited *inter alia* during the proceedings before the Opposition Division and the Board of Appeal:

(1) Research Disclosure, No. 318, 1990, pages 832 and 833

III. The decision of the Opposition Division pronounced on 17 November 1997, and posted on 27 November 1997

revoked the patent under Article 102(1)EPC for lack of inventive step.

Although the Opposition Division was of the opinion that the subject-matter of the claimed sodium cromoglycate formulation was novel over the disclosure in document (1) because of the selected range of sodium cromoglycate, it concluded that the choice of the particular range of sodium cromoglycate in relation to the use of glycerol as tonicity-adjusting agent in low viscous formulations was not inventive as no unexpected effects were shown for it.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. By a communication dated 1 October 2000, the Board drew the attention of the parties to the fact that the case was ready for decision at the conclusion of the oral proceedings and pointed out that any possible amended claims should be filed no later than one month before the date appointed for the oral proceedings.

VI. Oral proceedings were held before the Board on 28 March 2001. During the oral proceedings, the appellant sought to introduce drafts of new first and second auxiliary requests, which were refused by the Board as filed too late.

VII. The appellant's submissions both in the written procedure and at the oral proceedings can be summarised as follows:

As to novelty, it argued that the claimed range of sodium cromoglycate rendered the subject-matter of

claim 1 of the contested patent novel because it was not derivable from the disclosure in document (1).

In its view, the claimed subject-matter was also inventive because of the unpredictable and surprising beneficial effect of glycerol on the stability of the solution containing sodium cromoglycate as shown by the comparative examples carried out with respect to sodium chloride, mannitol and propylene glycol and by the declarations on file.

VIII. The respondent (opponent) contested these arguments. Its submissions in support of its requests can be summarised as follows:

It first maintained that the subject-matter of the contested patent was not novel over document (1) because the claimed range of 3,5% w/v to 5% w/v of sodium cromoglycate was anticipated by the disclosure in this document which mentioned a range between 0.1% w/v and 5% w/v for said compound.

It moreover disputed the validity of the comparative experiments and stressed that no effect was in fact shown over the closest prior art document (1), ie over a solution containing glycerol and 3,5% w/v sodium cromoglycate instead of 2% w/v, as was held by the Opposition Division.

IX. The appellant requested that the decision under appeal be set aside and that the patent be maintained.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty*

2.1 Document (1) has been cited under Article 54 EPC as prejudicial to the novelty of the subject-matter of the patent in suit.

Document (1) describes a pharmaceutical formulation comprising an aqueous solution containing 2% w/v of 1,3-bis(2-carboxychromon-5-yloxy)-propan-2-ol sodium salt (sodium cromoglycate) as active ingredient and glycerol (see example on page 833, right column, in combination with lines 27 to 32).

Document (1) does not mention *expressis verbis* that this pharmaceutical formulation is a substantially clear aqueous solution which has a viscosity of less than 10 mPa.s and that the concentration in the formulation of ions of metals of groups IIA, IB, IIB and IVB of the periodic table or of transition metals is less than 20 ppm.

However, in reply to a question from the chairman of the Board, the patentee admitted that these features were not distinguishing features over document (1). Having regard to the similarity of the method of preparation of the pharmaceutical formulation according to the contested patent with that of document (1), the Board indeed sees no reason to expect a different viscosity or a different metal content in the two formulations.

Accordingly, it only remains to decide whether the remaining feature of claim 1 of the patent in suit, ie the range of 3,5 w/v to 5% w/v of sodium cromoglycate, could be regarded as novel over the disclosure of document (1).

In that respect, the Board notes that document (1) indicates that the concentration of sodium cromoglycate may be from 0.1% w/v to 10% w/v and that it is preferred that the concentration of sodium cromoglycate be less than **5%** w/v (see page 832, lines 19 to 21).

Thus, document (1) discloses several ranges and individual values of sodium cromoglycate concentration, ie, the broadest range from 0.1% w/v to 10% w/v with the individual values 0.1% w/v and 10% w/v, a sub-range from 0.1% w/v up to less than 5% w/v, excluding the value of 5% w/v of sodium cromoglycate, and a sub-range starting with the value of 5% w/v of sodium cromoglycate.

The general reader as well as the skilled person will inevitably read the value of 5% w/v for the concentration of sodium cromoglycate in this document as the following value which comes immediately after the range defined up to less than 5% w/v, ie up to 4,9 (recurring).

Accordingly, this individualised value anticipates the claimed range of 3,5% w/v to 5% w/v as this range encompasses the disclosed value of 5% w/v.

In conclusion, the subject-matter of claim 1 of the patent in suit lacks novelty under Article 54 EPC.

2.2 The appellant patentee emphasized that document (1) taught that sugars, and in particular mannitol, were preferred to glycerol, that the preferred sodium cromoglycate concentrations were 1% w/v and 2% w/v as confirmed by the concrete examples and that the claimed range of 3,5% w/v to 5% w/v of sodium cromoglycate was not to be found in document (1) as such.

The Board does not dispute these facts. However, these considerations, which might be relevant for the assessment of inventive step do not change the relevance of the disclosure of document (1) with respect to novelty as explained at 3.1 above.

As to the disclosure of the range 3,5% w/v to 5% w/v as such, it is pointed out that it is sufficient that a single value falling within the claimed range is disclosed in the prior art in order to destroy its novelty, which is precisely the case here with document (1).

2.3 In the light of these facts, the Board can only conclude that the subject-matter of claim 1 is not novel contrary to the requirement of Article 54 EPC.

Since claim 1 of the only set of claims under consideration is not allowable, there is no need for the Board o consider the remaining claims.

3 *Admissibility of late-filed requests*

3.1 As mentioned at VI above, the appellant sought to introduce two new sets of amended claims as auxiliary requests during the oral proceedings. The Board held these requests inadmissible for the following reasons.

3.2 These requests would, if admissible, have substantially altered the nature of the invention claimed by the patent in suit, thus presenting the Board and the respondent with a largely different case to consider at the very end of the appeal proceedings. The requests were produced by the appellant in response to the direction taken by the discussion of novelty during the oral proceedings. That direction was however entirely predictable and to some extent the result of the way the appellant itself chose to conduct its appeal. At first instance the appellant had succeeded on the issue of novelty but none the less dealt with it in detail in its Grounds of Appeal filed on 31 March 1998. That inevitably meant that novelty was an issue which received as much attention in the appeal proceedings as inventive step, the issue on which the Opposition Division had revoked the patent and thus caused the appellant to appeal. The appellant thus having had, in the context of the appeal proceedings alone, almost three years before the oral proceedings in which to prepare its case on novelty including, if it so chose, to file auxiliary requests, it would be wrong to allow such requests at this stage.

3.3 Further, and more significantly, the Board had by its communication of 1 October 2000 (see V above) directed the appellant to file any possible amended claims no later than one month before the oral proceedings. The unmistakable purpose of that direction was to ensure the Board and the respondent had sufficient time to consider such requests before the oral proceedings and to avoid the possible delays which late filing can always produce. The Board has always to consider that delays can prejudice not just other parties to the appeal in question but other appeals pending before it.

It would be inequitable to "reward" the appellant for ignoring that direction by allowing it to file at the last moment claims which the respondent might have difficulty in dealing with without an adjournment of the oral proceedings, or continuation of the proceedings in writing and, in either event, avoidable delay.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Townend U. Oswald