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Datasheet for the decision of 16 January 2009

Case Number: T 1636/06 - 3.3.02

Application Number: 91918144.6

Publication Number: 0554291

IPC: A61K 31/60

Language of the proceedings: EN

Title of invention:
Treatment of non-inflammatory bowel disordres

Patentee:
CENTRE FOR DIGESTIVE DISEASES PTY LTD

Opponent:
Dr. Falk Pharma GmbH

Headword:
Bowel disordres/CENTRE FOR DIGESTIVE DISEASES PTY LTD.

Relevant legal provisions:
EPC Art. 123, 54, 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Added matter - no: restriction to a preferred embodiment"
"Novelty - yes: undisclosed technical effect"
"Inventive step - yes: non obvious property of a known pharmaceutical"

Decisions cited:
-

Catchword:
-

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Case Number: T 1636/06 - 3.3.02

DECISION
of the Technical Board of Appeal 3.3.02
of 16 January 2009

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 22 August 2006 revoking European patent No. 0554291 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
P. Mühlens

Summary of Facts and Submissions

I. European patent No. 0 554 291, based on European application No. 91 918 144.6, was granted on the basis of 5 claims.

Independent claim 1 as granted read as follows:

"1. The use of an anti-inflammatory agent, being a salicylic acid derivative, in the manufacture of a medicine for use in the treatment of non-inflammatory bowel disorders."

II. Opposition was filed against the patent under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(c) EPC (added subject-matter).

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

(2) H. Siebner et al, Ther. d. Gegnw. 114 (1975), 982-992
(3) GB-A-2 021 409

III. By its decision pronounced on 27 June 2006, the Opposition Division revoked the patent.

On Article 123(2) EPC, the Examining Division was of the opinion that the term "anti-inflammatory agent", which replaced the wording "antibiotic agent" in the claims during the examination proceedings, was not disclosed in the application as originally filed.

In its view, since the group of salycilic acid derivatives having anti-inflammatory activity and the one having antibiotic activity were not identical, the amendment resulted in a different group which extended the subject-matter of the patent beyond that of the application as originally filed.

Novelty was acknowledged by the Opposition Division vis-à-vis documents (2) and (3).

The opponent based the novelty objection on the disclosure in document (2) and argued that this document, which disclosed the treatment of the inflammatory disease diverticulitis with sulfasalazin (i.e. a salycilic acid derivative), anticipated the subject-matter of the claims because non-inflammatory diverticular disease, which was the primary disease, was treated at the same time.

The Opposition Division did not share this view. It was of the opinion that document (2) clearly indicated that the patients treated were suffering from diverticulitis (page 983, second paragraph and table), ie an inflammatory disease, and that there was nothing to confirme the opponent's statement that the non-inflammatory diverticular disease was still present when diverticulitis had developed and/or that this non-inflammatory condition was also treated.

The opponent based its novelty objection also on document (3) and submitted that this document disclosed that aminosalicylic acids (ASAs) could be used in the

treatment of non-inflammatory irritable bowel syndrome (IBS) (page 1, lines 27 to 39; page 3, lines 54 to 59).

Again, the Opposition Division did not agree. In its view, and as argued by the patent proprietor, as the composition containing ASA comprised sodium cromoglycate, which was known to treat IBS conditions, the skilled person had no incentive to believe that ASA, which was a well-known anti-inflammatory pharmaceutical, was the active substance involved in the treatment of this non-inflammatory condition. The more so because the aim of document (3) was only to diminish the negative side-effects of ASA and not at all an attempt to find new indications for ASA (page 1, lines 18 to 24).

With respect to inventive step, the only objection raised by the opponent was based on the assumption that it was not shown in the patent in suit that all anti-inflammatory derivatives of salicylic acid could be used for all non-inflammatory bowel disorders.

In that respect, it referred to the disclosure in the patent in suit which indicates that only amino ASA compounds could be used for the treatment of IBS.

As to inventive step, the Opposition Division was of the opinion that, as none of the available prior art documents dealt with non-inflammatory bowel disorders in relation with ASA, the claimed use could not be deduced from the prior art and was therefore inventive as far as ASA derivatives were concerned.

It however expressed the view that derivatives different from ASA would not solve the problem of treating IBS in the light of the disclosure in the patent in suit quoted by the opponent.

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

It filed a new set of claims with its letter dated 5 June 2008.

Independent claim 1 of this set of 4 claims reads as follows:

"1. The use of 5-aminosalicylic acid in the manufacture of a medicine for use in the treatment of non-inflammatory bowel disorders."

Dependent claims 2, 3 and 4 correspond respectively to the accordingly restricted and renumbered claims 2, 4 and 5 as granted.

V. In a letter dated 4 August 2008, the respondent informed the appellant and the Board that it would not attend or be represented at the oral proceedings scheduled for 12 September 2008.

VI. By a fax dated 11 September 2008, the oral proceedings were cancelled.

VII. In its written submissions, the appellant held that the claims were now specifically restricted to a single compound, namely 5-aminosalicylic acid (5-ASA), which was specifically disclosed in the application as

originally filed. Thus the requirements of Article 123(2) EPC were fulfilled.

It further added that the removal of the term "anti-inflammatory agent" did not extend the scope of the claim, as it was known when the specification was filed that 5-aminoslicylic acid was an anti-inflammatory drug. Thus the requirements of Article 123(3) EPC were also fulfilled.

It moreover pointed out that the Opposition Division had already held in its decision that the use of aminosalicylic compounds such as 5-aminosalicylic acid (5-ASA) to treat non-inflammatory bowel disorders was inventive.

VIII. In its brief reply to the grounds of appeal the respondent made only the general comment that the suppression of a feature contravened Article 123(3) EPC.

IX. In its letter dated 13 October 2008, the respondent asked for information about the continuation of the procedure.

X. With its communication dated 13 November 2008, the Board informed the respondent that, as it was clear from the circumstances of the present case, the procedure will be terminated by a written decision based on the facts on file as they stood at the day of the cancelation of the oral proceedings.

XI. The appellant requested in writing that the decision of the Opposition Division be set aside and that the

patent be granted on the basis of the set of claims filed with the letter dated 5 June 2008.

The respondent requested in writing that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2. *Admissibility of the set of claims filed 5 June 2008*

This set of claims corresponds to the set of claims filed with the grounds of appeal wherein dependents claims 2 and 3 were deleted as well as the terms "irritable bowel syndrome" in claim 4.

As these simple amendments do not delay the proceedings and as they have been submitted over three months before the date of the cancelled oral proceedings, the Board decides to admit this set of claims into the proceedings.

In that respect, the Board notes also that the respondent did not contest they admission before the date of the cancelled oral proceedings.

2.1 Article 100c) EPC

Claim 1 is now limited to 5-aminosalicylic acid (5-ASA). A basis for this preferred compound can be found on page 4, lines 13 to 16 and in claims 12 and 13 of the application as originally filed.

Claim 1 as amended therefore does not contravene Article 123(2) EPC.

Moreover, the suppression of the redundant functional feature "anti-inflammatory" in relation with the chemical structure 5-ASA does not contravene Article 123(3) EPC.

The respondent's general comment therefore does not apply in this case, as the functional feature merely recites a well-known property of the chemical structure (see appellant's grounds of appeal, page 1, paragraph 6).

Accordingly the Opposition Division's decision does not hold good for this set of claims and must be set aside.

2.2 Novelty and inventive step

The Board agrees with the analysis and the favourable conclusions of the Opposition Division in respect of novelty and inventive step. That applies of course also in full to the present restricted subject-matter (see details above under III, and the Opposition Division's decision, point III and IV).

Moreover, as the respondent has neither said why the Opposition Division's decision was incorrect as regards its favourable conclusions and analysis with respect to novelty and inventive step, nor submitted any new elements in that respect, the Board has nothing to add to the Opposition's Division's decision.

In addition, as the restricted claims do not cover derivatives different from ASA, the Opposition Division's view that derivatives different from ASA would not solve the problem of longer treating IBS is no relevant.

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 with the order to maintain the patent in amended form on the basis of claims 1 to 4 filed with letter of 5 June 2008 and a description to be adapted.

The Registrar The Chairman

N. Maslin U. Oswald