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Datasheet for the decision of 9 January 2015

Case Number: T 1026/11 - 3.3.07

Application Number: 03736462.7

Publication Number: 1503739

IPC: A61K9/20

Language of the proceedings: EN

Title of invention:
SUSTAINED RELEASE OF GUAIFENESIN COMBINATION DRUGS

Applicant:
Reckitt Benckiser LLC

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - added subject-matter (yes)

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Case Number: T 1026/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 9 January 2015

Appellant: (Applicant)	Reckitt Benckiser LLC Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054 (US)
Representative:	O'Brien, Niall James Reckitt Benckiser Corporate Services Limited Legal Department - Patents Group Dansom Lane Hull HU8 7DS (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 8 December 2010 refusing European patent application No. 03736462.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	D. Semino
	P. Schmitz

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division announced at oral proceedings on 11 November 2010 to refuse European patent application n° 03 736 462.7.

II. Claims 1, 2 and 5 of the application as originally filed read as follows:

"1. A drug delivery system in which a unit dose form comprises a sustained release portion comprising guaifenesin, and optionally a second drug and a release-delaying matrix comprising a hydrophilic polymer and a water-insoluble polymer; an immediate release portion comprising guaifenesin; wherein the guaifenesin is bioavailable at a therapeutically effective level for at least twelve hours following a single dose."

"2. The drug delivery system of claim 1, wherein said optional drug is selected from dextromethorphan and pseudoephedrine."

"5. The drug delivery system of claim 2, wherein said optional drug is in both the immediate release portion and the sustained release portion."

III. The decision was based on the set of claims 1 to 23 filed with the letter of 2 May 2008 as main request and the set of claims 1 to 23 of the auxiliary request filed at oral proceedings before the examining division on 11 November 2010.

Claim 1 of the main request read as follows:

"A drug product comprising an immediate release portion comprising guaifenesin and a second drug wherein the immediate release portion is formulated to dissolve in an aqueous medium, such as that found in the stomach, to provide rapid release of the guaifenesin and the second drug in the subject's stomach; and a sustained release portion comprising guaifenesin and optionally the second drug."

Claim 1 of the auxiliary request corresponded to claim 1 of the main request whereby the second drug was selected from a specific list.

IV. According to the decision under appeal:

a) The subject-matter of claim 1 of the main request differed from the disclosure in D1 (WO-A-01/82895), taken as the closest prior art, in that the immediate release portion also comprised a second drug. The effect was seen as the immediate release of an additional drug and the problem was the provision of further compositions comprising guaifenesin. The solution was considered obvious in view of D1 in combination with either D3 (US-A-4 552 899) or D4 (US-A-2002/0022058).

b) The subject-matter of claim 1 of the auxiliary request was also not inventive over D1 in combination with either D3 or D4.

V. The applicant (appellant) filed an appeal against that decision. With the statement setting out the grounds of appeal, the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or alternatively of one of the sets of claims of the

first, second or third auxiliary requests, all filed with that statement.

Claim 1 of the main request read as follows:

"1. A drug product comprising an immediate release portion comprising guaifenesin and a second drug wherein the immediate release portion is formulated to dissolve in an aqueous acidic medium, such as that found in the stomach, to provide rapid release of the guaifenesin and the second drug in the subject's stomach; and a sustained release portion comprising guaifenesin and the second drug wherein the second drug is selected from dextromethorphan or pseudoephedrine."

In claim 1 of the first auxiliary request the second drug was specified to be dextromethorphan. In claim 1 of the second auxiliary request it was further added that "the ratio of the dextromethorphan in the immediate release portion to dextromethorphan in the sustained release portion is 3:2 to about 9:1, preferably from 3:1 to 4:1, by weight". In claim 1 of the third auxiliary request it was additionally specified that "the dextromethorphan is bioavailable at a therapeutically available level for at least twelve hours following a single dose".

VI. With the communication sent in preparation for oral proceedings, the Board noted that the subject-matter of claim 1 of the main request did not appear to correspond to the basis indicated by the appellant in the statement setting out the grounds of appeal, as a number of features were missing and others were added, and that consequently, whether the requirements of Article 123(2) EPC were met was in doubt. Furthermore, no basis had been indicated in respect of the auxiliary

requests. The Board also provided detailed reasons as to why the requirements of Article 56 EPC did not appear to be fulfilled in respect of any of the requests on file (pages 4 to 9 of the communication).

VII. With letter of 26 September 2014 the appellant withdrew its request for oral proceedings and requested the issuance of a decision "based on the file as it currently stands". With respect to the substantive issues raised by the Board under Articles 56 and 123(2) EPC, no counter-arguments were provided.

VIII. In view of that, oral proceedings scheduled for 2 October 2014 were cancelled.

IX. The appellant's arguments, as far as relevant to the present decision, may be summarised as follows:

Main request - added subject matter

The claims have been limited to a composition comprising guaifenesin and one additional drug selected from pseudoephedrine or dextromethorphan. Claim 1 of the main request is based on a combination of claims 1, 2 and 5 of the application as filed, while the remaining claims are based on the claim set filed with the letter of 3 March 2005.

Reasons for the Decision

All requests - added subject-matter

1.1 The Board cannot follow the appellant's written submission that claim 1 of the main request corresponds to the combination of claims 1, 2 and 5 of the application as originally filed. In fact, a number of

features comprised within claim 1 as originally filed are missing, such as the "release-delaying matrix comprising a hydrophilic polymer and a water-insoluble polymer" and the feature whereby "the guaifenesin is bioavailable at a therapeutically effective level for at least twelve hours following a single dose", while other features are added, such as the feature whereby "the immediate release portion is formulated to dissolve in an aqueous acidic medium, such as that found in the stomach".

1.2 Claim 1 of the main request is therefore not directly and unambiguously derivable from the basis provided by the appellant.

1.3 The Board is not aware of a further basis in the application as filed for claim 1 of the main request and the appellant in reply to the Board's communication did not indicate any further basis, nor provided any rebuttal to the objections of the Board, but simply requested a decision "based on the file as it currently stands".

1.4 It follows that the main request does not fulfill the requirements of Article 123(2) EPC.

1.5 The first auxiliary request corresponds to the main request whereby the second drug has been limited to dextromethorphan. The second and third auxiliary requests correspond to the first auxiliary request with the addition of further limiting technical features, which still does not result in the combination of original claims 1, 2 and 5. It follows that the same infringement of Article 123(2) EPC in respect of these requests applies as for the main request.

Conclusions

2. Since the requirements of Article 123(2) EPC have not been met in respect of all requests, the appeal must be dismissed. Moreover, the objection of lack of inventive step as set out in the communication of the Board (see point VI, above) still applies unchanged in the absence of any rebuttal from the appellant.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

U. Bultmann J. Riolo

Decision electronically authenticated