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Datasheet for the decision of 12 January 2015

Case Number: T 2041/13 - 3.3.07

Application Number: 10177509.6

Publication Number: 2283816

IPC: A61K9/14, A61K9/22, A61K9/52

Language of the proceedings: EN

Title of invention:
Melt-extruded orally administrable opioid formulations

Applicant:
Euro-Celtique S.A.

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - sequence of divisional applications
Divisional application - subject-matter extends beyond content of earlier application (yes)

Decisions cited:
G 0001/05, G 0001/06

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Case Number: T 2041/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 12 January 2015

Appellant: (Applicant)	Euro-Celtique S.A. 2, avenue Charles de Gaulle 1653 Luxembourg (LU)
Representative:	Bühler, Dirk Maiwald Patentanwalts GmbH Elisenhof Elisenstraße 3 80335 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 11 April 2013 refusing European patent application No. 10177509.6 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 posted on 11 April 2013 refusing European patent application No. 10 177 509.6.

II. The refused application was filed as a divisional of European patent application No. 04 022 651.6 (second generation divisional), which in its turn was a divisional of European patent application No. 03 015 267.2 (first generation divisional), which itself was a divisional of European patent application No. 95 939 928.8 (root application).

The first generation divisional was on filing identical to the root application. The second generation divisional had on filing a description containing the description and the claims of the root application, amended claims and drawings identical to those of the root application. The present application, as a third generation divisional, was identical on filing to the second generation divisional.

III. The decision was based on a single set of claims including claim 1 filed with letter of 11 August 2011 and claims 2 to 17 as originally filed.

Claim 1 read as follows:

"1. An oral sustained release dosage form which comprises a melt-extruded multiparticulate mu-antagonist combination comprising 5 mg to 400 mg oxycodone or a salt thereof; a pharmaceutically acceptable hydrophobic material and a retardant selected from waxes, fatty alcohols and fatty acids, dispersed in a matrix."

IV. According to the decision under appeal, the requirements of Article 76(1) EPC were not met in view of the lack of a clear and unambiguous disclosure of the features "mu-antagonist combination" and "oxycodone" in combination, each of which had to be selected from the same list of opioid analgesics.

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 on which the decision was based.

VI. With the communication sent in preparation for oral proceedings the Board expressed a preliminary view on the relevant issues and detailed the reasons why it considered that the requirements of Article 76(1) EPC did not appear to be met in view of the the feature objected to in the decision under appeal (see in particular points 1 and 2 of the communication).

VII. With letter of 27 October 2014 the appellant withdrew the request for oral proceedings. That letter did not contain any further submission, nor any further request.

VIII. Oral proceedings which were to be held on 4 November 2014 were thereafter cancelled by the Board.

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

The first paragraph on page 12 of the application as filed comprised a list of actives, ranging from alfentanil to tilidine, which included agonists and antagonists. That list ended by saying that the actives

might be present as salts, mixtures of actives, mixed mu-agonists/antagonists and mu-antagonists combinations without disclosing any further different actives. A skilled person would understand by that that any listed active (e.g. oxycodone) could be used in any of the listed forms, e.g. in the form of its salts (e.g. a salt of oxycodone). On that basis also the combination of oxycodone with generic mu-antagonists would be directly and unambiguously derivable from the list. Moreover, the assumption that twofold selections from one or two lists implied an automatic contravention of Article 123(2) EPC was not correct. Instead the only acceptable criterion in view of G 0002/10 (OJ EPO 2012, 376, see the headnote) was to consider what a skilled person understands from the disclosure, employing his skills and experience. By using that criterion the skilled person would conclude that the amendments were allowable.

Reasons for the Decision

Amendments

1. The present application being a divisional application, it has to meet the requirements of both Article 76(1) EPC, second sentence and Article 123(2) EPC.

1.1 As far as Article 123(2) EPC is concerned, the condition is that the present application is not amended in such a way that it contains subject-matter with extends beyond the content of the application as filed (i.e. the present application as third generation divisional at filing).

1.2 As the application belongs to a sequence of applications consisting of a root application followed by divisional

applications, each divided from its predecessor (see point II, above), it is a necessary and sufficient condition to comply with Article 76(1), second sentence, EPC that anything disclosed in the present divisional application be directly and unambiguously derivable from what is disclosed in each of the preceding applications as filed (i.e. the root application, the first generation divisional and the second generation divisional at filing, see the headnote of G 0001/06, OJ EPO 2008, 307). Also this condition is to be decided on the amended text submitted by the applicant after any objections have been drawn to its attention and he has been afforded an opportunity to comment and also an opportunity to overcome the objection by means of an amendment (G 0001/05, OJ EPO 2008, 271, point 3, in the reasons, see in particular point 3.2).

1.3 In view of the fact that the first, second and third generation divisional applications all include the whole content of the root application (with the claims of the root application either repeated as claims or added to the description, see point II, above), it is sufficient in the present case to check whether the claims on file are directly and unambiguously derivable from the root application as filed. If it is the case, both the requirements of Article 76(1) EPC, second sentence and those of Article 123(2) EPC are met. If it is not, at least the requirements of Article 76(1) EPC, second sentence are not met.

2. The crucial issue discussed all along the proceedings concerns the combination of the features "mu-antagonist combination" and "oxycodone" in claim 1 of the single request on file. From what has been detailed above, it is to be determined whether this combination is

directly and unambiguously derivable from the root application as filed.

2.1 The relevant paragraph to be analysed is the first paragraph on page 12 of the description of the root application, whose first sentence reads as follows:

"In embodiments of the invention directed to opioid analgesics, the opioid analgesics used in accordance with the present invention include alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, cyclazocine, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levallorphan, levorphanol, levophenacylmorphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metopon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, opium, **oxycodone**, oxymorphone,papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, piminodine, piritramide, propheptazine, promedol, properidine, propiram, propoxyphene, sufentanil, tramadol, tilidine, salts thereof, mixtures of any of the foregoing, mixed mu-agonists/antagonists, **mu-antagonist combinations**, and the like." (emphasis added by the Board)

2.2 The long list of that paragraph discloses therefore individual compounds from alfentanil to tilidine, including both mu-agonists (e.g. oxycodone) and mu-

antagonists (e.g. nalorphine), salts of the listed compounds, mixtures of the listed compounds, mixed mu-agonists/antagonists (i.e. mixtures containing both mu-agonists and mu-antagonists with no reference to the previously listed compounds) and mu-antagonists combinations (i.e. mixtures of a plurality of mu-antagonists with no reference to the previously listed compounds).

2.3 A combination of a mu-antagonist combination (i.e. a mixture of a plurality of mu-antagonists) with oxycodone (a specific mu-agonist mentioned in the first part of the list) is neither explicitly disclosed, nor is it directly and unambiguously derivable from the classes enumerated at the end of the list.

2.4 In this respect the Board does not follow the parallel drawn by the appellant with the salts of the listed compounds. While salts of the listed compounds are explicitly mentioned at the end of the list, this is not the case for the combination of a mu-antagonist combination with one of the listed compounds, such as oxycodone. The skilled person, even employing its skills and knowledge, would not consider such a combination as directly and unambiguously derivable from the disclosure in the first paragraph of page 12 of the root application.

2.5 As no other part of the root application relates to the critical combination (nor any part has been cited by the appellant), the requirements of Article 76(1), second sentence, EPC, are not met.

Conclusion

3. As the single request on file does not meet the requirements of Article 76(1), second sentence, EPC, there is no need for the Board to decide on any other issue and the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated