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Datasheet for the decision of 3 July 2014

Case Number: T 0673/13 - 3.3.07

Application Number: 01995903.0

Publication Number: 1453487

IPC: A61K9/28, A61K9/48

Language of the proceedings: EN

Title of invention:
PHARMACEUTICAL DOSAGE FORM WITH MULTIPLE COATINGS

Patent Proprietor:
Warner Chilcott Company, LLC

Opponents:
Tillotts Pharma AG
Dr. Falk Pharma GmbH

Headword:

Relevant legal provisions:
EPC Art. 111(1), 123

Keyword:
Amendments - added subject-matter (no)
Amendments - broadening of claim (no)
Appeal decision -
remittal to the department of first instance (yes)

Decisions cited:

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European Patent Office
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Case Number: T 0673/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 3 July 2014

Appellant: (Patent Proprietor)	Warner Chilcott Company, LLC Union Street KM 1.1 Fajardo Puerto Rico 00738 (PR)
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Respondent: (Opponent 1)	Tillotts Pharma AG Hauptstrasse 27 4417 Ziefen (CH)
Representative:	Stones, James Alexander Beck Greener Fulwood House 12 Fulwood Place London WC1V 6HR (GB)
Respondent: (Opponent 2)	Dr. Falk Pharma GmbH Leinenweberstr.5 79108 Freiburg (DE)
Representative:	Keller, Günter Lederer & Keller Patentanwälte Unsöldstrasse 2 80538 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 January 2013 revoking European patent No. 1453487 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division announced at the oral proceedings on 29 November 2012 to revoke European Patent 1 453 487. The granted patent comprised 7 claims, claim 1 according to the version of the claims mentioned in the decision to grant reading as follows:

"1. A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal comprising:
a. a safe and effective amount of a therapeutically active agent comprising 5-aminosalicylic compounds, 4-aminosalicylic compounds, sulfalazin or mixture thereof;
b. an inner coating layer selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:2, poly(methacrylic acid, methyl methacrylate) 1:1, and mixtures thereof, preferably the inner coating is poly(methacrylic acid, methyl methacrylate) 1:2.; and
c. an outer coating layer comprising an enteric polymer applied onto the inner coating layer,
wherein the inner coating layer is not the same as the outer coating layer; wherein if the inner coating layer is poly(methacrylic acid, methyl methacrylate) 1:1 then the outer coating layer is not poly(methacrylic acid, methyl methacrylate) 1:2 or is not a mixture of poly(methacrylic acid, methyl methacrylate) 1:1 and poly(methacrylic acid, methyl methacrylate) 1:2; and wherein the inner coating layer and the outer coating layer contain no therapeutically active agent." (underlining of two characters added by the Board)

Claim 1 in the specification (the B-publication) lacked with respect thereto the two characters underlined by the Board. Two further small differences were present in claims 3 and 4 of the B-publication with respect to the text mentioned in the decision to grant.

II. Two notices of opposition were filed against the granted patent requesting revocation of the patent in its entirety on the grounds of lack of novelty and lack of inventive step, insufficiency of disclosure and extension of the subject-matter beyond the content of the application as filed in accordance with Article 100(a), (b) and (c) EPC.

III. The decision was based as main request on the patent as granted, as auxiliary request 1 on a set of claims filed during oral proceedings on 29 November 2012 and as auxiliary request 2 on a further set of claims filed with letter of 28 September 2012 (then as auxiliary request 1).

In claim 1 according to auxiliary request 1 the option of mixtures of the therapeutically active agents was deleted, the inner coating layer was redefined as "comprising poly(methacrylic acid, methyl methacrylate) 1:2" and the outer coating layer as comprising "a mixture of poly(methacrylic acid, methyl methacrylate) 1:1 and poly(methacrylic acid, methyl methacrylate) 1:2". Moreover some dependent claims were deleted and some were added. Claim 1 according to auxiliary request 2 corresponded to claim 1 according to the version of the claims mentioned in the decision to grant with the correction of the spelling of the active compound "sulfasalazine" and the use of the plural "mixtures" in the alternative for the active agents.

IV. The decision of the opposition division can be summarised as follows:

a) Claim 1 as granted extended beyond the content of the application as filed, because there was no disclosure therein of mixtures of the specific active agents 5-aminosalicylic compounds, 4-aminosalicylic compounds and sulfalazine, nor was there any basis for an outer coating layer "applied onto the inner coating layer". This expression could only be interpreted in the sense that the outer coating layer was directly applied onto the inner coating layer without any intermediate layer and there was no general disclosure of such a direct application.

b) The addition of dependent claims in auxiliary request 1 violated the requirements of Rule 80 EPC. The specific combination of therapeutically active agents and materials for the inner and the outer coating layers of claim 1 of auxiliary request 1 was not disclosed in the application as filed against the requirements of Article 123(2) EPC. The amendment of the definition of the material of the inner coating layer from "selected from" to "comprising" represented a broadening of the scope of the claim contrary to the requirements of Article 123(3) EPC.

c) The objection related to the mixtures of active agents raised against claim 1 as granted equally applied to claim 1 of auxiliary request 2.

V. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal

the appellant filed twelve set of claims as main request and first to fifth auxiliary requests, all in a first version indicated as a request "with Rule 140 correction" and in a second version without that indication. Claim 1 according to the main request with Rule 140 correction corresponded to claim 1 according to the version of the claims mentioned in the decision to grant with the amendment of feature a. into "a safe and effective amount of a therapeutically active agent comprising 5-aminosalicylic compounds, 4-aminosalicylic compounds or sulfalazin", thereby deleting the option of mixtures of the therapeutically active agents. Claim 1 according to the main request (without the indication "Rule 140 correction") included the same amendment, but took as a starting point claim 1 of the B-publication.

VI. Oral proceedings were held on 3 July 2014 in the absence of respondent-opponent 1 as announced with letter of 19 May 2014. During the oral proceedings the appellant resubmitted the main request with Rule 140 correction filed with the statement of grounds and named it simply "main request".

VII. The arguments of the appellant can be summarised as follows:

Amendments

a) The claims of the main request used as a starting point the claims contained in the text as approved by the proprietor during grant proceedings and not those of the B-publication, as they included a number of errors.

b) The three compounds listed as being comprised in the therapeutically active agent belonged to a

single list of compounds and appeared one after the other as members of the same class in the original disclosure. Their specification did not result therefore in an extension of the claimed subject-matter beyond the content of the application as filed.

c) The deletion of the feature "or mixture thereof" in claim 1 of the main request solved the issue raised in the decision and could not result in an extension of the protection conferred as compositions in which one of the three listed agents was present in combination with further agents were already within the scope of claim 1 as granted in view of the term "comprising".

d) The specification that the outer coating layer was applied onto the inner coating layer was based on the original application in spite of the lack of a literal support. That specification clearly meant that only these two layers were present with nothing in between. The disclosure of a dosage form with three coating layers in the description of the background art and the mention of only the inner and outer coating layers in the summary of the invention clearly implied that only two layers were present and no other. No disclosure of an intermediate layer was to be found in the original application and a total thickness of the two layers together was given. In the description of the method of preparation of the dosage form the outer layer was applied immediately after the inner layer, which excluded the presence of anything in between. Also the products of the examples did not include any other layer. A reading of the original disclosure as implying the

presence of further layers corresponded therefore to an illogical and unreasonable interpretation.

VIII. The arguments of the respondents (opponents 1 and 2) can be summarised as follows:

Amendments

a) The indication of three specific compounds for the therapeutically active agent in claim 1 of the main request resulted from several choices out of a plurality of lists disclosed in the original application, namely the choice of the treatment of colon, of a specific colon disease and of specific agents for treating that disease. On that basis, it extended beyond the content of the application as filed.

b) Claim 1 of the main request did not meet the requirements of Article 123(3) EPC in view of the deletion of the feature "or mixtures thereof" with reference to the substances comprised in the therapeutically active agent, as the amended claim covered also compositions in which one of the three listed agents was present in combination with further agents.

c) The specification that the outer coating layer was applied onto the inner coating layer had no basis in the original application. The submissions of the appellant in respect of the feature were contradictory, as the appellant confirmed in first instance proceedings that claim 1 did not exclude the presence of an intermediate layer, while the contrary was held in appeal. In any case, even if one accepted the interpretation given in appeal

proceedings, there was no explicit support for the added feature and such a feature could neither be derived from the acknowledgement of the prior art, nor from the rest of the disclosure. It was indeed not excluded in the original disclosure that there was an intermediate layer between the two coatings. The presence of such an intermediate layer was on the contrary implicit for the skilled reader. Moreover, the disclosure of the application of the outer coating layer to the core of the unit dosage form did no imply the absence of an intermediate layer and an indication of the total thickness of the inner and outer coating layers was only given in the context of a specific embodiment. While examples 3 to 6 of the original application were not relevant, as they did not fall within the subject-matter of claim 1 of the main request, examples 1 and 2 disclosed a two-step process for the application of the inner coating layer, which therefore resulted in an intermediate coating layer being present between the inner and the outer one. Moreover, these examples differed from the part of the disclosure indicating the application of the outer coating layer within seconds after the application of the inner one.

IX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution based on the main request filed during the oral proceedings.

X. The respondents requested that the appeal be dismissed.

Reasons for the Decision

Main request - amendments

1. The claims of the main request correspond to the claims mentioned in the decision to grant with the amendment of feature a. into "a safe and effective amount of a therapeutically active agent comprising 5-aminosalicylic compounds, 4-aminosalicylic compounds or sulfalazin", thereby deleting the option of mixtures of the therapeutically active agents.

1.1 The Board underlines that the decision to grant is legally binding as regards existence and scope of the patent and that the specification (the B-publication) is only meant to reproduce that decision. This means that the correct starting point for introducing amendments relating to grounds of opposition (in the present case the deletion of the words "or mixture thereof") is the version mentioned in the decision to grant and not the B-publication (if, as in the present case, the two are different).

1.2 On that basis, the set of claims of the main request is a request which contains with respect to the granted version only the desired amendment.

2. The amendment of feature a. of claim 1 renders moot the objection in the appealed decision relating to the lack of disclosure of mixtures of the specific active agents, as the option of mixtures of the therapeutically active agents is thereby deleted.

2.1 As to the further objections related to feature a., namely that the indication of the three specific compounds results from several choices out of a

plurality of lists disclosed in the original application and that the deletion of the feature "or mixture thereof" results in an extension of the protection conferred, the Board cannot follow the arguments of the respondents for the reasons which follow.

2.2 The original description contains a section in which information about the therapeutically active agent to be used in the invention is given (paragraph bridging pages 3 and 4 and following paragraphs on page 4). In this section first it is disclosed that therapeutic agents suitable for the claimed invention are those for the treatment of the colon (paragraph bridging pages 3 and 4, second sentence), then it is specified that they include therapeutic agents useful for the treatment of a number of listed diseases of the colon (paragraph bridging pages 3 and 4, third sentence) and finally a list of specific compounds is given with the specification of both the function of the compounds (e.g. actives for constipation and laxatives) and their chemical name (e.g. picosulfate) (paragraph bridging pages 3 and 4, fourth sentence), whereby this list includes 5-aminosalicylic compounds, 4-aminosalicylic compounds and sulfalazine (page 3, last two lines).

2.3 This latter list amounts to the disclosure of a single list of compounds which are all individually suitable to be used as therapeutically active agents of the claimed invention. The fact that a function is indicated for most of the compounds and that some preliminary information is given of which diseases may be treated by the therapeutically active agents suitable for the invention does not change the fact that the skilled person is presented with the unequivocal information that each and every of the

compounds listed is as such suitable for the claimed invention, so that its indication in claim 1 of the main request is the result of a single disclosed choice within the disclosure of the application as originally filed.

2.4 These considerations are valid in particular for 5-aminosalicylic compounds, 4-aminosalicylic compounds and sulfalazine, so that the specification in feature a. that the therapeutic agent comprises "5-aminosalicylic compounds, 4-aminosalicylic compounds or sulfalazin" does not result in an extension of the claimed subject-matter beyond the content of the application as filed.

2.5 With regard to the objection relating to the extent of protection, it suffices to note that granted claim 1 includes several times the word "comprising", in particular once right at the start ("A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal comprising", emphasis by the Board) and once within feature a. ("a safe and effective amount of a therapeutically active agent comprising 5-aminosalicylic compounds, 4-aminosalicylic compounds, sulfalazin or mixture thereof", emphasis by the Board), which results in an open formulation and implies that compositions in which one of the three listed agents is present in combination with further not-mentioned agents fall within the protection conferred by granted claim 1 (clearly if all remaining features are met). The fact that such compositions are also covered by claim 1 of the main request does not result therefore in an extension of the protection conferred.

3. With regard to the feature that the outer coating layer is "applied onto the inner coating layer", the wording of the claim does not leave any room for the possibility of an intermediate layer to be present between the inner and outer coating layer. In this respect any possible declaration of the appellant in the present or in previous proceedings cannot change the clear and unequivocal wording of the claim.

3.1 While it is true that a literal basis cannot be found in the application as originally filed for the expression "applied onto", the Board is convinced that the disputed feature is directly and unambiguously derivable for the application as originally filed for the reasons which follow.

3.2 The invention disclosed in the original application relates to coated dosage forms (see "Technical field" on page 1 and claim 1 of the application as filed) and the background art cited in the introductory part of the description mentions coating systems with at least one inner coating layer and one outer coating layer and also pharmaceutical preparations having a core coated with three protective layers (paragraph bridging pages 1 and 2).

3.3 In spite of that in the whole of the disclosure related to the invention of the application from which the disputed patent originated (from "Summary of the invention" on page 2 to the end of the description on page 15 and claims 1 to 10 of the application as filed) only an inner coating layer and an outer coating layer are consistently mentioned.

3.4 This is in particular the case for the "Summary of the invention" (pages 2 to 3), for the part of the

description related to the coatings (from page 4, last two paragraphs to page 8, last but one paragraph), for all of the examples and for all of the claims. In this respect it is not relevant that a number of the examples no longer fall under claim 1 of the main request, as long as the analysis is accomplished of whether a general teaching related to the presence exclusively of the inner and the outer coating layers (so that the outer coating layer has necessarily to be applied onto the inner coating layer) is directly and unambiguously derivable from the application as originally filed.

3.5 Already on the basis of the consistency of this teaching in the whole of the original application, it can be concluded that the skilled person is directly and unambiguously taught that dosage forms according to the application as originally filed have an inner coating layer and an outer coating layer with no intermediate layer in between, so that the outer coating layer is applied onto the inner coating layer.

3.6 This teaching is reinforced by further specific disclosures in the application as filed related to the total coating thickness and to the method of making the dosage form.

3.6.1 As to the former, preferred values for a total coating thickness of the inner and outer coating layers together are indicated both in the description (page 7, fourth full paragraph) and in the claims (original claim 5), which would make little sense in the presence of further intermediate layers.

3.6.2 With regard to the method of making the dosage forms, embodiments are disclosed in which "the outer coating

layer is applied after the inner coating layer but before the inner coating layer is dried and/or cured" and "the outer coating layer is applied immediately, e.g. within seconds, after the inner coating layer is applied" (page 11, first full paragraph). Also with regard to this disclosure, even if the presence of an intermediate layer is not verbally excluded, it is practically incompatible with the disclosed embodiments.

3.6.3 With regard to the examples in the application as filed in which the inner layer is applied by a two-step procedure, namely by first pouring a portion of the coating formula and then by spray coating (examples 1, 2 and 3 on pages 11 and 12, second paragraph in each of the examples), it is clear from the wording of the examples that the result of this two-step procedure is a single inner layer of a single specific substance (EUDRAGIT ® S in all three examples) and not two separate layers, one of which could be considered as an intermediate layer.

3.7 On that basis, the presence of an outer coating layer "applied onto" the inner coating layer in the claimed dosage form is directly and unambiguously derivable from the application as originally filed.

Remittal

4. The opposition division rejected all requests on file on the basis of Article 123 EPC, but did not decide on the grounds of lack of sufficiency of disclosure, novelty and inventive step. These issues, however, formed, *inter alia*, the basis for the request that the patent be revoked in its entirety and are clearly essential substantive issues of the case.

4.1 It is the essential function of an appeal to consider whether the decision issued by the first-instance department is correct. Moreover, no reasons can be seen by the Board in the present case to deprive the parties of the opportunity of two readings of the important elements of the case, nor any such reason has been invoked by the parties.

4.2 On that basis, the Board decides to remit the case to the opposition division for the analysis of the remaining issues on the basis of the claims of the main request.

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 on the basis of the main request filed during oral proceedings.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated