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Datasheet for the decision of 5 February 2019

Case Number: T 0511/17 - 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:
Allergan Pharmaceuticals International Limited

Opponents:
Tillotts Pharma AG
Dr. Falk Pharma GmbH

Headword:
Multiple coatings/ ALLERGAN

Relevant legal provisions:
EPC Art. 56, 123(2), 123(3)

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Keyword:

Inventive step - main request (no) - auxiliary request 5a (yes)
Amendments - auxiliary requests 1-4 (no) - auxiliary request 5 - broadening of claim (yes)

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Case Number: T 0511/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 February 2019

Appellant: (Patent Proprietor)	Allergan Pharmaceuticals International Limited Clonshaugh Industrial Estate Coolock Dublin 17 (IE)
Representative:	FRKelly 27 Clyde Road Dublin D04 F838 (IE)
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Representative:	Keller, Günter Lederer & Keller Patentanwälte Partnerschaft mbB Unsöldstrasse 2 80538 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 December 2016 revoking European patent No. 1453487 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	D. Boulois
Members:	A. Usuelli
	C. Schmidt

Summary of Facts and Submissions

I. Two oppositions have been filed against the grant of European Patent 1 453 487 on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed. The patent was revoked by the opposition division in its decision of 14 January 2013. This decision was appealed by the patent proprietor (case T 673/13). The competent Board rejected the opponents' objections pursuant to Article 123(2) and (3) EPC and decided to set aside the decision of the opposition division and to remit the case for further prosecution.

II. The present appeal of the patent proprietor (the appellant) lies against the second decision of the opposition division to revoke the patent. The decision announced during the oral proceedings held on 28 September 2016 was based on a main request and three auxiliary requests (auxiliary requests 1, 2 and 9), all filed on 28 July 2016.

Claim 1 of the main request read 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-aminosaiicylic compounds, 4-aminosalicylic compounds, or sulfalazin;
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."

III. The following documents were among those cited during the first-instance proceedings:

D1: US 5,914,132
D2: US 5,541,170
D15: Pharma Polymers No.7, October 2000
D17: Experimental report N°1 by Mr Balan
D18: Experimental report N°2 by Mr Balan
D19: Asacol®, 400 mg tablets
D20: Asacol® HD, 800 mg tablets, October 2010

IV. In the appealed decision, the opposition division considered that document D2 was the closest prior art for the assessment of inventive step. The composition defined in claim 1 of the main request differed from the compositions disclosed in D2 in that it had a second layer of enteric polymer. The experimental reports filed by the patent proprietor did not convincingly show that the composition according to the main request was more resistant to fracturing. Therefore, the objective technical problem was the provision of an alternative dosage unit which released

the active agent in the gastrointestinal tract. Several prior art documents, such as D1 and D15, disclosed compositions with a double enteric coating. Thus, the subject-matter of the main request was not inventive over the teaching of D2 in combination with, for example, D1.

The subject-matter of auxiliary requests 1 and 2 did not comply with the requirements of Article 56 EPC substantially for the same reasons as the main request. Auxiliary request 9 specified the process for the application of the outer coating. This process was known in the art and did not result in any unexpected effect. Hence, auxiliary request 9 also did not comply with the requirements of Article 56 EPC.

V. With the statement setting out the grounds of appeal filed on 28 April 2017, the appellant submitted a main request and four auxiliary requests. The main request was identical to the main request forming part of the basis of the appealed decision (see point II above).

Claim 1 of auxiliary requests 1 to 4 differed from claim 1 of the main request in, *inter alia*, the definition of component "a", which read as follows:

"a. a safe and effective amount of a therapeutically active agent comprising 5-aminosalicylic compounds, 4-aminosalicylic compounds, or sulfalazin, at a dosage range of from 700 mg to 900 mg;".

With the same submission, the appellant filed, *inter alia*, the following documents:

D37: Experimental report "Asacol® HD" - 19 March 2009
D38: Laboratory notebook - Project 8553

D38a: Technical report - Project 309B
D44: Revised Appendix A from D34

VI. Opponent-1 (respondent-1) and opponent-2 (respondent-2) filed their replies to the appeal on 18 September 2017 and 12 September 2017.

Together with its reply respondent-1 submitted, *inter alia*, the following document:

D48: Experimental report by Dr Felipe Varum

VII. In a communication pursuant to Article 15(1) RPBA issued on 12 December 2018, the Board expressed the opinion that the subject-matter of the main request was not inventive starting from D2 as the closest prior art. It furthermore considered that the indication of the amount of active ingredients in claim 1 of auxiliary requests 1 to 4 did not appear to have a proper basis in page 4 of the original application as argued by the appellant. Thus, the auxiliary requests appeared to contravene Article 123(2) EPC.

VIII. By letter of 4 January 2019, the appellant filed two sets of claims as auxiliary requests 5 and 6.

In claim 1 of both requests, component "a" of the composition was defined as follows:

"a. a safe and effective amount of a therapeutically active agent, wherein the therapeutically active agent is 5-aminosalicylic acid or pharmaceutically acceptable salts or esters thereof, at a dosage range of from 700 mg to 900 mg".

IX. During the oral proceedings held on 5 February 2019 the appellant submitted two sets of claims as auxiliary requests 5a and 6a in response to some observations made by the Board in relation to the requirement of Article 123(3) EPC in respect to auxiliary requests 5 and 6.

Claim 1 of auxiliary request 5a read 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, wherein the therapeutically active agent is 5-amino salicylic acid at a dosage range of from 700 mg to 900 mg;
b. an inner coating layer wherein 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 outer coating layer is a mixture of poly(methacrylic acid, methyl methacrylate) 1:1 and poly (methacrylicacid, methyl methacrylate) 1:2; wherein the inner coating layer and the outer coating layer contain no therapeutically active agent; and wherein the solid unit dosage form is a tablet."

(Auxiliary request 6a is not relevant for this decision).

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

(a) Main request - inventive step

Document D2 was the closest prior art for the assessment of inventive step. The tablets defined in claim 1 differed from the tablets disclosed in D2 in that they had a second coating layer. The appellant's experiments showed the difficulties involved in providing pharmaceutical compositions for delivering a drug to the large intestine or colon containing a high load of active ingredient. Document D37 showed that for a single-coated tablet containing 800 mg of 5-aminosalicylic acid (5-ASA), it was possible to obtain a pharmacokinetic profile closer to the desired profile if only a thin coating was applied to the tablet. However, as shown for instance in D38a, a thick coating was necessary to obtain tablets of adequate robustness. The inventors found a solution to this "coating paradox" by providing tablets with a double-layered coating arrangement. The experiments disclosed in D44 and D17 demonstrated that this arrangement allowed for large dosage forms with improved resistance while achieving the desired release profile. It also resulted in the advantage of reducing the amount of plasticiser in the coating. Neither D2 nor the other cited references taught a composition containing a high load of active ingredient suitable for delivering the drug to a specific region of the gastrointestinal tract using a double-coating system. Hence, the main request met the requirements of Article 56 EPC.

(b) Auxiliary requests 1 to 4 - Article 123(2) EPC

The indication of the amount of active ingredient was based on the disclosure on page 4 (lines 16 to 20) of the original application.

(c) Auxiliary request 5 - Article 123(3) EPC

Claim 1 of the patent as granted referred to "5-aminosalicyclic compounds". This expression covered also salts and esters of 5-ASA. Hence, the feature "or pharmaceutically acceptable salts or ester thereof" in claim 1 of auxiliary request 5 did not result in an extension of the protection conferred by the patent.

(d) Auxiliary request 5a

The subject-matter of this claim had a basis in original claim 1 in combination with page 4 of the description. It no longer referred to salts and ester. Hence, the claim complied with Articles 123(2) and 123(3) EPC. The subject-matter of this claim was inventive for the same reasons given for the main request.

XI. The respondents' arguments, as far as relevant to the present decision, can be summarised as follows:

(a) Main request - inventive step

There were several shortcomings in the experiments submitted by the appellant. For instance, the comparative tests carried out in D44 were meaningless because the double-coated tablets contained a higher amount of coating than the single-coated tablets. The single-coated tablets tested in D44 and D38a did not contain any plasticiser. The finding that these tablets were not sufficiently resistant was merely due to the absence of this substance. Furthermore, there was no evidence that a double-coated tablet containing 800 mg of 5-ASA was bioequivalent to two tablets of the product Asacol®, as alleged by the appellant. Hence,

there was no evidence of an improvement over the prior art. In any case, the argument that single-coated tablets with high amounts of active ingredients were not sufficiently robust was of no relevance with regard to the main request, which did not include any limitation as to the amount of active ingredient. There were many documents in the art, such as D1 and D15, teaching the use of double-coating systems in the preparation of compositions that released the drug in the intestine. The skilled person seeking to provide an alternative formulation to those of D2 would have considered the teaching of these documents. Accordingly, the main request did not comply with Article 56 EPC.

(b) Auxiliary requests 1 to 4 - Article 123(2) EPC

The feature "700 mg to 900 mg" introduced in claim 1 of these requests did not have proper basis in page 4 of the description as maintained by the appellant.

(c) Auxiliary request 5 - Article 123(3) EPC

Claim 1 of the patent as granted did not refer to salts and esters. Hence, this request did not comply with Article 123(3) EPC.

(d) Auxiliary request 5a

The original application did not disclose a tablet having the same combination of features characterising the tablet of claim 1 of auxiliary request 5a. Thus, this request infringed Article 123(2) EPC.

As for the subject-matter of the main request, there were no comparative data that demonstrated an

improvement, in terms of the robustness of the coating, over the formulation of D2. The experiments of D48 showed that by adding a plasticiser, it was possible to prepare single-coated tablets with a high amount of active ingredient having an adequate robustness. Thus, the tablets claimed in this request were a mere alternative to the 5-ASA tablet disclosed in D2. Several prior art documents, such as D13 (Figure 1), suggested the same double-coating system used for the tables in auxiliary request 5a. Thus, the skilled person would have arrived at the subject-matter of this request by combining the teachings of these documents.

XII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or on the basis of one of the auxiliary requests 1 to 5, 5a, 6 and 6a wherein:

(a) the main request and auxiliary requests 1 to 4 had been filed with the letter setting out the grounds of appeal dated 27 April 2017
(b) auxiliary requests 5 and 6 had been filed with the letter dated 4 January 2019, and
(c) auxiliary requests 5a and 6a had been filed during the oral proceedings before the Board.

XIII. The respondents requested that the appeal be dismissed.

Reasons for the Decision

Main Request

1. Inventive step

The invention underlying the main request relates to unit dosage forms designed to deliver the active substance to desired regions of the gastrointestinal tract.

1.1 Closest prior art

1.1.1 Document D2 discloses pharmaceutical compositions containing 5-ASA as the active ingredient. These compositions are suitable for delivering the active ingredient to the large intestine, especially the colon (see paragraph linking columns 3 and 4). The Board agrees with the opposition division and with the parties that document D2 is the closest prior art for the assessment of inventive step.

1.1.2 Example VI of D2 describes a 5-ASA tablet coated by a film containing EUDRAGIT S100, i.e. poly(methacrylic acid, methyl methacrylate) 1:2. The tablets defined in claim 1 of the main request differ from the tablets disclosed in this example in D2 in that they have a second coating layer.

1.2 Technical problem

1.2.1 In its written and oral submissions, the appellant pointed out the difficulties that a skilled person would have encountered in developing pharmaceutical compositions that could deliver high doses of active ingredient to the colon that were at the same time

mechanically robust and resistant to defects such as the fracturing of the coating. It referred in particular to the experimental reports D38/D38a and D44, which relate to the assessment of the coating robustness of tablets containing 5-ASA.

1.2.2 Indeed, these reports indicate that tablets with a single-layer coating, containing 800 mg of 5-ASA, may not have the desired robustness, especially if the coating is thin (see Table 1 in D38a and the table in D44). In contrast, it is possible to prepare 800 mg tablets of adequate robustness if a double-coating system is used.

On the other hand, Table 1 in D38a shows that in a tablet containing only 400 mg of 5-ASA the single-layer coating is also sufficiently robust (see the data for BN 324454). This is also in line with the considerations made by the appellant in its statement setting out the grounds of appeal according to which the Asacol® tablets containing 400 mg were not be expected to experience a fracture problem of the same magnitude as tablets containing 800 mg of active ingredient (page 11, last paragraph).

Thus, problems concerning the robustness of the coating are unlikely to arise in single-coated tablets containing low amounts of active ingredient. In any case, no evidence has been submitted by the appellant to show that double-coated tablets containing 400 mg or less of 5-ASA are better in terms of mechanical robustness than single-coated tablets containing the same amount of active ingredient.

1.2.3 Claim 1 does not contain any limitation as to the amount of active ingredient and therefore covers also

tablets having a drug loading of less than 400 mg. In view of the above considerations, the issues concerning the robustness of the coating do not play any role in the assessment of inventive step of the main request.

1.2.4 The appellant also submitted experimental data concerning pharmacokinetic studies. These experiments (discussed in greater detail in point 6.2 below) aim to show that a double-coated tablet containing 800 mg of 5-ASA provides a plasma concentration of active ingredient closer to the one provided by two tablets of 400 mg than single-coated tablet of 800 mg. However, these experiments are also irrelevant with regard to claim 1 of the main request since this claim contains no limitations as to the amount of active ingredient.

1.2.5 Therefore, the technical problem underlying the invention of the main request is the provision of an alternative dosage form for a site-specific delivery of the active ingredient.

1.3 Obviousness

1.3.1 Compositions for delivering the active ingredient to specific sites in the gastrointestinal tract and comprising two layers based on methacrylic polymers were already known before the priority date of the patent in suit. For instance, Example 3 of D1 and Figure 1 of D15 (page 2) describe 5-ASA tablets comprising an inner coating and an outer enteric coating both made of Eudragit polymers, i.e. methacrylate-based polymers. The skilled person seeking an alternative to the tablet in Example VI of D2 would have found that D1 or D15 hinted at using of a double-coating system as defined in claim 1 of the main request.

1.4 Hence, the subject-matter of the main request does not comply with the requirements of Article 56 EPC.

Auxiliary requests 1 to 4

2. Claim 1 of each of these requests defines a pharmaceutical composition comprising 5-aminosalicylic compounds, 4-aminosalicylic compounds, or sulfasalazine, at a dosage range of from 700 mg to 900 mg.

2.1 The passage of the original description referred to by the appellant as a possible basis for the indication of the amount of active ingredient (page 4, lines 16 to 20) concerns only the active ingredient 5-amino salicylic acid (or salts or esters thereof). There is no mention in this passage of the other active ingredients recited in claim 1 of auxiliary requests 1 to 4.

Hence, page 4 of the description does not provide a valid basis within the meaning of Article 123(2) EPC for a composition containing, for example, from 700 mg to 900 mg of sulfasalazine. Nor can such a composition be directly and unambiguously derivable from any other part of the original application.

2.2 Thus, auxiliary requests 1 to 4 do not comply with the requirements of Article 123(2) EPC.

Auxiliary request 5

3. Claim 1 of this request concerns compositions comprising 5-aminosalicylic acid or pharmaceutically

acceptable salts or esters thereof at a dosage range of from 700 mg to 900 mg.

3.1 Claim 1 as granted did not contain any reference to salts or esters. Thus, the question arises whether the inclusion of these derivatives results in an extension of the protection conferred by the patent, contrary to the requirements of Article 123(3) EPC.

3.2 The appellant argued that the expression "5-aminosalicyclic compounds" used in claim 1 as granted covered all 5-ASA derivatives including salts and esters.

3.3 The Board notes in this regard that the description does not provide any definition for the expression used in claim 1. The plural term "compounds" indicates that the expression covers more than one compound. Yet the exact boundaries of this expression remains undefined. It could be argued that the term "compounds" has been used, for instance, to cover the salts of 5-ASA but not its esters, or to cover various crystalline forms of 5-ASA. Hence, salts and esters are not unambiguously covered by the scope of the patent. Thus, the subject-matter of auxiliary request 5 infringes Article 123(3) EPC.

Auxiliary request 5a

4. Article 123(2) EPC

4.1 Claim 1 is based on the subject-matter of the originally filed claim 1 and further includes some limitations with regard to the definitions of the active ingredient and the second coating layer.

4.1.1 The indication that the active ingredient is 5-amino salicylic acid at a dosage range of from 700 mg to 900 mg is based on the disclosure of page 4, lines 17 to 20, of the original application. The compositions of the inner and outer coating layers find their basis in original claims 1 and 4, respectively. They are furthermore disclosed in the paragraph linking pages 4 and 5 of the description (inner coating layer) and on page 7, lines 5 to 7 (outer coating layer).

4.1.2 The disclosure on page 4 of the original application of solid dosage forms containing from 700 mg to 900 mg of 5-ASA is not restricted by any condition as to the composition of the coating layers. Thus, the combination of the features defining the amount and type of active ingredient with the features defining the composition of the layers does not result in the addition of subject-matter.

4.2 Thus, claim 1 of auxiliary request 5a meets the requirements of Article 123(2) EPC.

5. Article 123(3) EPC

5.1 Claim 1 of auxiliary request 5a no longer refers to salts and esters as claim 1 of auxiliary request 5. Thus, the requirements of Article 123(3) EPC are met.

6. Inventive step

6.1 Closest prior art

6.1.1 It is common ground that D2 is again the closest prior art for the assessment of inventive step. The tablets defined in claim 1 of auxiliary request 5a differ from

the disclosure of D2 in the amount of active ingredient and in that there are two coating layers.

6.2 Technical problem

6.2.1 The appellant submitted several experimental reports intended to demonstrate that the technical problem was the provision of highly loaded tablets having certain pharmacokinetic properties which were at the same time mechanically robust. Some counter-experiments have also been done by the respondents. The relevant experiments of the parties are discussed in the following sections.

6.2.2 The appellant's report D17 describes a clinical study conducted with healthy volunteers. The patients were orally administered one tablet containing 800 mg of 5-ASA or two tablets containing 400 mg. The latter treatment represents the standard dosage of the commercial product Asacol® (see D19, page 8). The 800 mg tablet was either a double-coated tablet according to claim 1 or a single-coated tablet of the type described in D2. The results in D17 show that a 800 mg tablet with double-coating has a Tmax and Tlag closer to the reference treatment ("2 X 400 mg") than a single-coated tablet having the same amount of active ingredient and polymer coating.

In a further experimental report (document D37), the appellant investigated the effect of the amount of coating on the pharmacokinetic properties of single-coated tablets. The results disclosed in Table 6 show that when the amount of coating in a single-coated composition is increased, the pharmacokinetic parameters deviate to a greater extent from those of the reference treatment ("2 X 400 mg"). The best results in terms of similarity to the reference

treatment are obtained with the tablet containing the lowest amount of coating, namely, 52.8 mg of methacrylate polymer per tablet. The single-coated tablet with the highest amount of coating (62.2 mg) is the least similar, in terms of pharmacokinetic parameters, to the reference treatment.

6.2.3 The appellant's comparative experiments disclosed in D44 demonstrate that a single-coating tablet containing 800 mg of active ingredient and 46 mg of methacrylate polymer in the coating is less robust than a double-coated tablet containing 800 mg of active ingredient and a total amount of 66 mg of methacrylate polymer in the coating layers.

The robustness of single-coated tablets was further investigated by the appellant in the experiments disclosed in D38 and D38a. Table 1 of D38a shows that the robustness of the coating increases as the amount of methacrylate polymer in the coating is increased. The poorest results are provided by the formulation defined as "low" in D38. As explained by the appellant in the statement setting out the grounds of appeal (page 6), this formulation contains 52.8 mg of methacrylate polymer.

6.2.4 The data concerning the robustness of the tablets combined with those concerning the pharmacokinetic properties confirms the appellant's position that in single-coated tablets there is an inherent conflict between the coating thickness required to meet the desired pharmacokinetic properties and the coating thickness required for adequate robustness. Indeed, the single-coated tablet providing the best results in terms of pharmacokinetic properties is the one containing 52.8 mg of methacrylate polymer in the

coating (see 6.2.2 above). This is, however, the single-coated tablet with the lowest mechanical robustness (see 6.2.3 above).

In contrast, the data disclosed in D44 and D17 indicate that by using a double-coating system it is possible to achieve good results in terms of robustness of the coating while maintaining the desired pharmacokinetic parameters.

6.2.5 The respondents questioned the relevance of the experiments disclosed in D44 observing that the amount of coating in the single-coated tablets (46 mg) was much less than the total coating present in the double-coated tablets (66 mg). The higher mechanical resistance of the double-coated tablets was therefore to be ascribed to the use of a greater amount of coating.

The Board agrees with the respondents that in the comparative experiments of D44 the tablets tested do not differ only in the number of coating layers but also in the total mass of methacrylate polymer used for the coating. Nevertheless, the experiments concerning the robustness of the coating should be considered together with the experiments concerning the release profile of the compositions, in particular D17 and D37. Increasing the amount of coating in the single-coated tablet tested in D44 to reach the same amount used for the double-coated tablet (66 mg) may well result in an improvement of its robustness. However, as demonstrated in D17 and D37 (see point 6.2.2 above), this would be detrimental for its pharmacokinetic properties. Hence, considering the appellant's experiments as a whole, a single-coated tablet does not allow achieving an

appropriate balance of mechanical and pharmacokinetic needs, whereas a double-coated tablet does.

6.2.6 As a further argument, the respondents put forward that the alleged problem of robustness of the single-coated tablets observed by the appellant in experimental reports D38 and D38a was simply due to the absence of a plasticiser in the coating. They referred to the experimental report filed by respondent-1 (document D48) showing that single-coated tablets containing 800 mg of 5-ASA and dibutyl phthalate as a plasticiser in the coating did not suffer from coating fractures.

The Board agrees with the appellant's observation that the amount of dibutyl phthalate included in the tablets tested in D48 (9.2 or 13.2 mg per tablet) appears excessively high. D20 is a post-published document concerning the product Asacol® HD tablets containing 800 mg of 5-ASA. It explains in paragraph 8.1 that the daily intake of dibutyl phthalate from the maximum recommended dose of Asacol® HD tablets is about 48 mg. This maximum dose corresponds to the administration of six tablets (paragraph 2 of D20). At this dosage, the tablets tested in D48 would result in a daily intake of dibutyl phthalate much higher than the maximum intake considered in D20. In this regard it is noted that D20 warns about possible negative effects of high doses of dibutyl phthalate during pregnancy (paragraph 8.1). Hence, the problems of poor robustness of the single-coated tablets can apparently be remedied only by using very high amounts of plasticiser that a skilled person would not have considered for reasons of safety.

Additionally, it is not clear whether the tablets tested in D48 would provide positive results in terms of pharmacokinetic properties having regard to the high

amount of plasticiser used. D48 does not provide any data in this respect.

Hence, D48 does not invalidate the conclusions drawn in paragraph 6.2.5 above.

6.2.7 In the light of the above, the technical problem can be formulated as the provision of tablets for a site-specific delivery of 5-ASA containing a larger dose of active ingredient that are resistant to coating fractures and provide a plasma drug concentration similar to when 2 tablets containing 400 mg of 5-ASA are administered.

6.3 Obviousness

6.3.1 The skilled person confronted with the problem of providing a tablet containing a large amount of 5-ASA would first have considered the simplest solution, namely, to increase the amount of active ingredient in the single-coated tablets of D2. However, as illustrated above, by proceeding in this manner he would have been faced with the problem of finding an appropriate balance between the mechanical stability of the tablet and the need to achieve the desired pharmacokinetic properties. This problem is not recognised in D2 for the simple reason that D2 does not disclose any tablet containing more than 400 mg of 5-ASA. Hence, the skilled person would have found no guidance in the closest prior art in this respect.

6.3.2 As discussed above (see point 1.3.1), some prior art documents, such as D1 and D15, describe tablets comprising an inner coating and an outer enteric coating both made of methacrylate-based polymers. However, there is no teaching in these documents that

by using this double-coating system it would be possible to prepare tablets that solve the technical problem defined in point 6.2.7 above.

6.4 Therefore, the subject-matter of auxiliary request 5a meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of auxiliary request 5a, filed at the oral proceedings before the Board of 5 February 2019, and a description to be adapted.

The Registrar: The Chairman:

I. Aperribay D. Boulois

Decision electronically authenticated