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Application No. / Patent No.	Ref.	Date
10 821 232.5 - 1112 / 2 482 822 / 01	ESP00422FAL	25.08.2021
Proprietor Ellodi Pharmaceuticals, L.P.		

Decision revoking the European Patent (Art. 101(3)(b) EPC)

The Opposition Division - at the oral proceedings dated 08.03.2021 - has decided:

European Patent No. EP-B- 2 482 822 is revoked.

The reasons for the decision are enclosed.

Possibility of appeal
This decision is open to appeal. Attention is drawn to the attached text of Articles 106 to 108 and Rules 97 to 98 EPC.

Opposition Division:

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2nd Examiner: Wörth, Christian
1st Examiner: Giró, Annalisa

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Enclosure(s): 19 page(s) reasons for the decision (Form 2916)
Wording of Articles 106 - 108 and Rules 97-98 EPC (Form 2019)

to EPO postal service: 20.08.21

I. Summary of Facts and Submissions

1 European patent 2 482 822 having the title "ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS" is based upon European patent application No. 10 821 232.5 filed on 30-09-2010. It claims priority of US 247642 filed on 01-10-2009. The mention of the grant of the patent has been published in the European Patent Bulletin 2018/31 of 01-08-2018. Proprietor (P) of the patent is Ellodi Pharmaceuticals, L.P. (US).

2 A notice of opposition has been filed by Dr. Falk Pharma GmbH (DE) on 01-03-2019. The Opponent (O1) requested revocation of the patent in its entirety based on Article 100(a) EPC for lack of novelty (Article 54 EPC) and of inventive step (Article 56 EPC), on Article 100(b) EPC for insufficiency of disclosure (Article 83 EPC) and on Article 100(c) EPC for extension of the subject-matter (Article 123(2) EPC). O1 cited documents D1-D6 in support of their arguments. O1 further requested oral proceedings as an auxiliary measure (Article 116 EPC).

3 In a letter received on 20-09-2019 the proprietor requested the rejection of the opposition (Article 101(2) EPC). P cited D7-D12. As an auxiliary measure, oral proceedings were requested (Article 116 EPC).

4 With letter received on 29-10-2019 O1 requested acceleration of the proceedings and filed arguments and the additional documents D13, D14a and D14b.

5 With an online filing dated 16-12-2019 P filed further arguments, an Auxiliary Request and requested not to admit documents D14a and D14b.

6 In a letter received on 14-01-2020 O1 filed additional arguments together with documents D15 and D16. O1 also raised objections under Articles 123(2), 83 and 56 EPC against the Auxiliary Request.

7 On 13-02-2020 the Opposition Division (OD) issued summons to attend oral proceedings on 18-09-2020.

8 With letter received on 17-07-2020 O1 filed additional arguments together with documents D17, D17a-D17d, D18 and D19.

9 With an online filing dated 17-07-2020 P filed new Auxiliary Requests 1, 2 and 4-7 and renumbered the Auxiliary Request filed on 16-12-2019 as Auxiliary Request 3. P also requested not to admit D15 and D16 filed by O1 on 14-01-2020 and further submitted D20-D25.

10 Due to the COVID-19 situation, the oral hearing scheduled for 18-02-2020 had to be postponed. The OD issued on 20-11-2020 new summons to attend oral proceedings on 08-03-2021.

11 With letter received on 08-12-2020 O1 requested not to admit all documents and requests filed by P after their reply to notice of opposition (letter of 20-09-2019), should the documents filed from their side not be admitted by the OD. O1 further filed D26.

12 With letter received on 08-01-2021 P withdrew Auxiliary Requests 1, 2, 4-7 and filed a new Main Request (II), a new Auxiliary Request 3 (II) and new Auxiliary Requests 1, 2 and 4-7. P further provided arguments in favour of all the requests and requested not to admit D17, D17a-d, D18, D19 and D26.

13 With letter received on 01-03-2021 O1 requested not to admit the Main Request (II), the Auxiliary Request 3 (II), as well as Auxiliary Requests 1, 2 and 4-7. O1 filed Annexes A and B in order to illustrate their submissions.

14 On 08-03-2021 oral proceedings were held as videoconference. During the hearing, P renumbered the auxiliary requests on file as follows:

- Auxiliary Request 1 corresponding to Main Request (II) filed on 08-01-2021

- Auxiliary Requests 2, 3, 5-9, respectively corresponding to Auxiliary Requests 1, 2, 3(II), 4-7 filed on 08-01-2021

- Auxiliary Request 4 corresponding to Auxiliary Request 3 filed on 17-07-2020.

15 At the end of the oral proceedings the OD came to the conclusion that none of the Main Request or Auxiliary Requests 1-9 meets the requirements of the EPC. Accordingly, the OD announced the decision to revoke the patent under Art. 101(3)(b) EPC.

16 The decision is based on the following requests:

Main Request: patent as granted

Auxiliary Requests 1-3, 5-9: filed with letter of 08-01-2021 respectively as Main Request (II) and Auxiliary Requests 1, 2, 3(II), 4-7

Auxiliary Request 4: filed with letter of 17-07-2020 as Auxiliary Request 3

17 The arguments of the parties relevant to the decision are summarized with each point of the Reasons for the Decision.

18 In the course of the proceedings, the following documents have been submitted as evidence by the parties:

EPO	CITATIONS	P	O1

D1	US 2007/0111978, Dohil		D1
D2	WO 2010/144865, Meritage Pharma, Inc.		D2
D3	Prioritatsbeleg von D2, US 61/186,777		D3
D4	US 2003/0099701, Takaishi		D4
D5	EP 1 595 533 A1, Nippon Shinyaku		D5
D6	EP 1 323 417, Yamanouchi Pharmaceutical Co. Ltd.		D6
D7	Jorveza, first published 18.01.2018	D7	
D8	Jorveza, 1 mg tablets, dated 15.03.2018	D8	
D9	Breuer et al, Pure Appl. Chem., 2009; 81 (5): 971-999	D9	
D10	PubChem extract, information available as of 15 October 2015	D10	
D11	Bonnet et al, Pharm 2018; 3(2): 91-99	D11	
D12	Miehlke et al., Gut 2016; 65: 390-399	D12	
D13	Klageschrift eingereicht beim LG Mannheim 7 O 75/19		D13
D14a	WO 2009/064457 Meritage		D14a
D14b	EP 2214679 B1 Meritage		D14b
D15	WO 2009/086046 A1		D15
D16	WO 2004/091585 A1		D16
D17	Eingabe vom 2. Juli 2020		D17
D17a	Hilfsantrage I		D17a

D17b	Hilfsantrage II		D17b
D17c	Hilfsantrage III		D17c
D17d	Hilfsantrage IV		D17d
D18	Tabellarische Zusammenstellung der Merkmale des Dokuments D17d gegenüber den Fundstellen in Dokument D1		D18
D19	US 6 596 311 B		D19
D20	Declaration of Stephen Perrett, MBA, Ph.D.	D17	
D21	"Nurofen" tablet package insert (provided in German only	D18	
D22	"Dolo-Dobendan" lozenge package insert (provided in German only)	D19	
D23	Pelle et al., Hosp Pharm (2006), 13, 133-136	D20	
D24	Opponent's Statement of Grounds of Opposition against D14b	D21	
D25	Report of Professor Geoffrey Lee, Ph.D. on measurement of disintegration time of "Jorveza® 1 mg orodispersible tablet".	D22	
D26	Beschluss der Gebrauchsmusterabeiteilung		D26

II. Reasons for the Decision

19 The opposition is admissible because it meets all requirements of Article 99(1) and 100 EPC and Rules 3(1) and 76(1)(2) EPC.

20 **Admissibility**

20.1 O1 requested not to admit AR1-AR9 because said requests are late filed and not converging.

The OD admits AR1-AR9 into the proceedings because they constitute a reaction to the opposition division's preliminary opinions annexed to the two summons to attend oral proceedings. With respect to the alleged lack of convergence of the auxiliary requests the OD notes that the auxiliary requests exhibit divergence only related to three aspects: the weight range, the tablet disintegration time and the disintegrant ingredient, which do not result in a substantial lack of convergence.

20.2 P requested not to admit D14a, D14b, D15, D16, D19 and D26 as being late filed and not prima facie relevant to the question of inventive step. In their written submissions, O1 requested not to admit documents D20-D25 as late filed and not relevant.

20.3 The OD notes that the above documents have not been cited or discussed by the parties at the oral proceedings. Further more, the OD assesses that D14a does not mention at all orally dispersing dosage formulations, which is the technology at the core of the present invention. Thus, notwithstanding the official investigation mandate of the OD and the fact that it was filed one year before the oral proceedings, OD nevertheless considers that D14a is not prima facie more relevant than evidence already in the proceedings. By contrast, as D15, D16 and D19-D21, D24 and D25 specifically focus on orally dispersing tablets (ODTs), their teachings in relation to the specifics of this kind of formulations might be of relevance for the present case. D22 concerns orally dissolving lozenges and might be relevant during the novelty discussion over D1. For these reasons, D15, D16 and D19-D22, D24 and D25 are admitted in the proceedings, while D14a is not. D14b was cited in support of the novelty objections raised in the light of D14a. However, being D14b published after the priority date and after the filing date of the patent in suit, it does not form part of the state of the art in the sense of Article 54 EPC and it is thus not relevant for the maintenance of the patent. Thus, also this document is not admitted in the proceedings. D23 and D26 are not admitted as they concern different cases having no bearing on the present procedure.

21 Main Request (MR, patent as granted)

Claim 1 of the MR reads:

Dr. Falk Pharma Ex. 1004
PGR Petition - USP 12,290,598

An orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract.

22 Sufficiency of disclosure (Articles 100(b) and 83 EPC)

22.1 During the discussion of the requirements of Article 83 EPC at the oral proceedings, both parties referred to their written submissions.

22.2 In their written submissions, O1 argued that budesonide solvates and esters defined in claim 1 are not known in the art and that, as the patent in suit does not teach how to obtain them, the skilled person is not able to reproduce the invention.

22.3 The OD is however of the opinion that O1's allegation concerning solvates and esters of budesonide has not been supported by evidence. In fact, no serious doubts, substantiated by verifiable facts, have been raised as to the impossibility of the skilled person to prepare an ester or a solvate of budesonide. Therefore, this objection of lack of sufficient disclosure is considered void. Moreover, the OD notes, e.g., that budesonide possesses two hydroxy groups, which appear to allow the formation of ester derivatives.

22.4 O1 further objected in writing that the features "at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity" and "the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract" defined in claim 1 represent results to be achieved and that the patent leaves the skilled person with no clear guidance as how to select said ingredient in order to obtain the desired tablet dispersal in the oral cavity and as how to achieve the desired topical administration in the upper gastrointestinal tract. In particular, O1 stressed that none of the examples reported in the original application falls under the definition of claim 1.

22.5 The OD notes that granted claim 1 is directed to a product and not to a purpose-related product or use and, hence, in order for the requirements of Article 83 EPC to be fulfilled, the skilled person should be put in a position to reproduce the claimed product. ODTs are very well known dosage forms in the field of galenics. In view of his common general knowledge, the skilled person is well aware of which specific pharmaceutical excipients are required for oral dispersion among those described in the original application (page 3, lines 19-25 and page 12, lines 13-17). In addition, the OD agrees with P that, even if

example 1 does not fall within the scope of claim 1, it provides additional guidance as to the identification of suitable excipients. O1 did not submit any substantiated facts as to why an ODT comprising budesonide could not be reproduced on the basis of example 1. The OD takes thus the view that the skilled person is in a position to prepare an ODT comprising budesonide without undue burden based on the information available in the patent in suit.

22.6 Further, the OD is of the opinion that the claimed suitability for topical administration of budesonide in the upper gastrointestinal tract does not represent a technical feature substantially limiting the product of claim 1. Thus, while the skilled person appears to be well in a position to prepare the claimed ODT, the OD cannot follow how, according to the allegation of O1, an insufficiency of disclosure can arise from a non-limiting feature. The question whether the claimed ODT actually allows such an administration, and whether this has been credibly shown by the patent in suit, is rather an issue to be discussed within the context of Article 56 EPC.

23 Added subject-matter (Articles 100(c) and 123(2) EPC)

23.1 O1 argued that the subject-matter of claim 1 as granted finds no basis in the application as originally filed (WO2011/041509), as the claim constitutes an undisclosed combination of features selected from different lists. In particular, in view of the omission of a specific disintegration time, O1 considered granted claim 1 to correspond to the composition disclosed as isolated embodiment on page 15, lines 3-9, of the original disclosure, wherein however the budesonide content has been inadmissibly extended from the range of "about 0.5 mg to about 20 mg" to "less than or equal to 20 mg". In O1's opinion, further selections are represented by:

- an orally dispersing tablet among the dosage forms disclosed on page 7, lines 16-19 of the application as filed

- the selection of budesonide from a list of various corticosteroids from page 10, lines 10-13 of the application as filed

- the topical administration to the *upper* gastrointestinal tract selected over the gastrointestinal tract in general or over other specific parts of the gastrointestinal tract, such as the esophagus, as disclosed on page 5, lines 12-14 of the original application, or those parts disclosed in connection with various inflammatory conditions on page 5, line 20 to page 7, line 2.

23.2 With regard to the omission of a specific disintegration time in granted claim 1, the OD concurs with P in that the language "in other embodiments" used to introduce the passage on page 15, lines 3-9 of the original application represents a mere drafting style and it does not justify the interpretation of said passage as an embodiment isolated from the rest of the original disclosure. On the contrary, said passage clearly teaches that the *solid pharmaceutical compositions of the present invention* can have any rate of disintegration or dissolution in the oral cavity, i.e. such an unrestricted disintegration rate appears to be a feature applying to all solid compositions described throughout the original application. Thus, a disintegration time within 60 seconds does not represent an essential feature and it can be omitted.

23.3 P also argued that the application as filed points at a preference for both ODTs as dosage form and budesonide as active agent, so that a combination of these two features shall be considered supported. P referred to page 10, lines 13-15 of the original specification for an individualised disclosure of budesonide, and to page 2, lines 8-14, page 5, lines 12-14, page 7, lines 3-7, example 1 and original claim 1 for solid compositions, and in particular of ODTs, being always mentioned first, i.e. preferred, over liquid compositions.

23.4 The OD, however, comes to the conclusion that ODTs and budesonide are not highlighted as preferred embodiments in the originally filed description. In fact, both liquid and solid compositions are described throughout the original application as alternatives, i.e. equally preferred dosage forms of the invention (see, e.g., page 2, lines 8-29, page 5, line 12, page 7, line 13, page 11, lines 6-10). This is confirmed by the fact that the examples describe not only an ODT (example 1), but also a gel (example 2). While it is true that ODTs are mentioned in several passages of the application as originally filed within the context of the solid dosage forms, also liquid formulations are extensively described (see page 7, line 20 to page 10, line 9). Thus, within the disclosure of the original specification, a first selection between liquid and solid compositions shall be done.

Similarly, the fact that budesonide is recited first in some lists of active agents reported in the original description is regarded neither as an explicit preference nor as a potential pointer towards a preference. The same applies also to the individualized disclosure of budesonide on page 10, lines 14-15, which follows an identical individualized disclosure of fluticasone (see the preceding sentence lines 13-14). In this context, these two agents are thus described in the original

description with the same level of preference, so that a selection between them needs to be done. If any, a preference rather emerges for fluticasone (and not for budesonide), as this agent is used in the examples of the specification.

23.5 The OD agrees however with P that original claim 27 offers a basis for the combination of the feature budesonide with an ODT as defined in granted claim 1, as only the selection of budesonide among the corticosteroids mentioned in claim 27 is necessary. In addition, the OD does not consider the presence of "*at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity*" in granted claim 1 as introducing a new teaching over the disclosure of original claim 27. In fact, the general definition of an ODT given on page 3, lines 14-22, confirms that the presence of such an excipient in an ODT is self-evident for the skilled person. Finally, the omission of the disintegration time from claim 1 as granted is not regarded as extending beyond the disclosure of original claim 27 for the same reasons mentioned under point 23.2. Therefore, the OD considers claim 1 as granted to find basis within the meaning of Article 123(2) EPC in original claim 27 in connection with the skilled person's common general knowledge about ODTs as reflected on page 3, lines 14-22, of the original specification.

23.6 The OD takes however the view that no basis can be found for granted dependent claims 3-15, 18 and 19. In fact, these dependent claims define additional features which are not directly disclosed in claim 27 as filed, but have to be selected from different parts of the original disclosure (such as unrelated claims or parts of the description), in addition to the selection of budesonide from claim 27. For example, the disintegration time of 30 seconds defined in granted claim 3 needs to be selected from a list of time periods on page 14, lines 24-27. The ingredient defined in granted claim 6 needs to be selected from a list of ingredients on page 3, lines 19-25. Therefore, the subject-matter of each of claims 3-15, 18 and 19 as granted is a result of multiple selections from different lists, contrary to the requirements of Article 123(2) EPC.

24 Auxiliary Request 1 (AR1, filed as MR(II) on 08.01.2021)

Claims 1-4 of the AR1 correspond to claims 1, 2, 16 and 17 of the MR. Dependent claims 3-15, 18 and 19 of the MR have been deleted.

25 Added subject-matter (Article 123(2) EPC)

25.1 O1 objected that claims 3 and 4 of the AR1 do not meet the requirements of Article 123(2) EPC, because the medical indications addressed therein are not disclosed in the original application in connection with the ODT as defined in claim 1.

25.2 The OD concurs with P that the claimed medical indications are disclosed on page 1, lines 7-9, page 2, lines 3-6 and page 5, lines 20-22 and 25-29 of the description as originally filed in such a general way that they clearly apply to all embodiments of the invention. Therefore, their combination with the ODT addressed in claim 1 of the AR1 (corresponding to claim 1 of the MR and considered allowable for the reasons mentioned above) does not present the skilled person with new technical information extending beyond the content of the application as originally filed. The AR1 meets thus the requirements of Article 123(2) EPC.

26 Novelty (Article 54 EPC)

26.1 O1 raised a novelty objection based on D1 against the subject-matter of claim 1 of the AR1. D1 describes in [0032] that "*Budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus*".

26.2 P countered that [0032] does not directly and unambiguously disclose an ODT, in particular because corticosteroid-containing ODTs were not known at D1's publication date (17-05-2007). Rather, said passage refers to tablets similar to lozenges, i.e. tablets which are sucked in order to dissolve the active in the mouth and which are finally chewed (see D9, see page 990 "lozenge", and D20, see page 1, item 7). In P's opinion, lozenges dissolve slower than the claimed ODTs, as they do not contain a disintegrant. By contrast, ODTs disintegrate rapidly without the need for chewing, thereby forming a dispersion of the active in the mouth. P thus held that the “rapidly dissolving formulations” mentioned in [0032] of D1 do not correspond to the ODTs within the meaning of the patent and that the term “rapidly” is used therein merely to distinguish the disintegration of said formulations with the “slow release” formulations described at the end of the same paragraph.

26.3 The OD is of the opinion that orally dispersing tablets as dosage forms were known to the formulator skilled in the art at D1's date of publication. As stressed by O1, this is confirmed by the disclosures of D15 (see page 1, line 21 to page

2. line 8, page 4, lines 18-22, page 6, lines 25-27, page 11, lines 7-15), D16 (see page 1, paragraph 1, page 6, lines 14-16, page 17, line 4, claims 2, 3) and D19 (see the abstract). It is therefore to be established whether, when faced with the disclosure of D1, the skilled person would understand that the dosage forms described therein correspond to, or at least overlap with the claimed ODT of the AR1. To this extent, the OD considers it useful to assess the definition of the claimed ODT in the patent in suit. According to [0009] of the patent in suit, said ODTs are solid dosage forms which rapidly disintegrate in the oral cavity of a patient after administration and which can contain pharmaceutically acceptable ingredients which swell, dissolve or otherwise facilitate the disintegration or dissolution of the ODT composition. Also [0022] of the patent in suit confirms that said ODT disintegrates or dissolves rapidly in the mouth to form a solution or dispersion. The ODTs can comprise ingredients facilitating the disintegration or dissolution, which can include a disintegrant, a sugar alcohol, a saccharide, a water-soluble binder, a meltable solid, such as a wax (see [0009] of the patent in suit). Therefore, the specific presence of a disintegrant in the ODT of the invention is not regarded as mandatory.

26.4 The OD acknowledges that D1 does not disclose *expressis verbis* an "orally dispersing tablet" or an "ODT". However, [0032] clearly describes a lozenge or similar tablet, which rapidly dissolves in the mouth. The OD is persuaded that said tablet is not interpreted by the skilled person as being a conventional tablet to be swallowed, simply because the latter is not meant to dissolve in the mouth. On the contrary, in view of its general knowledge, the skilled person would understand that the tablets addressed in [0032] of D1 necessarily require an excipient which facilitates their dispersion and dissolution. This consideration is consistent with the analysis under point 23.5 above, which led to a positive conclusion on the requirements of Article 123(2) EPC for claim 1 of the MR. As a consequence, the OD concludes that the dosage forms described in [0032] of D1 at least overlap the ODT addressed in claim 1 of the AR1.

26.5 P argued that the claimed combination of the features "tablet" and rapidly dissolving "in the mouth" cannot directly and unambiguously be deduced from [0032] of D1 because the tablet needs to be selected from lozenge or other similar tablet, capsule, or other solid and the dissolution takes place either in the mouth or in the esophagus. The OD however considers that the skilled person would not interpret the phrase "dissolve rapidly in the mouth or esophagus" as a list of alternatives, because a dosage form which rapidly dissolves in the esophagus necessarily start its dissolution already in the mouth.

26.6 The OD notes that [0032] of D1 does not mention the amount of budesonide present in the solid dosage forms. The OD agrees with P that a novelty objection cannot be based on the budesonide amounts disclosed in D1 in connection with liquid formulations, such as in example 2, [0053] and [0058]. The OD is however of the opinion that the embodiment disclosed in [0032] can be combined with the general disclosure of [0015]. This paragraph teaches that the compositions described in D1 are intended for a daily administration of 1-2 mg or 2-3 mg corticosteroids. Thus, at most, i.e. in case of a once daily administration, the compositions of D1 comprise 3 mg corticosteroid. As noted by O1, in case of a multiple daily administration, a lower amount of budesonide would be comprised in each tablet, thereby leading to tablets which still fall within the scope of claim 1. The OD concurs with O1 that this is not in contrast with the teaching of [0031] of D1, from which the skilled person learns that said dosage may be modulated depending on parameters such as the route and the form of administration, as well as the subject to be treated. Therefore, when reading the disclosure of [0032] in the light of the teaching of [0015], the skilled person understands that the orally dispersing tablet disclosed therein comprises at most 3 mg budesonide.

26.7 Finally, P's allegation that [0015] of D1 rather relates to liquid formulations cannot be followed. Said paragraph clearly refers in general terms to "the pharmaceutical composition", which according to D1 can be in either in a liquid or in a solid form. As stressed by O1, the presence of a viscosity-increasing agent as essential feature of the composition addressed in claim 1 of D1 does not necessarily imply that said composition is liquid. In fact, according to [0037] of D1, also tablets can comprise such excipients, which are meant to increase the viscosity of the liquid resulting from the dissolution of the tablet.

26.8 For these reasons, the OD comes to the conclusion that D1 is novelty destroying for an orally dispersing tablet comprising less than or equal to 20 mg of budesonide as defined in claim 1 of the AR1.

27 Auxiliary Request 2 (AR2, filed as AR1 on 08.01.2021)

The subject-matter of claim 1 of the AR2 corresponds to claim 1 of the Main Request, wherein the amount of budesonide or a solvate or ester thereof has been limited to the range "from about 0.5 mg to 20 mg". In addition, dependent claims 2-15, 18 and 19 of the MR have been deleted.

28 Added subject-matter (Article 123(2) EPC)

28.1 P cited the passage on page 15, lines 3-9, of the original description as basis for the subject-matter of claim 1 of the AR2.

28.2 The OD however concurs with O1 that said passage does not disclose the amount of corticosteroid comprised in the solid dosage compositions mentioned therein, but it rather refers to the amount to be provided by the composition to the inflamed tissue of the gastrointestinal tract to be treated. Therefore, claim 1 of the AR2 does not meet the requirements of Article 123(2) EPC.

29 **Auxiliary Request 3 (AR3, filed as AR2 on 08.01.2021)**

The AR3 corresponds to the AR2, wherein claim 1 comprises the additional feature "wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant".

30 **Added subject-matter (Article 123(2) EPC)**

30.1 P cites the passage on page 3, lines 22-23, of the original description as basis for the subject-matter of claim 1 of the AR3.

30.2 As the subject-matter of claim 1 of the AR3 comprise all features of claim 1 of AR2, it does not to fulfill the requirements of Article 123(2) EPC at least for the same reasons mentioned with regard to the AR2.

31 **Auxiliary Request 4 (AR4, filed as AR3 on 17.07.2020)**

The subject-matter of claim 1 of the AR4 corresponds to the MR, wherein the features "wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test" and "wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant" have been incorporated. In addition, claims 2, 6 and 14 as granted have been deleted.

32 **Added subject-matter (Article 123(2) EPC)**

32.1 P provided as a basis for current claim 1 the granted claims 1, 2 and cited the passage on page 3, lines 22-23, of the original description.

32.2 The OD finds a support for the subject-matter of claim 1 of the AR4 in original claim 27 for the reasons mentioned under item 23.5 above. It is additionally noted that original claim 27 discloses the disintegration time addressed in claim 1 of the AR4.

32.3 However, in line with the reasoning provided under item 23.6, the subject-matter of claims 2-17 of the AR4 is regarded as deriving from multiple selections from different lists, contrary to the requirements of Article 123(2) EPC.

33 **Auxiliary Request 5 (AR5, filed as AR3(II) on 08.01.2021)**

The subject-matter of claim 1 of the AR5 corresponds to the MR, wherein the feature "wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test" has been incorporated. In addition, dependent claims 2-15, 18 and 19 of the MR have been deleted.

34 **Added subject-matter (Article 123(2) EPC)**

34.1 P provided granted claims 1 and 2 as a basis for current claim 1 of AR5. O1 held the subject-matter of claim 1 of the AR5 to extend beyond the disclosure of the original application for the same reasons raised in connection with claim 1 of the MR.

34.2 The OD takes the view that subject-matter of claim 1 of the AR5 finds support in original claim 27 for the reasons mentioned under item 24.5 above. It is noted that original claim 27 discloses the disintegration time addressed in claim 1 of the AR4.

35 **Novelty (Article 54 EPC)**

35.1 O1 considered the subject-matter of claim 1 of the AR5 not to be novel over D1 for the same reasons mentioned in connection of claim 1 of the MR. He argued that the claimed disintegration time was an inherent feature of the fast dissolving tablet disclosed in [0032] of D1 and that it thus could not establish novelty.

35.2 As acknowledged by O1, D1 does not directly and unambiguously disclose a disintegration time within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test. O1 has not provided proof that said disintegration time is an implicit feature of the budesonide tablets described in

[0032] of D1, or that essentially all ODT necessarily dissolve within 60 seconds. By contrast, P raised reasonable doubts that this is the case, by showing that Nurofen, an example of an ODT, disintegrates over a period of two minutes in water (see sections 4.3.29-4.3.32 of P's submissions of 17-07-2020). O1 has not provided evidence that Nurofen's disintegration time in simulated saliva fluid would be less than the time reported by P. Therefore, the OD comes to the conclusion that the disclosure of D1 cannot be considered as novelty destroying over the subject-matter of claim 1 of the AR5.

35.3 During the oral proceedings, the parties referred to their written submissions as to novelty objections raised by O1 over D2 and D4 in connection with the MR.

35.4 The OD considers the AR5 to be novel over D2. This document does not directly and unambiguously disclose an orally dispersing tablet comprising less than or equal to 20 mg of budesonide. O1's objection under Article 54(3) EPC is based on the combination of various features selected from different lists. In fact, at least budesonide shall be selected among the corticosteroids disclosed in [0022] and an ODT shall be selected among the various dosage forms disclosed throughout the whole document (see in particular [0006], [0008], [0078] and also [0079]-[0259]). No pointer to the combination of said features can be found in D2.

35.5 Also D4 is not considered relevant to novelty of the AR5. While this document mentions budesonide in a long list of actives (see [0043]), it does not disclose at all an amount of less than or equal to 20 mg, let alone in connection with the specific choice of budesonide.

35.6 The subject-matter of the AR5 thus meets the requirements of Article 54 EPC.

36 Inventive step (Article 56 EPC)

36.1 The OD agrees with the parties in the choice of D1 as the **closest prior art** as it is also directed to oral dosage forms comprising corticosteroids for the topical treatment of the upper GI tract, e.g. of the esophagus (see [0010]-[0013]).

36.2 P argues that the inventive step analysis shall start from the liquid formulations of D1, as these are disclosed therein as the preferred embodiment (see all of the examples and the title). While it is true that D1 focuses on liquid formulations, solid compositions are also explicitly mentioned in various passages of the document (see [0013], [0032], [0037], [0039], [0040], claims 19 and 20) as suitable dosage forms for the topical treatment of the upper GI tract.

36.3 The OD acknowledges that D1 offers several starting points for assessing inventive step, and that, even if less preferred, the dosage forms disclosed in [0032] represent the closest starting point to the claimed subject-matter, as the dosage form in [0032] and the claimed ODT have same release mechanism. In fact, said rapidly dissolving solid compositions are proposed in D1 as an alternative, indirect way of forming a budesonide-containing liquid in situ in the mouth, which is able to coat the esophagus.

36.4 Therefore, in line with the considerations on novelty reported under point 35.2, the **feature distinguishing** the subject-matter of claim 1 of the AR5 from D1 is the claimed disintegration time within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

36.5 P argues that the **technical effect** linked to said distinguishing feature is the production of a solution with a small volume, which has the surprising advantage of effectively coating the esophagus and and which is preferred by patients. This effect is allegedly made plausible by the results reported in the example of the patent in suit and in D12 (see page 390 left column "conclusions" and lower third of right column).

36.6 The OD is however of the opinion that neither the results reported in the example of the patent nor those of the post-published document D12 are of relevance for the present discussion, as they concern tablets not according to claim 1 of the AR5. The reasons are that the tablets in said example comprise fluticasone and not budesonide and that D12 specifically relates to effervescent tablets, which are not even mentioned in the patent in suit. In addition, and more importantly, the OD concurs with O1 in that the claimed disintegration time only refers to an USP disintegration test carried out in an excess of fluid, which does not correspond to the amount of saliva naturally present in the mouth of a patient. Therefore, the claimed disintegration time does not correlate to the dissolution in the mouth and no effect in vivo can be plausibly linked thereto.

36.7 Therefore, starting from the teaching of D1, the **objective technical problem** underlying the AR5 is regarded as the provision of a budesonide orally dispersible tablet.

36.8 The OD is of the opinion that a budesonide ODT showing a disintegration time within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test is an obvious **solution** to the problem. As demonstrated in D6 (see page 6, line 37, page 16, line 45, claim 1, the title, the abstract), D15 (see page 1, line 21 to page 2. line 8, page 4, lines 18-22, page 6, lines 25-27, page 11, lines 7-15), D16 (see page 1, paragraph 1, page 6, lines 14-16, page 17, line 4, claims 2, 3) and D19 (see the abstract), ODTs are well-known

dosage forms and belong to the common technical knowledge of the skilled formulator. The skilled person is aware that their disintegration time can be modulated in order to obtain the desired therapeutic effect. Therefore, the claimed disintegration time is regarded as one of the options available to the skilled person when putting into practice the general disclosure of [0032] of D1.

36.9 Therefore, the subject-matter of the AR5 does not comply with the requirements of Article 56 EPC.

37 **Auxiliary Request 6 (AR6, filed as AR4 with letter of 08-01-2021)**

The subject-matter of claim 1 of the AR6 corresponds to claim 1 of the AR5, wherein the feature "wherein the at least on pharmaceutically acceptable ingredient is at least one disintegrant" is incorporated.

38 **Added subject-matter (Article 123(2) EPC)**

P provided as basis for this additional feature granted claim 6 and the passage on page 3, lines 22-25 of the description as originally filed.

The subject-matter of claim 1 of the AR5 does not to fulfill the requirements of Article 123(2) EPC for the same reasons mentioned in the context of the dependent claims of the MR. Further, the presence of a disintegrant in the orally dispersing tablet of current claim 1 is not based on claim 27 as originally filed, but has to be selected from different parts of the original disclosure (such as page 3, lines 22-25 and page 13, lines 4-5), in addition to the selection of budesonide from the list of actives in claim 27. Therefore, the subject-matter of claim 1 of the AR5 is considered to result from multiple selections from different lists, contrary to the requirements of Article 123(2) EPC.

39 **Auxiliary Request 7 (AR7, filed as AR5 with letter of 08-01-2021)**

The subject-matter of claim 1 of the AR7 corresponds to claim 1 of the AR5, wherein the amount of budesonide or a solvate or ester thereof has been limited to the range "from about 0.5 mg to 1 mg".

40 **Added subject-matter (Article 123(2) EPC)**

P cited the passage on page 10, line 24 - page 11, line 5 of the original description as basis for the claimed budesonide amount. The OD notes that the claimed subrange results from the combination of various ranges disclosed in said passage. Thus, the choice of the claimed budesonide amount represents a further selection in addition to the selection of budesonide as active agent from original claim 27. Because no pointer for the combination of budesonide with the defined weight range can be found in the application as originally filed, the combination is not allowable and contravenes Article 123(2) EPC.

41 **Auxiliary Request 8 (AR8, filed as AR6 with letter of 08-01-2021)**

The subject-matter of claim 1 of the AR8 corresponds to a combination of claim 1 of the AR7 wherein the feature "wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant" is incorporated. For the same reasons mentioned against AR7, also AR8 does not fulfil the requirements of Article 123(2) EPC.

42 **Auxiliary Request 9 (AR8, filed as AR7 with letter of 08-01-2021)**

The subject-matter of claim 1 of the AR9 corresponds to claim 1 of the AR8, wherein the amount of budesonide or a solvate or ester thereof has been limited to "1 mg".

43 **Added subject-matter (Article 123(2) EPC)**

P cited the passage on page 11, lines 1 and 7 of the original description as basis for the claimed budesonide amount. The OD notes however that the choice of the claimed budesonide amount represents a further selection in addition to the selection of budesonide as active agent from original claim 27. This leads to an unallowable combination of features, because no pointer can be found in the application as filed. The AR9 does not meet the requirements of Article 123(2) EPC.

III. Decision

The opposition division concludes that even taking into consideration the amendments

made during opposition proceedings, the patent and the invention to which it relates do not meet the requirements of the EPC. The patent is revoked (Art. 101(3)(b) EPC).

Dr. Falk Pharma Ex. 1004
PGR Petition - USP 12,290,598

Claims – Main Request (II)

1. An orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract.

2. The orally dispersing tablet of claim 1, wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

3. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

4. The orally dispersing tablet for use according to claim 3, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

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Claims – New Auxiliary Request 1

1. An orally dispersing tablet comprising from about 0.5 mg to 20 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract.

2. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

3. The orally dispersing tablet for use according to claim 2, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

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Claims – New Auxiliary Request 2

1. An orally dispersing tablet comprising from about 0.5 mg to 20 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract, and wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

2. The orally dispersing tablet of claim 1, wherein the at least one disintegrant is selected from the group consisting of crospovidone and mannitol.

3. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

4. The orally dispersing tablet for use according to claim 3, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

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Claims – Auxiliary Request 3

1. An orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract, and wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

2. The orally dispersing tablet of claim 1, wherein said tablet disintegrates within 30 seconds.

3. The orally dispersing tablet of claim 1 or claim 2, further comprising an adhesive agent, wherein the adhesive agent is selected from the group consisting of sucrose aluminum sulfate complex, chitosan and derivatives thereof, polyvinylpyrrolidone, methylcellulose, sodium carboxymethylcellulose, hydroxypropyl cellulose, cross-linked or uncross-linked polyacrylates, cross-linked polyarylates, acidic cross-linked or uncross-linked polyacrylates, polyacrylic acid homopolymers or copolymers, aminoalkyl methacrylate copolymers, methacrylic acid/methylmethacrylate copolymer, alkylacrylate/alkylmethacrylate copolymers, ammoniomethacrylate copolymers, carbomer homopolymers or copolymers, hydrophilic polysaccharide gums, maltodextrins, cross-linked alginate gum gels, polycarboxylated vinyl polymers, pectins, xanthan gums, alginic acid, modified alginic acids, and combinations thereof.

4. The orally dispersing tablet of claim 3, wherein the adhesive agent and the budesonide or solvate or ester thereof are intimately associated.

5. The orally dispersing tablet of claim 1, wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

6. The orally dispersing tablet of claim 5, wherein the at least one disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

7. The orally dispersing tablet of claim 1, further comprising an excipient selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, cyclodextrin, and combinations thereof.

8. The orally dispersing tablet of claim 1, which is free of lubricant.

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9. The orally dispersing tablet of claim 5, wherein the tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the budesonide or solvate or ester thereof, and the rapidly dispersing granules comprise the at least one disintegrant and a sugar alcohol and/or saccharide.

10. The orally dispersing tablet of claim 9, wherein the drug particles have an average particle size of less than 400 µm, the rapidly dispersing granules have an average particle size of less than 300 µm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than 30 µm; or wherein the budesonide or solvate or ester thereof is disposed over the surface of an excipient, the rapidly dispersing granules have an average particle size of less than 300 µm, and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than 30 µm.

11. The orally dispersing tablet of claim 9 or claim 10, wherein the tablet comprises a lyophilized matrix, wherein the lyophilized matrix comprises the budesonide or solvate or ester thereof in combination with at least one excipient.

12. The orally dispersing tablet of claim 11, wherein the excipient is selected from the group consisting of mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, and combinations thereof.

13. The orally dispersing tablet of claim 5, wherein the tablet comprises 0.05-0.3 mg budesonide.

14. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

15. The orally dispersing tablet for use according to claim 14, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

16. The orally dispersing tablet of claim 1 comprising from 0.01 mg to 20 mg budesonide.

17. The orally dispersing tablet of claim 1 comprising from 2 mg to 20 mg budesonide.

Claims – Auxiliary Request 3 (II)

1. An orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract, and wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

2. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

3. The orally dispersing tablet for use according to claim 2, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

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Claims – New Auxiliary Request 4

1. An orally dispersing tablet comprising less than or equal to 20 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract, wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test, and wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

2. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

3. The orally dispersing tablet for use according to claim 2, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

Dr. Falk Pharma Ex. 1004
PGR Petition - USP 12,290,598

Claims – New Auxiliary Request 5

1. An orally dispersing tablet comprising from about 0.5 mg to about 1 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract, and wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

2. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

3. The orally dispersing tablet for use according to claim 2, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

Dr. Falk Pharma Ex. 1004
PGR Petition - USP 12,290,598

Claims – New Auxiliary Request 6

1. An orally dispersing tablet comprising from about 0.5 mg to about 1 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract, wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test and wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

2. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

3. The orally dispersing tablet for use according to claim 2, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

Dr. Falk Pharma Ex. 1004
PGR Petition - USP 12,290,598

Claims – New Auxiliary Request 7

1. An orally dispersing tablet comprising about 1 mg of budesonide or a solvate or ester thereof, and at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity, wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract, wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test and wherein the at least one pharmaceutically acceptable ingredient is at least one disintegrant.

2. An orally dispersing tablet as claimed in claim 1 for use in treating an inflammatory condition of the gastrointestinal tract.

3. The orally dispersing tablet for use according to claim 2, wherein said inflammatory condition of the gastrointestinal tract comprises inflammation of the esophagus, eosinophilic esophagitis, or inflammation of the glottis, epiglottis, tonsils, or oropharynx.

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