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Datasheet for the decision of 20 November 2024

Case Number: T 0295/22 - 3.3.07

Application Number: 15177140.9

Publication Number: 2962690

IPC: A61K31/4035, C07D209/48, A61P35/00, C07C317/28

Language of the proceedings: EN

Title of invention:

(+)-2-[1-(3-ETHOXY-4-METHOXYPHENYL)-2-METHYLSULFONYLETHYL]-4-ACETYLAMINOISOINDOLINE-1,3-DIONE: METHODS OF USING AND COMPOSITIONS THEREOF

Patent Proprietor:

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Headword:
Orally administered apremilast/AMGEN

Relevant legal provisions:
EPC Art. 123(2), 56
RPBA 2020 Art. 12(4), 13(2)
Guidelines for examination G-VI 6.1.2

Keyword:
Amendments - main request - allowable (no)
Inventive step - auxiliary request (no)
Amendment to case - amendment within meaning of Art. 12(4) RPBA 2020 - allowable (yes)
Amendment after notification of Art. 15(1) RPBA communication - auxiliary request - exceptional circumstances (yes) - additional auxiliary request - exceptional circumstances (no)

Decisions cited:
T 0051/93, G 0002/08, G 0005/83, T 0230/01, T 0072/18, T 1654/22, T 1126/19, T 1287/14, T 0970/00, T 1356/21

Catchword:

The requirement underlying the specificity of the use within the meaning of Article 54(5) of the EPC 2000 is according to the explicit conclusion in G 2/08 (see reasons 5.10.3) to be construed merely by contrast to the generic broad protection conferred by the first claimed medical application of a substance or composition, and is in principle not confined to a particular medical indication (see reasons 4.1).

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 0295/22 - 3.3.07

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of 20 November 2024

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 19 January 2022 concerning maintenance of the European Patent No. 2962690 in amended form.**

Composition of the Board:

Chairman A. Usuelli
Members: M. Steendijk
Y. Podbielski

Summary of Facts and Submissions

I. European patent 2 962 690 ("the patent") derives from a divisional application with respect to European application 09003138.6, which on its turn was filed as a divisional application with respect to European application 03721414.5, which was originally filed as the international application published as WO 03/080049 A1.

II. The patent was granted on the basis of twenty claims.

Independent claim 1 as granted defined:

"A compound which is (+)-2-[1-(3-Ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione, or a pharmaceutically acceptable polymorph, salt, solvate or hydrate thereof."

The compound (+)-2-[1-(3-Ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione has become known under the name "apremilast".

III. Fifteen oppositions were filed against the grant of the patent on the grounds that its subject-matter lacked novelty and inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the application as originally filed.

The opposition division decided that the patent as amended in accordance with auxiliary request 3 met the requirements of the EPC. The patent proprietor and

opponents 1-8 and 11-14 filed appeals against this interlocutory decision.

The decision under appeal was based on the main request filed on 1 October 2021, auxiliary requests 1 filed as auxiliary request 3 on 1 October 2021 and auxiliary requests 2-3 filed during the oral proceedings on 1 December 2021.

Claim 1 of the main request defined the compound (+)-2-[1-(3-Ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione (apremilast) or pharmaceutically acceptable polymorph, salt, solvate or hydrate thereof for use as a medicament, wherein the medicament is administered orally. Claim 4 of the main request defined the use of apremilast or a pharmaceutically acceptable polymorph, salt, solvate or hydrate thereof, for the manufacture of a medicament for the treatment or prevention of an inflammatory disease, wherein the medicament is administered orally.

Claims 1 and 4 of auxiliary request 1 defined with respect to the claims of the main request that the compound is stereomerically pure apremilast comprising greater than 80% by weight of the (+) enantiomer and less than 20% by weight of the (-) enantiomer.

Claims 1 and 4 of auxiliary request 2 defined with respect to the claims of the main request that the compound is stereomerically pure apremilast.

Claims 1 and 4 of auxiliary request 3 defined with respect to the claims of the main request that the compound is stereomerically pure apremilast comprising greater than 97% by weight of the (+) enantiomer and less than 3% by weight of the (-) enantiomer.

The opposition division cited *inter alia* the following documents:

D1: US 6,020,358
D72: Exp. Opin. Ther. Patents (2002) 12(1): 93-111
D73: Exp. Opin. Ther. Patents (1999) 9(8): 1101 -1118
D74: Declaration by Prof. R. Knowles, 19 August 2020
D76: Current Pharmaceutical Design (2002), 8(14):1255-1296
D92: Chemical Biology (2001), vol. 5:432-438.

The opposition division arrived at the following conclusions:

(a) Claim 1 of the main request did not comply with Articles 76(1) and 123(2) EPC.

(b) Claim 1 of auxiliary request 1 lacked clarity, because it introduced the contradictory definition of the features that the compound was stereomerically pure and at the same time comprised greater than 80 wt% of the (+) enantiomer and less than 20 wt% of the (-) enantiomer.

(c) Claim 1 of auxiliary request 2 lacked clarity, because the feature "stereomerically pure" had no specifically defined meaning in the art.

(d) Claim 1 of auxiliary request 3 additionally defined the features that the compound was stereomerically pure apremilast comprising greater than 97 wt% of the (+) enantiomer and less than 3 wt% of the (-) enantiomer.

Auxiliary request 3 complied with Articles 83, 84, 123(2)/76(1) and 123(3) EPC.

The prior art, including document D1, did not specifically disclose the feature of the compound comprising greater than 97 wt% of the (+) enantiomer and less than 3 wt% of the (-) enantiomer in combination with the feature of oral administration. The subject-matter of auxiliary request 3 was therefore new over the prior art.

Starting from document D1 as closest prior art, in particular example 12 describing the racemic compound, the objective technical problem concerned the provision of an alternative optically active isomer of apremilast for the treatment of inflammatory diseases using an alternative route of administration. As the solution to this problem the subject-matter of claim 1 of auxiliary 3 was not obvious taking account of the 3.5-fold greater aqueous solubility and the more selective PDE4 inhibitory activity of the (+) enantiomer with respect to the racemate. Accordingly, the subject-matter of auxiliary request 3 also involved an inventive step.

IV. With the statement of grounds of appeal the patent proprietor maintained the main request on which the decision under appeal was based and filed auxiliary requests 1-12. Auxiliary requests 2 and 3 corresponded respectively to auxiliary requests 1 and 3 on which the decision under appeal was based. Auxiliary request 10 was derived from the main request in which claim 4 and its dependent claims were deleted. Auxiliary request 12 was derived from the main request in which claim 1-3 were deleted and the use of claim 4 was amended to

define that the inflammatory disease is psoriasis or Behçet's disease.

In the statement of grounds of appeal the patent proprietor declared that for procedural efficiency and reduced complexity multiple series of auxiliary requests in which auxiliary requests 6-12 are modified by amendments corresponding to those of auxiliary requests 1-5 had not been filed. In this context the patent proprietor requested the opportunity to file amendments introducing any of the features from auxiliary requests 1-5 into the claims of auxiliary requests 6-12 before an adverse decision by the Board, including *inter alia:*

- an amendment to the independent claim(s) to state that the compound is "stereomerically pure" and the compound comprises "greater than 80% by weight of the (+) enantiomer and less than 20% by weight of the (-) enantiomer" in accordance with the definition in auxiliary request 2

- an amendment to the independent claim(s) to state that the compound is "stereomerically pure" and the compound comprises "greater than 97% by weight of the (+) enantiomer and less than 3% by weight of the (-) enantiomer" in accordance with the definition in auxiliary request 3.

V. The following documents were *inter alia* filed during the appeal proceedings:

A124: IUPAC "Gold Book": definition of "enantiomerically pure", "enantiomeric excess" and

"optical purity" (by opponent 1 with the statement of grounds of appeal)

A127: "Spektroskopische Methoden in der organischen Chemie", 6., überarbeitete Auflage, Georg Thieme Verlag, Stuttgart, Germany, 2002, pp. 24-25 (by opponent 4 with the statement of grounds of appeal)

A133: "Drug stereochenustry: analytical methods and pharmacology", edited by Irving W. Wainer, 2nd ed., rev. and expanded, 1993, pp. 4-6.

VI. In its communication under Article 15(1) RPBA the Board indicated that it intended to admit documents A124 and A127 and not to admit document A133. The Board questioned whether the originally filed application specifically disclosed the combination of the definition of the compound to be used regardless of its stereomeric purity with the definition of the oral administration. The Board further shared its preliminary opinion that the patent reported for apremilast an apparently outstanding therapeutic index when orally administered together with an outstanding PDE4 selectivity and that, in as far as these effects are indeed achieved in accordance with the claimed subject-matter, the objective technical problem starting from the individual (+) enantiomer of example 12 in document D1 may not be formulated as the mere provision of an alternative route for administration of apremilast. In this context the Board indicated that during the oral proceedings it could be discussed to what extent these effects are indeed achieved in accordance with the subject-matter claimed according to the main request. The Board further questioned whether these effects could be considered to represent mere

bonus effects resulting from an anyway obvious development following the disclosure in document D1.

VII. Oral proceedings were held on 19 and 20 November 2024.

During the oral proceedings the patent proprietor relied on auxiliary request 2 filed with the statement of grounds of appeal as its new main request (hereinafter "the new main request"). Following the announcement of the Board's conclusion that claim 1 of the main request complied with Article 123(2) EPC, but that claim 4 of the main request did not, the patent proprietor filed "Main request A". Following the announcement of the Board's conclusion that "Main request A" did not comply with the requirement of inventive step the patent proprietor filed "Main request B".

Claim 1 of the new main request defines:

"A compound which is stereomerically pure (+)-2-[1-(3-Ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione comprising greater than 80% by weight of the (+) enantiomer and less than 20% by weight of the (-) enantiomer, or a pharmaceutically acceptable polymorph, salt, solvate or hydrate thereof for use as a medicament, wherein the medicament is administered orally."

Claim 4 of the new main request defines:

"Use of stereomerically pure (+)-2-[1-(3-Ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione comprising greater than 80% by weight of the (+) enantiomer and less than 20% by weight of the (-) enantiomer, or a

pharmaceutically acceptable polymorph, salt, solvate or hydrate thereof, for the manufacture of a medicament for the treatment or prevention of an inflammatory disease, wherein the medicament is administered orally."

The auxiliary request "Main request A" corresponds to the main request except for the deletion of claim 4 and its depending claims which had been formulated in the format of the use of the compound in the manufacture of a medicament.

The auxiliary request "Main request B" only comprises claims in the format of the use of the compound in the manufacture of a medicament. Independent claim 1 of this request defines:

"Use of stereomerically pure (+)-2-[1-(3-Ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1,3-dione comprising greater than 97% by weight of the (+) enantiomer and less than 3% by weight of the (-) enantiomer, or a pharmaceutically acceptable polymorph, salt, solvate or hydrate thereof, for the manufacture of a medicament for the treatment or prevention of an inflammatory disease, wherein the medicament is administered orally, and wherein the inflammatory disease is psoriasis or Behçet's disease."

VIII. The arguments of the opponents relevant to the present decision are summarized as follows:

(a) Admittance documents A124 and A127

Documents A124 and A127 represented common general knowledge regarding the meaning of the terms

"enantiomerically pure", "optical purity" and "enantiomer excess". The filing of these documents with the statements of grounds of appeal was justified following the admittance of auxiliary request 3, which included claims defining stereomerically pure apremilast comprising greater than 97% by weight of the (+) enantiomer and less than 3% of the (-) enantiomer and had been filed by the patent proprietor during the oral proceedings before the opposition division.

(b) Main request

Claim 4 of the main request defined the combination of the feature that the stereomerically pure apremilast comprises greater than 80% by weight of the (+) enantiomer and the feature that the medicament is for the treatment or prevention of an inflammatory disease. The quantitative definition of the stereomeric purity and the definition of the type of disease in this claim represented multiple selections with respect to the content of the application as originally filed. The original disclosure provided no basis for the combination of these selected features.

(c) "Main request A"

"Main request A" was filed during the oral proceedings. The provisions of Article 13(2) RPBA therefore applied. No exceptional circumstances justified the late filing of this request.

Document D1 disclosed pharmacologically active compounds which can be used as a medicament with PDE4 and TNFα inhibiting activity useful in the

treatment of inflammatory disease. Document D1 described the preparation of the racemate of apremilast as an example and explicitly indicated that the individual enantiomers of the disclosed compounds can be separated and purified, for instance up to an optical purity of more than 95%, and thereby indicated that these enantiomers are also within the scope of the disclosed invention. Document D1 furthermore prominently described the oral administration of the disclosed compounds by specific references to particular oral dosage forms. The circumstance that 5 of the 6 examples of pharmaceutical formulations presented in document D1 related to tablets and capsules provided a further pointer towards oral administration as the preferred route of administration.

Insofar as the subject-matter of claim 1 of "Main request A" was new, it lacked an inventive step starting from the disclosure of the purified form of apremilast in document D1 as a medicament for the treatment of inflammatory disease.

The difference between this starting point in the prior art and the claimed subject-matter could only concern the definition of the oral administration.

The patent presented experimental results concerning the PDE4 selectivity, the therapeutic index and the solubility of stereomerically highly pure apremilast. These results did not substantiate any effect for the apremilast with a low level of stereomeric purity as included by the definition in claim 1 of "Main request A". In addition, the therapeutic index reported in the patent only concerned a model for a particular therapeutic

indication relative to a particular side effect, which did not substantiate an advantage of oral administration for the whole scope of the therapeutic indications for apremilast covered by claim 1 of "Main request A".

The experimental results reported in the patent related anyway only to the inherent properties of stereomerically pure apremilast as the active anti-inflammatory agent, which represented the starting point in the prior art. These experimental results did thus not concern effects arising from the purported difference with the prior art, namely the oral administration, and could therefore not be taken into account for the formulation of the objective technical problem.

The problem to be solved starting from the stereomerically purified apremilast as described in document D1 was therefore merely the provision of an alternative or a suitable route for its administration.

The oral administration as defined in claim 1 of "Main request A" was in view of the prior art obvious as the solution to this objective technical problem, because document D1 already prominently described the oral administration for the disclosed anti-inflammatory agents. In this context the expert declaration in document D74 only explained that the oral administration of PDE4 inhibitors was associated with challenges. An actual prejudice in the prior art deterring the skilled person from therapy with apremilast by oral administration had thereby not been established, especially taking

account of the reports of orally administered PDE4 inhibitors in documents D72, D76 and D1.

Even if the experimental results reported in the patent concerning the effects of stereomerically pure apremilast were taken into account and the stereomerically pure apremilast could be considered as particularly safe and tolerable for oral administration, the claimed subject-matter was nevertheless obvious to the skilled person. The skilled person would anyway have been motivated to administer apremilast orally in view of the well known advantageous aspects of oral administration in general, the encouraging therapeutic index versus emesis reported in document D76 for the structurally related compound "CDC-801" and the oral administration prominently described in document D1 itself.

(d) "Main request B"

"Main request B" was filed on the second day of the oral proceedings after the Board's conclusion that "Main request A" did not comply with the requirement of inventive step. The provisions of Article 13(2) RPBA applied. No exceptional circumstances justified the late filing of this request, in particular considering that "Main request B" gave rise to a renewed debate regarding its compliance with Article 123(2) EPC and did not *prima facie* overcome the objection of lack of inventive step against the subject-matter of claim 1 of the "Main request A".

IX. The arguments of the patent proprietor relevant to the present decision are summarized as follows:

(a) Admittance documents A124 and A127

Documents A124 and A127 were not to be admitted, because these documents should have been filed during the first instance proceedings.

(b) Main request

The application as originally filed described a typical stereomerically pure compound as comprising greater than about 80% of one stereoisomer of the compound and less than about 20% by weight of other stereoisomers of the compound. The quantitative definition of the stereomeric purity of apremilast in claim 4 of the main request was based on this disclosure of what is typically intended with the expression "stereomerically pure" in the application as filed. This definition did anyway not represent a selection with respect to the original disclosure, because it corresponded to the broadest quantitative specification of stereomeric purity provided in the application as filed.

The application as originally filed furthermore highlighted the use involving the oral administration of enantiomerically pure apremilast in the prevention and treatment of inflammatory diseases by specific references in the description and the claims. The definition of the disease in claim 4 of the main request could not be considered as newly selected with respect to the original disclosure, because the defined therapeutic

indication was already identified as preferred in the application as originally filed.

(c) "Main request A"

"Main request A" corresponded to auxiliary request 10 as filed with the statement of grounds of appeal in which the stereomeric purity of the apremilast was defined in line with the amendment of auxiliary request 2 as expressly mentioned in the statement of grounds of appeal. "Main request A" differed from the main request merely by the deletion of claims and thereby evidently overcame any objection regarding the deleted claims without giving rise to any new issue. Exceptional circumstances therefore justified the filing of this request.

The claimed subject-matter related to a compound providing safe, well-tolerated and effective treatment of PDE4-mediated diseases following oral administration.

Document D1 described the potential therapeutic utility of a generically defined group of compounds, mentioned the possible separation and purification of the enantiomers of the disclosed compounds and described the preparation of twenty exemplified compounds, including the racemate of apremilast. Document D1 did not present any experimental results demonstrating the therapeutic utility of any of the exemplified compounds and therefore failed to provide an enabling disclosure of the use of the disclosed compounds as a medicament.

The examples of actual pharmaceutical dosage forms described in document D1, which included formulations for oral administration, did not comprise the racemate of apremilast or any of its purified enantiomers as active agent. Apremilast was therefore not disclosed as the closest embodiment from which to start the assessment of inventive step within document D1, but at best as a possibly therapeutically useful compound in a list of examples.

Insofar as the skilled person would nevertheless consider the therapeutical utility of stereomerically purified apremilast as a suitable starting point for the assessment of inventive step within the disclosure of document D1, the subject-matter of claim 1 of "Main request A" differed from this starting point in the feature of the oral administration.

The effects derivable from the experimental results reported in the patent and associated with the oral administration of apremilast concerned the high PDE4 selectivity and potency, the favourable tolerability with regard to emesis and the high aqueous solubility.

The argument that the experimental results in the patent did not demonstrate any effect for the whole scope of the claims of "Main request A" was only raised at an unjustifiably late stage of the appeal proceedings and anyway lacked merit.

The PDE4 selectivity and potency, the favourable tolerability and the high solubility determined the suitability of apremilast for the safe, well-

tolerated and effective therapeutic treatment by oral administration. These effects, which had remained unrecognized in document D1, could therefore not be disregarded as properties that were inherent in the starting point in the prior art and unrelated to the distinguishing feature of the oral administration.

In view of the difference with the prior art and the associated effects the objective technical problem concerned the provision of a compound that, when administered via the chosen route of administration, provides a safe and well-tolerated effective treatment for PDE4-mediated diseases.

As explained in the declaration in document D74 with reference to the review in documents D73 and D76 and further illustrated by documents D72 and D92 the provision of safe and well-tolerated treatment for PDE4-mediated diseases had remained a considerable challenge in the prior art. The skilled person would not expect that the subject-matter of claim 1 of "Main request A" represented a solution to such a qualified problem on the basis of any prior art. In this context document D1 explicitly recognized that selective inhibition of PDE4 would minimize cardiovascular and anti-platelet side effects, but nevertheless described that the disclosed compounds were useful for inhibiting both PDE3 and PDE4.

(d) "Main request B"

"Main request B" corresponded to auxiliary request 12 as filed with the statement of grounds of appeal in which the stereomeric purity of the apremilast

was defined in line with the amendment of auxiliary request 3. This combination of features in a potential new request had already been mentioned in the statement of grounds of appeal and was thus not surprising. The claims of "Main request B" included the most preferred quantitative definition of the stereomeric purity of the apremilast in the application as originally filed and limited the therapeutic indication to originally disclosed specific inflammatory diseases. "Main request B" did therefore not give rise to any additional objection under Article 123(2) EPC. Moreover, by the definition of the specific inflammatory disease "Main request B" evidently addressed and resolved any objection of lack of inventive step held against "Main request A". Exceptional circumstances therefore justified the filing of "Main request B".

X. The appellants-opponents requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The opponents further requested that "Main request A" and "Main request B" not be admitted.

XI. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the new main request, which had been originally filed with the statement of grounds of appeal as auxiliary request 2.

As an auxiliary measure the patent proprietor requested that the patent be maintained on the basis of "Main request A" or "Main request B" filed during the oral proceedings. All other requests involving amendments of the claims were withdrawn.

The patent proprietor further requested that documents A124 and A127 not be admitted.

The patent proprietor also requested that the argument by the opponents, that the effect relied upon by the patent proprietor was not achieved over the whole scope of claim 1 of "Main request A", not be admitted.

Reasons for the Decision

1. Admittance documents A124, A127 and A133

1.1 Documents A124 and A127 represent the common general knowledge regarding the meaning of the terms "enantiomerically pure", "optical purity" and "enantiomer excess".

Auxiliary request 3 on which the decision under appeal was based had been filed during the oral proceedings before the opposition division. This auxiliary request introduced the definition of stereomerically pure apremilast as comprising greater than 97% by weight of the (+) enantiomer and less than 3% of the (-) enantiomer in the claims.

Taking account of the late stage of the first instance proceedings at which auxiliary request 3 had been filed and the relevance of the content of documents A124 and A127 in relation to the subject-matter defined in that request the Board considers that the filing of documents A124 and A127 by opponents 1 and 4 with their statements of grounds of appeal to support their objections against this definition is justified to address issues which led to the decision under appeal.

Accordingly, the Board has decided to admit documents A124 and A127 under Article 12(4) RPBA.

1.2 Document A133 was filed by the patent proprietor with the reply to the appeals to support the argument that at the early stage of drug-development represented by document D1 the separation of enantiomers was of no primary concern.

In its communication pursuant to Article 15 RPBA the Board questioned whether the content of document A133 is suitable to actually support the patent proprietor's argument, because the document would indicate the possible interest in investigation of enantiomers already during the first months of development (see Figure 1), which would correspond with the stage of development in document Dl. The Board did further not recognize any justification for the late filing of document A133.

At the oral proceedings the appellant-opponent relied on its written submissions.

The Board therefore confirmed the opinion expressed in the communication pursuant to Article 15 RPBA and has therefore not admitted document A133 into the appeal proceedings under Article 12(4) RPBA.

2. Main request, added subject-matter

2.1 It was not in dispute that the content of the international application as originally filed is also decisive for the assessment of compliance with Article 123(2) EPC. The references by the Board to the original

disclosure or the application as originally filed are therefore based on its publication in WO 03/080049 A1.

2.2 Claim 4 of the main request defines stereomerically pure apremilast to comprise greater than 80% by weight of the (+) enantiomer and less than 20% by weight of the (-) enantiomer and defines the utility thereof in the treatment or prevention of an inflammatory disease.

2.3 The application as originally filed (see page 7, lines 22 to 27) states that unless otherwise indicated the term "stereomerically pure" means a composition that comprises one stereoisomer of a compound and is substantially free of other stereoisomers of that compound. The application as filed (see page 7, line 28 to page 8, line 2) continues to explain that a typical stereomerically pure compound comprises greater than about 80% by weight of one stereoisomer of the compound and less than about 20% by weight of other stereoisomers of the compound, more preferably greater than about 90% by weight of one stereoisomer of the compound and less than about 10% by weight of the other stereoisomers of the compound, even more preferably greater than about 95% by weight of one stereoisomer of the compound and less than about 5% by weight of the other stereoisomers of the compound, and most preferably greater than about 97% by weight of one stereoisomer of the compound and less than about 3% by weight of the other stereoisomers of the compound.

The application as originally filed thus presents various definitions of what may be comprised by the term "stereomerically pure" and the definition in claim 4 of the main request corresponds to one of these definitions which is not presented as particularly preferred. The definition of the stereomeric purity in

claim 4 of the main request therefore involves a first selection with respect to the content of the application as originally filed.

2.4 The application as originally filed (see pages 1-3) describes under the heading "Background of the invention" the role of enhanced or unregulated TNFα in a number of diseases and medical conditions, including inflammatory diseases, the inhibition of inflammatory mediator release and the relaxation of airway smooth muscle by inhibition of PDE4 and the related therapeutic potential of compounds that inhibit PDE4 or that block the activity of TNFα. The application as filed subsequently states under the headings "Summary of invention" and "Detailed description of the invention" that the disclosed invention encompasses the use of apremilast in the treatment or prevention of diseases ameliorated by the inhibition of TNFα or by the inhibition of PDE4, including cancer, viral disease and inflammatory disease (see pages 4, 8-10, 17). The application as filed furthermore refers to inflammatory diseases in the context of testing for inhibition of TNFα (see page 30, example 3) and investigating the therapeutic index in a ferret model for anti-inflammatory and emetic effects of PDE4 inhibitors (see page 36, example 8). The claims of the application as originally filed define methods involving the administration of apremilast for the treatment or prevention of diseases ameliorated by the reduction of levels of TNFα or the inhibition of PDE4, including inflammatory diseases as well as a number of further diseases such as cancer (see claims 5-6 and 19-20). The original disclosure does thereby not indicate a particular preference concerning the treatment or prevention of inflammatory disease.

The application as originally filed thus discloses the utility of apremilast in the treatment and prevention of a variety of diseases and the definition in claim 4 of the main request corresponds to one type of disease, namely inflammatory disease. The definition of the type of disease in claim 4 of the main request therefore corresponds to a further selection with respect to the content of the application as originally filed.

2.5 Claim 4 of the main request thus involves with respect to the original disclosure the combined selection with regard to the stereomeric purity of the apremilast and the type of disease. This combination of features cannot be derived directly and unambiguously from the application as filed.

The main request does therefore not comply with Article 123(2) EPC.

3. "Main request A", admittance

3.1 "Main request A" was filed by the patent proprietor during the oral proceedings. "Main request A" only differs from the main request in the deletion of claim 4 and its dependent claims. "Main request A" thereby evidently overcomes the objection under Article 123(2) EPC against the main request without affecting the issues, submissions and conclusions with regard to the remaining claims.
The Board therefore considers that the filing of "Main request A" is justified by exceptional circumstances and has accordingly admitted this request into the appeal proceedings under Article 13(2) RPBA.

4. Inventive step

4.1 Interpretation of claim 1 of "Main request A"

Claim 1 of "Main request A" is formulated in the "compound for use" format of Articles 54(4) and 54(5) EPC, wherein the utility as a medicament is further specified as the use as a medicament which is administered orally.

The Guidelines for Examination G-VI 6.1.2 (2024) (see example 2: "Composition comprising X for use in therapy by topical administration") suggest with reference to T 51/93 that in a claim which only defines the mode of delivery but no specific therapeutic effect, the definition of the mode of delivery is merely illustrative and not a restrictive technical feature capable of establishing novelty.

However, the requirement underlying the specificity of the use within the meaning of Article 54(5) of the EPC 2000 is according to the explicit conclusion in G 2/08 (see reasons 5.10.3) to be construed merely by contrast to the generic broad protection conferred by the first claimed medical application of a substance or composition, and is in principle not confined to a particular medical indication.

Contrary to the suggestion in the Guidelines the decision in T 51/93 actually recognizes without reference to any requirement regarding the definition of a specific medical condition that the definition of the mode of administration of a medicament represents a characterizing feature of a claim formulated in the so-called "Swiss-type" format as approved according to G 5/83 for defining inventions relating to new medical

uses of known pharmaceuticals under the provisions of the EPC 1973 (see T 51/93, reasons 3.1.2).

The decision in T 51/93 further confirms that in a claim formulated as a "Process for making X for use Y comprising the steps of..." the definition of a specific medical purpose under Y illustrates what X can be used for, but does not further characterize the claimed subject-matter under the provisions of the EPC 1973 (see T 51/93, reason 2.2.2). However, the format of the claim discussed in this part of the decision neither corresponds to the "Swiss-type" format as approved according to G 5/83 for defining inventions relating to new medical uses nor to the format outlined in Article 54(5) EPC 2000.

In line with the considerations in G 2/08 (see reasons 5.10.3) the Board therefore considers that the oral administration as defined in claim 1 of "Main request A" represents, in accordance with Article 54(5) EPC, a characterizing feature of the claimed subject-matter.

4.2 Starting point in the prior art

4.2.1 Document D1 describes compounds of a general formula (see D1, column 5), exemplified by a variety of specific compounds, including in example 12 the racemate of apremilast (see D1, column 14, lines 35-56), and discloses that these compounds act as inhibitors of PDE3 and PDE4, decrease the levels of TNFα and are useful in treatment of *inter alia* inflammatory diseases (see D1, column 1, lines 5-11; column 4, lines 28-32 and lines 61-63). Document D1 further specifically teaches that the individual enantiomers of the disclosed compounds, which may be provided in a form with an optical purity of more than

95%, are within the scope of the disclosed invention (see D1, columns 8-9, bridging paragraph). Moreover, document D1 indicates that the compounds may be administered orally, rectally or parenterally as well as topically (see D1, column 7, lines 1-13; column 9, lines 22-30) and provides examples of certain specific compounds formulated in tablets and capsules (examples 21-25) or a solution for injection or infusion (example 26). These specific formulations exemplified in document D1 do not comprise apremilast or its racemate.

Taking account of the established jurisprudence concerning the unambiguous disclosure of enantiomers in individualised form (see Case Law of the Boards of Appeal of the EPO, 10th Edition, 2022, I.C.6.2.1; see in particular T 658/91, reasons 2.4; see also T 600/95, reasons 3.3) the Board considers that document D1 thereby provides a specific and verifiable teaching regarding the therapeutic potential of the disclosed compounds, including the (+) enantiomer of example 12 corresponding to apremilast in a form with an optical purity of more than 95%. In accordance with the definitions in documents A124 and A127 an optical purity of 95% is indicative for the presence 97.5% of one enantiomer and 2.5% of the other enantiomer.

The patent proprietor has contested that document D1 provides an enabling disclosure regarding the use of the described compounds in medicine, because document D1 lacks experimental evidence in support of such use. However, having regard to the established jurisprudence concerning the required level of evidence to establish that a disclosure is non-enabling (see Case Law of the Boards of Appeal of the EPO, *supra*, I.C.4.9; see in particular T 230/01, reasons 5) the Board considers that the patent proprietor has thereby not justified

the disqualification of the mentioned teaching in document D1 as non-enabling.

4.2.2 According to the established jurisprudence (see Case Law of the Boards of Appeal of the EPO, *supra*, I.D.3.2) a central consideration in selecting the closest prior art is that it must be directed to the same purpose or effect as the claimed invention.

The opponents selected example 12 and more specifically one of its enantiomers, namely apremilast in a form with an optical purity of more than 95% as a starting point within document D1, although this document does not describe any embodiment involving a particular pharmaceutical formulation comprising this compound.

This selection of the starting point cannot *a priori* be excluded when applying the problem-solution approach (see T 72/18, reasons 3.9.2; see T 1654/22, reasons 1.1.4-1.1.5).

4.3 Difference with the prior art

4.3.1 The difference of the claimed subject-matter with respect to the teaching in document D1, in particular the disclosure of apremilast in a form with an optical purity of more than 95% as an example of compounds which are described to inhibit PDE3 and PDE4, decrease the levels of TNFα and to be useful in treatment of *inter alia* inflammatory disease, concerns the feature of the oral administration of this particular compound.

4.3.2 The opponents contested this difference arguing that oral administration was in document D1 disclosed as the preferred route of administration in view of the prominent references to particular oral dosage forms

(see D1, column 9, lines 22-52) and the circumstance that of the total 6 examples of actual pharmaceutical formulations 5 concerned compositions for oral administration (see D1, columns 17-20, examples 21-26). This argument is not convincing, because document D1 describes oral administration as one option in a list together with rectal, parenteral and topical administration (see D1, column 7, lines 1-13; column 9, lines 22-30) and discloses in addition to the particular dosage forms for oral administration other pharmaceutical formulations, including an example of an solution for injection or infusion, with similar prominence and support in the examples.

4.3.3 The patent proprietor maintained with reference to the considerations in T 1126/19 (see reasons 6.2.2) that the selection of apremilast from the list of exemplified compounds and enantiomers thereof in document D1 represented an additional difference with the closest prior art.

In the case of T 1126/19 the prior art mentioned the camsylate salt within a list of possible pharmaceutically acceptable salts of rucaparib without further illustrating the camsylate salt of rucaparib or presenting it as a standalone embodiment. In view of this level of disclosure the competent Board considered that in the specific circumstances of that case the starting point in that prior art was represented by a list of options for the pharmaceutical salts and not the camsylate salt of rucaparib. However, the specific starting point for assessing inventive step is normally a set of features disclosed in combination in a document, typically in the form of an embodiment or example (see T 1287/14, reasons 5.2.1), which in the case of document D1 is suitably represented by the

disclosure of apremilast in a form with an optical purity of more than 95%. The selection of apremilast from the list of exemplified compounds and enantiomers thereof in document D1 can therefore not be considered as an additional difference with the starting point in the prior art.

4.4 Formulation of the objective technical problem

4.4.1 The patent presents experimental results indicating that "Compound A", which is apremilast in 98% enantiomeric excess (ee) (see patent, paragraph [0101]), acts as a potent inhibitor of PDE4 with outstanding selectivity over PDE3 (see patent, paragraph [0108], Table 1) and provides for an outstanding therapeutic index versus emesis following oral administration (see patent, paragraph [0131], Table IV) taking account of the therapeutic index of the known orally administered PDE4 inhibitors rolipram or cilomilast (see D74, sections 3.14-3.17). In addition, the patent reports for this compound a 3.5-fold greater aqueous solubility than the racemic mixture (see patent, paragraph [0117]).

4.4.2 Taking account of the definition of enantiomeric access (see documents A124 and A127) these experimental results were obtained with apremilast comprising 99% of the (+) enantiomer and 1% of the (-) enantiomer. The opponents argued that these results were not indicative for any effects that could be obtained over the whole scope of claim 1 of "Main request A", which included apremilast comprising merely greater than 80% of the (+) enantiomer with less than 20% of the (-) enantiomer and thus having an enantiomeric excess as low as about 60%. However, the opponents have not provided evidence sustaining any serious doubts that this still

considerable enantiomeric excess gives rise to similar effects as reported in the patent for the compound in an enantiomeric excess of 98%. The argument by the opponents is therefore not considered convincing. The patent proprietor's objection to the admittance of this argument remains thus without consequence.

The opponents also argued that the therapeutic index reported in the patent does not concern a favourable effect across all therapeutic indications of apremilast covered by claim 1 of "Main request A", for instance because local delivery may for certain indications of apremilast be more effective and better tolerated than oral administration. The Board observes in this context that the outstanding therapeutic index for orally administered apremilast reported in the patent is based on experimental results involving an established ferret model for investigating the anti-inflammatory effects versus the emetic effects of PDE4 inhibitors following oral administration (see patent, paragraph [0118]; compare D76, page 1259, right column). The Board is therefore satisfied that the outstanding therapeutic index concerning the anti-inflammatory efficacy in relation to the stimulation of emesis reported in the patent represents a favourable effect for an orally administered PDE4 inhibitor and thus also for the whole scope of claim 1 of "Main request A".

The Board therefore concludes that the subject-matter of claim 1 is associated with the potent inhibition of PDE4 with outstanding selectivity over PDE3, an outstanding therapeutic effect following oral administration and favourable aqueous solubility, at least with respect to the racemate.

4.4.3 The opponents further maintained that the objective technical problem could only be formulated on the basis of effects arising from the difference with the prior art and thus not on the basis of properties inherent in the starting point in the prior art. The experimental results regarding the selective PDE4 inhibition, the therapeutic index and the aqueous solubility reported in the patent did in their view not concern effects that could be attributed to the difference with the prior art, namely the oral administration, but were inherent properties of stereomerically pure apremilast as an active anti-inflammatory agent, which represented the starting point in the prior art.

However, as explained in T 970/00 (see reasons 4.1.2), any conclusion going beyond what the skilled person would have objectively inferred from the prior art, without the benefit of hindsight knowledge of the invention, is of necessity at variance with a proper application of the problem-solution approach. In this context it has to be kept in mind that document D1 does not provide any experimental data on the activity or solubility of the described compounds and does not disclose any specific dosage form involving the compound of example 12, let alone the stereomerically pure (+) enantiomer thereof. Insofar as the experimental evidence regarding the selective PDE4 inhibition, the therapeutic index and the aqueous solubility could be considered to relate to inherent properties associated with stereomerically pure apremilast as active anti-inflammatory agents, these properties had thus remained unrecognized in the prior art. At the same time these properties, especially the therapeutic index, determine that the stereomerically pure apremilast is particularly suitable for oral administration, because the favourable therapeutic

index ensures intestinal tolerability, whilst the PDE4 selectivity still avoids systemic side-effects and the aqueous solubility may favour the bioavailability of apremilast following oral administration. Accordingly, the relevant properties of apremilast which had remained unrecognized in the prior art resulted in meaningful technical effects following the oral administration of apremilast as defined in claim 1 of "Main request A". The Board therefore considers that these effects, in particular the therapeutic index, are associated with the differentiating feature of claim 1 of "Main request A" and cannot be ignored for the formulation of the objective technical problem.

4.4.4 The opponents formulated the objective technical problem as the provision of an alternative or suitable administration route for stereomerically pure apremilast. The Board cannot agree with this formulation, because it does not take account of the relevant effects discussed in section 4.4.3 above.

The patent proprietor formulated the objective technical problem as the provision of a compound that, when administered via the chosen route of administration, provides a safe and well-tolerated effective treatment for PDE4-mediated diseases. The Board cannot agree with this formulation either, because it refers to the provision of a compound, whereas stereomerically pure apremilast as an anti-inflammatory compound with PDE4 inhibitory activity was already available as the starting point in the prior art.

Starting from stereomerically pure apremilast as an anti-inflammatory compound with PDE4 inhibiting activity and taking account of the relevant effects

discussed in section 4.4.3 above the Board formulates the objective technical problem as the provision of an administration route for stereomerically pure apremilast which allows for the safe and well-tolerated effective treatment for PDE4-mediated diseases.

4.5 Assessment of the solution

4.5.1 It was not in dispute that the oral administration of PDE4 inhibitors represented challenges associated with the potential cardiovascular side effects following systemic delivery due to a lack of selectivity for PDE4 and concomitant PDE3 inhibition and the propensity of PDE4 inhibitors to induce emesis (see D74, page 2, section 3.9, page 5, sections 3.21-3.22 and page 9, section 6.4; see also: D1, column 4, lines 23-27; D76, page 1255, Abstract and page 1262; D72, page 93, Introduction, and page 94, right column; D73, page 1114, left column; D92, page 433, right column).

The Board considers that the reported challenges regarding the oral administration of PDE4 inhibitors reflect the skilled person's compelling motivation to seek the oral administration of PDE4 inhibitors, which represents typically his first choice for systemic delivery of a pharmaceutically active agents because of the ease of administration.

In fact, at the priority date for the patent the development of orally administered PDE4 inhibitors was ongoing and promising. This is evidenced by documents D72 and D76, which report positive results concerning the oral administration of the PDE4 inhibitors cilomilast and roflumilast (see D72, pages 94-95, D76, pages 1260-1261). No established prejudice against the

oral administration of PDE4 inhibitors would therefore have prevented the skilled person to administer apremilast via the oral route.

Notably, document D76 specifically reports the favourable therapeutic index versus emesis of the compound "CDC-801", which is like apremilast a thalidomid analog (see D76, page 1264, left column). Taking further account of the prominent mention of oral administration in document D1 itself, including examples of oral dosage forms, the Board considers that the prior art provided the skilled person with a reasonable expectation that the oral administration of stereomerically pure apremilast would provide for the safe and well-tolerated effective treatment for PDE4-mediated diseases.

4.5.2 The skilled person may not have predicted the actual level of the PDE4 selectivity, the level of the therapeutic index versus emesis and the level of the solubility of stereomerically pure apremilast as indicated by the experimental results reported in the patent.

According to the established jurisprudence, an effect which may be said to be unexpected can be regarded as an indication of an inventive step, but certain preconditions have to be met. If, having regard to the state of the art, it would already have been obvious for a skilled person to arrive at the subject-matter defined in a claim, because an advantageous effect could be expected to result from the prior art documents, such a claim may lack an inventive step, irrespective of the circumstance that an extra effect (possibly unforeseen) was obtained (see Case Law of the Boards of Appeal of the EPO, *supra*, I.D.10.8). As

pointed out in T 1356/21 (see reasons 3.4.3) this jurisprudence, which typically concerns cases involving a so-called "one-way-street" situation in which practical alternative solutions are absent, may not apply to any situation of a plurality of technical effects without regard to their respective technical and practical importance.

Taking account of this jurisprudence the Board considers that in the present case the reasonable expectation that orally administered apremilast allows for safe and well-tolerated effective treatment prevails over any unforeseen level of the PDE4 selectivity, the therapeutic index versus emesis or the solubility of stereomerically pure apremilast as reported in the patent having regard to the compelling motivation to administer PDE4 inhibitors by the oral route.

Accordingly, the Board concludes that the subject-matter according to "Main request A" does not involve an inventive step.

5. "Main request B"

5.1 Claim 1 of "Main request B" differs from claim 1 of "Main request A" in that it is formulated in the so-called "Swiss-type" format, that the stereomerical purity is specified in accordance with the most preferred definition in the application as originally filed and that the medicament is for the treatment or prevention of an inflammatory disease which is psoriasis or Behçet’s disease.

"Main request B" was filed by the patent proprietor on the second day of the oral proceedings after the Board

had concluded that the subject-matter of "Main request A" did not involve an inventive step. Although "Main request B" corresponds to the amendment of auxiliary request 12 in line with auxiliary request 3 and is thus encompassed by the possible amendments envisaged in the patent proprietor's statement of grounds of appeal, "Main request B" still represents an amendment to the patent proprietor's appeal case within the meaning of Article 13(2) RPBA.

5.2 The fact that the amendment in accordance with "Main request B" was encompassed by the possible amendments envisaged in the patent proprietor's statement of grounds of appeal demonstrates that the "Main request B" could have been filed with the statement of grounds of appeal and does therefore not represent an exceptional circumstance that could justify the late filing of "Main request B".

The circumstance that claim 1 of "Main request B" specifies the stereomerical purity in accordance with the most preferred definition in the application and defines the medicament for the treatment or prevention of an inflammatory disease which is psoriasis or Behçet’s in order to address and resolve any objections under Article 123(2) and 56 EPC against the main request and "Main request A" could also hardly be considered exceptional, as amendments to the claims filed during opposition proceedings and subsequent appeal proceedings are generally filed with the intention to ensure compliance with the EPC. In this context the Board further observes that the definition that the medicament is for the treatment or prevention of psoriasis or Behçet’s does not *prima facie* overcome the objection of lack of inventive step held against "Main request A", because document D1 already indicates

the utility of the disclosed compounds in the treatment of inflammatory diseases.

5.3 The filing of "Main request B" is therefore not justified by any exceptional circumstance. Accordingly, the Board has decided not to admit this request into the appeal proceedings under Article 13(2) RPBA.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated