Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 13 January 2023

Case Number: T 0044/20 - 3.3.07

Application Number: 10752585.9

Publication Number: 2477611

IPC: A61K9/20, A61K31/277

Language of the proceedings: EN

Title of invention:
(Z)-2-CYANO-3-HYDROXY-BUT-2-ENOIC ACID-(4'-TRIFLUORMETHYLPHENYL)-AMIDE TABLET FORMULATIONS WITH IMPROVED STABILITY

Patent Proprietor:
Sanofi-Aventis Deutschland GmbH

Opponents:
Cooke, Richard
Wuesthoff & Wuesthoff Patentanwälte PartG mbB
Pentafarma Sociedade Técnico-Medicinal S.A.

Headword:
Teriflunomide formulations / SANOFI-AVENTIS

Relevant legal provisions:
EPC Art. 84, 123(2)
RPBA 2020 Art. 11
Guidelines for examination F.IV,4.2

Keyword:
Claims - clarity after amendment (no)
Amendments - added subject-matter (yes)

Decisions cited:
T 0002/80, T 1170/07, T 0759/10, T 1634/13, T 2002/13, G 0003/14

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0044/20 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 13 January 2023

Appellant: (Opponent 1)	Cooke, Richard Elkington and Fife LLP Patents Department 3-4 Holborn Circus London EC1N 2HA (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Appellant: (Opponent 2)	Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstrasse 2 81541 Munich (DE)
Representative:	Wibbelmann, Jobst Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstrasse 2 81541 München (DE)
Appellant: (Opponent 3)	Pentafarma Sociedade Técnico-Medicinal S.A. Rua da Tapa Grande 2-Abrunheira 2710-089 Sintra (PT)
Representative:	Lederer & Keller Patentanwälte Partnerschaft mbB Unsöldstraße 2 80538 München (DE)
Respondent: (Patent Proprietor)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50 65929 Frankfurt am Main (DE)

Representative: Weickmann & Weickmann PartmbB
Postfach 860 820
81635 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 November 2019 concerning maintenance of the European Patent No. 2477611 in amended form.**

Composition of the Board:

Chairman A. Usuelli
Members: M. Steendijk
A. Jimenez

Summary of Facts and Submissions

I. European patent 2 477 611 ("the patent") was granted on the basis of thirteen claims.

Independent claim 1 as granted defined:

"A solid pharmaceutical composition consisting essentially of
a) 1 % to 30 % weight : weight Teriflunomide, or a pharmaceutically acceptable basic addition salt thereof,
b) 5 % to 20 % weight: weight disintegrant,
c) 0 % to 40 % weight : weight binder,
d) 0.1 % to 2 % weight : weight lubricant and
e) the remaining percentage comprising diluents,

provided that said solid pharmaceutical composition does not contain colloidal silicon dioxide."

II. Three oppositions had been 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 filed. All three opponents filed appeals against the interlocutory decision of the opposition division that the patent as amended in accordance with auxiliary request 1 met the requirements of the EPC.

The decision was based on the patent as granted (main request) and auxiliary request 1 filed on 25 July 2019.

Claim 1 of this auxiliary request 1 defined:

"A solid pharmaceutical composition consisting essentially of
a) 1 % to 30 % weight : weight Teriflunomide, or a pharmaceutically acceptable basic addition salt thereof,
b) 5 % to 20 % weight : weight disintegrant, wherein said disintegrant is selected from the group consisting of low substituted hydroxyproyl cellulose, microcrystalline cellulose, powdered cellulose, croscarmellose sodium, sodium starch glycolate or a mixture of one or more of said disintegrants,
c) 0 % to 40 % weight : weight binder, wherein said binder is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, pregelatinized starch, potato starch, corn starch or cereal starch or a mixture of one or more of said binders,
d) 0.1 % to 2 % weight : weight lubricant wherein said lubricant is selected from the group consisting of sodium stearyl fumarate and magnesium stearate or a mixture of one or more of said lubricants, and
e) the remaining percentage consisting of diluents, wherein said diluent is selected from the group consisting of lactose, lactose mono hydrate, mannitol or a mixture of one or more of said diluents,

provided that said solid pharmaceutical composition does not contain colloidal silicon dioxide."

The opposition division arrived *inter alia* at the following conclusions:

(a) The patent as granted did not comply with the requirement of sufficient disclosure due to the overlap in the definitions of the components.

(b) The definition of the particular agents in claim 1 of auxiliary request 1 was adequately based on original claims 3, 5, 7 and 9, which evidently defined these agents as preferred. The amended claim clearly defined the components of the composition exhaustively by specifying that the remaining percentage consisted of diluents. This exhaustive definition was implicitly supported by the disclosed examples 0A and 0D.

Auxiliary request 1 therefore complied with Articles 84 and 123(2) EPC. This request was also considered to comply with the requirements of novelty, sufficiency of disclosure and inventive step.

III. With the reply to the appeals the respondent maintained auxiliary request 1 on which the decision under appeal was based as its main request and filed twelve sets of claims with further amendments as auxiliary requests I-XII.

With respect to the main request auxiliary request **I** additionally requires in claim 1 that the composition is a tablet or a pill coated with a non-functional coating. Claim 1 of auxiliary request **II** additionally requires in claim 1 that the composition is a tablet or a pill coated with a hypromellose-based coating.

Claim 1 of auxiliary request **III** differs from claim 1 of the main request by replacement of the wording "consisting essentially of" by "consisting of".

Auxiliary requests **IV** and **V** differ from auxiliary request III by the definition in claim 1 that the composition is a tablet or a pill coated with a non-functional coating (auxiliary request IV) or a hypromellose-based coating (auxiliary request V).

Claim 1 of request **VI** defines:

"A solid pharmaceutical composition consisting essentially of:
a) 2 % to 15 % weight: weight Teriflunomide,
b) 7 % to 15 % weight: weight disintegrant selected from one or more of
microcrystalline cellulose or sodium starch glycolate,
c) 15 % to 35 % weight: weight binder selected from one or more of hydroxyproyl cellulose or corn starch,
d) 0.1 % to 1.0 % weight: weight lubricant selected from magnesium stearate and,
e) the remaining percentage consisting of diluents selected from lactose mono hydrate

provided that said solid pharmaceutical composition does not contain colloidal silicon dioxide."

Auxiliary requests **VII** and **VIII** additionally require with respect to auxiliary request VI in claim 1 that the composition is a tablet or a pill coated with a non-functional coating (auxiliary request VII) or a hypromellose-based coating (auxiliary request VIII).

Auxiliary request **IX** corresponds to auxiliary request VI except for the replacement of the wording "consisting essentially of" by "consisting of" and the omission of the proviso regarding colloidal silicon dioxide. Auxiliary requests **X** and **XI** additionally require with respect to auxiliary request IX in claim 1

that the composition is a tablet or a pill coated with a non-functional coating (auxiliary request X) or a hypromellose-based coating (auxiliary request XI).

Auxiliary request **XII** corresponds to auxiliary request VI except for the replacement of the wording "consisting essentially of" by "consisting of".

IV. In its communication pursuant to Article 15(1) RPBA the Board expressed *inter alia* the preliminary opinion that claim 1 of the main request lacked clarity and did not comply with Article 123(2), that auxiliary requests I-XII did not resolve these issues and that no special reasons justified a remittal of the case to the first instance.

V. Oral proceedings were held on 13 January 2023.

VI. The arguments of the appellant-opponents relevant to the present decision are summarized as follows:

(a) Article 84 EPC

The replacement of "the remaining percentage comprising diluents" under e) in claim 1 as granted by "the remaining percentage consisting of diluents" in claim 1 of the main request resulted in an exhaustive listing of the components of the composition under features a) to e) of the claim. This definition was inconsistent with the wording "consisting essentially of" in the preamble and the proviso excluding colloidal silicon dioxide as retained in claim 1 of the main request. Claim 1 of the main request did therefore not comply with Article 84 EPC, which according to the established

jurisprudence, including T 2/80, required that the claims are free of contradictions.

(b) Article 123(2) EPC

Claim 1 of the main request included the amendment that under e) the remaining percentage is defined as consisting of diluents. Claim 1 of the main request thereby limited the original generic definition of the compositions, which allowed for additional components, to a subgroup of compositions which had originally not been specifically disclosed, namely those that do not contain any other components in addition to those listed under a) to e). Examples 0A and 0D of the application as filed related to specific tablets, which did not provide a basis for this subgroup of compositions.

(c) The objection under Article 123(2) equally applied to the auxiliary requests. A remittal to the first instance was not justified.

VII. The arguments of the respondent relevant to the present decision are summarized as follows:

(a) Article 84 EPC

The wording "consisting essentially of" and the proviso were present in the claims as granted and therefore not objectionable under Article 84 EPC,

According to the Guidelines F.IV,4.2 and as explained in T 1170/07 the claims should be interpreted in a technically reasonable way. The introduced wording "consisting of" under e) in

claim 1 of the main request clearly defined the feature that the presence of further components was excluded. Irrespective of the less restrictive expression "essentially consisting of" in the preamble and the included proviso claim 1 of the main request thereby required without ambiguity that the defined composition did not comprise components beyond those listed under a) to e). Claim 1 was therefore not objectionable under Article 84 EPC, which required that the scope of the claims can be determined without ambiguity.

(b) Article 123(2) EPC

The replacement of the term "comprising" by the expression "consisting of" under e) in claim 1 of the main request limited the components of the defined composition and their amounts to those mentioned under a) to e). The term "comprising" had been acknowledged as a possible basis for the expression "consisting of" in the relevant jurisprudence, including T 759/10 and T 1634/13. The application as filed did not require the presence of components beyond those listed under a) to e) and confirmed in examples 0A and 0D that the presence of just these components was indeed sufficient. Claim 1 therefore complied with Article 123(2) EPC.

(c) Auxiliary requests IX to XII resolved any issue under Article 84 EPC. The requested remittal to the first instance on the basis of auxiliary requests IX to XII was justified, because the claims of these requests differed substantially from the claims of the main request, which was held allowable in the decision under appeal. Any ground

for an objection under Article 123(2) against the main request did not apply to the auxiliary requests IX to XII, which were based on a further embodiment disclosed in the application as filed and supported by example 0A.

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

IX. The respondent requested that the appeals be dismissed (main request).

Subsidiarily the respondent requested that the patent be maintained on the basis of auxiliary requests I-VIII as filed with the reply to the appeals or that the case be remitted to the first instance for further prosecution of auxiliary requests IX-XII as filed with the reply to the appeals.

Reasons for the Decision

Main request

1. Article 84 EPC

1.1 The Board observes that the open terminology "consisting essentially of" in the preamble of the claim 1 implies in line with the undisputed definition adopted in T 759/10 (section 3.4) that the defined pharmaceutical composition may beyond the components listed under a) to e) include further components which do not materially affect the essential characteristics of the composition. This implication of the used open terminology in the preamble of claim 1 is consistent with the presence of the proviso in the concluding part

of the claim, which specifically excludes the presence of colloidal silicon dioxide and thereby indicates that other components may still be included in the defined composition.

The closed terminology used under e) in claim 1 of the main request, which requires following the definition of the percentages for the components defined under a) to d) the remaining percentage to consists of diluents, implies that the composition does not include components beyond those listed under a) to e), irrespective of whether these would affect the characteristics of the composition.

The closed terminology used under e) of claim 1 of the main request thereby contradicts the open terminology in the preamble of the claim and the defined proviso.

1.2 Due to this inconsistency it is questionable whether indeed any additional component is excluded by the claim, as seems indicated by the closed terminology under e), or whether components which do not materially affect the essential characteristics of the composition may still be included, as seems indicated by the open terminology "consisting essentially of" and the proviso. None of these options can *a priori* be excluded as nonsensical. Whilst in accordance with the Guidelines for Examination F.IV,4.2 and the established jurisprudence, as for instance represented by T 1170/07, illogical or technically meaningless interpretations of a claim should be ruled out, the Board observes that an inconsistent and unclear claim may not simply out of benevolence be read and understood to comply with Article 84 EPC (compare T 2/80, reasons 2 and T 2002/13, reasons 6).

1.3 The mentioned inconsistency in the wording of claim 1 of the main request results from the amendment to claim 1 of the patent as granted introducing the closed terminology under e). In accordance with the principles explained in G 3/14 it is therefore irrelevant that the open terminology in the preamble and the proviso were present in the claims as granted and that the closed terminology under e) may per se be clear.

1.4 The Board therefore concludes that claim 1 of the main request does not comply with Article 84 EPC.

2. Article 123(2) EPC

2.1 Claim 1 of the application as originally filed defined:

"A solid pharmaceutical composition comprising
a) 1 % to 30 % weight : weight Teriflunomide, or a pharmaceutically
acceptable basic addition salt thereof,
b) 5 % to 20 % weight: weight disintegrant,
c) 0 % to 40 % weight : weight binder,
d) 0.1 % to 2 % weight : weight lubricant and
e) the remaining percentage comprising diluents,

provided that said solid pharmaceutical composition does not contain colloidal silicon dioxide." [underlining by the Board]

The amendments in claim 1 of the main request with respect to claim 1 as originally filed concern the replacement of the terms "comprising" by respectively "consisting essentially of" and "consisting of" and the incorporation of the definitions of the disintegrant, binder, lubricant and diluents defined in dependent

claims 3, 5, 7 and 9 as granted with the omission of starches from claim 9 as granted.

The description of the application as originally filed (see page 3, lines 12-17 and page 4, lines 3-12) presents definitions of a composition using the same open terminology ("comprising") as original claim 1. Further embodiments of such composition are described in the application as filed (see pages 6 to page 7, line 17) by using again the same open terminology ("comprising") or by reference to the amounts as previously defined under a) to e). The application as filed further presents a table (see pages 15-16, Table 1) with the following examples of tablets prepared by a wet granulation process with (0B and 0C) and without (0A and 0D) colloidal silicon dioxide:

Example	0A	0B	0C	0D
Teriflunomide [mg]	7.000	7.000	7.000	7.000
Lactose mono-hydrate [mg]	81.000	81.000	xx	xx
Mannitol [mg]	xx	xx	101.0	101.0
Corn starch [mg]	40.000	40.000	20.00	20.00
Hydroxypropyl cellulose [mg]	3.500	3.500	3.500	3.500
Mass granules [mg]	131.500	131.500	131.500	131.500
Microcrystalline Cellulose [mg]	10.500	10.000	10.000	10.500
Sodium starch glycolate [mg]	7.500	7.500	7.500	7.500
Colloidal silicon dioxide [mg]	xx	0.500	0.500	xx
Magnesium stearate [mg]	0.500	0.500	0.500	0.500
Total mass [mg]	150.000	150.000	150.000	150.000
Tablet dimensions	7 mm round biconvex			

In the above table “xx” means no addition of the component

It was not in dispute that the application as filed did not explicitly disclose the composition as defined in claim 1 of the main request using the closed terminology ("consisting of") to define the remaining percentage under e) as diluents.

2.2 The Board agrees with the observation in T 759/10 (see reasons 3.4) that the terms "comprising" and "consisting of" have different technical meanings, the former allowing the presence of further components and

the latter excluding such further components, and that the skilled person is not at liberty to attribute whichever of these meanings when reading the term "comprises". As further pointed out in T 759/10 (see reasons 5.3 and 5.6) an amended feature must be directly and unambiguously derivable from the application as filed in order to be allowable under Article 123(2) EPC, which can only be assessed by reference to the application in question. The same standard was also applied in T 1634/13 (see section 2.3) referred to by the respondent.

2.3 The replacement of the wording "the remaining percentage comprising diluents" by "the remaining percentage consisting of diluents" [underlining by the Board] in claim 1 under e) excludes other components from this remaining part of the composition. Following the definition of the ranges for the percentage of the components as defined under a) to d), which in total amount from 6.1% to 92%, the amendment in claim 1 of the main request thereby results under e) in the definition of a specific range of 8% to 93.9% for the amount of the diluents making up the remainder.

2.4 This specific range for the amount of diluents was not directly and unambiguously derivable from the definition of composition in claim 1 as originally filed or the generic embodiments described in similar terms in the application as filed, because the remaining percentage of 8% to 93.9% is there defined to possibly include further components, which leaves the actual percentage of the diluent undetermined.

As argued by the respondent, the application as originally filed does not disclose that beyond the components specifically mentioned under a) to e) of

claim 1 of the main request additional components are required. Furthermore, the application presents in examples 0A and 0D tablets which indeed do not include such additional components. However, the Board considers that in the context of the generic disclosure of the amounts of components of the composition as originally defined with the open terminology "comprising", the critical specific absence of additional components introduced by the closed terminology "consisting of" cannot be directly and unambiguously derived from the absence of a disclosure that additional components are required. In this respect the application as originally filed further merely discloses in examples 0A and 0D that tablets may be suitably prepared by wet granulation using specific amounts of specific combinations of the components as defined under a) to e) of claim 1 of the main request. However, the generic definition of the components and their amounts in claim 1 of the main request, including the specific definition of the percentage for the diluents, cannot be directly and unambiguously derived from the application as originally filed on the basis of this limited information in examples 0A and 0D.

2.5 Accordingly the Board concludes that claim 1 of the main request does not comply with Article 123(2) EPC.

Auxiliary requests

3. Auxiliary requests I to V

The independent claims of auxiliary requests I to V each define under under a) to e) the components of the composition and their amounts in the same terms as claim 1 of the main request.

The Board therefore concludes that auxiliary requests I to V do not comply with Article 123(2) EPC for the same reasons as explained above in section 2 with respect to the main request.

4. Auxiliary requests VI to XII

4.1 The independent claims of auxiliary requests VI to XII each present under under a) to e) a more restrictive definition of the components of the composition than the main request.

The respondent relied for this more restrictive definition on the following further embodiment described in the application as originally filed (see page 7, lines 11-17):

"In a further embodiment the invention relates to a solid pharmaceutical composition comprising from 2 % to 15 % weight: weight Teriflunomide, 7 % to 15 % weight: weight disintegrant selected from one or more of microcrystalline cellulose or sodium starch glycolate, 15 % to 35 % weight: weight binder selected from one or 15 more of hydroxyproylcellulose or corn starch, 0, 1 % to 1,0 % weight: weight lubricant selected from magnesium stearate and the remaining percentage comprising diluents selected from lactose mono-hydrate." [underlining by the Board]

The definition of the components and their amounts under a) to e) in the independent claims of auxiliary requests VI to XII corresponds to this further embodiment disclosed in the application as originally filed except for the replacement of the open terminology "comprising" by the closed terminology

"consisting of" in the definition under e) of the remaining percentage including the diluents.

4.2 As explained above in section 2.3 in the context of the main request, such replacement of the term "comprising" by "consisting of" results in the specific definition of the percentage of the diluents of the composition, which in case of auxiliary requests VI to XII corresponds to 34% to 75.9% lactose mono-hydrate for the remainder.

This specific percentage of the diluent cannot be directly and unambiguously derived from the generic disclosure of the components and their amounts defined with the open terminology "comprising" in the application as filed relied upon by the respondent, because the original open terminology leaves the actual percentage of the diluent undetermined. Moreover, the generic definition of the components and their amounts in accordance with auxiliary requests VI to XII, including the definition of the specific percentage for the diluent, cannot be directly and unambiguously derived on the basis of the limited information in example 0A. The same considerations as set out above in section 2.4 with respect to the main request also apply in the context of auxiliary requests VI to XII.

4.3 The Board therefore concludes that auxiliary requests VI to XII do not comply with Article 123(2) EPC.

5. Request for remittal

As explained above, the Board considers that contrary to the finding in the decision under appeal the main request does not comply with the requirement of Article

123(2) EPC and that essentially the same considerations also apply to the auxiliary requests.

Accordingly, the Board finds no special reasons to remit the case to the first instance for the further prosecution of auxiliary requests IX to XII as requested by the respondent (Article 11 RPBA 2020).

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