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Datasheet for the decision of 16 November 2023

Case Number: T 0728/21 - 3.3.07

Application Number: 10708442.8

Publication Number: 2464337

IPC: A61K9/14, A61K31/47, A61P19/10, A61P19/00, A61P43/00, A61K45/06, A61K31/44

Language of the proceedings: EN

Title of invention:

Tablet formulation of N-[2,4-bis(1,1-dimethylethyl)-5-hydroxyphenyl]-1,4-dihydro-4-oxoquinoline-3-carboxamide for use in the treatment of cystic fibrosis

Patent Proprietor:

Vertex Pharmaceuticals Incorporated

Opponent:

Teva Pharmaceutical Industries Ltd.

Headword:

Cystic fibrosis / VERTEX

Relevant legal provisions:

EPC Art. 56, 83

Keyword:
Inventive step - unexpected optimization
Sufficiency of disclosure - enabling disclosure (yes)

Decisions cited:
G 0001/03, G 0002/21, T 0609/02, T 0391/18

Catchword:
In accordance with the jurisprudence exemplified by T 609/02 (see section 9), the suitability of the claimed composition for the defined therapeutic use needs to be disclosed in the patent, "unless this is already known". This jurisprudence confirms in the Boards view that the disclosed utility of the claimed composition may also derive its credibility from the prior art, even if this prior art does not represent common general knowledge (see point 3.3).

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Case Number: T 0728/21 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 16 November 2023

Appellant: (Patent Proprietor)	Vertex Pharmaceuticals Incorporated 50 Northern Avenue Boston, MA 02210 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Appellant: (Opponent)	Teva Pharmaceutical Industries Ltd. 124 Dvora HaNevi'a St. 6944020 Tel Aviv (IL)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 March 2021 concerning maintenance of the European Patent No. 2464337 in amended form.**

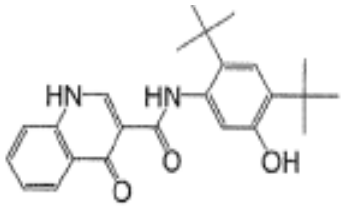
Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	S. Ruhwinkel

Summary of Facts and Submissions

I. European patent 2 464 337 ("the patent") was granted on the basis of six claims.

Claim 1 as granted related to a specific tablet composition including 34.1 wt% of a solid dispersion containing 80 wt% of substantially amorphous or amorphous N-[2,4-Bis(1,1-dimethylethyl)-5-hydroxyphenyl]-1,4-dihydro-4-oxoquinoline-3-carboxamide (Compound 1)



Compound 1

for use in combination with one or more other desired therapeutics in treatment of cystic fibrosis in a patient with a ΔF508 mutation on both alleles.

This Compound 1 is herein referred to by its international non-proprietary name: ivacaftor.

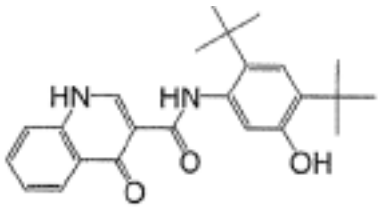
II. The grant of the patent was originally opposed on the grounds that its subject-matter lacked novelty and inventive step and that the patent comprised subject-matter extending beyond the content of the application as filed.

The patent proprietor and the opponent filed appeals against the interlocutory decision of the opposition division that the patent as amended in accordance with the proprietor's auxiliary request 16 met the

requirements of the EPC. The patent proprietor withdrew its appeal on 24 January 2022.

Claim 1 of the mentioned auxiliary request 16 defined:

"A pharmaceutical composition comprising about 34.1 wt% of a solid dispersion by weight of the composition, wherein the dispersion comprises 80 wt% of substantially amorphous or amorphous N-[2,4-Bis(1,1-dimethylethyl)-5-hydroxyphenyl]-1,4-dihydro-4-oxoquinoline-3-carboxamide (Compound 1)



Compound 1

by weight of the dispersion, 19.5 wt% of HPMCAS by weight of the dispersion, and 0.5 wt% SLS by weight of the dispersion; about 30.5 wt% of microcrystalline cellulose by weight of the composition; about 30.4 wt% of lactose by weight of the composition; about 3 wt% of sodium croscarmellose by weight of the composition; about 0.5 wt% of SLS by weight of the composition; about 0.5 wt% of colloidal silicon dioxide by weight of the composition; about 1 wt% of magnesium stearate by weight of the composition;
wherein the pharmaceutical composition is made into a tablet;
for use in treating or lessening the severity of cystic fibrosis in a patient;
wherein said use comprises administering the pharmaceutical composition concurrently with, prior to, or subsequent to one or more other desired therapeutics;

wherein the patient possesses a cystic fibrosis transmembrane receptor (CFTR) with a ΔF508 mutation on both alleles; and
wherein the other desired therapeutic is a CFTR modulator other than compound 1." [underlining by the Board to indicate the amendment with respect to claim 1 as granted]

In its decision the opposition division cited *inter alia* the following documents:

D2: WO 2007/079139 A2
D5: Vertex Press Release from 27 May 2009
D7: Vertex Press Release from 25. March 2009
D12: "Handbook of pharmaceutical excipients", 2009, 6th ed., pages v-xiii, 129-133, 185-188, 206-208, 376-378, 404, 651-653
D15: Chest, 2012, 142(3), 718-724
D16A: Poster Session Abstracts from The 21st Annual North American Cystic Fibrosis Conference 2007, page 289, Abstract 248
D20: European medicine Agency, "Orkambi (lumacaftor / ivacaftor), An overview of Orkambi and why it is authorised in the EU" (last update 08-2022)

The opposition division arrived at the following conclusions:

(a) The late filed ground of opposition under Article 100(b) EPC and document D15 filed in support of this ground were admitted in view of their *prima facie* relevance with respect to the claims as granted. The main request did not meet the requirement of sufficient disclosure having regard to the information in document D15, which indicated

that ivacaftor was not effective in treatment of homozygous ΔF508 patients.

(b) The objection of lack of sufficient disclosure against claim 1 of the main request also applied with respect to auxiliary requests 1-15.

(c) Auxiliary request 16 incorporated in claim 1 the feature of claim 5 as granted that the other desired therapeutic agent is a CFTR modulator other than ivacaftor.

Auxiliary request 16 complied with Article 123(2) EPC.

The late filed document D20 was admitted in view of its *prima facie* relevance, because it confirmed that combinations of ivacaftor with other CFTR modulators were effective in the treatment of homozygous ΔF508 patients. Auxiliary request 16 complied with Article 83 EPC taking account of the list of possible other CFTR modulators disclosed in the patent and the information in documents D7 and document D20.

Document D2 represented the closest prior art describing solid dispersions of amorphous ivacaftor. In the absence of specific examples of actually manufactured administration forms in document D2, the appropriate starting point within document D2 was the composition comprising 50% of ivacaftor, 49.5% HPMCAS and 0.5% SLS as disclosed in claim 46 and paragraph [0047].

The problem to be solved concerned the provision of a stable and bioavailable ivacaftor dosage form

simple to manufacture and with low pill burden for the patients to be treated. The experimental results provided with the proprietor's letter of 3 March 2020 demonstrated that this problem was indeed solved in accordance with the claimed formulation including the dispersion comprising 80% ivacaftor in spite of the crystal precipitation observed with this formulation in *in vitro* assays. In view of the disclosure of good stability and bioavailability for amorphous ivacaftor by its incorporation in a solid dispersion with equal amounts of a polymer in document D2 and in view of the mentioned discouraging *in vitro* results with dispersions comprising 80% ivacaftor the skilled person would have expected the increased amount of ivacaftor to decrease its bioavailability. The skilled person would therefore not have arrived at the claimed solution in an obvious manner. The subject-matter of auxiliary request 16 thus involved an inventive step.

III. During the appeal proceedings the following further documents were *inter alia* filed:

D21: Expert report of Professor Isidoro Caraballo
D33: WO 2006/127588 A2
D34: WO 2007/134279 A2
D35: Handbook of Modern Pharmaceutical Analysis (2001), Chapter 5: Preformulation Studies, 173, 190-93

The appellant (opponent) filed document D21 with the statement of grounds of appeal.

The respondent (patent proprietor) filed document D33 with the reply to the appeal and documents D34-D35 with the letter of 14 September 2023.

IV. In the statement of grounds of appeal the appellant contested the findings in the decision under appeal that auxiliary request 16 complied with the requirements of sufficiency of disclosure and inventive step.

V. With the reply to the appeal the respondent upheld auxiliary request 16 as filed on 9 August 2021 as its main request and maintained auxiliary requests 17-31 as filed on 9 August 2021 as its auxiliary requests 1-15.

VI. In its communication pursuant to Article 15(1) RPBA the Board expressed *inter alia* the following preliminary assessment:

- the main request complied with Article 83 EPC

- neither the prior art nor the *in vitro* results reported by the proprietor discouraged the skilled person from implementing the defined high drug loading of the solid dispersion

- the assessment of inventive step could depend on the evaluation of effects from the defined amounts of the defined excipients.

VII. Oral proceedings were held on 16 November 2023.

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

(a) Admittance of evidence and arguments

The submissions presented in the appellant's letter of 6 March 2023 merely developed the arguments presented in the statement of grounds of appeal.

Document D35 was not responsive to the appellant's submissions of 6 March 2023, and merely addressed the declaration in document D21, which had been filed with the statement of grounds of appeal. The late filing of document D35 therefore lacked adequate justification.

(b) Inventive step

Document D2 described the advantageous incorporation of amorphous ivacaftor together with a polymer and a detergent in a solid dispersion. The document indicated high loadings for ivacaftor, including up to 80%, and described HPMCAS as a preferred polymer and SLS as the preferred detergent. Document D2 further mentioned the formulation of tablets using conventional excipients. Document D12 demonstrated that the excipients and their amounts as defined in claim 1 of the main request concerned conventional excipients for tablets used in conventional amounts. The application as filed did not foreshadow any particular effect from the defined amounts of the lactose, the microcrystalline cellulose, the croscarmellose and the solid dispersion. Post-published evidence for such an effect could therefore not support any inventive step. The post-published evidence relied upon by the proprietor was anyway not suitable to substantiate any unexpected effect from the defined amounts of the tablet components, because the presented experimental results concerned tablets

comprising 40 wt% and 50 wt% of the solid dispersion and not the 34.1 wt% as defined in the claims of the main request.

(c) Sufficiency of disclosure

The patent merely presented the statement that ivacaftor acts as CFTR potentiator together with a list of intended further CFTR modulators, but failed to provide any experimental data supporting the therapeutic efficacy of ivacaftor or any other CFTR modulator in homozygous ΔF508 patients. According to the established jurisprudence, exemplified by T 609/02 and T 2059/13, the patent did not sufficiently disclose the suitability of the claimed composition for the defined therapeutic with such mere verbal statements.

The proprietor could not rely on some specific prior art to support the suitability of the claimed composition for the defined use, because the sufficiency of the disclosure could only be based on the content of the patent and the common general knowledge.

In as far as the skilled person could nevertheless take account of the information in documents D5, D7 and D16A regarding the effects of the CFTR potentiator VX-770, this information would be of no relevance, because it was not evident that the compound VX-770 mentioned in these documents was ivacaftor. Moreover, documents D5 and D7 merely referred to planned clinical trials, whereas document D16 only presented experimental results regarding the effects of ivacaftor in ΔF508 cell-lines. Any reference to the utility of ivacaftor in

treatment of homozygous ΔF508 patients in document D2 lacked experimental evidence in the same way as the patent itself and therefore provided no further support for the defined utility of the claimed composition.

In contrast, the post-published document D15 reported the lack of clinical benefit from treatment of homozygous ΔF508 patients with the CFTR potentiator ivacaftor alone. The proprietor had not appealed the finding by the opposition division based on the information in document D15 that ivacaftor alone is not suitable for treatment of homozygous ΔF508 patients. The lack of clinical efficacy from CFTR potentiation with ivacaftor indicated in document D15 also raised serious doubts regarding the suitability of ivacaftor for treating the defined patients when administered concurrently with a further CFTR modulator, such as a mere additional CFTR potientiator, which was encompassed by the definition "CFTR modulator" used in claim 1 of the main request.

These serious doubts could not be overcome by reference to the post-published evidence in document D20 regarding the efficacy of combinations of the CFTR potentiator ivacaftor with certain specific CFTR correctors, because sufficiency of disclosure was to be assessed on the basis of the content of the patent and the common knowledge. The patent itself failed to disclose the relevant criteria that allowed the skilled person to identify amongst all the further unspecified CFTR modulators defined in the claim those agents, such as the specific CFTR correctors mentioned in document D20, which are suitable to achieve the

clinical benefit that was not achievable with the CFTR potentiation by ivacaftor alone.

The patent further failed to provide any information on relevant drug-drug interactions, which in line with the considerations in T 391/18 gave rise to the undue burden of identifying the other CFTR modulators which are compatible with administration of ivacaftor.

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

(a) Admittance of evidence and arguments

Document D35 was filed in response to the appellant's submissions of 6 March 2023 and should be admitted, if the submissions presented in the appellant's letter of 6 March 2023 were admitted.

(b) Inventive step

Document D2 described various solid forms for ivacaftor, including solid dispersions comprising amorphous ivacaftor, but failed to disclose any particular tablet formulation. The subject-matter of the main request differed from this prior art in the definition of the particular constitution of the claimed tablet.

Post-published experimental evidence indicated optimized dissolution from tablets prepared with lactose and microcrystalline cellulose in a 1:1 weight ratio and with 3% sodium croscarmellose. The defined amounts of the solid dispersion comprising the high loading of 80 wt% ivacaftor together with

the defined amounts of the further excipients was thus associated with advantageous properties of the tablets, which was not obvious in view of the prior art.

(c) Sufficiency of disclosure

The patent credibly disclosed the suitability of the defined composition for the described therapeutic indication by explaining that

- the ΔF508 mutation leads in patients with cystic fibrosis to impaired trafficking to the membrane and defective channel gating of the mutant CFTR,

- ivacaftor was known to potentiate the activity of CFTR with a ΔF508 mutation and

- ivacaftor can be effectively combined with other CFTR modulators, such as lumacaftor.

The patent could rely on the known activity of ivacaftor as a potentiator of the mutant CFTR, even if the knowledge of this activity was not demonstrated to be part of the common general knowledge. Document D16A already reported the restoration of normal gating in ΔF508 mutant CFTR by VX-770 and documents D5 and D7 announced clinical trials for use of the CFTR potentiator VX-770 and the CFTR corrector VX-809 in homozygous ΔF508 patients with reference to a rationale for exploring the clinical potential of combining these types of compounds. Document D34 demonstrated in this context that VX-770 was known to correspond to ivacaftor. Moreover, document D2, which was cited in the application as filed, also disclosed

ivacaftor as useful in the treatment of the relevant patient group. Furthermore, document D33 demonstrated that a variety of other CFTR modulators had been available in the art.

Document D15 reported measurable effects from administration of ivacaftor in homozygous ΔF508 patients, be it that no statistically significant clinical benefit could be demonstrated. The treatment described in document D15 further involved CFTR potentiation with ivacaftor alone. Document D15 could therefore not raise serious doubts regarding the efficacy of the treatment involving ivacaftor in combination with a further CFTR modulator as defined in claim 1 of the main request.

The efficacy of the defined treatment was indeed confirmed in document D20, which reports EMA-approval of combinations of ivacaftor for treatment of homozygous ΔF508 patients including *inter alia* the combination with lumacaftor (VX-809).

No evidence suggested that the treatment involving ivacaftor would not be compatible with the administration with a further CFTR modulator. This distinguished the case from the situation in T 391/18.

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

XI. The respondent requested that the appeal be dismissed and the patent be maintained on the basis of auxiliary

request 16 as filed before the opposition division on 4 February 2021 (renamed as main request).

Reasons for the Decision

1. Admittance of evidence and arguments

1.1 Document D35

The respondent filed document D35 with its letter of 14 September 2023 (see page 3, last paragraph and page 7, section 4.16) in response to the appellant's letter of 6 March 2023. In this letter (see page 8, sections 2.16 and 2.17) the appellant argued that no evidence from the prior art or common general knowledge indicated that solid dispersions with 80 wt% of ivacaftor would be disadvantageous.

Document D35 represents common general knowledge regarding the relevance of the solubility of an active agent on the dosage design and indicates that a solubility of less than 1% (10 mg/ml) may result in absorption problems. Document D35 may thus be considered responsive to appellant's submission of 6 March 2023. The Board has therefore admitted document D35 into the appeal proceedings (Article 13(3) RPBA).

1.2 Following the admittance of document D35 the parties did not object against the admittance of the further evidence and submissions filed during the appeal proceedings. The Board itself had no objection of the kind either and therefore admitted the further evidence and submissions, including the appellant's submissions filed with the letter of 6 March 2023 and document D34

filed by the proprietor in response, into the appeal proceedings.

Main request

2. Inventive step

2.1 Document D2 describes various solid forms of ivacaftor, including solid dispersions comprising amorphous ivacaftor together with a polymer such as HPMCAS and a detergent such as SLS. The document indicates that the ivacaftor may be present in an amount of from about 10 wt% to 80 wt% (see D2, paragraphs [0029]-[0036]). Document D2 further indicates that the active compound, ivacaftor, may be provided in the form of tablets and mentions in this context the use of conventional excipients, including excipients as defined in claim 1 of the main request (see D2, paragraph [0197]).

It was not in dispute that document D2 represented the closest prior art and that this document did not disclose any specific tablet formulation.

The difference between the subject-matter of the main request and the closest prior art therefore concerns the definition of the particular constitution of the claimed tablet.

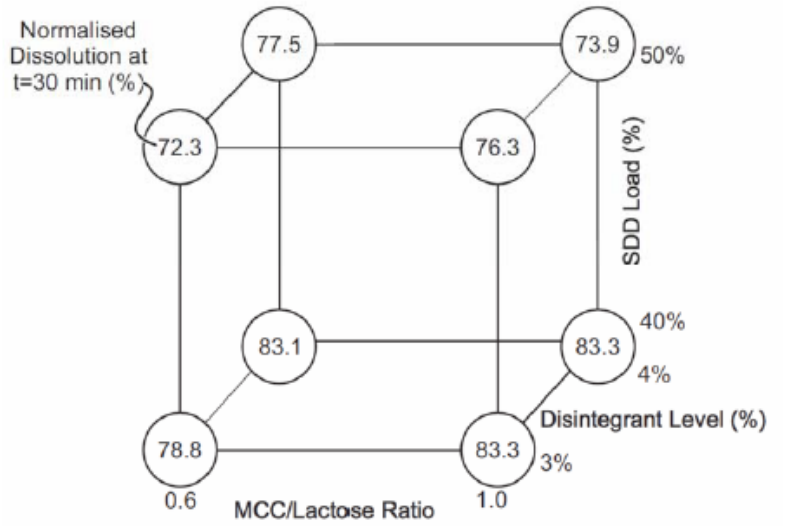
2.2 The respondent presented in its reply to the appeal (see pages 28-30, sections 5.70-5.76) results form experiments concerning the combined effect of the weight ratio of the lactose and microcrystalline cellulose, the amount of the croscarmellose, and the amount of the solid dispersion containing 80 wt% ivacaftor on the dissolution properties of the prepared tablets. The same evidence had previously been

presented before the opposition division (see letter of 3 March 2020).

The experiments involved tablet formulations with the following variations in composition:

Tablet formulation	Amount of solid dispersion (wt%)	MCC:lactose ratio	Amount of sodium croscarmellose (wt%)
1	40	0.6	3.0
2	40	1.0	3.0
3	50	1.0	4.0
4	50	0.6	4.0
5	50	1.0	3.0
6	50	0.6	3.0
7	40	0.6	4.0
8	40	1.0	4.0

The results were presented in the following diagram:



The presented results indicate for a tablet comprising the lower amount of 3 wt% croscarmellose ("Disintegrant Level") and the lower amount of 40% solid dispersion ("SLS Load") an optimization of the dissolution when

the weight ratio of the lactose and microcrystalline cellulose ("MCC/Lactose Ratio") is 1:1 (normalised dissolution 83.3). In view of the consistent increase in dissolution from the decrease in the amount of the solid dispersion from 50% to 40% the Board considers it reasonable to assume that the same optimization from the weight ratio 1:1 for the lactose and microcrystalline cellulose in combination with 3 wt% of croscarmellose is achieved with the 34.1% of the solid dispersion as defined in claim 1 of the main request.

According to G 2/21 a technical effect may be relied upon for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention. The application as originally filed (WO 2011/019413) explicitly addressed the dissolution of tablets comprising a solid dispersion as an aspect of the disclosed invention (see paragraph [0031]) and specifically described the claimed tablet composition as an embodiment of the disclosed invention. The effect of the optimization of the dissolution associated with the specific tablet composition defined in claim 1 of the main request may therefore in accordance with the principles established in G 2/21 be taken into account for the assessment of inventive step.

According, the objective technical problem may be seen in the provision of a tablet formulation comprising a solid dispersion of amorphous ivacaftor which exhibits optimized dissolution.

2.3 The appellant relied on document D12 to argue that claim 1 of the main request merely defined excipients

and their amounts which were conventional in the preparation of tablets.

The Board observes that document D12 indeed describes the defined excipients as conventional components for tablets and that the defined amounts of these excipients fall within the ranges for the conventionally used amounts. However, document D12 does not provide any suggestion that the combination of the lactose and microcrystalline cellulose in the defined amounts resulting in a 1:1 weight ratio, the amount of 3 wt% croscarmellose, and the amount of 34.1% of the solid dispersion containing 80 wt% ivacaftor would allow the preparation of a tablet which exhibits optimized dissolution.

The subject-matter of claim 1 of the main request was therefore not obvious as solution to the identified objective technical problem.

2.4 Accordingly, the Board concludes that the main request meets the requirement of inventive step.

3. Sufficiency

3.1 Article 83 EPC requires that the application discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

In case a patent defines a new therapeutical utility of a composition in a claim in the format of Article 54(5) EPC it is according to the established jurisprudence for compliance with Article 83 EPC necessary, in order to ensure that a patent is only granted if there is a corresponding contribution to the prior art, that the

patent at the date of its filing renders it credible that the claimed composition is indeed suitable for the defined therapeutic use (see G 2/21, section 74). A deficient disclosure cannot be remedied by post-published evidence (see G 2/21, section 77; compare G 1/03, sections 2.5.2-2.5.3).

3.2 The patent specifically explains that the ΔF508 mutation leads in patients with cystic fibrosis to impaired trafficking to the membrane and defective channel gating of the mutant CFTR (see paragraphs [0007]-[0008]). The patent also points out that ivacaftor is a potent and selective CFTR potentiator of wild-type and mutant forms of human CFTR, including ΔF508 (see paragraph [0012]). The patent further teaches that ivacaftor can be effectively combined with other CFTR modulators and lists examples of such agents (see paragraph [0248]). The patent does thereby not describe the activity of ivacaftor as a CFTR potentiator in the form of a simple verbal statement, which might in line with the considerations in T 609/02(see section 9) be considered not to be sufficient, but rather as specific and verifiable technical information supporting the defined therapeutic indication.

This information in the patent provides according to the Board a rational basis for the claimed invention, which rendered the utility of the claimed composition in the treatment of homozygous ΔF508 patients credible at the date of its filing.

3.3 In accordance with the jurisprudence exemplified by T 609/02 (see section 9), the suitability of the claimed composition for the defined use needs to be disclosed in the patent, "unless this is already

known". This jurisprudence confirms in the Boards view that the disclosed utility of the claimed composition may also derive its credibility from the prior art, even if this prior art does not represent common general knowledge.

Document D16A describes VX-770 as an orally bioavailable potentiator of CFTR with activity in cultures of ΔF508/ΔF508 human bronchial epithelia. The designation VX-770 was known to identify the same compound as the international non-proprietary name ivacaftor (see document D34, paragraph [098]). The information that ivacaftor is a CFTR potentiator of ΔF508 CFTR was therefore as a matter of fact already part of the prior art. In addition, document D2 already indicated the utility of ivacaftor in treatment of CFTR, including in homozygous ΔF508 patients (see D2, paragraph [0158]). The Board therefore considers that the prior art confirms the credibility of the disclosed utility of the claimed composition.

3.4 In as far as a patent provides a credible disclosure of the claimed invention a convincing objection of lack of sufficiency of disclosure presupposes according to the established jurisprudence that serious doubts substantiated by verifiable facts have been raised that the skilled person cannot carry out the claimed invention without undue burden on the basis of the teaching in the patent and the common general knowledge (see Case Law of the Boards of Appeal of the EPO, 10th Edition, 2022, sections II.C.7.1.4 and II.C.9).

The appellant argued that the post-published document D15 raises serious doubts regarding the utility of ivacaftor in the treatment of homozygous ΔF508 patients as defined in claim 1 of the main request, because this

document reported a lack of clinical benefit from treatment of homozygous ΔF508 patients with ivacaftor alone.

However, as pointed out by the respondent, document D15 actually reported that measurable effects from administration of ivacaftor in homozygous ΔF508 patients had been observed, be it that these effects could not be qualified as a statistically significant clinical benefit (see D15, page 721, under "Efficacy Measures"). According to the Board the mere lack of an observed clinical effect from treatment with ivacaftor alone reported in document D15 (see page 723, under "Conclusions") may well be due to the design of the study reported in document D15. In the Board's view this "lack" of observation does not qualify as verifiable evidence that raises serious doubts regarding the credibly disclosed suitability of the claimed composition comprising ivacaftor for the defined combination treatment of homozygous ΔF508 patients.

3.5 According to the appellant the patent further failed to provide any information on drug-drug interactions, which in line with the considerations in T 391/18 left the skilled person with the undue burden of identifying the CFTR modulators which are actually compatible for combination with ivacaftor. The Board observes that contrary to the situation in the case decided in T 391/18 (see sections 2.4.2 and 2.5), in the present proceedings no evidence has been submitted which suggests that the treatment involving ivacaftor may not be compatible with the administration of other CFTR modulators. The appellant's objection that the identification of CFTR modulators which are compatible

with the administration of ivacaftor required undue burden is therefore considered to lack substantiation.

3.6 Accordingly, the Board concludes that the main request meets the requirement of sufficiency of disclosure.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated