Internal distribution code:

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

Datasheet for the decision of 2 June 2025

Case Number: T 1535/23 - 3.3.02

Application Number: 18186675.7

Publication Number: 3431475

IPC: C07D471/04, A61K31/519, A61P35/00

Language of the proceedings: EN

Title of invention:
SOLID FORMS OF A SELECTIVE CDK4/6 INHIBITOR

Patent Proprietor:
Pfizer Inc.

Opponents:
STADA Arzneimittel AG
Teva Pharmaceutical Industries Ltd.
Galenicum Health S.L.U.
Generics [UK] Limited

Headword:

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - added subject-matter

Decisions cited:
G 0002/10
Decision of the Court of Appeal of the Unified Patent Court UPC_CoA_382/2024

Catchword:
Omission of a feature from a claim in the context of added matter: same legal approach taken by the UPC Court of Appeal and the EPO Boards of Appeal (see point 1.7 of the Reasons).

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

Case Number: T 1535/23 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 2 June 2025

Respondent: (Patent Proprietor)	Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001-2192 (US)
Representative:	Pfizer European Patent Department 23-25 avenue du Docteur Lannelongue 75668 Paris Cedex 14 (FR)
Appellant: (Opponent 1)	STADA Arzneimittel AG Stadastraße 2-18 61118 Bad Vilbel (DE)
Representative:	Hamm&Wittkopp Patentanwälte PartmbB Jungfernstieg 38 20354 Hamburg (DE)
Appellant: (Opponent 4)	Generics [UK] Limited Building 4, Trident Place Mosquito Way Hatfield Hertfordshire AL10 9UL (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Party as of right: (Opponent 2)	Teva Pharmaceutical Industries Ltd. 124 Dvora HaNevi'a St. 6944020 Tel Aviv (IL)
Representative:	D Young & Co LLP 3 Noble Street London EC2V 7BQ (GB)

Party as of right: (Opponent 3)	Galenicum Health S.L.U. CL Sant Gabriel n°50 08950 Esplugues de Llobregat (ES)
Representative:	Galenicum Health S.L.U. CL Sant Gabriel n°50 08950 Esplugues de Llobregat (ES)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 31 July 2023 concerning maintenance of the European Patent No. 3431475 in amended form.**

Composition of the Board:

Chairman	M. O. Müller
Members:	S. Bertrand
	M. Blasi

Summary of Facts and Submissions

I. The appeals by the patent proprietor, opponent 1 and opponent 4 are against the opposition division's interlocutory decision finding that European patent No. 3 431 475 as amended in the form of auxiliary request 5, comprising claims which had been filed on 2 May 2023, met the requirements of the EPC.

II. The patent is concerned with providing a crystalline form of the free base of the compound 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8*H*-pyrido[2,3-*d*]pyrimidin-7-one.

In the following, this compound is referred to by its common name, palbociclib.

III. In the impugned decision, the opposition division's conclusions included that the claims of auxiliary request 5 fulfilled the requirements of Article 76(1) and Article 123(2) EPC.

IV. This decision was contested by, *inter alia*, opponent 4.

V. The submissions of opponents 1, 2 and 4 in appeal included an objection made by opponent 4 that claim 1 of auxiliary request 5 did not comply with the requirements of Article 76(1) EPC.

VI. The board summoned the parties to oral proceedings as per their requests.

VII. The patent proprietor withdrew its appeal, thus becoming respondent to appellant-opponents 1's and 4's appeals, and its request for oral proceedings.

VIII. Oral proceedings before the board were cancelled.

IX. The parties' requests, where relevant to the decision, were as follows.

Appellant-opponents 1 and 4 request that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent requests that opponents 1's and 4's appeals be dismissed. This implies that the opposition division's decision finding auxiliary request 5 allowable be upheld.

The only request made by opponent 2 was that the patent proprietor's appeal be dismissed. In view of the withdrawal of the patent proprietor's appeal, this request has become moot.

X. Appellant-opponent 4's and the respondent's cases relevant to the present decision are summarised in the Reasons for the Decision section below. Appellant-opponent 1's submissions do not need to be addressed as the decision is based on aspects brought forward by appellant-opponent 4.

Reasons for the Decision

Auxiliary request 5

1. Added subject-matter - Claim 1 - Article 76(1) EPC

1.1 The patent was granted on European patent application No. 18 186 675.7, which is a divisional application of

earlier application No. 14 705 884.6 (parent application).

Claim 1 of auxiliary request 5 reads as follows:

"*1. A method of making a crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2 and 11.5 ± 0.2 (Form A) and a primary particle size distribution characterized by a D90 value of from 30 µm ± 20% to 125 µm ± 20%, comprising the steps of:*

(a) suspending 4-{6-[6-(1-butoxyl-vinyl)-8-cyclopentyl-5-methyl-7-oxo-7,8-dihydropyrido[2,3-d]pyrimidin-2-ylamino]-pyridin-3-yl}-piperazine-1-carboxylic acid tertbutyl ester in a mixture of water and n-butanol and heating to about 70°C achieve dissolution [sic]*;*

(b) adding concentrated HCl and heating at about 70°C for 4-6 hours;

(c) adding anisole and aqueous sodium hydroxide to achieve a biphasic mixture having a pH of more than 10;

(d) separating the layers and heating the organic layer to about 120°C to distill off water;

(e) cooling to about 80°C and providing seed crystals of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one free base Form A;

(f) maintaining the mixture at about 80°C for about 3 hours and then gradually cooling to about 10°C to achieve crystallization; and

(g) filtering to isolate the resulting product."

In the following, a "*primary particle size distribution characterized by a D90 value*" is referred to as a D90 value.

Claim 1 of auxiliary request 5 is derived from independent claim 19 of the parent application as filed.

Independent claim 19 of the parent application as filed relates to a method of making a crystalline free base of palbociclib having a specific surface area of ≤ 2 m^2 /g comprising the steps specified in claim 1 of auxiliary request 5.

Considering the above, claim 1 of auxiliary request 5 essentially differs from independent claim 19 of the parent application as filed in that the specific surface area of ≤ 2 m^2/g contained in independent claim 19 of the parent application as filed was omitted and instead the two characteristics of a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2 and 11.5 ± 0.2 and a D90 value of from 30 µm ± 20% to 125 µm ± 20% were added into the claim.

1.2 Appellant-opponent 4 objected that the parent application as filed could not provide a basis for the palbociclib free base defined by claim 1 of auxiliary request 5. The reason was that claim 1 of auxiliary request 5 was not limited to a particular specific

surface area, contrary to independent claim 19 of the parent application as filed.

1.3 The respondent submitted that the parent application as filed disclosed palbociclib free base having a large primary particle size, not having necessarily a specific surface area of ≤ 2 m^2/g. The parent application as filed explicitly indicated or even suggested that the particular specific surface area now omitted in claim 1 of auxiliary request 5 was not an essential feature of the invention disclosed in the parent application as filed. The respondent relied on the following passages of the parent application as filed: page 2, lines 7 to 9, 14, 19, 20, 25, 33, 34 and 36; page 3, lines 1 and 12 to 21; page 5, lines 22 to 25; page 9, lines 20 to 25; page 20, lines 26 and 27; and page 43, lines 3 to 5.

1.4 The passages of the parent application as filed relied on by the respondent disclose the following (bold type added by the board):

- "*The present invention provides compound **1** free base having larger primary particle size that demonstrates improved physicochemical and manufacturability properties.*" (page 2, lines 7 to 9)

- "*The large particle size compound **1** free base disclosed herein is distinguishable by a variety of methods.*" (page 2, lines 19 and 20)

- "*In other such embodiments, the crystalline free base has a primary particle size distribution characterized by: ... **a D90 value of from about 30 µm to about 125 µm*** " (page 3, lines 15 to 18)

- "*As used herein, the term **"about"** means within a statistically meaningful range of a value, such as a stated concentration range, time frame, molecular weight, particle size, temperature or pH. Such a range can be within an order of magnitude, **typically within 20%**, more typically within 10%, and even more typically within 5% of the indicated value or range.*" (page 5, lines 22 to 25)

- "*In another aspect, the invention provides a crystalline free base of 6-acetyl-8-cyclopentyl- 5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a primary particle size distribution having at least one of:*

  (a) a D10 value of from about 5 µm to about 10 µm;

  (b) a D50 value of from about 10 µm to about 45 µm; and

  (c) a D90 value of from about 30 µm to about 125 µm." (page 9, line 20 to 25)

- "*In preferred embodiments, the crystalline free base of compound **1** is a polymorph Form A of the free base.*" (page 2, lines 33 and 34)

- "*In still other embodiments, the crystalline free base has **a PXRD pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2, and 11.5 ± 0.2.***" (page 2, line 36 to page 3, line 1)

The respondent also relied on example 7 of the parent application as filed and argued that this example was directed to the "preparation of the large particle size" of palbociclib free base which was isolated as

polymorph form A (page 42, lines 1 and 2, and page 43, lines 3 to 5).

The board acknowledges that the above passages relied on by the respondent disclose a crystalline free base of palbociclib (page 2, lines 33 and 34), a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0 ± 0.2, 10.1 ± 0.2 and 11.5 ± 0.2 (page 2, line 36 to page 3, line 1), and a primary particle size distribution characterised by a D90 value of from 30 µm ± 20% to 125 µm ± 20% (page 3, lines 15 to 18 in combination with page 5, lines 22 to 25), i.e. the features characterising the palbociclib free base in claim 1 of auxiliary request 5.

However, contrary to the respondent's submissions, the above passages of the parent application as filed do not directly and unambiguously disclose that the specific surface area of ≤ 2 m^2/g disclosed in independent claim 19 of the parent application as filed can be omitted in the characterisation of Form A of the free base of palbociclib.

On the contrary, the parent application as filed discloses that the specific surface area of ≤ 2 m^2/g is an essential feature of the invention disclosed in the parent application as filed. As submitted by appellant-opponent 4, the independent claims of the parent application as filed (claims 1, 15 to 20) all require a specific surface area of ≤ 2 m^2/g, either directly or by reference to another independent claim. Furthermore, in the summary of the invention on page 2, lines 29 to 32, the parent application as filed refers, in a first broad aspect, to a crystalline free base of palbociclib having a specific surface area of ≤ 2 m^2/g.

Therefore, it is clear to the skilled person that the passages of the parent application as filed relied on by the respondent refer to embodiments all having this specific surface area. These passages therefore disclose features characterising the crystalline free base of palbociclib in addition to the specific surface area of ≤ 2 m^2/g.

Finally, example 7 of the parent application as filed provides, *inter alia*, the following analysis of Form A of the free base of palbociclib: powder X-ray diffraction analysis (page 43, line 7), particle size analysis (page 44, line 8) and specific surface area measurement. Thus, in example 7, the primary particle size, the powder X-ray diffraction and the specific surface area are inextricably linked. Therefore, example 7 of the parent application as filed does not disclose that Form A of the free base of palbociclib can be characterised without referring to the specific surface area. Consequently, it cannot be concluded that example 7 shows that the specific surface area is not an essential feature of the invention disclosed in the parent application as filed.

The parent application as filed thus comprises no teaching that the specific surface area referred to in independent claim 19 of the parent application as filed is not an essential feature of the invention disclosed which can be omitted to characterise Form A of the free base of palbociclib.

1.5 As submitted by appellant-opponent 4 and not disputed by the respondent, Form A of the free base of palbociclib having a D90 value of from 30 µm ± 20% to 125 µm ± 20% as required by claim 1 of auxiliary request 5 covers products having a specific surface area of larger than 2 m^2/g. In view of what has been

set out above, these embodiments are not based on the parent application as filed.

1.6 Therefore, the board concludes that the omission of the specific surface area of ≤ 2 m^2/g in claim 1 of auxiliary request 5 adds subject-matter beyond the content of the parent application as filed.

1.7 This conclusion is not in contradiction with the decision of the Court of Appeal of the Unified Patent Court UPC_CoA_382/2024.

In that case, independent claim 1 of the patent related to an on-body glucose monitoring device comprising a sensor assembly and an enclosure with an electronics assembly (sensor electronics) (point 2 of the Grounds for the Order). The point of dispute was whether the omission of an elastomeric sealing member for sealing the coupling between the sensor assembly and the electronics assembly in the wording of this independent claim added subject-matter (point 70 and subsequent points of the Grounds for the Order).

The Court of Appeal held that to ascertain whether there was added subject-matter, it had to first determine what the skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed, where implicitly disclosed subject-matter, i.e. matter that is a clear and unambiguous consequence of what is explicitly mentioned, must also be considered part of its content (point 52 of the Grounds for the Order). The Court of Appeal thus used the same test as applied by the EPO as its gold standard (see also G 2/10, OJ EPO 2012, 376).

In the case before it, the Court of Appeal came to the conclusion that it was clear from the description as filed that sealing was important to ensure that the contacts on the claimed sensor assembly and the contacts on the electronics assembly were protected from moisture and other contaminants and thus to prevent a short (point 72 of the Grounds for the Order). The Court of Appeal pointed out that the application as filed disclosed various ways to achieve this sealing (points 73 and 74 of the Grounds for the Order). The Court of Appeal concluded that even though a need for sealing was described in the application as filed, there was no described advantage or function of the use of the specific elastomeric material now omitted from the claim, other than that it provided sealing. Therefore, the skilled person understood from the application as filed that the exact method of sealing did not contribute to, and was thus not relevant for, the technical teaching of the invention as disclosed in the application as filed (point 75 of the Grounds for the Order). The omission of the use of an elastomeric sealing member from claim 1 of the patent did therefore not extend beyond the content of the application as filed (point 80 of the Grounds for the Order).

Hence, on the basis of the facts underlying the case before it, the Court of Appeal concluded that based on the application as filed, the skilled person would not have understood the omitted feature to be relevant for the technical teaching of the invention. This is different from the factual situation in the case at hand where, as set out above, the board has arrived at the conclusion that the skilled person would have considered the omitted surface area to be essential to the invention. Therefore, the fact that the Court of

Appeal acknowledged that the feature in question could be omitted without extending beyond the content of the application as filed while the board in the current case came to the opposite conclusion is based on different factual situations in the two cases rather than on a difference in legal considerations. In fact, as stated above, both the Court of Appeal and the board in this case, and the EPO in general, use the same principle in judging whether an amendment extends beyond the content of the application as filed.

2. The respondent's only request, i.e. auxiliary request 5, is thus not allowable. Therefore, the patent is to be revoked.

3. When the patent proprietor withdrew its appeal, the board had already summoned the parties to oral proceedings, but it had not yet issued its communication under Article 15(1) RPBA in preparation for the oral proceedings, drawing attention to matters that may be of significance for the decision to be taken. The withdrawal of the appeal by the patent proprietor thus occurred before expiry of the time limit prescribed in Rule 103(3)(a) EPC. Accordingly, the patent proprietor's appeal fee is to be reimbursed at 50%.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

3. The patent proprietor's appeal fee is to be reimbursed at 50%.

The Registrar: The Chairman:

U. Bultmann M. O. Müller

Decision electronically authenticated