

Internal distribution code:

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

**Datasheet for the decision
of 5 June 2023**

Case Number: T 0016/20 - 3.3.02

Application Number: 09751439.2

Publication Number: 2300455

IPC: C07D401/10, C07D487/04,
C07D253/07, A61K31/53,
A61P35/00

Language of the proceedings: EN

Title of invention:

SALTS OF 2-FLUORO-N-METHYL-4-[7-(QUINOLIN-6-YL-METHYL)-
IMIDAZO[1,2-B][1,2,4]TRIAZIN-2-YL]BENZAMIDE AND PROCESSES
RELATED TO PREPARING THE SAME

Patent Proprietor:

Incyte Holdings Corporation

Opponent:

Generics (U.K.) Limited

Headword:

Capmatinib/Incyte Holdings Corporation

Relevant legal provisions:

EPC Art. 54, 54(3), 56
RPBA 2020 Art. 13(1), 13(2)

Keyword:

Enabling disclosure (no)

Novelty - (yes)

Inventive step - (yes)

Late-filed objection

Decisions cited:

T 0206/83



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 0016/20 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 5 June 2023

Appellant: Generics (U.K.) Limited
(Opponent) Building 4, Trident Place
Mosquito Way
Hatfield Herts AL 10 9UL (GB)

Representative: Ter Meer Steinmeister & Partner
Patentanwälte mbB
Nymphenburger Straße 4
80335 München (DE)

Respondent: Incyte Holdings Corporation
(Patent Proprietor) 1801 Augustine Cut-Off
Wilmington, DE 19803 (US)

Representative: Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 15 October 2019
rejecting the opposition filed against European
patent No. 2300455 pursuant to
Article 101(2) EPC**

Composition of the Board:

Chairwoman M. Blasi
Members: P. O'Sullivan
A. Lenzen

Summary of Facts and Submissions

- I. The appeal of the opponent (hereinafter appellant) lies from the decision of the opposition division according to which the opposition against European patent 2 300 455 was rejected.
- II. The following documents *inter alia* were submitted by the parties in opposition proceedings:
- D1: CL2007003341
D1a: WO 2008/064157 A1
D1b: Published abstract ("3341-07") of D1 in the "*Diario Oficial de la Republica de Chile*", 18 April 2008.
D9: Affidavit of Andres Melossi dated 7 December 2018.
- III. With its statement of grounds of appeal the appellant submitted that the grounds for opposition under Article 100(a) EPC in combination with Articles 54 and 56 EPC prejudiced maintenance of the patent as granted.
- IV. In its reply, the patent proprietor (respondent) *inter alia* contested the prior art status of D1.
- V. In preparation for oral proceedings, scheduled according to the parties' requests, the board issued a communication pursuant to Article 15(1) RPBA 2020. Therein, the board *inter alia* expressed the preliminary view that example 7 of D1 did not form part of the state of the art to be taken into account for the assessment of novelty and inventive step (point 2.9).

VI. With a letter filed in response to the board's communication, the appellant submitted the following document:

D13: US 2008/0039457 A1

VII. Oral proceedings by videoconference before the board took place as scheduled on 5 June 2023 in the presence of both parties.

VIII. Requests

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

The respondent requested that the appeal be dismissed (main request), implying that the patent be maintained as granted, or, in the alternative, that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1 to 4 submitted with the reply to the statement of grounds of appeal.

The respondent also requested:

- that D13 and the submissions based thereon not be admitted into the proceedings,
- that the appellant's submissions based on D9 and a priority document of D1, made for the first time at the oral proceedings before the board, not be admitted into the proceedings, and
- that objections based on D1a not be admitted into the proceedings.

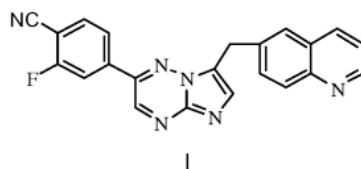
IX. The patent is concerned with dihydrochloric acid and dibenzenesulfonic acid salts of the kinase inhibitor 2-fluoro-N-methyl-4-[7-(quinolin-6-ylmethyl)imidazo[1,2-b][1,2,4]triazin-2-yl]benzamide

(hereinafter "capmatinib"). The patent includes the following independent claims:

"1. A salt which is [capmatinib] dihydrochloric acid salt, or a hydrate or solvate thereof.

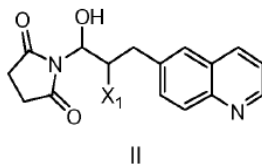
6. A salt which is [capmatinib] dibenzenesulfonic acid salt, or a hydrate or solvate thereof.

15. A process of preparing a compound of Formula I:

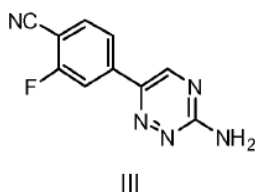


or salt thereof;

comprising reacting a compound of Formula II:



with a compound of Formula III:



to form a compound of Formula I, or salt thereof; wherein X_1 is chloro, bromo, or iodo."

X. For the parties' submissions relevant to the present decision, reference is made to the reasons for the decision provided below.

Reasons for the Decision

Main request (patent as granted) - Novelty and Inventive step -
Article 100(a) and Articles 54 and 56 EPC

1. Background

The patent in suit was filed on 20 May 2009 and claims the priority date of 21 May 2008. As set out above, claim 1 is directed to capmatinib dihydrochloric acid salt, claim 6 is directed to capmatinib dibenzenesulfonic acid salt, and claim 15 is a process claim.

The appellant submitted that the subject-matter of claim 1 lacked novelty and inventive step over example 7 of D1. Furthermore, the subject-matter of claim 6 and 15 lacked inventive step over D1.

Example 7 of D1 discloses the preparation of capmatinib (final structure on page 47) in free base form ("la base libre", page 51, line 5), and in the form of its monohydrochloric acid salt ("la sal de ácido clorhídrico", page 51, line 6).

2. Status of D1 as prior art under Article 54(2) EPC

2.1 The prior art status of D1 was a matter of dispute between the parties. The opposition division had held that at least those pages of D1 with a date stamp of November 2007 were state of the art within the meaning of Article 54(2) EPC. While the appellant endorsed this finding, the respondent argued that D1 should be disregarded as a whole.

- 2.2 D1 is a (Spanish language) Chilean patent application. According to the second page of D1 (left hand side, "(43) Fecha de Publicación"), the Chilean patent application was published on 18 April 2008, i.e. prior to the priority date of the patent.
- 2.3 The respondent submitted, however, that D1 could not be what was available to the public prior to the priority date of the patent.
- 2.4 As noted by the respondent and not disputed by the appellant, over a quarter of the pages of D1 are date-stamped (lower right hand corner) with dates later than the publication date of the Chilean patent application and later than the priority date of the patent, respectively (e.g. pages 30,31,43,54: 25 March 2013; page 52: 12 August 2011; page 57, 21 October 2010), while on other pages, the date stamp is illegible (e.g. pages 47 and 48).
- 2.5 The respondent argued that even if the publication date relating to the original Chilean patent application CL200703341 featured on page 2 of D1 (i.e. 18 April 2008) were assumed to be correct, the entirety of the document D1 cited in these proceedings, by virtue of the pages date-stamped later than the date on which the Chilean patent application had been filed, could not be a copy of what was available to the public prior to the priority date of the contested patent (i.e. the originally filed Chilean application CL200703341). D1 as a whole was hence defective, and did not unambiguously demonstrate what was available to the public before the priority date of the patent.

2.6 In the view of the board, it must be assumed that D1 in its entirety, by virtue of the pages depicting a later date stamp, is not a true copy of the Chilean application CL200703341 as made available to the public on the alleged publication date. However, there is no reason to question the legitimacy of D1 and the public availability of its content as state of the art pursuant to Article 54(2) EPC insofar as the pages thereof having a legible date stamp before the priority date of the contested patent are concerned, namely those pages legibly stamped in the bottom right hand corner with the date "22 Nov 2007".

2.7 On the other hand, the board does not consider any of the pages with a later date stamp of October 2010, August 2011 or March 2013 to form part of the state of the art under Article 54(2) EPC, since they were not part of the original application document made available to the public on 18 April 2008. Similarly, it cannot unambiguously be determined whether the pages having an illegible date stamp were part of the original application documents as made publicly available, such that these pages also cannot be considered part of the state of the art.

3. Example 7 of D1 - Enabling disclosure

3.1 The appellant's novelty and inventive step objections are solely based on example 7 of D1, which spans pages 47 to 51 of D1, and comprises 11 synthetic steps. As noted by the respondent and not disputed by the appellant, the date stamp is not legible on at least pages 47 and 48 of this example. Hence, as set out above, pages 47 and 48 of D1 are not considered part of the state of the art pursuant to Article 54(2) EPC.

- 3.2 Consequently, example 7 of D1 is incomplete, and comprises only pages 49, 50 and 51. These pages do not provide the skilled person with enough information to obtain capmatinib and its hydrochloride salt. More specifically, page 49 of D1 begins with step 5, which requires as starting material the compound "1-(4-bromo-3-fluorofenil)-2,2-dietoxietanona" (1-(4-bromo-3-fluorophenyl)-2,2-diethoxyethanone). In the absence of any evidence to the contrary, the preparation of this compound cannot be considered part of the common general knowledge of the skilled person. Unable to prepare this compound, the skilled person is also not enabled to carry out step 5 on page 49 of D1, and by the same token, any of the subsequent steps 6 to 11. Hence, D1 itself does not represent an enabling disclosure of capmatinib or its dihydrochloric acid salt, ultimately prepared according to step 11 of example 7.
- 3.3 It was uncontested by the appellant that if example 7 of D1 were not enabling for the skilled person, then D1 could not be considered as state of the art under Article 54(2) EPC insofar as the products of example 7 were concerned.
- 3.4 In its submissions the appellant argued, however, that the disclosure on pages 49, 50 and 51 relating to example 7 of D1 enabled the skilled person to prepare capmatinib and its hydrochloride salt on the basis of the information provided by
- patent document D13, and
 - affidavit D9 in combination with priority application US 60/957,236 of D1.

Each of these approaches are addressed in turn in the following.

3.5 Patent document D13

- 3.5.1 Document D13 was filed together with the appellant's letter replying to the board's communication pursuant to Article 15(1) RPBA 2020. The respondent requested that D13, and the submissions based thereon, not be admitted into the proceedings.

Admittance was to be decided upon pursuant to Article 13(2) RPBA 2020, applicable according to Articles 24 and 25 RPBA. Pursuant to Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The board decided to admit D13 together with the related submissions into the proceedings. It regarded the appellant's letter, submitted as a prompt reply to the board's communication pursuant to Article 15(1) RPBA 2020, as the appellant's fair attempt to address the board's point that it had serious doubts whether the pages stamped 22 November 2007 of example 7 provided the skilled person with enough information to obtain capmatinib and its hydrochloride salt. This point related to the issue of enablement of the prior art disclosure which had first been raised by the board in its communication. Raising this new issue was acknowledged by the board as the presence of exceptional circumstances.

- 3.5.2 D13 was published on 14 February 2008 and hence was public before the priority date of the contested patent.
- 3.5.3 In example 74 (paragraphs [0416] - [0419]; steps 1 to 4), D13 discloses the preparation of 1-(4-bromo-3-fluorophenyl)-2,2-diethoxyethanone, i.e. the starting material of step 5 on page 49 of D1.
- 3.5.4 The appellant argued that in view of D13, the preparation of 1-(4-bromo-3-fluorophenyl)-2,2-diethoxyethanone was known to the skilled person before the priority date of the patent. Hence, example 7 of D1 was an enabling disclosure.
- 3.5.5 The board disagrees. As argued by the respondent during oral proceedings, D13 is a patent document, which according to established case law, in particular T 206/83 (OJ EPO 1987, 5), does not form part of the common general knowledge of the skilled person.
- 3.5.6 In this regard the appellant submitted that decision T 206/83 (*supra*, Reasons 6) only set out that patent specifications were "not normally" part of the common general knowledge. In the present case, this did not apply to D13.
- 3.5.7 The appellant however did not explain why D13 would represent an exception to the normal situation set out in decision T 206/83. Hence, this argument must fail.

3.6 Affidavit D9 in combination with priority application US 60/957,236 of D1 - Admittance

3.6.1 In a second line of argumentation submitted for the first time during oral proceedings before the board, the appellant referred to D9 in combination with a priority application of D1.

D9 is an affidavit of a Chilean attorney. Point 3 thereof reads as follows:

"On April 18, 2008, Chilean Patent Application 200703341 was published in the Official Gazette. The publication makes the application, including the entire file with all the documents thereof, plenty available and accessible to the public in full length."

3.6.2 Based on this statement, the appellant argued that "the entire file with all the documents thereof" included the three priority application documents of D1 mentioned on page 2 thereof. Of these, priority application US 60/957,236 dated 22 August 2007 comprised example 7 of D1 in full. Since according to D9 the skilled person would have had access to this priority document on the publication date of D1, the information required to prepare example 7 of D1 was available as of that date. This conclusion should be drawn considering the principle of free evaluation of evidence and on the balance of probabilities. Hence, example 7 of D1 was enabling for the skilled person.

3.6.3 The respondent argued that the appellant's submission based on D9 represented an amendment to the appellant's case. It was presented very late and without exceptional circumstances. Hence, it was not to be admitted pursuant to Article 13(2) RPBA 2020. The

submissions relating to the content of the priority application could not be verified since the priority document was neither submitted nor on file.

- 3.6.4 The issue of admittance is governed by Article 13(2) RPBA 2020. Under this provision (see above for the wording), the board has discretion over the admittance of an amendment to a party's appeal case even if exceptional circumstances are present. Therefore, the criteria mentioned in Article 13(1) RPBA 2020 may also be taken into account in the context of Article 13(2) RPBA 2020.
- 3.6.5 The board's considerations were as follows. Even assuming in the appellant's favour that submissions based on D9 were justified as a reaction to the board's communication pursuant to Article 15(1) RPBA 2020 (in particular that example 7 of D1 might be considered as not enabling), there was no justification for making these submissions during oral proceedings before the board. Rather, said submissions could and should have been submitted in written proceedings, e.g. together with the appellant's letter filed in reply to the board's communication with which D13 was submitted. There were no exceptional circumstances at this late state of the proceedings, and indeed none were submitted by the appellant, justifying the admittance of said submission on the day of oral proceedings.
- 3.6.6 In the present situation, as noted by the respondent, it could not be concluded with sufficient degree of certainty on the basis of the statement in D9 that "the entire file with all the documents thereof" included also the priority documents, including the specific one of US 60/957,236, as alleged by the appellant.

3.6.7 Furthermore, the priority application US 60/957,236 was neither submitted by the appellant, nor was it on file in the present case. Hence its disclosure could not be verified at the oral proceedings and what it actually disclosed was a mere assertion, contested by the other party.

3.6.8 Therefore, the admittance of the new submissions based on D9 would have raised complex new issues for the first time and hence would have been detrimental to procedural economy.

3.6.9 Consequently, the board decided pursuant to Article 13(2) RPBA 2020 not to admit the appellant's submissions based on D9 and the priority application US 60/957,236 of D1 into the proceedings.

3.7 In view of the foregoing, example 7 of D1 does not represent an enabling disclosure insofar as capmatinib free base or the monohydrochloric acid salt thereof are concerned. Hence, it does not form part of the state of the art to be taken into account for the assessment of novelty and inventive step.

4. Admittance - Novelty objection based on D1a

4.1 During oral proceedings and after the board announced that D1 did not represent an enabling disclosure insofar as the product of example 7 was concerned, the appellant submitted that D1a had entered the European phase. It was a document pursuant to Article 54(3) EPC D1a and was relevant for the novelty of the subject-matter claimed in the patent, more specifically pursuant to Article 54(3) EPC for claim 1 and pursuant to Article 54(2) EPC for the process claims. D1a

comprised an example corresponding to example 7 of D1 in its entirety (pages 42 - 45).

- 4.2 The respondent requested that objections based on D1a not be admitted into the proceedings.
- 4.3 The appellant acknowledged that no explicit novelty objection based on D1a had been formulated in written appeal proceedings. However, the appellant's reliance on D1a as relevant for novelty could not come as a surprise, since it had been referred to in the statement of grounds of appeal (page 2, point 2, first paragraph), and in the respondent's reply (point 3.2). Hence an objection based on D1a had been implicit in the appellant's submissions from the outset of the appeal proceedings.
- 4.4 The board disagrees. As stated by the respondent, the appellant's reference to D1a in the statement of grounds of appeal cannot be understood as more than a mere passing reference. Specifically, point 2 of the grounds of appeal is entitled "D1 is Prior Art Under Article 54(2) EPC". D1a is cited merely as being a family member of D1 which is cited in the opposed patent, and was published after the priority date of the patent. There is however no explicit nor implicit indication that D1a entered the European phase, nor that it should form the basis for a separate novelty objection under Article 54(3) EPC to that formulated with regard to D1, let alone a separate objection for the process claims. Furthermore, even though D1a is mentioned in passing in the respondent's reply in a passage related to novelty (paragraph 3.2), it is clear from paragraphs 3.1 and 3.14, which refer only to D1, that the respondent had not understood the appellant's novelty objections to extend to D1a.

4.4.1 Hence objections starting from D1a were not part of the appellant's statement of grounds of appeal and therefore did not form part of the appellant's appeal case within the meaning of Article 12(3) RPBA 2020.

4.5 The objection based on D1a submitted for the first time at oral proceedings before the board was therefore an amendment to the appellant's appeal case, and hence the board had discretion as to its admittance into the proceedings under Article 13(2) RPBA 2020 (see above for the wording).

4.6 Since no exceptional circumstances justifying the submissions relating to a new objection based on D1a during oral proceedings were provided by the appellant and none were apparent to the board, the board decided not to admit the objection based on D1a into the proceedings.

5. Conclusions

5.1 As set out above, the grounds for opposition under Article 100(a) EPC relied upon by the appellant are solely based on example 7 of D1.

5.2 Since the board concluded that D1 does not represent an enabling disclosure insofar as the product of example 7 is concerned, it follows that this example cannot be invoked in an objection of lack of novelty or inventive step against that subject-matter claimed in the patent.

Hence, it must be concluded that the grounds for opposition under Article 100(a) EPC in combination with Articles 54 and 56 EPC do not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



M. Schalow

M. Blasi

Decision electronically authenticated