Internal distribution code:

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

Datasheet for the decision of 16 December 2025

Case Number: T 1919/23 - 3.3.02

Application Number: 19214275.0

Publication Number: 3656765

IPC: C07D275/06, C07D291/06, C07C215/54, A61K31/137, C07D239/545, C07C59/255

Language of the proceedings: EN

Title of invention:

SALTS OR CO-CRYSTALS OF 3-(3-DIMETHYLAMINO-1-ETHYL-2-METHYL-PROPYL)-PHENOL

Patent Proprietor:

Grünenthal GmbH

Opponents:

G. L. Pharma GmbH
Kraus & Lederer PartGmbB
Insud Pharma SL
MSN Laboratories Pvt Limited
Pajaro Limited
Hamm&Wittkopp Patentanwälte PartmbB

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54

Keyword:
Grounds for opposition - Novelty
Implicit disclosure

Decisions cited:
T 0095/97, T 0270/97, T 0583/01, T 0051/10, T 1170/19, G 0003/89, G 0011/91, G 0002/10

Catchword:

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 1919/23 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 16 December 2025

Appellant: (Patent Proprietor)	Grünenthal GmbH Zieglerstrasse 6 52078 Aachen (DE)
Representative:	Kutzenberger Wolff & Partner Waidmarkt 11 50676 Köln (DE)
Respondent: (Opponent 1)	G. L. Pharma GmbH Schlossplatz 1 8502 Lannach (AT)
Representative:	SONN Patentanwälte GmbH & Co KG Riemergasse 14 1010 Wien (AT)
Respondent: (Opponent 2)	Kraus & Lederer PartGmbB Thomas-Wimmer-Ring 15 80539 München (DE)
Representative:	Kraus & Lederer PartGmbB Thomas-Wimmer-Ring 15 80539 München (DE)
Respondent: (Opponent 3)	Insud Pharma SL C/Manuel Pombo Angulo 28, 3rd Floor 28050 Madrid (ES)
Representative:	Aera A/S Niels Hemmingsens Gade 10, 5th Floor 1153 Copenhagen K (DK)
Respondent:	MSN Laboratories Pvt Limited MSN R&D Center Plot No- 12, Industrial Park, Phase-IV Sy.No. 119 to 140, 258, 275 to 280

(Opponent 4)	Pashamylaram (V), Patancheru (M), Medak (D) 502 307 Telangana (IN)
Respondent: (Opponent 5)	Pajaro Limited 12 New Fetter Lane London EC4A 1JP (GB)
Representative:	Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)
Respondent: (Opponent 6)	Hamm&Wittkopp Patentanwälte PartmbB Jungfernstieg 38 20354 Hamburg (DE)
Representative:	Hamm&Wittkopp Patentanwälte PartmbB Jungfernstieg 38 20354 Hamburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 October 2023 revoking European patent No. 3656765 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	S. Bertrand
	B. Burm-Herregodts

Summary of Facts and Submissions

I. The appeal by the patent proprietor ("the appellant") is against the decision of the opposition division revoking European patent No. 3 656 765.

II. The patent was opposed by six opponents under Article 100(a) EPC (for lack of novelty and inventive step) and Article 100(b) and (c) EPC.

Opponents 1 to 3, 5 and 6 withdrew their oppositions prior to the oral proceedings before the opposition division.

III. The patent relates to a salt or cocrystal of tapentadol and L-(+)-tartaric acid for use as a medicament in the treatment of pain.

IV. The following documents are referred to in the present decision.

D1	WO 2006/002886 A1
D2	Rowe, Sheskey and Quinn, "Handbook of Pharmaceutical Excipients", 6th edition, Pharmaceutical Press, 2009, pages 732 to 733
D3	"European Pharmacopoeia", 7th edition, Council of Europe, 15 July 2010, page 3 038
D4	Stahl and Wermuth, "Handbook of Pharmaceutical Salts: Properties, Selection and Use", Verlag Helvetica Chimica Acta, 2002, chapter 12
D28	US 2003/0166701 A1
D29	US 2005/0148591 A1

D32 WO 00/03740 A2
D33 GB 922 214 A
D34 EP 1 254 662 A2
D37 WO 00/55131 A1
D38 WO 2005/075454 A2

V. In the impugned decision, the opposition division held, *inter alia*, that:

- the subject-matter of claim 1 of the main request was novel in view of D1, but
- the subject-matter of claim 1 of the main request did not involve an inventive step.

VI. In its statement of grounds of appeal, the appellant contested the decision of the opposition division.

VII. In its reply to the grounds of appeal, opponent 4 ("the respondent") contested the appellant's submissions and concurred with the conclusions of the opposition division.

VIII. The board summoned the parties to oral proceedings as per their requests and issued a communication under Article 15(1) RPBA.

IX. Oral proceedings before the board were held by videoconference on 16 December 2025, with both parties present.

X. The parties' requests were as follows.

The appellant requested that the appealed decision be set aside and that the patent be maintained as granted.

The respondent requested that the appeal be dismissed, implying that the decision of the opposition division revoking the patent be upheld.

XI. The parties' submissions, insofar as they are relevant to the present decision, are summarised below.

Reasons for the Decision

Main request

1. Novelty - claim 1 - Articles 100(a) and 54 EPC

1.1 Claim 1 of the main request reads as follows:

"*1. A salt or cocrystal of*

(a) (1R,2R)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl)-phenol, and
(b1) L-(+)-tartaric acid"

In the following, compound (a) is referred to as "tapentadol".

1.2 The respondent submitted that claim 1 of the main request lacks novelty in view of D1.

1.3 Claim 1 of D1 (page 36) discloses pharmaceutically acceptable salts of tapentadol. As a possible salt former, D1 mentions tartaric acid (claim 2 of D1; "Weinsäure").

1.4 D1 does not explicitly disclose whether the tartaric acid disclosed in this document is in the L-(+) or D-(-) form.

In view of D2 to D4, which represent common general knowledge, the skilled person would understand that, in the pharmaceutical field, tartaric acid invariably refers to the L-(+)-enantiomer.

More specifically, D2 is a handbook of pharmaceutical excipients and on page 731 thereof, it lists the following synonyms for tartaric acid: acidum tartaricum, L-(+)-2,3-dihydroxybutanedioic acid, (2R, 3R)-2,3-dihydroxybutane-1,4-dioic acid, 2,3-dihydroxysuccinic acid, E334, d-tartaric acid and L-(+)-tartaric acid. All the stereochemically defined entries in this list correspond to the L-(+)-form; this has not been contested by the appellant. Neither the D-(−)-enantiomer nor the meso form nor the racemic (D,L) form is mentioned. D2 therefore equates the term "tartaric acid" with L-(+)-tartaric acid.

D3 is an extract from the European Pharmacopoeia 7.0, which defines "tartaric acid" as (2R,3R)-2,3-dihydroxybutanedioic acid, i.e. L-(+)-tartaric acid. No other stereoisomeric form is disclosed in D3.

D4, a handbook of pharmaceutical salts, discloses L-(+)-tartaric acid and explicitly states (on page 308) that "*(+)-L-tartaric acid is the acid of choice*. The *other 2,3-dihydroxybutanedioic acids ((-)-D-tartaric acid, DL-tartaric acid (=racemic acid), meso-tartaric acid) are not used pharmaceutically*." D4 thus confirms that L-(+)-tartaric acid is the only stereoisomeric form used in the pharmaceutical field, which is the technical field of D1.

1.5 During the oral proceedings before the board, the appellant relied on documents D28, D29, D32, D33, D34, D37 and D38 and argued that, in the pharmaceutical field, the term "tartaric acid" did not inevitably denote L-(+)-tartaric acid. On this basis, the appellant submitted that novelty over D1 should be acknowledged.

The board is not persuaded by this line of argument, however.

Documents D28, D29, D32, D33, D34, D37 and D38 are all patent documents in the pharmaceutical field.

D28 discloses pharmaceutical compositions comprising tartrate salts (claim 1), wherein the tartrate may be in the L-(+)-, D-(−)-, racemic (D,L)- or meso-tartrate form (paragraph [0118]).

D29 discloses pharmaceutical compositions comprising L-(+)-tartrate salts (claim 1), while also indicating that D-(−)-, racemic (D,L)- or meso-tartrate salts may alternatively be used (paragraph [0115]).

D32 (claim 4), D33 (claim 10), D34 (claim 4) and D37 (claim 1) disclose pharmaceutical compositions comprising D-(−)-tartrate salts.

D38 discloses a pharmaceutical tartrate salt (claim 1), which may be either a D-(−)-tartrate or an L-(+)-tartrate.

The board acknowledges that these documents demonstrate that, in patent literature, various stereoisomeric forms of tartrate may be used in the pharmaceutical field. However, these documents do not call into question the common general knowledge established by D2 to D4, according to which, in the absence of any explicit indication to the contrary, the term "tartaric acid" is understood to denote L-(+)-tartaric acid.

Accordingly, where a deviation from this convention is intended, such as the use of the D-(−)-enantiomer, the meso form or the racemate, this deviation is explicitly specified. Since D1 contains no such specification, the

skilled person would understand the term "tartaric acid" in D1 as referring to L-(+)-tartaric acid.

1.6 The appellant further relied on T 95/97, T 270/97, T 583/01, T 51/10 and T 1170/19. It submitted that document D1 did not implicitly disclose the L-(+)-enantiomer of tartaric acid, in accordance with the principles set out in these decisions.

The board does not find the appellant's submissions persuasive, however.

These decisions are cited in section I.C.4.3 of the Case Law of the Boards of Appeal, 11th edition, 2025. It is stated therein that an alleged disclosure can only be regarded as implicit if it is immediately apparent to the skilled person that nothing other than the alleged implicit feature forms part of the subject-matter disclosed (T 95/97 and T 51/10). Furthermore, as also set out in the section referred to above, the assessment of novelty is a matter of inevitability rather than probability (T 270/97, T 583/01 and T 1170/19).

The board fully agrees with the principles set out in these decisions. In fact, for the reasons set out above, in the present case, the conclusion that the tartaric acid disclosed in D1 is implicitly L-(+)-tartaric acid is in line with these principles. More specifically, it is unequivocally derivable from D1 in light of common general knowledge (D2 to D4), and it is immediately apparent to the skilled person, that nothing other than L-(+)-tartaric acid forms part of the subject-matter disclosed in D1. The tartaric acid disclosed in D1 is therefore inevitably L-(+)-tartaric acid.

1.7 The appellant further submitted that replacing tartaric acid ("Weinsäure") with L-(+)-tartaric acid ("L-(+)-Weinsäure") in claim 2 of D1 would not comply with Article 123(2) EPC, since such an amendment would result in subject-matter not directly and unambiguously derivable from the application as filed of D1. In view of the conceptual similarity between the assessment of novelty vis-à-vis the prior art and that of added subject-matter, the disclosure of D1 could not prejudice the novelty of the subject-matter of claim 1 of the main request.

The board is not convinced by the appellant's submission, however.

According to the "gold standard" established in G 2/10 (OJ EPO 2012, 376), compliance with Article 123(2) EPC requires that any amendment to the disclosure of a European patent application or patent (i.e. the description, claims and drawings) may only be made within the limits of what the skilled person would derive directly and unambiguously, **using common general knowledge**, and seen objectively and relative to the filing date, from the application as filed as a whole (see also G 3/89, OJ EPO 1993, 117; G 11/91, OJ EPO 1993, 125). After the amendment, the skilled person must not be presented with new technical information.

The board acknowledges that the same standard applies when examining novelty. Hence, a claimed subject-matter lacks novelty over a prior-art document if this claimed subject-matter is directly and unambiguously disclosed in that prior-art document, taking the skilled person's common general knowledge into account.

In the present case, the skilled person would directly and unambiguously derive from claim 2 of D1, in light of common general knowledge (D2 to D4), that tartaric acid ("Weinsäure") in this claim of D1 refers to L-(+)-tartaric acid ("L-(+)-Weinsäure") in the pharmaceutical field. Consequently, contrary to the appellant's assertion, amending claim 2 of D1 to explicitly specify L-(+)-tartaric acid would not be regarded as adding subject-matter if this amendment were examined under Article 123(2) EPC.

1.8 It follows that the subject-matter of claim 1 of the main request lacks novelty over D1. The ground for opposition under Article 100(a) EPC in combination with Article 54 EPC prejudices the maintenance of the patent as granted.

2. Since the main request is the sole claim request on file, the appeal must be dismissed.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

U. Bultmann M. O. Müller

Decision electronically authenticated