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Datasheet for the decision of 25 February 2026

Case Number: T 0388/24 - 3.3.02

Application Number: 18721975.3

Publication Number: 3615518

IPC: C07D295/06

Language of the proceedings: EN

Title of invention:
PROCESS FOR THE MANUFACTURE OF VORTIOXETINE HBR ALPHA-FORM

Patent Proprietor:
H. Lundbeck A/S

Opponent:
Generics [UK] Limited

Headword:

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
Grounds for opposition - insufficiency of disclosure

Decisions cited:

Catchword:

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Case Number: T 0388/24 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 25 February 2026

Appellant: (Opponent)	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)
Respondent: (Patent Proprietor)	H. Lundbeck A/S Ottiliavej 9 2500 Valby (DK)
Representative:	Potter Clarkson Chapel Quarter Mount Street Nottingham NG1 6HQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 10 January 2024 rejecting the opposition filed against European patent No. 3615518 pursuant to Article 101(2) EPC.**

Composition of the Board:

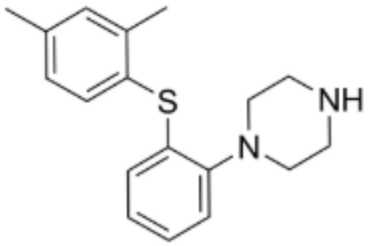
Chairman	M. O. Müller
Members:	S. Bertrand
	L. Bühler

Summary of Facts and Submissions

I. The appeal by the opponent ("appellant") is against the opposition division's decision to reject the opposition filed against European patent No. 3 615 518.

II. The patent relates to a process for manufacturing crystalline vortioxetine HBr α-form.

Vortioxetine has the following formula:



Vortioxetine is used for treating severe depression and generalised anxiety.

The term "α-form", as mentioned in the following, refers to crystalline vortioxetine HBr α-form.

III. In the impugned decision, the opposition division's conclusions included that the claims of the main request met the requirements of Article 83 EPC.

IV. In its statement of grounds of appeal and subsequent letters, the appellant contested the opposition division's decision. It submitted that the patent was not sufficiently disclosed and that this ground for opposition prejudiced the maintenance of the patent as granted.

V. In its reply to the grounds of appeal, the patent proprietor ("respondent") contested the appellant's submissions.

VI. The board summoned the parties to oral proceedings in accordance with their requests and issued a communication pursuant to Article 15(1) RPBA.

VII. Oral proceedings before the board were held by videoconference on 25 February 2026 with both parties present.

VIII. The parties' requests relevant to the present decision were as follows.

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

The respondent requested that the appeal be dismissed and the opposition division's decision to maintain the patent as granted be upheld, or, alternatively, that the patent be maintained in amended form according to one of auxiliary requests 1 to 8 filed with the letter dated 24 January 2023 before the opposition division.

Reasons for the Decision

Main request (patent as granted)

1. The appellant's only objection against the main request on appeal relied on lack of sufficiency of disclosure.

2. Sufficiency of disclosure – claim 1 – ground for opposition under Article 100(b) EPC

2.1 Claim 1 of the main request reads as follows:

"*1. A process for the manufacture of crystalline vortioxetine HBr α-form characterized by XRPD reflections at 5.85, 9.30, 17.49 and 18.58 (°2θ) (±0.1°), the process comprising the steps of*

a) obtaining a solution of vortioxetine in toluene, wherein the toluene is more than 90% pure;

b) mixing said solution obtained in step a) with HBr and C_1-C_3 carboxylic acid to obtain mixture b) at a temperature above 10 °C; and

c) collecting the precipitate obtained in step b)."

2.2 The appellant submitted that the invention defined in the claims of the main request was insufficiently disclosed in two respects:

- the type of HBr and the role of the C_1-C_3 carboxylic acid

- the temperature of step b)

2.3 The type of HBr and the role of the C_1-C_3 carboxylic acid

2.3.1 Claim 1 of the main request requires that a solution of vortioxetine in toluene is mixed with **HBr and a C_1-C_3 carboxylic acid.**

2.3.2 The appellant submitted that the C_1-C_3 carboxylic acid played no role in controlling the polymorph obtained. According to the appellant, the decisive factor was that hydrobromic acid had to be added in non-aqueous or non-gaseous form. None of the examples according to claim 1 of the main request showed that using aqueous or gaseous HBr could lead to the α-form. The examples according to claim 1 of the main request differed from the reference examples on account of not only the presence of the C_1-C_3 carboxylic acid but also the use of non-aqueous, non-gaseous HBr. The skilled person, after reading the patent, would therefore not have concluded that merely adding a C_1-C_3 carboxylic acid promoted formation of the α-form. Since claim 1 of the main request did not exclude the use of aqueous or gaseous HBr, the claimed process failed to reliably produce the α-form across its full scope.

The board is not convinced by this argument.

Examples 6 to 10, 12 and 13 of the application as filed disclose the preparation of the α-form as defined in claim 1 of the main request by dissolving vortioxetine in toluene and adding a solution of HBr in acetic acid (examples 6-10 and 12) or a solution of HBr in propionic acid (example 13), followed by isolation of the precipitate. In each case, the α-form is obtained in pure form. These examples fall within the scope of claim 1 of the main request and provide the skilled person with clear guidance on how to obtain the claimed

polymorph, namely by carrying out the reaction in the presence of a solution of HBr in acetic or propionic acid, i.e. using HBr dissolved in a C_1-C_3 carboxylic acid rather than aqueous or gaseous HBr.

The board accepts that using aqueous HBr alone (see examples 1 to 4 of the application as filed) or gaseous HBr alone (example 5 of the application as filed), which falls within the scope of claim 1 of the main request in terms of the HBr (but not the carboxylic acid), does not lead to the claimed product in a reasonable amount. In the appellant's view, this indirectly indicated that carrying out the claimed process with aqueous or gaseous HBr in the presence of a C_1-C_3 carboxylic acid would not yield the claimed product either.

However, comparing examples 5 (gaseous HBr in toluene) and 6 (HBr in acetic acid and toluene) of the application as filed shows that the presence of the carboxylic acid is associated with a change in the polymorphic outcome, converting the failure observed in example 5 into a success in example 6. This comparison therefore indicates that the presence of the C_1-C_3 carboxylic acid plays a decisive role in controlling the polymorphic outcome. In view of this evidence, and on the balance of probabilities, it is more likely that the polymorphic control provided by the C_1-C_3 carboxylic acid would also be achieved when using aqueous or gaseous HBr.

Consequently, the appellant has not shown that the claimed process fails to produce the α-form across the scope of claim 1 of the main request. The objection of lack of sufficiency as regards the type of HBr and the

role of the C_1-C_3 carboxylic acid is therefore not convincing.

2.4 The temperature

2.4.1 Claim 1 of the main request further requires that the solution of vortioxetine in toluene is mixed with HBr and the C_1-C_3 carboxylic acid at **a temperature above 10°C**.

2.4.2 The appellant submitted that in reference examples 11 and 14 of the patent, the vortioxetine/toluene mixture was stirred at 10°C, and HBr in acetic acid was then added "quickly". The appellant argued that since the temperature prior to the addition was 10°C and the addition of HBr in acetic acid would necessarily increase the temperature, the temperature of the mixture during addition had to be "above 10°C". According to the appellant, reference examples 11 and 14 therefore fulfilled all the features of claim 1 of the main request, including the addition of HBr at a temperature above 10°C, yet did not yield the α-form as required by claim 1 of the main request. The appellant further submitted that example 6 disclosed a similar process that did yield the α-form. This, in the appellant's view, demonstrated a lack of sufficiency of disclosure.

This submission is not convincing.

The board acknowledges that the claimed α-form is not obtained in reference examples 11 and 14.

However, as submitted by the respondent during the oral proceedings and not contested by the appellant, in these examples HBr in acetic acid is added to a mixture of vortioxetine and toluene "quickly" **at 10°C**, and the resulting mixture is immediately cooled in an ice water

bath. Such a process cannot be regarded as mixing the reagents at a temperature **above 10°C** within the meaning of claim 1 of the main request.

In example 6, by contrast, HBr in acetic acid is added to the toluene/vortioxetine mixture "quickly" **at room temperature**, and then the resulting solution is cooled using an ice water bath.

As submitted by the respondent, the starting temperature for the addition of HBr in acetic acid in example 6 (room temperature) is therefore higher than that in reference examples 11 and 14 (10°C). Contrary to the appellant's assertion, it therefore cannot be concluded that example 6 discloses a process similar to that of reference examples 11 and 14.

This assertion thus cannot support a lack of sufficiency of disclosure of claim 1 of the main request.

In any event, a comparison between example 6, which starts the process at a temperature above 10°C and yields the claimed α-form, and reference examples 11 and 14, which start at 10°C and do not yield the α-form, provides the skilled person with clear guidance on how to achieve the claimed result, i.e. how to turn the failure into success, namely by starting the process at a temperature above 10°C.

The patent therefore provides sufficient information enabling the skilled person to carry out the invention with respect to the temperature feature of claim 1 of the main request.

2.4.3 This conclusion was set out by the board in its communication under Article 15(1) RPBA and was not subsequently contested by the appellant.

2.5 Consequently, the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent as granted.

3. Admittance

3.1 The respondent requested that the appellant's following assertions not be admitted into the proceedings:

(a) "the presence of a carboxylic acid is irrelevant" and "the addition of a carboxylic acid does not play any role in the form of vortioxetine HBr obtained" (paragraphs (08) and (10) of the statement of grounds of appeal)

(b) "the key to providing the alpha form is that the HBr must not added [sic] as an aqueous solution or as a gas, when the salt formation and precipitation took place in toluene" (paragraph (08) of the statement of grounds of appeal)

(c) "the patentee has not met their burden of proof to show that the addition of carboxylic acid controls the form obtained" (paragraphs (16) to (34) of the statement of grounds of appeal)

(d) "the examples are clearly an investigation into finding an appropriate source of HBr, and the presence of acetic acid or propionic acid in the examples according to the claim is merely a way of using a non-aqueous and non-gaseous form of HBr" (paragraphs (35) to (43) of the statement of grounds of appeal)

(e) "the claim does not include the key feature needed to provide the alpha form" of vortioxetine HBr

(paragraph (47) of the statement of grounds of appeal)

(f) "Part (b) [of claim 1] requires that the mixing step takes place at a temperature above 10°C but does not require that the mixture is subsequently maintained at any particular temperature" and that "in such circumstances, it is not permissible to read further limitations into the claim based on the description" (paragraph (53) of the statement of grounds of appeal)

3.2 The board decided to admit these assertions into the proceedings. However, since they were found unconvincing (see points 2.3.2 and 2.4.2 above) and since the overall decision is in the respondent's favour, there is no need to provide any of the board's reasoning as regards the decision to reject the respondent's non-admittance request.

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