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Datasheet for the decision of 21 November 2022

Case Number: T 1303/18 - 3.3.02

Application Number: 08853236.1

Publication Number: 2215072

IPC: C07D333/20, A61K31/381, A61P25/00

Language of the proceedings: EN

Title of invention:
POLYMORPHIC FORM OF ROTIGOTINE

Patent Proprietor:
UCB Pharma GmbH

Opponents:
Interquim, S.A.
Hexal AG
Generics [UK] Limited
Luye Pharma AG
Wittkopp, Alexander
AMW GmbH
Alfred E. Tiefenbacher (GmbH & Co. KG)

Headword:
UCB PHARMA / ROTIGOTINE POLYMORPH

Relevant legal provisions:
EPC Art. 54, 56, 87(1)
RPBA 2020 Art. 13(1)

Keyword:
Earliest priority - identity of invention (no)
Amendment to appeal case (yes)
New allegation of fact - admitted (no)
Novelty - public prior use (yes)
Inventive step - auxiliary request 4 (no)

Decisions cited:
G 0002/98, G 0001/03, G 0002/10, G 0001/15, T 0012/81, T 0517/14, T 1684/16, T 2988/18

Catchword:

If the patent proprietor introduces various differences between the definition of a certain compound in a granted claim and that in the priority application and if despite these differences, the patent proprietor, in arguing that the effective date of the subject-matter of the granted claim is the claimed priority date, asserts that the compound of the granted claim is the same as that disclosed in the priority application, it is the patent proprietor who bears the burden of proving this assertion (point 2.13 of the reasons).

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Case Number: T 1303/18 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 21 November 2022

Appellant: (Patent Proprietor)	UCB Pharma GmbH Alfred-Nobel-Strasse 10 40789 Monheim (DE)
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Respondent 2: (Opponent 2)	Hexal AG Industriestrasse 25 83607 Holzkirchen (DE)
Representative:	Breuer, Markus Brienner Straße 1 80333 München (DE)
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Representative:	Dentons UK and Middle East LLP One Fleet Place London EC4M 7WS (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 March 2018 revoking European patent No. 2215072 pursuant to Article 101(2) and Article 101(3)(b) EPC**

Composition of the Board:

Chairman	M. O. Müller
Members:	M. Maremonti
	M. Blasi

Summary of Facts and Submissions

I. The appeal lodged by the patent proprietor ("appellant") lies from the decision of the opposition division to revoke European patent No. 2 215 072 ("the patent").

II. The patent as granted contains 14 claims, with independent claim 1 reading as follows:

"*1. Polymorphic form (II) of Rotigotine ((-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]-amino]-1-naphthalenol) having at least one of*

a X-ray powder diffraction spectrum comprising peaks at the following °2θ angles (± 0.2): 12.04, 13.68, 17.72 and 19.01, measured with Cu-Kα irradiation (1.54060 Å);

a Raman spectrum comprising peaks at the following wave numbers (± 3 cm^{-1}) selected from: 226.2, 297.0, 363.9, 710.0, 737.3, 743.3, 750.8, 847.3, 878.3, 1018.7, 1075.6, 1086.2, 1214.3, 1255.1, 1278.2, 1330.7, 1354.3 and 1448.7;

a DSC peak with a Tonset at 97°C ± 2°C measured with a heating rate of 10°/min;

a melting point of 97°C ± 2°C."

III. Oppositions by opponents 1 to 7 had been filed on the grounds under Article 100(a) to (c) EPC. The following documents D3, D6, D10, D39, D48, D49, D54 and D102 were referred to, *inter alia*, during the opposition proceedings:

D3: "SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE AMENDMENT OF THE MARKETING AUTHORISATION OF NEUPRO PRESENTED BY THE EMEA", 1 January 2009, pages 1-4, http://www.ema.europa.eu/docs/en_GB/

document_library/ EPAR_-_Scientific_Conclusion/ human/000626/WC500026400.pdf

D6: Nelson G., "*Neupro® (rotigotine transdermal patch) to be stored in refrigerator at pharmacy and by patients. UCB to implement replacement of existing Neupro® with cold-chain product*", UCB Pharma Ltd (UK), Letter to pharmacists, 10 June 2008, pages 1-2, http://www.mhra.gov.uk/home/ idcplg?ldcService=GET_FILE&dDocName=CON018261& RevisionSelectionMethod=Latest

D10: Press Release, "*EMEA recommends changes in the storage conditions for Neupro (rotigotine)*", European Medicines Agency Press Office (UK), 4 June 2008, http://www.emea.europa.eu/ humandocs/PDFs/EPAR/neupro/ 26875108en.pdf

D39: European Commission, "*Initiation of a procedure under Article 20 of Regulation (EC) No. 726/2004*"

D48: EP 07 121 795.4, filed on 28 November 2007; priority application of the patent

D49: US 60/990,721 P, filed on 28 November 2007; priority application of the patent

D54: WO 2004/058247 A1

D102: Consumer complaint to "Medical Information US", E-Mail dated 2 January 2008

IV. The opposition division came to, *inter alia*, the following conclusion on the main request (patent as granted) and auxiliary requests 1 to 4 of the patent proprietor.

- The subject-matter of the main request and auxiliary requests 1, 2 and 4 did not enjoy the earliest priority date.

- The subject-matter of claim 1 of the main request and claim 1 of auxiliary requests 1 and 2 was not novel over the public prior use of rotigotine form II in commercial Neupro® patches which occurred between the earliest and the subsequent priority date.

- Auxiliary request 3 was not admitted into the proceedings.

- The subject-matter of auxiliary request 4 did not involve an inventive step when starting from either document D54 or the public prior use of rotigotine form II in commercial Neupro® patches which occurred between the earliest and the subsequent priority date as the closest prior art.

V. In its statement of grounds of appeal, the appellant contested the opposition division's reasoning and submitted, *inter alia*, that the earliest priority was valid for the subject-matter of the granted claims. It also submitted sets of claims according to auxiliary requests 1 to 5.

VI. In their replies to the appeal, opponents 1 to 6 ("respondents 1 to 6") objected to, *inter alia*, the validity of the earliest priority. They further submitted that, since the earliest priority was invalid, the claimed subject-matter lacked novelty over the public prior use of rotigotine form II in commercial Neupro® patches which occurred between the earliest and the subsequent priority date. The respondents also raised objections to the admittance and patentability of the auxiliary requests.

VII. In a subsequent letter dated 21 August 2020, the appellant rebutted the arguments of the respondents and argued, *inter alia*, that the subject-matter of the

claims as granted was at least entitled to a partial priority from the earliest priority applications.

VIII. In subsequent letters, the respondents objected, *inter alia*, to the admittance of the appellant's defence relying on partial priority.

IX. By letter dated 8 June 2021, opponent 7 withdrew its opposition and ceased to be a party to the current proceedings.

X. The parties were summoned to oral proceedings as per their requests. In preparation for the oral proceedings, the board issued a communication under Article 15(1) RPBA 2020, in which it expressed, *inter alia*, the preliminary opinion that the subject-matter of claim 1 as granted and claim 1 of auxiliary requests 1, 2 and 4 was not entitled to the earliest priority date claimed. Moreover, the subject-matter of claim 1 as granted appeared to lack novelty over the public prior use of rotigotine form II in commercial Neupro® patches which occurred between the earliest and the subsequent priority date.

XI. By a subsequent letter, respondent 6 indicated that it would not attend the oral proceedings.

XII. Oral proceedings before the board were held on 21 November 2022 by videoconference in the absence of respondent 6 pursuant to Rule 115(2) EPC and Article 15(3) RPBA. During the oral proceedings, the appellant withdrew the previously filed auxiliary requests 3 and 5. Moreover, it requested that specific questions be referred to the Enlarged Board of Appeal (see below).

XIII. Final requests relevant to the decision

The appellant requested that the appealed decision be set aside and that the case be remitted to the opposition division for the assessment of sufficiency of disclosure and inventive step of the patent as granted (main request). Alternatively, it requested that the patent be maintained as granted (denoted "Main Substantive Request" by the appellant), or alternatively, that the patent be maintained in amended form on the basis of the claims of one of auxiliary requests 1, 2 or 4 as filed with the statement of grounds of appeal.

The appellant also requested, should the board envisage denying the validity of the earliest priority, that the following questions be referred to the Enlarged Board of Appeal:

"*In the case that the subject-matter of a claim is a polymorphic form of a chemical compound, which is defined by certain analytical data, is the requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC satisfied if the priority application unambiguously defines the same polymorphic form, but in terms of different analytical data?*

Is the requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC, satisfied if

(a) the subject-matter of a claim is a polymorphic form of a chemical compound, which is defined by certain analytical data,

(b) the previous application unambiguously discloses the same polymorphic form, but

(c) the analytical data used to define the claimed polymorphic form cannot as such be completely derived directly and unambiguously using common general knowledge, from the previous application as a whole?

In the case that the subject-matter of a claim of a European patent is a polymorphic form of a chemical compound that is defined by certain analytical data, does the requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC, imply that the claim must define the polymorphic form in terms of analytical data that can as such be clearly and unambiguously derived from the previous application? Or is it sufficient that the subject-matter of the claim of the European patent is clearly and unambiguously the same polymorphic form as the one disclosed in the previous application, even though defined by partially different data?"

The respondents requested that the appeal be dismissed, implying that the revocation of the patent be upheld. They also requested that the appellant's defence relying on partial priority, filed by the appellant on 21 August 2020, not be admitted into the proceedings.

XIV. The appellant's submissions relevant to the present decision are summarised as follows. For further details, reference is made to the reasons for the decision below.

Validity of the earliest priority

- There was no doubt that claim 1 as granted and the earliest priority applications D48/D49 disclosed the same invention within the meaning of Article 87(1) EPC and opinion G 2/98, i.e. polymorphic form II of rotigotine.

- Therefore, the earliest priority was valid.

Referral of questions to the Enlarged Board of Appeal

- Should the board envisage denying the validity of the earliest priority, specific questions (point XIII above) should be referred to the Enlarged Board of Appeal, to avoid a contradiction between the case law on novelty and that on validity of priority, and a violation of the unitary concept of disclosure.

Admittance of the defence relying on partial priority

- In the event of the earliest priority being declared invalid, the subject-matter of claim 1 as granted was at least entitled to a partial priority in view of decision G 1/15.
- This defence should be admitted into the proceedings since it did not constitute an amendment of the appellant's case.

Auxiliary requests 1, 2 and 4 - Validity of the earliest priority

- Claim 1 of auxiliary request 1 was identical to claim 1 as granted. Therefore, the same arguments applied.
- As regards the claims of auxiliary requests 2 and 4, figure 1 of the contested patent referred to in claim 1 was identical to figure 1 of the priority applications D48/D49.
- Therefore, there were no doubts that claim 1 of auxiliary requests 2 and 4 defined the same polymorphic form II as disclosed in D48/D49.
- The term "*substantially*" included in claim 1 of these requests did not change the identity of the compound.

- Therefore, it had to be concluded that the earliest priority was valid.

Auxiliary request 4 - Inventive step

- Polymorphic form II of rotigotine included in the commercial Neupro® patches publicly used between the earliest and the subsequent priority date might constitute the closest prior art.
- The objective technical problem had to be considered that of how to prepare a pharmaceutical composition including form II of rotigotine.
- No uses of form II were known at the relevant date. Only polymorphic form I of rotigotine had been used for preparing pharmaceutical compositions.
- Form II constituted a quality defect and using it for preparing pharmaceutical compositions would have been counter-intuitive.
- No pointer was present in the prior art which would have been an incentive for the skilled person to use form II for the preparation of pharmaceuticals. On the contrary, a work-around solution for avoiding the formation of form II was already known from e.g. D6 and D10.
- It had to be concluded that the subject-matter of claim 1 of auxiliary request 4 involved an inventive step.

XV. The respondents' submissions relevant to the present decision are summarised as follows.

Validity of the earliest priority

- The Enlarged Board of Appeal had clearly stated that the standard to be applied for assessing the

validity of priority was the same as for assessing compliance with Article 123(2) EPC.

- There was no doubt that the subject-matter of claim 1 as granted was not directly and unambiguously disclosed in the earliest priority applications D48/D49.

- The common designation of the compound in granted claim 1 and in D48/D49 as polymorphic form II of rotigotine was not sufficient to conclude that an identical compound was meant. The reason for this was that in claim 1, the polymorphic form was defined by a set of parameters that were different from the parameters disclosed in D48/D49. Therefore, the claimed compound was not the same as the one disclosed in the priority applications. The appellant bore the burden of proving that the two compounds were identical.

- The argument that only two polymorphic forms of rotigotine were known at the earliest priority date could not be accepted either since, in this case, the earliest priority would have become retroactively invalid if another crystal form of rotigotine was discovered later.

Referral of questions to the Enlarged Board of Appeal

- No referral to the Enlarged Board of Appeal was needed since no point of law was in dispute.

- In particular, denying the validity of the earliest priority would not have caused any conflict with the case law on novelty. The fact that priority applications D48/D49 would have anticipated the subject-matter of claim 1 as granted was irrelevant. The concept of anticipation was, namely, different from the one of direct and

unambiguous disclosure, which had to be used for assessing the validity of the earliest priority.

Admittance of the defence relying on partial priority

- The appellant's defence did not concern mere interpretation of law. It involved an extensive technical analysis and factual discussion since the subject-matter of claim 1 could not be seen as a clear "OR" situation as referred to in decision G 1/15.

- Before the opposition division and in its statement of grounds of appeal, the appellant had always asserted that there was a one-to-one match between the claimed subject-matter and the disclosure in the priority application such that the priority should have been considered valid. Only later in the appeal proceedings did the appellant argue that, while there was no one-to-one match, part of the claimed subject-matter enjoyed priority.

- Therefore, this defence did constitute an amendment of the appellant's case. This amendment raised complex questions at a late stage of the proceedings and the respondents had not had any time to respond properly.

- Hence, this appellant's defence should not be admitted into the proceedings.

Claim 1 as granted - novelty

- The appellant never contested that polymorphic form II of rotigotine as defined in claim 1 as granted was known from the public prior use of commercial Neupro® patches which occurred between the earliest and the subsequent priority date.

- Therefore, it had to be concluded that the subject-matter of claim 1 as granted lacked novelty over this public prior use.

Auxiliary requests 1, 2 and 4 - Validity of the earliest priority

- Claim 1 of auxiliary request 1 was identical to claim 1 as granted. Thus, the earliest priority was invalid for the same reasons.

- The term "*substantially*" included in claim 1 of auxiliary requests 2 and 4 allowed indeterminate deviations from the X-ray diffraction spectrum shown in figure 1 of the patent and priority applications D48/D49.

- This generalisation was not directly and unambiguously disclosed in D48/D49 and therefore identity of the polymorphic form between claim 1 and D48/D49 could not be established.

- It had to be concluded that the earliest priority was not valid for the subject-matter of claim 1 of auxiliary requests 2 and 4 either.

Auxiliary requests 1 and 2 - novelty

- The subject-matter of claim 1 of auxiliary requests 1 and 2 lacked novelty for the same reasons as claim 1 as granted.

Auxiliary request 4 - Inventive step

- Polymorphic form II of rotigotine as included in the commercial Neupro® patches publicly used between the earliest and the subsequent priority date might constitute the closest prior art.

- The distinguishing feature was the claimed use.

- The objective technical problem was the provision of a suitable use for polymorphic form II of rotigotine.
- The use of polymorphic form I of rotigotine for preparing pharmaceutical compositions was well known to the skilled person, e.g. from document D54.
- According to D54, the crystal form of rotigotine was destroyed before its use so that rotigotine was used in amorphous form.
- It was thus evident to the skilled person that the initial crystalline form of rotigotine was not relevant since rotigotine was ultimately used in amorphous form.
- When seeking a solution to the posed objective technical problem, it would have been obvious to the skilled person to use form II of rotigotine in all applications for which form I was known, and thus especially for the preparation of pharmaceutical compositions.
- It had to be concluded that the subject-matter of claim 1 of auxiliary request 4 lacked an inventive step.

Reasons for the Decision

Main request and main substantive request - the patent as granted - claim 1 - validity of the earliest priority under Article 87(1) EPC

1. The patent was granted with an earliest priority date of 28 November 2007 claimed from applications D48 and D49 filed on the same day. It is common ground that the content of these two priority applications is

identical. For ease of reference, the board refers hereinafter only to D49.

1.1 The respondents objected to the validity of this earliest priority. They argued that the subject-matter of claim 1 as granted was not directly and unambiguously disclosed in D49. They referred to opinion G 2/98.

1.2 The appellant argued that there was no doubt that the claims as granted and the whole disclosure of D49 concerned the same invention within the meaning of Article 87(1) EPC and opinion G 2/98, namely, polymorphic form II of rotigotine.

2. The board disagrees with the appellant for the following reasons.

2.1 As set out in opinion G 2/98 (OJ EPO 2001, page 413, Conclusion), the "*requirement for claiming priority of 'the same invention', referred to in Article 87(1) EPC, means that priority of a previous application in respect of* ***a claim*** *in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive* ***the subject-matter of the claim*** *directly and unambiguously, using common general knowledge, from the previous application as a whole*" (emphasis added by the board).

2.2 Therefore, in the current case, it is the subject-matter of claim 1 as granted that has to be directly and unambiguously derivable from D49. The appellant pointed out that the patent and D49 disclosed the same methods for characterising the mentioned polymorphic form and that the same figures resulted from this characterisation, thus demonstrating identity of the invention. However, the fact that the same characterisation methods like X-ray diffraction, Raman spectrum and DSC calorimetry are used to describe the

disclosed compound in both the patent and D49 plays no role when assessing the above requirement. Also the fact that the patent and D49 share the same figures is irrelevant; what is decisive is whether or not, using common general knowledge, a compound as defined in claim 1 of the patent is directly and unambiguously disclosed in D49 as a whole. In this respect, it should further be recalled that the disclosure as the basis for the right to priority under Article 87(1) EPC and as the basis for amendments in an application under Article 123(2) EPC has to be interpreted in the same way (decision G 1/03, OJ EPO 2004, 413, point 4 of the reasons and G 2/10, OJ EPO 2012, 376, point 4.3 of the reasons).

2.3 In claim 1 as granted (point II above), the claimed compound is said to be polymorphic form II of rotigotine and is defined by at least one of four properties, namely:

(a) a certain X-ray powder diffraction spectrum comprising four peaks with an error margin of ± 0.2, said to be measured with Cu-Kα irradiation (1.54060 Å);

(b) a Raman spectrum comprising specific peaks with an error margin of ± 3 cm^{-1};

(c) a DSC peak with a certain Tonset with an error margin of ± 2°C;

(d) a certain melting point with an error margin of ± 2°C.

2.4 As regards property (a), D49 discloses a polymorphic form of rotigotine, named "form (II)", defined in claim 1 of D49 as being characterised by "***any one, any two, any three, any four or more*** *of the powder X-ray diffraction peaks including, but not limited to: 12.04,*

12.32, 12.97, 13.68, 17.13, 17.72, 19.01, 20.40, 20.52, 21.84, 21.96, 22.01, 22.91 and 22.96 ***±0.1*** *(°2θ)*" (emphasis added by the board). The same disclosure is found on page 3, lines 14 to 20, and page 6, lines 3 to 9, of D49. Figure 1 of D49 shows the powder X-ray diffractogram of the polymorphic "form II" of rotigotine according to D49. The "*main peaks*" according to figure 1 are stated in D49, page 11, lines 20 to 26, to be at diffraction angles (°2θ) of 12.04, 12.32, 12.97, 13.68, 17.13, 17.72, 19.01, 20.40, 20.52, 21.84, 21.96, 22.01, 22.91 and 22.96. These angles are identical to those cited in claim 1, page 3, lines 14 to 20, and page 6, lines 3 to 9, of D49.

2.4.1 Comparing the definition in terms of property (a) given in claim 1 as granted with the above disclosures in D49 reveals the following differences.

- The set of peaks defined for the X-ray powder diffraction spectrum in claim 1 as granted is a set of four peaks, while that in the above disclosures of D49 is a set of 14 peaks.
- The X-ray powder diffraction spectrum according to claim 1 as granted must comprise all of the peaks mentioned in this claim (i.e. four peaks), while the above disclosures of D49 allow the spectrum to comprise only one, only two or only three of the peaks comprised in the set of peaks defined in these disclosures (see highlighted part above).
- An error margin of ±0.2 is cited in claim 1 as granted for the mentioned X-ray diffraction peaks, while an error margin of ±0.1 is given in the above disclosures of D49 (see highlighted part above).

2.4.2 It follows that, in order to arrive at the four peaks stated in claim 1 as granted, at least two selections within D49 are needed: a first selection for defining

the compound of D49 by means of a number of four peaks within the X-ray powder diffraction spectrum; and a second selection for arriving at the specific diffraction angles (°2θ) mentioned in claim 1 as granted for these four peaks. However, D49 contains no pointer towards these two specific selections.

2.4.3 Additionally, claim 1 as granted defines the four mentioned peaks with an error margin of ±0.2. This margin has been broadened as compared with the error margin of ±0.1 disclosed in D49 (see above). This means that, according to claim 1 as granted, the peaks can be shifted so that they no longer match the diffraction angles (°2θ) disclosed in D49. No disclosure of this broadening of the error margin can be found in D49.

2.4.4 Therefore, the skilled person, at the relevant date of the subsequent filing, would not have derived a compound as defined by the X-ray powder diffraction spectrum mentioned in claim 1 as granted directly and unambiguously, using common general knowledge, from the disclosure in D49.

2.4.5 The appellant referred to decision T 517/14, especially to point 5.4 of the reasons, which, in its view, confirmed that by mentioning in the claim five peaks of the X-ray powder diffraction reflections, the crystalline form of the claimed compound was defined in a unique way.

However, decision T 517/14 does not change the board's conclusion set out above. According to point 5.4 of the reasons referred to by the appellant, the entrusted board held that no evidence had been provided by the opponent that the five peaks of X-ray reflections used in claim 1 at issue for characterising the claimed compound (point I of T 517/14) were not sufficient to define the crystalline form of the claimed compound in

a unique way. However, in the current case, it is not in dispute that the peaks of the X-ray diffraction spectrum mentioned in claim 1 as granted are suitable for defining the claimed compound. What is decisive is that, for the reasons set out in the present decision, the claimed compound is not the same as that directly and unambiguously disclosed in priority application D49.

2.5 As regards property (b) (Raman spectrum), D49 discloses a polymorphic form of rotigotine, named "form II", defined in claim 3 of D49 as being characterised by "*its Raman spectrum with main peaks at the following wave numbers (cm^{-1}): 226.2, 297.0, 710.0, 737.3, 750.8, 847.3, 878.3, 1018.7, 1075.6, 1086.2, 1214.3, 1255.1, 1330.7, 1354.3 and 1448.7* ***± 1 cm^{-1}***" (emphasis added by the board). The same disclosure, with the addition of a main peak at 743.3 cm^{-1}, is found on page 3, lines 22 to 26, and, with reference to figure 5, on page 12, lines 1 to 11, of D49.

2.5.1 When comparing the definition in terms of property (b) given in claim 1 as granted with the above disclosures in D49, it is noted that claim 1 as granted mentions two additional peaks at 363.9 and 1278.2 cm^{-1}. A peak at 363.9 cm^{-1} is indicated in figure 5 of D49 representing the full Raman spectrum of form II of rotigotine according to D49. However, this peak is here shown together with a vast number of other peaks which are not mentioned in the above disclosures in claim 3 and on pages 3 and 12 of D49. As regards the peak at 1278.2 cm^{-1}, this is not indicated in figure 5 of D49.

2.5.2 Additionally, claim 1 as granted defines the recited peaks with an error margin of ±3 cm^{-1}. This margin has been broadened as compared with the error margin of ±1 cm^{-1} disclosed in D49 (see highlighted part above). This means that, according to claim 1 as granted, the

peaks can be shifted so that they no longer match the wave numbers disclosed in D49. No disclosure of this broadening of the error margin can be found in D49.

2.5.3 As a consequence, the skilled person, at the relevant date of the subsequent filing, would not have derived the Raman spectrum as defined in claim 1 as granted directly and unambiguously, using common general knowledge, from the disclosure in D49.

2.6 As regards properties (c) and (d) (DSC peak and melting point), D49 (page 12, lines 16 to 34, and figure 7) discloses a DSC analysis carried out on rotigotine form II according to D49 by using a heating rate of 10°C/min. An onset at 97.30°C is reported, while the melting point is not disclosed.

When comparing the definitions in terms of properties (c) and (d) given in claim 1 as granted with the above disclosures in D49, no basis exists in D49 for a broader onset at 97°C ± 2°C and a melting point of 97°C ± 2°C as defined in claim 1 as granted.

2.7 Thus, it follows that the definition given for the compound referred to in granted claim 1 differs in numerous aspects from that disclosed in priority application D49. As a consequence, it cannot be concluded that the compound of granted claim 1 is the same as that disclosed in D49.

2.8 The appellant argued that identity between the claimed compound and the compound disclosed in D49 was already evident from the fact that the polymorphic form of rotigotine was designated as form II in both claim 1 as granted and D49. While alleged discrepancies in the definition of form II were merely due to the different sets of analytical data used for defining form II, this did not change the fact that the same compound was disclosed. A polymorphic form of a given compound

remained the same regardless of the method used for characterising it.

2.9 This argument is not convincing. The common designation as "polymorphic form II of rotigotine" in both claim 1 as granted and D49 is not sufficient to conclude that the same compound as disclosed in D49 is defined in claim 1 as granted. In fact, the mere name "polymorphic form II of rotigotine" does not give the skilled person any information as regards the identity of the compound. Contrary to the appellant's view, it is the set of analytical data chosen to characterise the compound that gives the skilled person the information necessary to identify the compound referred to. For the reasons set out above, the set of analytical data used in claim 1 as granted is not directly and unambiguously disclosed in D49. Therefore, it cannot be concluded that the compound defined in claim 1 as granted is the same compound as disclosed in D49.

2.10 The appellant further submitted that only form I and form II of rotigotine were known at the earliest priority date and form II was clearly distinguished from form I. Stating that the priority from D49 was not valid amounted to insinuating that a third polymorphic form of rotigotine existed but this was clearly wrong.

2.11 However, the board concurs with the respondents that by accepting this argument, the earliest priority would become retroactively invalid if another crystal form of rotigotine was discovered later, which would fall under the definition given in claim 1 as granted but not under the disclosure of D49. Hence, this argument runs against the principle of legal certainty and must thus fail.

2.12 The appellant also argued that the respondents bore the burden of proving that claim 1 as granted defined a

compound different from the one disclosed in D49. No evidence in this respect had been presented.

2.13 However, it was the appellant (patent proprietor) who introduced various differences (see above) between the compound defined in granted claim 1 and that disclosed in D49. If, despite these differences, the appellant asserts that the compound of granted claim 1 is the same as that disclosed in D49, it is the appellant who bears the burden of proving this. In fact, it is for an applicant to ensure, where priority from a previous application is claimed, that the same invention is defined, according to the required standard, in the subsequent application as filed.

2.14 Additionally, the appellant submitted that structural properties allegedly lacking in D49 were implicitly disclosed to the skilled person since they were inherent to polymorphic form II and accessible by using the disclosed analytical methods. In this respect, the appellant further submitted that in the appealed decision the opposition division inconsistently applied two different standards for the assessment of the validity of the earliest priority on the one hand and novelty on the other hand. With respect to novelty, the mere reference to "polymorphic form II" of rotigotine in the prior art was sufficient to assume a novelty-destroying disclosure. On the other hand, the opposition division objected to a missing or slightly differing reproduction of the analytical data of granted claim 1 in D49 in a 1:1 manner and denied the disclosure in D49 of polymorphic form II of rotigotine as defined in granted claim 1 despite the fact that claim 1 as granted explicitly referred to "polymorphic form II" of rotigotine.

2.15 This argument is not convincing either. Priority has been claimed from a written disclosure (D49) and it is from this disclosure that the skilled person should have been able, at the relevant date, to derive directly and unambiguously, using common general knowledge, the subject-matter of claim 1 as granted. However, as set out above, D49 does not disclose the same compound as that defined in claim 1 as granted.

2.16 Moreover, even assuming that the skilled person could have been in a position to analyse a sample of the rotigotine form II disclosed in D49, the skilled person would have obtained, *inter alia*, the whole X-ray powder diffraction spectrum and Raman spectrum (which are in fact represented in figures 1 and 5 of D49). However, for the reasons given above, these whole spectra do not constitute an adequate basis for the definition of the polymorphic form of rotigotine as given in claim 1 as granted. For this reason, the board sees no inconsistency in the way the opposition division assessed the validity of priority on one hand and the novelty of the claimed subject-matter on the other. In fact, in terms of novelty (see corresponding point below), the relevant prior art is a sample of a polymorphic form of rotigotine, which could have been analysed by the skilled person so as to obtain, *inter alia*, its whole X-ray powder diffraction spectrum and Raman spectrum. These whole spectra were found by the opposition division to anticipate the definition of the polymorphic form of rotigotine as given in claim 1 as granted.

2.17 For these reasons, the board concludes that the subject-matter of claim 1 as granted does not enjoy the claimed earliest priority date of 28 November 2007 (Article 87(1) EPC and Article 89 EPC). Therefore, the earliest priority is not valid.

2.18 This conclusion is in line with decision T 1684/16 (points 2.1 to 2.5 of the reasons) concerning the ground for opposition under Article 100(c) EPC. The entrusted board found that the definition contained in granted claim 1 at issue of a polymorphic form I of a certain compound as five specific peaks of the X-ray diffraction pattern was not directly and unambiguously disclosed in the application as filed. Even though the latter disclosed a polymorphic form bearing the same name ("Form I"), this form was stated to be characterised by at least one of fifteen or twenty-four peaks. By analogy with the case at hand, the entrusted board found that the application as filed provided no teaching pointing to the selection of the five peaks mentioned in the claim at issue. The granted claim at issue therefore contained subject-matter extending beyond the content of the application as filed (Article 100(c) EPC). This conclusion, which implies that the claimed subject-matter lacks proper basis in the application as filed, is analogous to that drawn in the current case, namely that the subject-matter of claim 1 as granted is not based on priority application D49.

Referral of specific questions to the Enlarged Board of Appeal - Article 112(1)(a) EPC

3. The appellant requested, should the board envisage denying validity of the earliest priority, that specific questions (point XIII above) be referred to the Enlarged Board of Appeal. It argued that there was otherwise a risk of a contradiction between the case law on novelty and that on validity of priority and that the unitary concept of disclosure would be violated. In this regard, the appellant referred to section I.C.6.2 of the publication Case Law of the Boards of Appeal, mentioning, *inter alia*, decision

T 12/81, and stated that there was no doubt that priority application D49 would have been considered novelty-destroying for the subject-matter of claim 1 as granted.

4. The board finds these arguments unconvincing. As is derivable from each of the proposed questions (point XIII above), the request for a referral to the Enlarged Board of Appeal rests on the precondition that the same polymorphic form is defined in both the claim at issue and the priority application. However, for the reasons given above, the board has concluded that the polymorphic form defined in claim 1 as granted is not directly and unambiguously disclosed in the priority application D49. Therefore, what is claimed is not the same compound and the precondition for the questions to be referred according to the appellant is not met. Thus, the proposed questions, or answers thereto, respectively, would not have been pertinent for deciding the present case.

4.1 Furthermore, contrary to the appellant's view, no violation of the general principle of direct and unambiguous disclosure common to the assessment of compliance with Articles 123(2), 54 and 87(1) EPC derives from the board's conclusion above. In fact, it is acknowledged that the standard to be applied when deciding what an item of prior art and a priority application disclose must be the same for Articles 54 and 87 EPC. This standard is the gold standard established in decision G 2/10 and uses the test of direct and unambiguous disclosure. The application of one and the same standard for Articles 54 and 87 EPC does not, however, mean that the conclusions for novelty and validity of priority must necessarily be the same. More specifically, as set out by the respondents during the oral proceedings, a priority

application can directly and unambiguously disclose something falling within the scope of a claim of a subsequent application and thus anticipate the subject-matter of this claim while at the same time the latter still includes subject-matter not disclosed in the priority application, such that the priority is invalid.

4.2 The board's conclusion is also not in contradiction to the passage in section I.C.6.2 of the publication Case Law of the Boards of Appeal referred to by the appellant. By referring to landmark decision T 12/81 (OJ EPO 1982, page 296), this passage states that "*If a product cannot be defined by a sufficiently accurate generic formula, it is permissible to make the definition more precise by additional product parameters such as melting point, hydrophilic properties, NMR coupling constant or the method of preparation (product-by-process claims). From this it necessarily follows that patent documents using such definitions will be prejudicial to the novelty of later applications* ***claiming the same substance*** *defined in a different and perhaps more precise way*" (emphasis added by the board). Therefore, this passage concerns the case in which one and the same substance is defined in the claim and in the prior art in different ways. As explained above, the current situation is different since the subject-matter of claim 1 as granted and D49 do not define the same polymorphic form.

4.3 Accordingly, the board saw no deviation in its approach from pertinent case law of the Boards of Appeal and, accordingly, did not consider a decision from the Enlarged Board to be required in the circumstances of the present case. Thus, the board decided not to refer questions to the Enlarged Board and, consequently, to reject the appellant's request to this effect.

Appellant's defence relying on entitlement to partial priority filed on 21 August 2020 - admittance into the proceedings

5. In its letter dated 21 August 2020 (point 1.2.1.3 on pages 11 to 14), i.e. after the filing of the grounds of appeal and replies and before the summons to oral proceedings was issued (6 December 2021), the appellant argued for the first time that, should the priority from D49 be considered invalid, the subject-matter of claim 1 as granted should at least be entitled to a partial priority from D49 in accordance with decision G 1/15.

The respondents requested that this defence by the appellant not be admitted into the proceedings.

5.1 Under Article 12(2) RPBA 2007, applicable in the case at hand in accordance with Articles 24 and 25(1), (2) RPBA 2020 and Article 12(4) RPBA 2007, the statement of grounds of appeal shall contain the appellant's complete case. It shall set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify expressly all the facts, arguments and evidence relied on. Moreover, under Article 12(4) RPBA 2007, the board has the discretion to hold inadmissible *inter alia* allegations of facts presented together with the statement of grounds of appeal or the reply which could have been presented before the opposition division.

5.2 An objection as to the validity of the earliest priority claimed from D49 had already been raised by the respondents in their notices of opposition (see e.g. the notices of opposition of respondents 1 & 2, pages 29 to 31; the notice of opposition of respondent 4, pages 11 and 12; the notice of opposition of respondent 6, pages 17 to 20). Decision G 1/15 was

published in the Official Journal of the EPO in 2017, i.e. before the oral proceedings held on 15 February 2018 before the opposition division. Therefore, the appellant's defence claiming a right to partial priority could and should have been presented before the opposition division or included at the latest in the statement of grounds of appeal, so as to comply with the requirement to present the complete case at the outset of the appeal proceedings.

5.3 Since the appellant's defence was filed on 21 August 2020, i.e. after the statement of grounds of appeal and before the summons to oral proceedings, Article 13(1) RPBA 2020 was applicable in the circumstances of the present case (see Articles 24 and 25 RPBA 2020). Under this provision, any amendment to a party's appeal case after it has filed its grounds of appeal or reply is subject to the party's justification for its amendment. The party shall provide reasons for submitting the amendment at this stage of the proceedings. Any such amendment to a party's case may be admitted and considered only at the discretion of the board. The board shall exercise its discretion in view of, *inter alia*, the current state of the proceedings, the suitability of the amendment to resolve outstanding issues without giving rise to new objections and the need for procedural economy.

5.4 In its letter dated 21 August 2020, the appellant did not indicate any reason why the defence asserting a right to partial priority was only filed after its statement of grounds of appeal.

5.5 The appellant argued that this defence did not constitute an amendment of its appeal case. It only concerned interpretation of law by means of an argument based on a decision of the Enlarged Board of Appeal. Therefore, the appellant was allowed to make this

defence at any point during the proceedings. Reference was made to decision T 2988/18, especially points 1.2 and 1.4 of the reasons, and to the explanatory remarks to the Rules of Procedure of the Boards of Appeal which entered into force on 1 January 2020. The appellant's defence did not involve any new factual allegations. When taking decision G 1/15 into account, it was clear that the claimed subject-matter was at least entitled to a partial priority from D49. Since the appeal case had not been amended, complexity considerations concerning the defence made played no role with regard to admittance. Therefore, the defence based on entitlement to partial priority should be admitted into the proceedings.

5.6 The board's considerations were as follows.

5.6.1 Contrary to the appellant's view, the defence by which a right to partial priority was invoked was not merely a presentation of a new argument pertaining to the interpretation of law but comprised a new allegation of fact. The appellant namely asserted that priority application D49 directly and unambiguously disclosed in an enabling manner part of the subject-matter of claim 1 as granted, and specifically that claim 1 as granted encompassed this part as an alternative subject-matter by virtue of a "generic "OR"-claim" within the meaning of decision G 1/15 (order). Therefore, the submitted defence would have involved a new factual assessment of the subject-matter of claim 1 as granted and of priority application D49, namely as to precisely which part of claim 1 it was that allegedly enjoyed partial priority and where it was disclosed in D49.

5.6.2 Decision T 2988/18 (points 1.1 to 1.4 of the reasons), invoked by the appellant, could not support the appellant's submission. In fact, in the case underlying

this decision, the appellant/patent proprietor submitted an argument based on decision G 1/93 (OJ EPO 1994, 541) after the summons to oral proceedings had been issued by the entrusted board. In particular, the appellant/patent proprietor argued that an amendment to claim 1 as filed which had been introduced into claim 1 as granted was allowable in view of the principle set out in headnote 2 of decision G 1/93. The entrusted board concluded that the new argument was not an amendment of the appeal case since it only concerned how the interpretation of Article 123(2) EPC provided by the Enlarged Board of Appeal in G 1/93 applied to the facts of the case at issue. Therefore, contrary to the current case (see above), no new factual allegations were derived from the new argument submitted, which was purely based on the facts and evidence that had been already put forward. Hence, the *rationale* developed in T 2988/18 was not applicable to the case at hand.

5.6.3 The board's approach is also consistent with the explanatory remarks to the RPBA 2020 (supplementary publication 2, OJ EPO 2020, page 57). In the context of Article 12(4) RPBA 2020, it is stated that "*Submissions of a party* ***which concern only the interpretation of the law*** *are not an amendment within the meaning of proposed new paragraph 4*" (emphasis added by the board). However, for the reasons set out above, the appellant's defence asserting an entitlement to partial priority did not concern only the interpretation of the law but constituted a new allegation of fact.

5.6.4 The defence relying on partial priority therefore constituted an amendment to the appellant's appeal case within the meaning of Article 13(1) RPBA 2020, and, thus, the board had discretion over whether or not to admit this amendment.

5.6.5 As pointed out by the respondents, this new factual assessment would have been complex. This was evident from the fact that in some aspects the subject-matter of claim 1 as granted had been restricted as compared with the disclosure in D49 by inserting characteristics of the claimed compound such as a melting point and further Raman peaks which were not disclosed in D49. On the other hand, in other aspects, the subject-matter of claim 1 as granted had been broadened over the disclosure in D49 by e.g. extending the error margins of X-ray reflection peaks and Raman peaks (see also points 2.4 to 2.7 above).

5.6.6 Therefore, the appellant's defence raised new complex issues at a late stage of the appeal proceedings. The appellant provided no justification for this late amendment. Admittance of this defence would have led to an entirely *fresh case* on the issue of priority to be considered for the first time at a late stage of the appeal proceedings. This would have been detrimental to procedural economy. Given that this defence could already have been presented during the proceedings before the opposition division, considering it on appeal would also have been contrary to the primary object of the appeal proceedings of reviewing the decision under appeal in a judicial manner (Article 12(2) RPBA 2020).

5.7 For these reasons, the board decided, pursuant to Article 13(1) RPBA 2020, not to admit into the proceedings the appellant's defence relying on entitlement to partial priority.

Main request and main substantive request - claim 1 as granted - ground for opposition under Article 100(a) EPC - novelty under Article 54 EPC

6. The respondents objected to the novelty of the subject-matter of claim 1 as granted *inter alia* in view of polymorphic form II of rotigotine being known from the public prior use of commercial Neupro® patches which occurred between the earliest and the subsequent priority date of the patent.

6.1 The opposition division (appealed decision, point 4.1.2) concluded that the subject-matter of claim 1 as granted was anticipated by form II of rotigotine made available to the public after the earliest and before the subsequent priority date by means of the above prior use, and referred to D3, D39 and D102.

6.2 This finding of the opposition division has not been contested by the appellant, whether in its statement of grounds of appeal or in its subsequent letter dated 21 August 2020 or at the oral proceedings. The appellant only relied on the validity of the earliest priority from D49.

6.3 However, as stated above, the earliest priority was found invalid. Therefore, the board sees no reason to deviate from the conclusion of the opposition division (*ibid.*) that the subject-matter of claim 1 as granted lacks novelty over polymorphic form II of rotigotine as contained in commercial Neupro® patches publicly used between the earliest and the subsequent priority date as evidenced e.g. by D3, D39 and D102 (Article 54 EPC).

6.4 As a consequence, neither the appellant's main request nor its "Main Substantive Request" are allowable.

Auxiliary request 1 - claim 1 - novelty under Article 54 EPC

7. The claims of auxiliary request 1 differ from the claims as granted in that claims 3 to 7 as granted were deleted and the remaining claims renumbered accordingly. Claim 1 of auxiliary request 1 is thus identical to claim 1 as granted.

It follows that the same conclusion as regards the invalidity of the earliest priority and the lack of novelty of the subject-matter of claim 1 as granted applies *mutatis mutandis* to the subject-matter of claim 1 of auxiliary request 1.

Therefore, auxiliary request 1 is not allowable for the same reasons as the main request and the main substantive request.

Auxiliary request 2 - claim 1 - validity of the earliest priority under Article 87(1) EPC and novelty under Article 54 EPC

8. The set of claims of auxiliary request 2 is based on that of auxiliary request 1 with claim 1 having been deleted and the remaining claims renumbered accordingly.

8.1 Claim 1 of auxiliary request 2 is identical to claim 2 as granted and reads as follows:

"*A polymorphic form of Rotigotine having a X-ray powder diffraction spectrum measured with Cu-Kα irradiation (1.54060 Å) substantially as shown in Figure 1.*"

8.2 The appellant argued that in claim 1 of auxiliary request 2, polymorphic form II of rotigotine was defined by the X-ray powder diffraction spectrum of figure 1 of the patent. This figure was identical to figure 1 of D49. The required identity of invention between the subject-matter of claim 1 and D49 was thus

evident. As regards the term "*substantially*" in claim 1 of auxiliary request 2, the appellant did not contest that it was not mentioned in D49. However, it argued that the presence of this term did not change the identity of the compound as defined in both claim 1 and D49. This term merely took account of the fact that, for technical reasons, some deviations from figure 1 might occur when determining the X-ray diffraction spectrum. Moreover, this term reflected the error margins with respect to the X-ray diffraction peaks as disclosed in D49.

8.3 The board finds the appellant's arguments unconvincing. As acknowledged by the appellant, D49 does not disclose the term "*substantially*" in relation to the X-ray powder diffraction spectrum, see especially page 11, lines 14 to 30, where the results shown in figure 1 of D49 are discussed. As pointed out by the respondents, this term allows undefined deviations from the spectrum shown in figure 1 of the patent which are not disclosed by D49. In particular, contrary to the appellant's view, there is no basis in D49 which allows the term "*substantially*", referring in claim 1 to the whole X-ray diffraction spectrum, to be associated with the specific error margin of ±0.1 disclosed in D49 (claim 1, page 3, lines 14 to 20, and page 6, lines 3 to 9) with regard to some specific X-ray diffraction peaks. As for claim 1 as granted, the polymorphic form of rotigotine defined in claim 1 of auxiliary request 2 is thus not directly and unambiguously derivable, using common general knowledge, from D49. In other words, claim 1 of auxiliary request 2 and D49 do not define the same compound.

8.4 For these reasons, the board concluded that the subject-matter of claim 1 of auxiliary request 2 does not enjoy the claimed earliest priority date of

28 November 2007 (Article 87(1) EPC and Article 89 EPC). Therefore, the earliest priority is not valid.

8.5 At the oral proceedings, the appellant did not contest that the subject-matter of claim 1 of auxiliary request 2 was anticipated by polymorphic form II of rotigotine as contained in commercial Neupro® patches publicly used between the earliest and the subsequent priority date. Therefore, the board concludes that the subject-matter of claim 1 of auxiliary request 2 lacks novelty over the above-mentioned public prior use (Article 54 EPC). Hence, auxiliary request 2 is not allowable.

Auxiliary request 4 - claim 1 - validity of the earliest priority under Article 87(1) EPC and inventive step under Article 56 EPC

9. The set of claims of auxiliary request 4 is based on that of auxiliary request 2 with claims 1 and 3 having been merged and the remaining claims renumbered accordingly.

9.1 Claim 1 of auxiliary request 4 reads as follows:

"*Use of a polymorphic form of Rotigotine having a X-ray powder diffraction spectrum measured with Cu-Kα irradiation (1.54060 Å) substantially as shown in Figure 1 and at least one pharmaceutically acceptable excipient in a method for the production of a pharmaceutical composition.*"

9.2 As in claim 1 of auxiliary request 2 (see above), the term "*substantially*" is included in claim 1 of auxiliary request 4 with reference to the X-ray diffraction spectrum of figure 1. It follows that the same observations by the board concerning the invalidity of the earliest priority claimed for the

subject-matter of claim 1 of auxiliary request 2 apply *mutatis mutandis* to the subject-matter of claim 1 of auxiliary request 4.

9.3 It follows that the subject-matter of claim 1 of auxiliary request 4 does not enjoy the claimed earliest priority date of 28 November 2007 (Article 87(1) EPC and Article 89 EPC). Hence, the earliest priority is not valid.

10. Inventive step

10.1 Closest prior art

In view of the invalidity of the earliest priority, polymorphic form II of rotigotine as included in commercial Neupro® patches publicly used between the earliest and the subsequent priority date is prior art under Article 54(2) EPC and thus citable against inventive step.

By analogy with the appealed decision (point 6.2.2, penultimate paragraph), the appellant and respondents indicated this polymorphic form II of rotigotine as included in commercial Neupro® patches to be the closest prior art.

10.2 Distinguishing feature

It is common ground that the subject-matter of claim 1 of auxiliary request 4 differs from said closest prior art in the claimed use of the known form II of rotigotine, namely, use together with at least one pharmaceutically acceptable excipient in a method for the production of a pharmaceutical composition.

10.3 Objective technical problem

10.3.1 At the oral proceedings, the appellant formulated the objective technical problem deriving from the above-mentioned distinguishing feature as being that of how

to prepare a pharmaceutical composition including form II of rotigotine.

10.3.2 However, the board notes that this formulation of the technical problem would already contain the solution provided by claim 1. On the basis of this problem, the claimed solution would have been obvious. In the appellant's favour, the board instead adopted the formulation of the objective technical problem suggested by the respondents by analogy with the appealed decision (point 6.2.2, penultimate paragraph), as being the provision of a suitable use of the known polymorphic form II of rotigotine.

10.4 Obviousness of the claimed solution

10.4.1 The appellant argued that it would have been counter-intuitive to use polymorphic form II for preparing any pharmaceutical composition. The reason was that form II constituted the source of the quality defect identified in the commercial Neupro® patches prepared from form I of rotigotine. No pointer was present in the prior art that indicated form II as a suitable candidate for further pharmaceutical development. The appellant submitted that a pharmaceutical composition had to undergo several tests before being declared suitable for commercialisation. In addition, there was already a work-around solution for avoiding the crystallisation of polymorphic form II in the commercial patches, namely, the refrigerated storage of these Neupro® patches. This solution was known to the skilled person from both of documents D6 (page 1, 4th and 5th paragraph) and D10 (page 1, 1st paragraph). Thus, the skilled person would not have been prompted to change the preparation process of the commercial patches prepared from form I and to prepare them starting from polymorphic form II, which was known as the source of

the quality defect in the then available patches. Therefore, an inventive step should be acknowledged.

10.4.2 The board disagrees. The fact that from e.g. D6 and D10 a work-around solution was known to avoid the formation of form II in patches prepared from form I is not relevant. In fact, the objective technical problem to be solved is not that of how to avoid the formation of form II but instead that of finding a suitable use for this polymorphic form.

10.4.3 As submitted by the respondents and not contested by the appellant, pharmaceutical compositions including polymorphic form I of rotigotine were well known to the skilled person. By way of example, reference was made to document D54, which discloses (page 4, line 27 to page 5, line 14) transdermal patches prepared from form I of rotigotine. According to D54 (*loc. cit.*), preparation of the patches involves melting the crystals of form I so that rotigotine is then present in the patch in amorphous form. The skilled person would have inferred from this disclosure that the initial crystalline form of rotigotine was not relevant to its use since rotigotine was ultimately used in the pharmaceutical composition in amorphous form.

10.4.4 Therefore, the board concurs with the respondents that, when seeking a solution to the posed objective technical problem, the skilled person would have used form II of rotigotine in all applications for which form I was known, and thus especially for the preparation of pharmaceutical compositions with a pharmaceutically acceptable excipient. In so doing, the subject-matter of claim 1 of auxiliary request 4 would have been obtained.

10.5 Therefore, the board concludes that the subject-matter of claim 1 of auxiliary request 4 does not involve an

inventive step within the meaning of Article 56 EPC. Hence, auxiliary request 4 is not allowable.

Conclusion

11. None of the appellant's claim requests is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated