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Datasheet for the decision of 20 June 2024

Case Number: T 2157/21 - 3.3.04

Application Number: 15843405.0

Publication Number: 3229799

IPC: A61K31/41, C07D257/04, C07C233/47

Language of the proceedings: EN

Title of invention:
Crystalline forms of trisodium supramolecular complex comprising valsartan and AHU-377 and methods thereof

Patent Proprietors:
Crystal Pharmatech Co., Ltd.
Suzhou Pengxu Pharmatech Co., Ltd.

Opponent:
D Young & Co LLP

Relevant legal provisions:
EPC Art. 100(c), 123(2), 56

Keyword:
Amendments - added subject-matter (yes)
Inventive step - auxiliary requests 12, 12A, 13, 16, 16A, 17 (no)

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Case Number: T 2157/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 20 June 2024

Appellant: (Patent Proprietor 1)	Crystal Pharmatech Co., Ltd. B4-101, Biobay, 218 Xinghu Street Suzhou Industrial Park Suzhou, 215123 (CN)
Appellant: (Patent Proprietor 2)	Suzhou Pengxu Pharmatech Co., Ltd. 3rd Floor, Building 7 2358 Changan Road Wujiang Suzhou, 215200 (CN)
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Appellant: (Opponent)	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 October 2021 concerning maintenance of the European Patent No. 3229799 in amended form.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	R. Hauss
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 3 229 799 (patent in suit) was granted with a set of fifteen claims.

Claim 1 as granted reads as follows:

1. A crystalline form of trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3'-methyl-2'-(pentanoyl{2"-(tetrazol-5-ylate)biphenyl-4'-ylmethyl}amino)butyrate] hydrate, designated as Form II, characterized by an X-ray powder diffraction pattern comprising the following 2Θ values measured using CuKa radiation: 4.3°±0.2°, 10.9°±0.2°, and 14.6°±0.2°.

II. The compound identified in claim 1 is ***trisodium valsartan sacubitril***, a supramolecular complex combining the drugs valsartan and sacubitril. "AHU-377" is another name for sacubitril that has been used in the patent in suit and in the prior art (see paragraphs [0002] and [0006] of the patent in suit).

III. The patent in suit was opposed under Article 100(a) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step and extended beyond the content of the application as filed.

IV. The patent proprietors requested that the opposition be rejected (main request) and submitted a number of amended sets of claims as auxiliary requests.

V. The documents cited in the proceedings before the opposition division included the following:

D3: WO 2007/056546 A1

D4: European Pharmacopoeia 8.0, Chapter 2.9.33, pages 339-343 (2013)

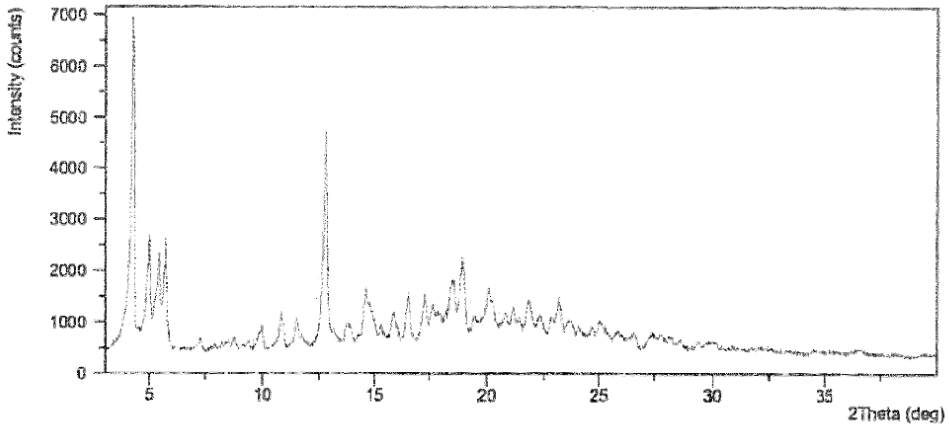
D5: Declaration Dr Jacob Overgaard (9 July 2021)

D5b: USP 35, Physical Tests/(941) X-Ray Powder Diffraction, pages 427-431 (2012)

VI. The decision under appeal is the opposition division's interlocutory decision, announced on 21 September 2021 and posted on 21 October 2021, rejecting the patent proprietors' main request and auxiliary requests 1 to 12 and finding that the patent as amended in the form of auxiliary request 13 (filed as auxiliary request 12' during the oral proceedings on 21 September 2021) met the requirements of the EPC.

VII. Claim 1 of the request deemed allowable by the opposition division reads as follows:

1. A crystalline form of trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butyl-carbamoyl) propionate-(S)-3'-methyl-2'-(pentanoyl {2"-(tetrazol-5-ylate)biphenyl-4'-ylmethyl} amino)butyrate] hydrate, designated as Form II, characterized by an X-ray powder diffraction pattern comprising 2θ values measured using CuKa radiation, wherein the X-ray powder diffraction pattern is the same as that shown in Fig. 7:



VIII. According to the decision under appeal:

(a) The claims of the main request and of each of auxiliary requests 1 to 12 contained added subject-matter (Articles 100(c) and 123(2) EPC).

(b) This objection was overcome by auxiliary request 13.

(c) There were no objections regarding lack of novelty in relation to auxiliary request 13.

(d) Inventive step was assessed starting from the disclosure of document D3. As shown in Examples 14 and 15 of the patent in suit, the polymorphic Form II of trisodium valsartan sacubitril according to the opposed patent had shown less moisture uptake and better flowability in comparison with the polymorphic form disclosed in D3. The objective technical problem was the provision of a further improved crystalline form of trisodium valsartan sacubitril. The claimed subject-matter was held to be inventive.

IX. Both the opponent and the patent proprietors appealed against this decision.

X. With the patent proprietors' statement setting out the grounds of appeal, 25 sets of claims were also filed, as auxiliary requests 1, 2, 2A, 3, 3A, 4, 5, 6, 6A, 7, 7A, 8, 9, 10, 10A, 11, 11A, 12, 12A, 13, 14, 15, 16, 16A and 17.

The claims of the ***main request*** are those of the patent as granted. For the wording of claim 1, see section I. above.

Claim 1 of ***auxiliary request 1*** is identical to claim 1 of the main request, except that "*10.9°±0.2°*" has been replaced by "*10.9°*".

Claim 1 of ***auxiliary request 2*** and of ***auxiliary request 2A*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.3°±0.2°, 5.0°±0.2°, 10.9°±0.2°, 12.8°±0.2° and 14.6°±0.2°

Claim 1 of ***auxiliary request 3*** and of ***auxiliary request 3A*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.3°±0.2°, 5.0°±0.2°, 10.9°, 12.8°±0.2° and 14.6 ±0.2°

The difference between this and the list of 2Θ values in auxiliary request 2 is that "*10.9°±0.2°*" has been replaced by *"10.9°"*.

Claim 1 of ***auxiliary request 4*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.2°±0.2°, 4.9°±0.2°, 10.8°±0.2°, 12.8°±0.2° and 14.5°±0.2°

Claim 1 of ***auxiliary request 5*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.2°, 4.9°, 10.8°, 12.8°±0.2° and 14.5°

Claim 1 of ***auxiliary request 6*** and of ***auxiliary request 6A*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.3°±0.2°, 5.0°±0.2°, 5.5°±0.2°, 5.8°±0.2°, 10.9°±0.2°, 12.8°±0.2°, 14.6°±0.2°, 18.5°±0.2°, 18.9°±0.2°, and 20.1°±0.2°

Claim 1 of ***auxiliary request 7*** and of ***auxiliary request 7A*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.3°±0.2°, 5.0°±0.2°, 5.5°±0.2°, 5.8°±0.2°, 10.9°, 12.8°±0.2°, 14.6°±0.2°, 18.5°±0.2°, 18.9 ±0.2°, and 20.1°±0.2°

The difference between this and the list of 2Θ values in auxiliary request 6 is that *"10.9°±0.2°"* has been replaced by *"10.9°"*.

Claim 1 of ***auxiliary request 8*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.2°±0.2°, 4.9°±0.2°, 5.4°±0.2°, 5.7°±0.2°, 10.8°±0.2°, 12.8°±0.2°, 14.5°±0.2°, 18.4°±0.2°, 18.9°±0.2°, and 20.1°±0.2°

Claim 1 of ***auxiliary request 9*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.2°, 4.9°, 5.4°, 5.7°, 10.8°, 12.8°±0.2°, 14.5°, 18.4°, 18.9°±0.2°, and 20.1°±0.2°

Claim 1 of ***auxiliary request 10*** and of ***auxiliary request 10A*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.3°±0.2°, 5.0°±0.2°, 5.5°±0.2°, 5.8°±0.2°, 10.0±0.2°, 10.9°±0.2°, 11.5±0.2°, 12.8°±0.2°, 13.8±0.2°, 14.6°±0.2°, 15.9±0.2°, 16.5±0.2°, 17.3±0.2°, 18.5°±0.2°, 18.9°±0.2°, 20.1°±0.2°, 21.8±0.2°, and 23.2±0.2°

Claim 1 of ***auxiliary request 11*** and of ***auxiliary request 11A*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.3°, 5.0°, 5.5°, 5.8°, 10.0°, 10.9°, 11.5°, 12.8°, 13.8°, 14.6°, 15.9°, 16.5°, 17.3°, 18.5°, 18.9°, 20.1°, 21.8°, and 23.2°

Claim 2 of ***auxiliary request 10*** and of ***auxiliary request 11*** reads as follows:

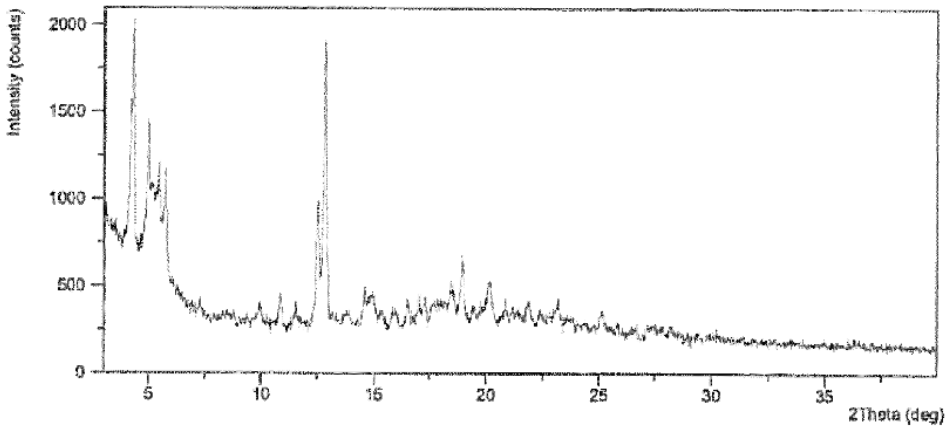
2. A process of preparing the crystalline Form II according to claim 1, comprising

• adding 9.9 mg of trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butyl-carbamoyl) propionate-(S)-3'-methyl-2'-(pentanoyl {2"-(tetrazol-5-ylate)biphenyl-4'-ylmethyl}amino) butyrate] hemipenta-hydrate to 0.2 mL of methanol;
• heating the suspension at an 80°C hot-stage plate for about 2 hours,
• filtering it and and collecting the hot supernatant;
• equilibrating the hot supernatant at 80°C for about 2 hours;
• then adding 2.0 ml toluene to the hot supernatant drop-wise,
• stirring it at room temperature overnight;
• then placing it for evaporation with cap open at room temperature.

Claim 1 of ***auxiliary request 12*** and of ***auxiliary request 12A*** is identical to claim 1 of former auxiliary request 13, which was deemed allowable by the opposition division (see section VII. above).

Claim 1 of ***auxiliary request 13*** is identical to claim 1 of the main request, except that the characterising part reads as follows:

characterized by an X-ray powder diffraction pattern comprising 2Θ values measured using CuKa radiation, wherein the X-ray powder diffraction pattern is the same as that shown in Fig. 8



Claim 1 of ***auxiliary request 14*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.2°±0.2°, 4.9°±0.2°, 5.4°±0.2°, 5.7°±0.2°, 9.9 ±0.2°, 10.8°±0.2°, 12.4°±0.2°, 12.8°±0.2°, 14.5°±0.2°, 14.9°±0.2°, 16.5°±0.2°, 17.2°±0.2°, 18.4°±0.2°, 18.9°±0.2°, 19.4°±0.2°, 20.1°±0.2°, 20.8°±0.2°, 21.8°±0.2°, 22.3°±0.2°, 23.1°±0.2°, and 25.1°±0.2°

Claim 1 of ***auxiliary request 15*** is identical to claim 1 of the main request, except that the list of 2Θ values has been replaced by the following list:

4.2°, 4.9°, 5.4°, 5.7°, 9.9°, 10.8°, 12.4°, 12.8°, 14.5°, 14.9°, 16.5°, 17.2°, 18.4°, 18.9°, 19.4°, 20.1°, 20.8°, 21.8°, 22.3°, 23.1°, and 25.1°

Claim 1 of ***auxiliary request 16*** and of ***auxiliary request 16A*** is identical to claim 1 of the main request, except that the characterising part reads as follows:

characterized by an X-ray powder diffraction pattern comprising the following 2Θ values measured using CuKa radiation, d-spacing [Å] and relative intensity [%] values:

Pos.[°2Th.]	d-spacing [Å]	Rel. Int. [%]
4.3	20.7	100.0
5.0	17.7	34.7
5.5	16.2	28.5
5.8	15.3	33.1
10.0	8.9	6.6
10.9	8.1	11.1
11.5	7.7	9.5
12.8	6.9	66.4
13.8	6.4	7.9
14.6	6.1	18.6
15.9	5.6	11.0
16.5	5.4	17.3
17.3	5.1	16.0
18.5	4.8	21.0
18.9	4.7	28.2
20.1	4.4	17.3
21.8	4.1	15.2
23.2	3.8	15.2

Claim 1 of ***auxiliary request 17*** is identical to claim 1 of the main request, except that the characterising part reads as follows:

characterized by an X-ray powder diffraction pattern comprising the following 2Θ values measured using CuKa radiation, d-spacing [Å] and relative intensity [%] values:

Pos.[°2Th.]	d-spacing [Å]	Rel. Int. [%]
4.2	20.9	81.7
4.9	18.0	49.6
5.4	16.4	40.9
5.7	15.6	38.7
9.9	9.0	5.2
10.8	8.2	9.0
12.4	7.1	44.1
12.8	6.9	100
14.5	6.1	12.4
14.9	6.0	9.8
16.5	5.4	9.4
17.2	5.2	9.9
18.4	4.8	15.9
18.9	4.7	23.9
19.4	4.6	7.3
20.1	4.4	17.2
20.8	4.3	11.3
21.8	4.1	10.0
22.3	4.0	6.8
23.1	3.9	10.1
25.1	3.6	7.8

XI. With the opponent's statement setting out the grounds of appeal, the following document was filed:

D7: Declaration of Prof. Ivica Đilović (21 February 2022)

XII. With the patent proprietors' reply to the opponent's appeal, the following documents were filed:

D8: Further Declaration of Dr Jacob Overgaard (20 July 2022)

D9: Supplementary Experimental Data: Repetition of Example 3 from the Priority Document

XIII. In a communication under Article 15(1) RPBA issued in preparation for oral proceedings and advising the parties of its preliminary opinion, the board made, *inter alia*, the following comments:

- Applying the pertinent criterion of direct and unambiguous disclosure, the board was of the view that claim 1 as granted did not find a basis in the application as filed (Article 100(c) EPC).
- Auxiliary requests 1 to 11 defined the claimed crystalline Form II by varied combinations of 2Θ values. Compliance with Article 123(2) EPC was one of the relevant issues.
- In the case of claim 1 of auxiliary requests 12 and 12A, inventive step appeared to be a crucial issue.

XIV. The patent proprietors advised the board that they would neither be attending nor be represented at the oral proceedings.

XV. Oral proceedings before the board took place on 20 June 2024 in the form of a videoconference, in the absence of the patent proprietors. The patent

proprietors were deemed to be relying on their written submissions (Article 15(3) RPBA and Rule 115(2) EPC).

XVI. The opponent's pertinent arguments can be summarised as follows.

Added subject-matter

The characterisation of the claimed crystalline "Form II" as defined in claim 1 of the main request and claim 1 of each of auxiliary requests 1, 2, 2A, 3, 3A, 4, 5, 6, 6A, 7, 7A, 8, 9, 10, 10A, 11, 11A, 14, and 15 was not disclosed directly and unambiguously in the application as filed.

In particular, there was no basis in the application as filed for picking new combinations of 2Θ values to define the claimed crystalline form, for adding error ranges of ±0.2° to 2Θ values originally disclosed without an error range, or for omitting relative line intensities in connection with values which were originally disclosed only in combination with a specified relative line intensity.

The patent proprietors misinterpreted the conclusions in decisions T 1684/16 and T 1442/18. The opposition division's decision in relation to compliance with Article 123(2) EPC, as well as decisions T 1684/16 and T 1442/18 cited by the opposition division, all applied the correct criterion of direct and unambiguous disclosure in the same way. The facts underlying decision T 325/16 (cited by the patent proprietors) were different from the situation in the case at hand.

Inventive step

The technical feature distinguishing the subject-matter of claim 1 of auxiliary requests 12 and 12A from the

disclosure of document D3 was the specific crystalline form of trisodium valsartan sacubitril.

Examples 6 and 7 of the patent in suit disclosed different processes for preparing a crystalline form of trisodium valsartan sacubitril leading to different crystalline materials, as shown in Tables 4 and 5 and the XRPD patterns in Figures 7 and 8. Although Examples 6 and 7 related to different crystalline materials, both were designated as "Form II" in the patent in suit.

Examples 14 and 15 of the patent presented data obtained in comparative tests, where the comparison was with the same crystalline form as disclosed in D3. Based on the available information, it was not clear which of the crystalline materials, the one prepared according to Example 6 or the one prepared according to Example 7, had actually been tested. Hence, the Examples could not show that the improved properties observed for the tested "Form II" product were indeed attained by the crystalline form of claim 1 of auxiliary requests 12 and 12A, which was the form obtained according to Example 6 and characterised in Table 4 and Figure 7 of the patent.

Since no particular technical advantage could be attributed to the specific crystalline Form II as claimed, the objective technical problem was the provision of an alternative form of trisodium valsartan sacubitril. According to the established jurisprudence of the EPO, the solution to such a problem would have been obvious to the person skilled in the art.

The same line of argument applied, *mutatis mutandis*, in the case of claim 1 of auxiliary requests 16 and 16A, which defined the claimed "Form II" product by reproducing Table 4 rather than Figure 7, and by analogy in the case of claim 1 of auxiliary requests 13

and 17, which defined the claimed "Form II" product by reproducing Figure 8 or Table 5 according to Example 7.

XVII. The patent proprietors' pertinent arguments, as presented in writing, can be summarised as follows.

Added subject-matter

Claim 1 as granted, and claim 1 of auxiliary requests 1, 2, 2A, 3 and 3A, found support in claims 7 and 9 and in Table 4 of the application as filed.

Claim 1 of auxiliary requests 4 and 5 found support in claim 7 and in Table 5 of the application as filed.

Claim 1 of auxiliary requests 6, 6A, 7, 7A, 10, 10A, 11 and 11A found support in claims 7 to 9 and Table 4 of the application as filed.

Claim 1 of auxiliary requests 8, 9, 14 and 15 found support in claims 7 to 9 and Table 5 of the application as filed.

Decisions T 1684/16 and T 1442/18, which were cited by the opposition division in section 6.1 of its reasoning in the decision under appeal, were not applicable to the case at hand. Contrary to the situation underlying these cases, the application as filed defined the polymorph according to "Form II" by, *inter alia*, a list of three lines (in claim 7), thus teaching that three lines were sufficient to characterise the claimed polymorph. Furthermore, two of the three lines in claim 1 as granted were disclosed in the context of preferred embodiments in claims 7 and 9.

It would be clear to any reader that "Form II" was the same product throughout the application as filed, and in particular, that Figures 7 and 8 represented two duplicate measurements of the same crystalline form (albeit prepared according to different processes, as

described in Examples 6 and 7). This form could be characterised by any selection of lines from its XRPD diffractograms, provided that these were representative or characteristic, as this did not change the identity of the product. The 2Θ values shown in Tables 4 and 5 of the application as filed had been selected precisely because they were representative. If the amended claims described the crystalline form by a different set of lines taken from Tables 4 and 5, this did not change the definition of the crystalline form but only the selection of representative or characteristic lines for characterising one and the same Form II, which remained identical to that defined in the application as filed.

Reference was made to decision T 325/16 by way of representative case law. A similar re-definition of the crystalline form, combining technical features taken from different parts of the application relating to the general disclosure and from the experimental part, had been found allowable under Article 123(2) EPC (section 10 of the Reasons).

Literal support for including the error range of ±0.2° was not required. All 2Θ values in the original claims were presented with an error range of ±0.2°. A person skilled in the art would infer from this general context that the same error range of ±0.2° must apply to all characterising values recited in the application as filed, and that all such values were taken from the XRPD measurements presented in Tables 4 and 5. Moreover, it was common general knowledge in the technical field in question that the standard variation for characteristic lines in XRPD measurements was typically reported as ±0.2° of 2Θ. In this context, reference was made to documents D4 (page 342) and D5 (section III.2).

Inventive step

The patent proprietors' arguments in favour of an inventive step of the subject-matter of claim 1 of each of auxiliary requests 12, 12A, 13, 16, 16A and 17 were identical and did not differ from their arguments relating to the main request (see the patent proprietors' grounds of appeal, sections 4.4, 22.3, 23.4, 24.4, 27.4, 28.4, 29.3 and the patent proprietors' reply to the opponent's appeal, section 4).

The patent proprietors also stated that they agreed with the opposition division's decision on inventive step in relation to claim 1 of former auxiliary request 13, which is identical to claim 1 of current auxiliary requests 12 and 12A.

Examples 14 and 15 of the patent in suit showed that "Form II" of the patent in suit compared favourably with the "patent form" disclosed in US8877938B2 (the US equivalent of D3) in terms of moisture uptake and flowability. An inventive step should be acknowledged on the basis of these technical advantages.

The patent proprietors disagreed with the opponent's view that it was not clear for which chemical species the data in Examples 14 and 15 had been obtained. A person skilled in the art would be aware that the term "Form II" designated the same species throughout the application as filed, and that the material obtained according to Examples 6 and 7 had to be identical.

Hence, the application as filed did show, in Examples 14 and 15, that the claimed crystalline form had superior properties in comparison with that disclosed

in D3, and in Example 16, that it was stable at different temperatures and humidity conditions.

Document D9 provided additional evidence in support of the patent proprietors' argument that the XRPD patterns of crystalline Form II obtained from Example 6 and from Example 7 were, in fact, identical. The line appearing at $2\Theta = 12.4^{\circ}$ in Figure 8 (associated with Example 7) but not in Figure 7 (associated with Example 6) was the only pronounced difference, and this had to be an artefact that was either associated with a preferred orientation effect or with the sample holder employed.

Irrespective of whether the material from Example 6 or Example 7 was used for the experiments subsequently presented in Examples 14 to 16, since these represented the same crystalline form the technical effects observed could be directly attributed to the specific material claimed.

XVIII. The patent proprietors' requests were as follows:

- In respect of the main request (patent as granted) or one of auxiliary requests 1, 2, 2A, 3, 3A, 4, 5, 6, 6A, 7, 7A, 8, 9, 10, 10A, 11, 11A, and 12, they requested that the decision under appeal be set aside and that the case be remitted to the opposition division for consideration of any ground of opposition not yet decided on by the opposition division for that respective request, or, in the alternative, that the patent be maintained on the basis of the claims of one of these requests.
- In respect of auxiliary request 12A, they requested that the opponent's appeal be dismissed.
- In respect of auxiliary requests 13, 14, 15, 16, 16A and 17, they requested that the case be remitted to the opposition division for further

consideration or, in the alternative, that the patent in suit be maintained on the basis of the claims of one of these requests.

The patent proprietors also requested that auxiliary requests 2A, 3A, 6A, 7A, 10A, 11A and 16A be admitted, and that document D7 not be admitted.

XIX. The opponent requested that the decision under appeal be set aside and that the patent be revoked.

The opponent also requested that documents D8 and D9 and auxiliary request 12A not be admitted.

Furthermore, the opponent was against remittal of the case to the opposition division for consideration of any ground of opposition not yet decided on by the opposition division.

Reasons for the Decision

1. Amendments (Articles 100(c) and 123(2) EPC)

1.1 The objections raised in relation to added subject-matter were mainly concerned with the characterisation of the claimed crystalline "Form II" in the claims in question.

Technical background

1.2 Crystalline solids are often characterised by X-ray powder diffraction (XRPD) patterns (or diffractograms), such as those rendered in Figures 7 and 8 of the patent in suit and the application as filed, which show a plot of the intensity of the lines observed over a continuous range of 2Θ values, wherein Θ is the scattering angle. As for terminology, these lines are called "peaks" in both the application as filed and the patent in suit.

1.3 Lists of 2Θ values, associated in the accompanying text with "Form II", are disclosed in Tables 4 and 5 and in paragraphs [0037] to [0040] of the patent in suit (corresponding to Tables 4 and 5 and page 8, lines 1 to 13, of the application as filed). Such lists are combinations of certain selected lines that are considered characteristic of the product in question. They do not contain the complete information from the corresponding diffractogram. In particular, it cannot be derived from a list of 2Θ values whether further lines at other 2Θ values are present or absent in the corresponding diffractogram. The lists in Table 4 (showing eighteen 2Θ values) and Table 5 (showing twenty-one 2Θ values) include d-spacing and line

intensities, whereas the lists on page 8 of the application as filed do not.

Legal background

1.4 According to the established jurisprudence of the boards of appeal, and as summarised and confirmed in decision G2/10 (OJ EPO 2012, 376; Reasons 4.3) with reference to G3/89 and G11/91, the following basic principle (the so-called "gold standard") applies:

Any amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) is subject to the mandatory prohibition on extension laid down in Article 123(2) EPC and can therefore, irrespective of the context of the amendment made, only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed.

1.5 What can be derived directly and unambiguously has to be determined according to the circumstances of the individual case.

Main request

1.6 Claim 1 as granted (main request) defines the claimed crystalline product by an X-ray powder diffraction pattern which, as the sole requirement, must comprise lines at the following 2Θ values, measured using CuKa radiation: 4.3±0.2°, 10.9°±0.2°, and 14.6°±0.2°.

1.7 The specific combination consisting of these three values is not disclosed anywhere in the application as filed. There is thus no teaching that this

particular combination might suffice for characterising the crystalline "Form II" of the application.

1.7.1 Combinations of 2Θ values intended to describe the crystalline "Form II" are set out in the application as filed on page 8, in claims 7 to 9 and in Tables 4 and 5 as follows:

(a) 4.3°, 5.0° and 12.8°, each ±0.2° (see claim 7 and page 8, line 3)

(b) 4.3°, 5.0°, 5.5°, 5.8°, 12.8° and 18.9°, each ±0.2° (see claim 8 and page 8, lines 4 to 6)

(c) 4.3°, 5.0°, 12.8°, 14.6°, 18.5° and 20.1°, each ±0.2° (see claim 9 and page 8, lines 7 to 9)

(d) 4.3°, 5.0°, 5.5°, 5.8°, 12.8°, 14.6°, 18.5°, 18.9° and 20.1°, each ±0.2° (see claim 9 and page 8, lines 7 to 9 and 10 to 13)

(e) eighteen 2Θ values with corresponding d-spacings and relative intensities, without error ranges (Table 4 on pages 19 to 20)

(f) twenty-one 2Θ values with corresponding d-spacings and relative intensities, without error ranges (Table 5 on pages 20 to 21)

1.7.2 The combinations of 2Θ values disclosed in Table 5, on page 8 of the description and in claims 7 to 9 as filed do not contain the value 10.9°±0.2°. All but one of these lists also combine more than three values. Table 5 shows a combination of twenty-one 2Θ values including line intensities.

The combination with only three values is *"4.3°±0.2°, 5.0°±0.2°, and 12.8°±0.2°"* (see page 8, lines 1 to 3 and claim 7), thus deviating in two of the specified values from claim 1 as granted.

Hence, none of these passages specifically discloses the combination of lines as defined in claim 1 as granted.

1.7.3 Table 4 in the application as filed shows a combination of eighteen 2Θ values, including 10.9°, 4.3° and 14.6°. However, the table also includes line intensities (absent in claim 1 as granted) and requires the presence of fifteen more lines which are not mandatory according to claim 1 as granted.

1.8 In these circumstances, neither the specific combination of 2Θ values in claim 1 as granted, nor the information that this combination may serve to characterise the product designated as "Form II" is derivable directly and unambiguously, using common general knowledge, from the application as filed. Contrary to the patent proprietors' argument in this regard, it is not implicit that any selection from a table listing eighteen characteristic values, such as the combination of any three values, will suffice to characterise the compound in question.

1.9 In line with the "gold standard" set out in section 1.4 above, a combination of 2Θ values used to characterise a crystalline form in any pending claim request has to be specifically disclosed in the application as filed. If that is not the case, the new combination constitutes added subject-matter.

1.10 The opposition division mentioned decisions T 1684/16 and T 1442/18 in its reasoning.

In the case underlying T 1684/16, the claim under consideration defined the crystalline form in question by a list of five 2Θ values (these are called "peaks" in the decision), whereas it was defined in the

application as filed by two lists of fifteen and twenty-four 2θ values.

In the case underlying T 1442/18, the claims under consideration defined the crystalline form in question by lists of eleven or seventeen 2θ values, whereas the application as filed defined it by a list of thirty-nine 2θ values.

In both cases, the respective case board, applying the standard of direct and unambiguous disclosure, did not allow claim amendments that defined a claimed crystalline form by new sets of 2θ values that were not specifically disclosed in the application as filed (T 1684/16, sections 2.1 to 2.5 of the Reasons; T 1442/18, section 14.1 of the Reasons). The opposition division's reference to these decisions regarding this point is thus correct.

The patent proprietors' reading of T 1684/16 is not correct. In that decision, the board held that the amendment in question was not allowable because the list of five 2θ values in the claim under consideration was not specifically disclosed in the application as filed. It was not even disclosed that five 2θ values could suffice for characterising the claimed crystalline form. This last point is, however, not crucial for the outcome. It cannot be interpreted (as the patent proprietors did) in the sense that the proposed amendment would have been allowed if it could have been inferred from the application as filed that the crystalline form could be characterised by (any) five 2θ values. As is made clear by the board in T 1684/16, the relevant requirement is that the specific list of five values should be disclosed in the application as filed, in line with the standard set out in sections 1.4, 1.8 and 1.9 above.

Thus, the board states in section 2.4 of the Reasons:

> *"[...] the list of five peaks in claim 1 of the patent as granted, and more specifically the fact that Form I can be characterised (and possibly distinguished) by just these five specific peaks, amounts to technical information which is not directly and unambiguously derivable from the whole content of the application as filed."*

1.11 The circumstances underlying decision T 325/16 (cited by the patent proprietors) are different from those in the case at hand since the four 2Θ values recited in the claim under consideration were identified as characterising lines in Example 3 of the application as filed, in the same specific set of four values (see T 325/16, section 9 of the Reasons). In contrast, in the case at hand, the patent proprietors relied in their reasoning on sets of 2Θ values in the application as filed which are different from the list in claim 1 as granted.

1.12 For the reasons set out in sections 1.2 to 1.11 above, the ground of opposition under Article 100(c) EPC prejudices the maintenance of the patent as granted.

Auxiliary requests 1, 2, 2A, 3, 3A, 6, 6A, 7 and 7A

1.13 The finding according to section 1.8 also applies, for analogous reasons, to claim 1 of each of auxiliary requests 1, 2, 2A, 3, 3A, 6, 6A, 7 and 7A, as all of these define the claimed "Form II" product by varied combinations of a number of up to ten 2Θ values including the three values listed in claim 1 as granted. None of these combinations is specifically disclosed in the application as filed as characterising "Form II".

1.14 As a consequence, the subject-matter of claim 1 of each of auxiliary requests 1, 2, 2A, 3, 3A, 6, 6A, 7 and 7A extends beyond the content of the application as filed (Article 123(2) EPC).

Auxiliary requests 10, 10A, 11 and 11A

1.15 Claim 1 of auxiliary requests 10, 10A, 11 and 11A characterises the claimed "Form II" product by eighteen 2Θ values that are identical to those in Table 4 of the application as filed.

1.16 However, in Table 4 of the application as filed, these values were disclosed together with the respective line intensities. As this limitation is not present in claim 1 of auxiliary requests 10, 10A, 11 and 11A, the claims in question contain added subject-matter.
The relevant criterion for the allowability of the amendment is disclosure in the application as filed, irrespective of any considerations relating to the reproducibility of line intensities observed with XRPD.

1.17 Moreover, error ranges of ±0.2°, which are not present in Table 4 of the application as filed, were added in auxiliary requests 10 and 10A. The board is not convinced by the patent proprietors' argument that the person skilled in the art would have inferred, by context and on the basis of common general knowledge, that error ranges of ±0.2° are inherent and must apply to all 2Θ values provided in the application as filed.

1.17.1 The disclosures and comments in D4 and D5 (relied on by the patent proprietors) do not warrant such a categorical conclusion.

D5, an expert declaration provided by the patent proprietors, states that the standard variation for characteristic peaks in XRPD measurements is typically

reported as ±0.2 degrees 2Θ, and in this context refers to D5b.

Both D4 (European Pharmacopoeia 8.0) and D5b (USP 35), state the following in their chapters on XRPD measurement:

> *"For most organic crystals, when using CuK_a radiation, it is appropriate to record the diffraction pattern in a 2Θ-range from as near 0° as possible to at least 40°. The agreement in the 2Θ-diffraction angles between different specimen and reference is within 0.2° for the same crystal form, while relative intensities between specimen and reference may vary considerably due to preferred orientation effects."*

1.17.2 While D4 and D5b may thus suggest that the error range of ±0.2° is typical, there is no common-general-knowledge evidence that no other error range can apply in individual cases. Indeed, in decision T 325/16 cited by the patent proprietors, the error range was indicated as ±0.1° (see sections 1 and 9 of the Reasons). The declaration D5 itself mentions several factors that may influence 2Θ measurements (see D5: section III.2, which mentions zero calibration, the height at which the sample sits in the diffractometer, and the surface planarity of the sample).

1.17.3 The application as filed does not define at any point that the range of ±0.2° is to be applied to all 2Θ values where no error range is indicated, in particular the values as combined in Tables 4 or 5.

1.18 A further objection relates to claim 2 of auxiliary requests 10 and 11 (see section X. above).

1.18.1 This claim, by reference to the product of claim 1, combines the process of preparation as described in Example 7 with the 2Θ values from Table 4. Table 4 is disclosed in the application as filed in the context of Example 6, however, where the material described was obtained with a different process of preparation (see the application as filed, Example 7, page 20, lines 5 to 15 and Example 6, Table 4 bridging pages 19 and 20). The process described in Example 6 is as follows:

> *"To 11.0 mL of Methanol/Toluene (1/10; v/v) was dissolved 66.7 mg of trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butyl-carbamoyl)propionate-(S)-3'-methyl-2'-(pentanoyl {2"-(tetrazol-5-ylate)biphenyl-4'-ylmethyl}amino) butyrate] hemipentahydrate in a glass vial. Filtered the solution through a 0.45 µm filter and put to room temperature (RT) for slow evaporation with a pin-holed parafilm. The solid was isolated [...]"*

This differs in all process steps from the process according to claim 2 of auxiliary requests 10 and 11 and Example 7 in the application as filed, where a different concentration of the complex in methanol (no toluene present) was heated to 80°C, after which toluene was added.

1.18.2 Thus, Table 4 is not directly and unambiguously disclosed in the application as filed together with the process of preparation from Example 7.

1.18.3 The mere fact that both the product obtained according to Example 6 and the product obtained according to Example 7 are designated as "Form II" in the application as filed does not prove that they were indeed the same material, since by itself, this amounts to no more than an assertion. Contrary indications are

that these products were obtained by different processes and showed certain differences in their XRPD diffractograms, which can be seen when comparing the process descriptions in Examples 6 and 7, the diffractograms in Figures 7 and 8 and the tabulated lists of 2Θ values in Tables 4 and 5. Obvious differences are the absence/presence of a number of lines both in the diffractograms and in the tabulated lists, most prominently the absence of the line at 12.4° in the case of the product of Example 6. These differences are not explained in the application as filed, and they cannot just be ignored. A comparison of Table 4 with Table 5 and of Figure 7 with Figure 8 does not permit the conclusion to be drawn that the materials are identical as regards the crystal form, especially in view of the different processes of preparation.

1.18.4 In the context of their submissions on inventive step, the patent proprietors presented a further argument in support of their view that the crystalline products prepared according to Example 6 and Example 7 were identical. This argument will be dealt with in the following, as it is relevant for concluding the issue of added subject-matter.

Basically, the patent proprietors argued that the only relevant difference was the line at 12.4° that occurred in Figure 8 (associated with Example 7) but not in Figure 7 (associated with Example 6), and that this could be explained by suboptimal measurement conditions.

In particular, the patent proprietors hypothesised that the line observed at 12.4° for the product according to Example 7 was due to a "preferred orientation effect" or was associated with the sample holder employed.

The process of preparation according to Example 3 of the priority document (which corresponds to the process according to Example 7) and the XRPD measurement had been repeated with a new sample holder. As demonstrated by the diffractograms presented in the corresponding test report (D9), no line at 12.4° had been observed.

This argument is not convincing. The patent proprietors were responsible for carrying out their measurements correctly in the sense of analysing for and eliminating potential sources of systematic measurement error. The data in Figure 8 and Table 5 is presented in the application as filed without qualification. As the differences between the data associated with Examples 6 and 7 are not addressed, it cannot be inferred from any passage in the application as filed that the line shown at 12.4° for the product prepared according to Example 7 was believed to be an artefact, or that the further differences between Tables 4 and 5 were believed to be irrelevant.

1.19 For the reasons set out in sections 1.15 to 1.18.4 above, the subject-matter of auxiliary requests 10, 10A, 11 and 11A extends beyond the content of the application as filed (Article 123(2) EPC).

Auxiliary requests 4, 5, 8 and 9

1.20 The combinations of 2θ values in claim 1 of auxiliary requests 4, 5, 8 and 9 are not specifically disclosed anywhere in the application as filed.

1.21 The claims in question disclose combinations of five or ten 2θ values taken from Table 5 of the application as filed. However, the disclosure of Table 5 is that of a combination of twenty-one values together with the respective line intensities. This does not constitute a

direct and unambiguous disclosure of combinations of a selection of only some values from this table, without the associated line intensities.

1.22 Moreover, error ranges of ±0.2°, which are not present in Table 5 of the application as filed, were added in auxiliary requests 4 and 8. Analogous reasons to those set out in section 1.17 above apply in relation to this difference.

1.23 For these reasons, the subject-matter of auxiliary requests 4, 5, 8 and 9 extends beyond the content of the application as filed (Article 123(2) EPC).

Auxiliary requests 14 and 15

1.24 The combination of 2Θ values in claim 1 of auxiliary requests 14 and 15 corresponds to that in Table 5 of the application as filed. In both claims, the line intensities are absent. In claim 1 of auxiliary request 14, error ranges of ±0.2° were added, which are absent in Table 5.

1.25 For analogous reasons to those set out above in relation to auxiliary requests 10, 10A, 11 and 11A (see sections 1.16 and 1.17 above), the subject-matter of claim 1 of auxiliary requests 14 and 15 therefore extends beyond the content of the application as filed (Article 123(2) EPC).

Summary

1.26 To summarise the findings above, neither the main request nor any of auxiliary requests 1, 2, 2A, 3, 3A, 4, 5, 6, 6A, 7, 7A, 8, 9, 10, 10A, 11, 11A, 14 and 15 is allowable, because the subject-matter defined in claim 1 of each of these requests extends beyond the

content of the application as filed (Articles 100(c) and 123(2) EPC).

2. Inventive step - auxiliary requests 12 and 12A (Articles 100(a), 52 (1) and 56 EPC)

Patent in suit and claimed subject-matter

2.1 The patent in suit relates to crystalline forms of a trisodium supramolecular complex comprising valsartan, which is an angiotensin receptor blocker, and AHU-377 (also called sacubitril), which is a neprilysin inhibitor, as well as pharmaceutical compositions and medical uses thereof and processes for preparing the crystalline forms.

2.2 As reported in the patent in suit (paragraph [0006]) and the application as filed (page 2), a supramolecular complex comprising valsartan and sacubitril, called LCZ696, had been approved by the FDA under the brand name "Entresto" for the treatment of heart failure with reduced ejection fraction.

2.3 The patent in suit identifies a need for new crystalline forms, in particular stable polymorphs with superior pharmacological activities suitable for formulation, and convenient methods for preparing them (paragraph [0010]).

2.4 Claim 1 of auxiliary request 12, which is identical to claim 1 of auxiliary request 12A, claims a crystalline form designated as "Form II" which is characterised by an XRPD pattern comprising lines at 2θ values measured using CuKa radiation, wherein the X-ray powder diffraction pattern is the same as that shown in Figure 7.

Starting point in the prior art

2.5 As in the decision under appeal, inventive step is assessed starting from the disclosure of document D3.

2.6 It was not in dispute that D3 discloses a crystalline form of trisodium valsartan sacubitril which differs from "Form II" as defined in the current claim requests (see D3, page 24, second full paragraph).

Distinguishing technical feature

2.7 Thus, the feature distinguishing the subject-matter of claim 1 of auxiliary requests 12 and 12A from the disclosure of D3 is the crystal form, as characterised by Figure 7.

Technical problem and solution

2.8 According to the established jurisprudence of the boards of appeal of the EPO, the mere provision of a further polymorph does not involve an inventive step, since screening for polymorphs is a routine activity in the context of pharmaceutical development (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, I.D.9.9.5). Thus, the question that is decisive for the acknowledgement of an inventive step is whether the claimed polymorph provides an unexpected advantage in comparison with forms disclosed in the prior art.

2.9 The patent proprietors relied, in this regard, on the data presented in Examples 14 to 16 of the patent in suit.

2.10 Examples 6, 7, 14, 15 and 16 of the patent in suit are present identically in the application as filed. The board's considerations in section 1. above in relation

to Examples 6 and 7 also apply to the identical examples in the patent in suit.

2.11 Examples 14 and 15 of the patent in suit compare "Form II" of the patent in suit with the so-called "patent form" disclosed in US8877938B2 (i.e. the US equivalent of D3) in terms of moisture uptake and flowability. It was not in dispute that the comparative experiments reported in Examples 14 and 15 represent a comparison of "Form II" with the crystalline form of trisodium valsartan sacubitril as disclosed in document D3. The reported outcome is that "Form II" showed better flowability (Example 15) and less moisture uptake when exposed to humidity (Example 14). Samples of "Form II" also showed storage stability (retaining the same crystal form) at varying humidity and temperature conditions (Example 16, not realised as a comparative test).

2.12 However, it is not disclosed in the patent specification whether the samples tested according to Examples 14 to 16 were obtained according to the process of preparation described in Example 6, or according to the process described in Example 7. In both Examples 6 and 7, the respective product that was prepared is designated as "Form II".

2.13 As established above (see sections 1.18.3 and 1.18.4), it cannot be confirmed on the basis of the available evidence that the crystalline products of Example 6 and Example 7 are indeed identical, as argued by the patent proprietors. As a consequence, the exclusive use of the term "Form II" in Examples 14 to 16 does not permit the reader to infer that, specifically, the product according to Example 6 and corresponding Figure 7 and Table 4 was tested in these examples. For this reason, it cannot be confirmed that the specific product

claimed in claim 1 of auxiliary requests 12 and 12A, which is characterised by the diffractogram in Figure 7, indeed exhibited the favourable properties described in Examples 14 to 16.

2.14 As a consequence, it has not been shown that the claimed crystalline product has superior properties in comparison with the crystalline form of D3.

2.15 The objective technical problem is, therefore, the provision of a further crystalline form of trisodium valsartan sacubitril.

2.16 The solution to this problem is the crystalline form according to claim 1 of auxiliary requests 12 and 12A.

Obviousness of the solution

2.17 For inventive step to be acknowledged, the selection of a specific crystalline form must not be arbitrary.

2.18 The skilled person in the field of pharmaceutical drug development would have been aware of the fact that instances of polymorphism were commonplace in molecules of interest to the pharmaceutical industry, and would have routinely screened for polymorphs early on in the drug development process. In the absence of any technical prejudice and in the absence of any technical advantage such as superiority of properties in comparison with known polymorphs, the mere provision of a further crystalline form of a known pharmaceutically active compound cannot be regarded as involving an inventive step.

2.19 For these reasons, the subject-matter of claim 1 of auxiliary request 12 and of the identical claim 1 of

auxiliary request 12A does not involve an inventive step within the meaning of Article 56 EPC.

3. Inventive step - auxiliary request 13

3.1 Claim 1 of auxiliary request 13 differs from claim 1 of auxiliary request 12 by characterising the claimed crystalline product by reference to Figure 8 instead of Figure 7.

3.2 By analogy, the same reasoning applies: since it cannot be confirmed that the crystalline product prepared according to Example 7, as characterised by Figure 8 (and Table 5), was used in the experiments described in Examples 14 to 16, it has not been conclusively shown that the claimed product has superior properties in comparison with the crystalline form of D3. Accordingly, the same objective technical problem and the same conclusions regarding obviousness apply as those set out above with respect to auxiliary requests 12 and 12A.

3.3 As a consequence, the subject-matter of claim 1 of auxiliary request 13 does not involve an inventive step within the meaning of Article 56 EPC.

4. Inventive step - auxiliary requests 16, 16A and 17

4.1 The claimed crystalline form in claim 1 of auxiliary request 16 and the identical claim 1 of auxiliary request 16A is characterised by a table of 2Θ values, d-spacings and relative line intensities which is identical to Table 4. Like Figure 7, Table 4 is used in Example 6 to characterise the crystalline product prepared according to the process of Example 6.

4.2 The same considerations and conclusions regarding inventive step apply as those set out in the case of auxiliary requests 12 and 12A (see section 2. above).

4.3 The claimed crystalline form in claim 1 of auxiliary request 17 is characterised by a table of 2Θ values, d-spacings and relative line intensities which is identical to Table 5. Like Figure 8, Table 5 is used in Example 7 to characterise the crystalline product prepared according to the process of Example 7.

4.4 The same considerations and conclusions regarding inventive step apply as those set out in the case of auxiliary request 13 (see section 3. above).

4.5 As a consequence, neither the subject-matter of claim 1 of auxiliary requests 16 and 16A nor that of claim 1 of auxiliary request 17 involves an inventive step within the meaning of Article 56 EPC.

5. Admittance of documents D7, D8 and D9

5.1 Documents D7, D8 and D9 were filed by the parties in the context of a debate on the validity of the priority of the patent in suit. The patent proprietors also referred to D9 in their reasoning on inventive step.

5.2 The patent proprietors' arguments in relation to inventive step based on D9 were taken into account by the board (see sections 1.18.4 and 2.13 above). Since the outcome of the inventive-step assessment is in the opponent's favour, it is not necessary to address the admittance of D9 in this context.

5.3 As the priority issue is not relevant to the board's decision, it is not necessary to address the admittance of D7, D8 and D9 in the context of the priority issue.

6. Admittance of new auxiliary requests

6.1 The admittance of auxiliary requests 2A, 3A, 6A, 7A, 10A, 11A, 12A and 16A need not be addressed, in view of the negative conclusions reached in sections 1.14, 1.19, 2.19 and 4.5 above on the compliance of these requests with Articles 123(2) and 56 EPC.

7. Patent proprietors' request for remittal of the case (Article 111(1) EPC)

7.1 The subject of remittal did not arise in relation to the main request and auxiliary requests 1, 2, 2A, 3, 3A, 4, 5, 6, 6A, 7, 7A, 8, 9, 10, 10A, 11, 11A, 12 and 12A. This is because the board's conclusion that none of these requests is allowable is based, in each case, on objections that were also considered in the decision under appeal in relation to the same subject-matter, namely non-compliance with Article 123(2) EPC or Article 56 EPC.

7.2 The remittal of the case to the opposition division on the basis of any of the remaining auxiliary requests was not considered appropriate for the following reasons.

7.2.1 The considerations concerning the compliance of auxiliary requests 14 and 15 with Article 123(2) EPC were, by analogy, the same as those set out in relation to auxiliary requests 10, 10A, 11 and 11A (see section 1.25 above). As a consequence, there was no occasion for remittal in respect of these claim requests.

7.2.2 In the case of auxiliary requests 13, 16, 16A and 17, the definition of the crystal form in each of these requests is based on Figure 7 or Table 4, or alternatively on Figure 8 or Table 5. As a consequence,

the claimed subject-matter could be assessed for inventiveness on the basis of the same considerations, or the same considerations by analogy, as those set out with respect to auxiliary requests 12 and 12A (see sections 3. and 4. above). Indeed, the patent proprietors' arguments in support of inventive step were identical for all requests (see the patent proprietors' grounds of appeal, sections 4.4, 5.3, 6.4, 7.4, 8.5, 9.4, 10.4, 11.4, 12.4, 13.4, 14.4, 15.4, 16.4, 17.4, 18.4, 19.4, 20.4, 21.4, 22.3, 23.4, 24.4, 25.4, 26.4, 27.4, 28.4 and 29.3, and the patent proprietors' reply to the opponent's appeal, section 4).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated