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**Datasheet for the decision  
of 15 January 2026**

**Case Number:** T 0479/24 - 3.3.02

**Application Number:** 18189607.7

**Publication Number:** 3470397

**IPC:** C07D217/26

**Language of the proceedings:** EN

**Title of invention:**

CRYSTALLINE FORMS OF A PROLYL HYDROXYLASE INHIBITOR

**Patent Proprietor:**

Fibrogen, Inc.

**Opponents:**

Sandoz AG  
Teva Pharmaceutical Industries Ltd  
Generics [UK] Limited

**Relevant legal provisions:**

EPC Art. 100(c), 54, 56

**Keyword:**

Grounds for opposition - amendments  
Novelty  
Inventive step

**Decisions cited:**

G 0003/14, T 0777/08, T 0334/10, T 1402/14, T 0325/16,  
T 1684/16, T 0648/21



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 0479/24 - 3.3.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.02**  
**of 15 January 2026**

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**Decision under appeal:**            **Decision of the Opposition Division of the  
European Patent Office posted on  
12 February 2024 rejecting the opposition filed  
against European patent No. 3470397 pursuant to  
Article 101(2) EPC.**

**Composition of the Board:**

**Chairman**            M. O. Müller  
**Members:**            A. Lenzen  
                          M. Blasi

## Summary of Facts and Submissions

- I. Opponents 1 to 3 (appellants 1 to 3) lodged appeals against the opposition division's decision (decision under appeal) to reject the oppositions against European patent No. 3 470 397 (patent).

The patent was granted on European patent application No. 18189607.7 (application), which is a divisional application of European patent application No. 13740185.7. The latter had been filed as a PCT application published as WO 2014/014835 A2.

- II. Reference is made in the present decision to the following documents filed with the opposition division:

- D1 US 2004/0254215 A1
- D2 Experimental report - repetition of example D-81 of US 2004/0254215 (May 2019) (18 pages)
- D3 Report on the synthesis of roxadustat according to US 2004/0254215 A1 and comparison of XRD spectra with those published in EP 2 872 488 (11 pages)
- D4 Notice of opposition filed by Zentiva k.s. in the proceedings of European Patent No. 2 872 488
- D14 WO 2014/014835 A2, the parent application as published
- D19 WO 2004/108681 A1
- D20 US 7,323,475 B2
- D21 WO 2012/097331 A1
- D27 Technical Annex 1 (4 pages)
- D28 Technical Annex 2 (2 pages)
- D30 Declaration from Mr Martinelli
- D32 Experimental report (25 pages)

III. With the reply to the appellants' statements of grounds of appeal, the patent proprietor (respondent) filed the following document:

D44 Experimental report (25 pages)

IV. By letter dated 19 March 2025, appellant 3 filed another substantive submission.

V. In preparation for the oral proceedings, which had been arranged at the parties' request, the board issued a communication under Article 15(1) RPBA. In that communication, it summarised the parties' previous substantive submissions and expressed its preliminary opinion on several issues.

VI. By letters dated 8 December 2025 and 9 January 2026 respectively, appellants 1 and 3 informed the board that they would not be attending the scheduled oral proceedings. Appellant 3 additionally submitted further substantive arguments with its letter.

VII. Oral proceedings before the board were held by videoconference on 15 January 2026 in the presence of appellant 2 and the respondent. At the end of the oral proceedings, the chair announced the order of the present decision.

VIII. The parties' final requests at the end of the oral proceedings, in so far as they are relevant to this decision, were as follows:

- Appellants 1, 2 and 3 requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

- The respondent requested that the appeals be dismissed, implying that the decision under appeal rejecting the oppositions be upheld (main request).

IX. Summaries of the parties' submissions relevant to the present decision are set out in the reasons for the decision below.

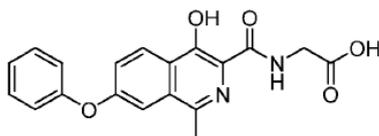
### Reasons for the Decision

Main request (patent as granted)

1. Claim 1 of the main request reads as follows:

*"A pharmaceutical composition comprising crystalline [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid (Compound A Form A) characterized by an X-ray powder diffractogram comprising the following peaks: 8.5, 12.8, 16.2, 21.6, 22.9, and 27.4 °2θ ± 0.2 °2θ, when measured using Cu Kα radiation, and a pharmaceutically acceptable excipient, for use in a method of treating, pretreating, or delaying onset or progression of anemia, wherein at least about 85% of Compound A in the pharmaceutical composition is in Form A."*

2. Compound A of claim 1, i.e. [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, has the following structure:



It is referred to below by its INN roxadustat.

3. Thus claim 1 is essentially directed to a (second) medical use of a pharmaceutical composition comprising a pharmaceutically acceptable excipient and a specific solid form (polymorph) of roxadustat, i.e. form A, which is characterised by six XRPD peaks. The actual medical use is the "*treating, pretreating, or delaying onset or progression of anemia*". At least about 85% of all roxadustat in the pharmaceutical composition is in form A (below, this is referred to as the "degree of purity").

4. Clarity (Article 84 EPC)

In the statement of grounds of appeal, appellant 2 raised a clarity objection against the degree-of-purity feature in claim 1. In its view, this feature was defined in a way that rendered it impossible to distinguish the subject-matter claimed from that of the prior art.

However, this objection cannot succeed, because it is claim 1 as granted that is at issue here (G 3/14, OJ EPO 2015, A102, order). The position of appellant 2 on clarity also fails to convince because it is inconsistent with another of its statements relating to the very same feature, according to which the degree of purity can be determined by the skilled person by means of routine experimentation. These points were already set out in the board's communication under Article 15(1) RPBA and were not disputed by appellant 2 during the oral proceedings.

5. Amendments (Article 100(c) EPC)

5.1 According to the appellants, the subject-matter of claim 1 of the main request extended beyond the content of the application and the parent application as filed.

5.2 All parties agreed that the disclosure content of the application as filed was identical to that of the parent application as filed and that, therefore, the result of the assessment of added subject-matter would be the same in both cases. In line with the appellants, the board uses the parent application as filed (D14, hereinafter "parent application").

5.3 In the appellants' view, starting for example from claim 55 of the parent application, and in order to arrive at the subject-matter of claim 1 of the main request, at least two of the following three features had to be selected from corresponding lists of equally preferred alternatives disclosed in the parent application:

- (a) the actual solid form of roxadustat, i.e. form A
- (b) the degree of purity of roxadustat (*"wherein at least about 85% of Compound A in the pharmaceutical composition is in Form A"*)
- (c) the medical use (*"treating, pretreating, or delaying onset or progression of anemia"*)

However, the parent application was devoid of corresponding pointers to the combination of features ultimately claimed.

5.4 The board, however, shares the opposition division's and the respondent's view that claim 1 of the main

request does not contain added subject-matter. This is for the following reasons.

5.4.1 Ad (a) (actual solid form of roxadustat, i.e. form A)

In addition to form A, the parent application also discloses forms B, C and D of roxadustat, see for example paragraphs [0006] to [0009]. The limitation to roxadustat form A in claim 1 of the main request therefore does indeed constitute a selection of this form from among the forms disclosed in the parent application.

Paragraph [0003] of the parent application sets out the importance of the stability of a crystalline form of a drug for drug development. In this context, paragraph [0095] of the parent application explains that, among forms A, B, C and D, form A is the most stable crystalline form of roxadustat. Moreover, only form A was chosen for biological tests in the parent application (paragraph [0220]). Finally, as regards pharmaceutical compositions and medical uses, the corresponding independent claims (claims 55, 64, 68 and 69) of the parent application refer to different forms of roxadustat, whereas only form A is singled out in the corresponding dependent claims (claims 56 to 63 and 70 to 77). Therefore the parent application teaches a preference for form A of roxadustat.

5.4.2 Ad (b) (degree of purity of roxadustat)

It was undisputed between the parties that the degree of purity of roxadustat incorporated into claim 1 of the main request corresponds to the broadest range disclosed in this respect in the parent application: see, for example, dependent claims 57 to 63, which each

disclose a degree of purity of at least about 85%, 90%, 95%, 99%, 99.5%, 99.9% and 99.99%, respectively (analogously: the sequence of separate consecutive sentences in paragraphs [0098] and [0120]). These numerical ranges are not mutually exclusive, but are converging from the broadest to the narrowest range. The board is of the view that the limitation to the broadest numerical range of such a sequence of converging ranges does not constitute a selection, and agrees with the views expressed in T 334/10 (point 10.4 of the Reasons), T 648/21 (point 2.3.4 of the Reasons) and T 1402/14 (point 4.1.4 of the Reasons).

Appellant 2 argued that case T 334/10 was not relevant to the present one. This was because the application in that case presented the numerical ranges in a single sentence. By contrast, in the present case, the parent application disclosed the ranges in different consecutive dependent claims or in separate consecutive sentences, i.e. as distinct individualised embodiments. However, the board agrees with the respondent that the skilled person would interpret the presentation in the present case in the same way as in case T 334/10, namely as a sequence of converging numerical ranges that relate to the same parameter (sequence homology in case T 334/10, degree of purity of roxadustat in the present case). The board therefore follows the approach set out in decision T 334/10.

#### 5.4.3 Ad (c) (medical use)

Independent claims 64, 68 and 69 of the parent application relate to different medical uses of roxadustat and its different solid-state forms. The limitation in claim 1 of the main request to the use of claim 69 of the parent application ("*treating,*

*pretreating, or delaying onset or progression of anemia*") therefore does constitute a selection of this use from among the uses disclosed in claims 64, 68 and 69 of the parent application.

While claim 69 of the parent application defines the medical use by reference to the specific condition itself, namely anaemia, the medical uses in claims 64 and 68 are defined functionally in terms of hypoxia inducible factor (HIF) / erythropoietin (EPO) mediation. Since it is known that anaemia is associated with HIF/EPO (parent application, paragraph [0220]), the skilled person would consider the medical use of claim 69 to be a specific and preferred embodiment of the medical uses of claims 64 and 68. Accordingly, the skilled person would understand the parent application as preferring the treatment of anaemia from among the disclosed medical uses.

- 5.5 Thus, in summary, starting from claim 55 of the parent application as filed, only two selections are necessary to arrive at the subject-matter of claim 1 of the main request (see (a) and (c) above). As there are pointers in the parent application in terms of preferences towards these selections, the resulting subject-matter does not extend beyond the content of the (parent) application as filed.

It follows that Article 100(c) EPC does not prejudice maintenance of the patent as granted.

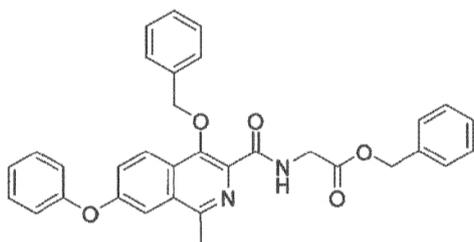
6. Novelty (Articles 100(a), 52(1) and 54 EPC)

- 6.1 Appellants 1 and 3 raised novelty objections against the subject-matter of claim 1 of the main request. These objections may be summarised as follows:

- Appellant 1 submitted that D1 disclosed the synthesis of roxadustat in example D-81. This synthesis yielded roxadustat as required by claim 1 of the main request, i.e. in form A and with a degree of purity of at least about 85%.
- Appellant 3 essentially argued that roxadustat as required by claim 1 of the main request was disclosed in D21 by virtue of its reference (page 6, lines 11 to 13) to the syntheses in D19 (pages 211 to 212, example D-81) and D20 (columns 137 and 138, example D-81), which were identical to the synthesis disclosed in example D-81 of D1.
- The remaining features of claim 1 of the main request were likewise disclosed in D1 and D21, respectively.

6.2 Both novelty objections therefore share the central issue in the present appeal proceedings of whether the synthesis described identically in D1, D19 and D20 yields roxadustat as defined in claim 1, i.e. in form A and with a degree of purity of at least about 85%. For the sake of brevity, the board refers below to only one of these three documents, namely D1.

6.3 Example D-81 of D1 discloses the synthesis of roxadustat in 5 steps, a) to e). For the purposes of the present decision, only step e) is relevant. This final step relates to the hydrogenolysis of the two benzyl protecting groups present in the following compound (referred to below as "the roxadustat precursor")



to obtain roxadustat. Importantly, this reaction is not described as such in D1. Rather, it is stated to be carried out by analogy with the hydrogenolysis described in step d) of example D-78, which relates to a different compound. Step d) of example D-78 reads as follows (D1, paragraph [1037]; emphasis and annotation in square brackets added by the board):

*"A mixture of [a compound different from the roxadustat precursor] (134 mg, 0.285 mmol), Pd/C (100 mg, 10 wt % Pd), EtOAc (10 ml) and MeOH (50 ml) was stirred under a H<sub>2</sub>-atmosphere at ambient pressure and temperature for 18 h. Then the mixture was filtered through a pad of celite. **Celite and filter cake were washed thoroughly with EtOAc and the combined organic phases were concentrated in vacuo to give the title compound as a tan solid (74 mg); MS-(-)-ion: M-1=289.2."***

This reaction is defined with specificity with regard to the amounts of reactants and solvents used for the actual hydrogenolysis. However, the conditions to be used for the concentration of the combined organic phases *in vacuo* are not specified. Furthermore, the amount of ethyl acetate to be used for washing celite and filter cake is only defined as being sufficient to allow for thorough washing.

6.4 Example D-81 of D1 does not disclose in which physical form roxadustat is obtained at the end of step e), e.g.

oil, amorphous solid, crystalline solid, (crystalline) form A or other. As noted by the respondent, the mere fact that step d) of example D-78 results in a solid (see quotation above) does not, as such, allow the conclusion to be drawn that step e) of example D-81, which relates to a different compound with different physical properties and which is carried out merely by analogy, likewise results in a solid.

6.5 In this context, the appellants pointed to D2, D3 and D4. These documents described repetitions of step d) of example D-78 but using the roxadustat precursor. Each repetition yielded roxadustat as defined in claim 1, i.e. in form A and with a degree of purity of at least about 85%. It could be concluded that roxadustat as defined in claim 1 was implicitly disclosed in D1.

6.6 However, the board does not agree, for the following reasons:

(a) D3 (page 8) describes a repetition in which celite and filter cake are washed with ethyl acetate. The combined organic phases are concentrated *in vacuo* using a rotary evaporator to give a brown viscous oil. Even if subsequent concentration under more stringent conditions ultimately leads to form A of roxadustat, the board, in agreement with the respondent, sees no reason not already to regard the repetition up to the stage of obtaining the brown viscous oil as a reasonable repetition of D1.

(b) In another repetition, described in D4 (page 9, batch no. ROX-IC-178), celite and filter cake are washed with ethyl acetate. The combined organic phases are concentrated *in vacuo* using a rotary evaporator to give a brown gel. Even if subsequent

"standing open to air at room temperature for three days", as stated in D4, ultimately leads to form A of roxadustat, the board, in agreement with the respondent, sees no reason not already to regard the repetition up to the stage of obtaining the brown gel as a reasonable repetition of D1. This is because D1 merely requires concentration *in vacuo*, but does not require the resultant residue to stand for any further period of time in order to crystallise.

It follows from the consideration of D3 and D4 alone that the disclosure of D1, at least as far as the concentration *in vacuo* is concerned, leaves such a degree of latitude that the repetition of example D-81 of D1 does not even necessarily result in a solid form of roxadustat (see above: brown viscous oil/brown gel), let alone roxadustat form A. If anything, it is to be concluded that example D-81 of D1 discloses roxadustat only in a generic form.

6.7 In addition, the respondent submitted its own experimental data (D32, D44). The experiments described in these two experimental reports essentially demonstrate that, at a given reaction scale, roxadustat form A is obtained only if the volume of ethyl acetate used for washing celite and filter cake exceeds a certain threshold. Below this threshold, only amorphous roxadustat is formed under the conditions chosen for concentration *in vacuo*. Thus it must be concluded that the disclosure of D1 leaves such a degree of latitude also as far as the washing with ethyl acetate is concerned that the repetition of example D-81 of D1 does at least not necessarily result in roxadustat form A.

The appellants countered that, in those experiments described in D32/D44 which did not lead to roxadustat form A, too small an amount of ethyl acetate had been used. This, they argued, did not correspond to the thorough washing disclosed in D1, and the corresponding repetitions in D32/D44 were therefore not reasonable. The same argument was also advanced by appellant 3 with regard to the repetition described above in D4, as this used, as stated in D4 itself, only a "minimum amount" (20 mL) of ethyl acetate.

However, as already established above, the disclosure of D1 leaves such a degree of latitude already as regards the concentration *in vacuo* that the repetition of example D-81 of D1 does not necessarily result in a solid form of roxadustat, let alone roxadustat form A. Therefore, strictly speaking, the question of whether this also applies to the washing with ethyl acetate is irrelevant. However, irrespective of this, the board agrees with the respondent and the opposition division on this point as well. More specifically, there is no apparent reason why the amounts of ethyl acetate used in the repetitions of D32, D44 and D4 which do not result in roxadustat form A would be insufficient to achieve the thorough washing described in D1. As argued by the respondent, the term "thorough washing" is not a well-defined term and encompasses a wide range of different solvent volumes. The exact solvent volume considered necessary for thorough washing will vary depending on a number of factors, including the preferences of the experimenter. The amount of ethyl acetate required will, for example, depend on the amount of celite used to filter off the heterogeneous catalyst Pd/C. With regard to the amount of celite used, the authors of D32/D44 considered the washing volumes of ethyl acetate appropriate for thorough

washing (D44: page 9, last paragraph). The amount of celite is not specified in D4. However, contrary to the position of appellant 3, appellant 1, from whom this document originates, did not consider the repetition described above to be unreasonable.

- 6.8 In summary, the board agrees with the opposition division and the respondent that D1 discloses roxadustat only in a generic form, more specifically in a form which is not even necessarily solid. In view of the fact that D1 does not disclose roxadustat in the form required by claim 1, the novelty objections raised by appellants 1 and 3 must fail.

Hence the ground for opposition under Article 100(a) and Article 54 EPC does not prejudice maintenance of the patent as granted

7. Inventive step (Articles 100(a), 52(1) and 56 EPC)

- 7.1 Closest prior art

All the appellants considered D1 (example D-81) as the closest prior art. Appellant 3 also considered D21 as the closest prior art, but conceded that an assessment starting from D1 or D21 would ultimately give the same result. The following assessment therefore focuses on D1 as the closest prior art.

- 7.2 Distinguishing features

As set out above, example D-81 of D1 discloses roxadustat only in a generic form. Therefore the subject-matter of claim 1 of the main request differs from D1 at least in that it relates to roxadustat form A with a degree of purity of at least about 85%.

7.3 Technical effects and objective technical problem

7.3.1 In its reply to the statements of grounds of appeal, the respondent - by referring to the corresponding experimental data in the patent, D27, D28 and D30 - compared form A with other crystalline forms of roxadustat, specifically form B (a water solvate), form C (a hexafluoropropan-2-ol solvate) and form D (a dimethyl sulfoxide/water solvate). Form A (i) was unsolvated, (ii) was non-hygroscopic, (iii) exhibited high thermal, polymorphic and chemical stability under storage at both high and low temperatures and under conditions of high humidity, and (iv) remained stable during the manufacture of pharmaceutical compositions and their storage under harsh conditions. By contrast, none of forms B, C and D exhibited all of these properties. The respondent concluded that form A of roxadustat possessed an improved combination of properties compared with forms B, C and D.

Not only does the board find these submissions persuasive, but the comparisons between forms A, B, C and D carried out by the respondent were not disputed by any of the appellants either.

In line with the respondent's submission, the objective technical problem can therefore be considered as being to provide a pharmaceutical composition for use in a method of treating anaemia, the composition comprising roxadustat with an improved combination of properties.

7.3.2 As set out above, the appellants did not dispute the conclusions drawn by the respondent from the comparison of forms A, B, C and D. Nevertheless, they disagreed with the objective technical problem as formulated

above. The reason for this was that, in their view, comparing form A with forms B, C and D was the wrong comparison. They argued as follows:

- (a) The experimental evidence provided by the appellants (D2, D3 and D4) and the respondent (D32, D44) demonstrated that a repetition of example D-81 of D1 could yield only one of two distinct products - either roxadustat in accordance with claim 1 or amorphous roxadustat. The board could acknowledge novelty only on the assumption that example D-81 of D1 disclosed amorphous roxadustat.
- (b) Forms B, C and D - by virtue of being solvates - were more distant from form A than amorphous roxadustat. In this context, appellant 2 argued during the oral proceedings that one reason for this was that an amorphous form of a compound did not contain any solvent.
- (c) The solvents contained in the crystal structures of forms B, C and D (see above: water, hexafluoropropan-2-ol and/or dimethyl sulfoxide) were not used in example D-81 of D1 (see above: methanol, ethyl acetate). This demonstrated that none of these three solvates could ever result from example D-81 of D1 and that they could not be considered as representing a valid comparator. Furthermore, these forms had been prepared for the first time in the patent and were not known before the effective date of the patent.
- (d) For the reasons stated above, the respondent should have compared form A with amorphous roxadustat in order to derive a technical effect over the closest prior art.

7.3.3 The board does not find these arguments convincing, for the following reasons.

As set out above, example D-81 of D1 discloses roxadustat only in a generic form. Since D1 does not disclose amorphous roxadustat, there is no reason to require a comparison of form A with amorphous roxadustat for the purpose of demonstrating a technical effect.

As regards appellant 2's argument (b), the board notes that all the forms A, B, C and D are crystalline. Each of these forms is thus characterised by an ordered structure, while the amorphous form lacks any such order. Therefore the board agrees with the respondent's view that form A is closer to forms B, C and D than to the amorphous form. Appellant 2's position that form A was closer to the amorphous form than to forms B, C and D, since unlike forms B, C and D form A and the amorphous form did not contain any solvent, lacks any substantiation. It was in particular neither shown by the appellant that the amorphous form did indeed not contain any solvent, nor that if it did indeed not do so that this moved form A so far away from the solvent-containing forms B, C and D that the similarity based on their ordered structures was outweighed. The board therefore does not find appellant 2's allegation convincing. Consequently, there was no need at the oral proceedings to decide on the respondent's request for appellant 2's allegation that an amorphous form of a compound did not contain any solvent not to be admitted.

In view of the fact that the closest prior art does not disclose any particular solid form with which form A could have been compared, the board - in line with the opposition division - considers the respondent's comparison of form A with forms B, C and D to be both

appropriate and justified, even though these forms cannot be considered as being encompassed by the teaching of D1. If the respondent were denied this possibility, the consequence would be that the provision of the very first solid form of a substance could never be regarded as inventive, even if that first solid form were, in terms of its properties, a "one-size-fits-all" solution.

#### 7.4 Obviousness

The mere suggestion in the prior art to screen for solid forms with advantageous properties, contrary to the appellants' argument, is not in itself sufficient to deny roxadustat form A an inventive step.

Inventive step can be denied only if the prior art contains a clear pointer that this form solves the objective technical problem identified above, or if it at least creates a reasonable expectation that a suggested investigation will be successful (see also T 1684/16, point 4.3.4 of the Reasons, and T 325/16, point 16.5.2 of the Reasons). However, in the present case, the appellants did not provide any arguments to that effect. In this respect, appellant 3's allegation made in point 81 of its statement of grounds of appeal that the skilled person would have had a general expectation that, starting from the amorphous form, a routine polymorph screen would provide a stable form suitable for commercial use is an unsubstantiated allegation and hence not convincing.

Accordingly, the board agrees with the opposition division and the respondent that the solution to the objective technical problem identified above would not have been obvious to the skilled person.

7.5 For the sake of completeness, the board wishes to add that an inventive step would still have to be acknowledged even if the appellants' arguments

- (i) that D1 discloses only one of two distinct products, namely either roxadustat in accordance with claim 1 or amorphous roxadustat,
- (ii) that - in view of the board's conclusion on novelty - it had to be concluded that D1 disclosed amorphous roxadustat,
- (iii) that the improvements relied on by the respondent for inventive step, namely essentially an improvement in terms of stability and hygroscopicity, had to be expected for a crystalline form such as form A when compared with amorphous roxadustat

were accepted in their favour. The reason for this is that form A is not merely an arbitrary selection of a specific solid form from a group of equally suitable candidates (see T 777/08, point 5.2 of the Reasons) but rather a purposeful one, as demonstrated by the respondent with the comparison of form A with forms B, C and D.

7.6 It follows that the subject-matter of claim 1 of the main request involves an inventive step.

In summary, the ground for opposition under Article 100(a) and Article 56 EPC does not prejudice maintenance of the patent as granted either.

**Order**

**For these reasons it is decided that:**

The appeals are dismissed.

The Registrar:

The Chairman:



U. Bultmann

M. O. Müller

Decision electronically authenticated