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Datasheet for the decision of 22 November 2019

Case Number: T 1744/14 - 3.3.02

Application Number: 04015299.3

Publication Number: 1493745

IPC: C07D487/04, A61K31/519, A61P7/02, A61P9/10

Language of the proceedings: EN

Title of invention:
New crystalline and amorphous form of a triazolo(4,5-D)pyrimidine compound

Patent Proprietor:
AstraZeneca AB

Opponent:
Hexal AG

Headword:

Relevant legal provisions:
EPC Art. 123(2), 83, 54(3), 87(1), 56
RPBA Art. 12(2), 13(1), 13(3)

Keyword:
Novelty - (yes)
Priority - basis in priority document (yes)

Decisions cited:
T 0593/09, T 1845/14, T 1311/15, T 2001/12, T 0777/08

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1744/14 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 22 November 2019

Appellant: (Patent Proprietor)	AstraZeneca AB 151 85 Södertälje (SE)
Representative:	Potter Clarkson The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Respondent: (Opponent)	Hexal AG Industriestrasse 25 83607 Holzkirchen (DE)
Representative:	Guggenberger, Christoph Hexal AG Industriestraße 25 83607 Holzkirchen (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 June 2014 revoking European patent No. 1493745 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	P. O'Sullivan
	P. de Heij

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies from the decision of the opposition division to revoke European patent 1 493 745.

II. The patent was opposed under Article 100(a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, the invention defined in the claims was not sufficiently disclosed, and its subject-matter extended beyond the content of the application as filed.

III. According to the contested decision, the respective claim 1 of the main request and auxiliary requests 1 to 5 lacked novelty over the disclosure in D1, auxiliary request 6 contravened the requirements of Articles 123(2) and 84 EPC and auxiliary request 7 lacked an inventive step pursuant to Article 56 EPC.

IV. During opposition proceedings, *inter alia* the following documents were cited:

D1 WO 00/34283 A
D2 Stephen Byrn *et al.*, Pharmaceutical Research, Vol. 12, No. 7, 1995
D4 Report: "Ticagrelor crystallization Experiments"

V. Subsequent to the filing of the statement of grounds of appeal, a reply thereto from the opponent (respondent) and a reply thereto from the appellant, a communication of the board pursuant to Article 15(1) RPBA was sent in preparation of oral proceedings, scheduled in accordance with the corresponding requests of the parties.

VI. Oral proceedings before the board were held on 22 November 2019.

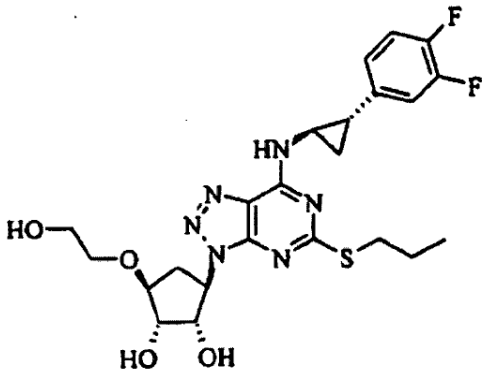
VII. The requests of the parties relevant to the decision were as follows:

The appellant requested that the contested decision be set aside and the patent be maintained in amended form according to the set of claims of the main request submitted with the statement of grounds.

The respondent requested dismissal of the appeal.

VIII. Independent claims 1 and 5 of the main request read as follows:

"1. A compound of formula (I):



(I)

in a substantially crystalline form ***characterised by*** *an X-ray powder diffraction pattern containing specific peaks of high intensity at 5.5° (±0.1°), 13.5° (±0.1°), 18.3° (±0.1°), 22.7° (±0.1°) and 24.3° (±0.1°) 2θ.*

5. A mixture of a compound of formula (I) as claimed in any one of claims 1 to 4 and a compound of formula (I) ***characterised by*** *an X-ray powder diffraction pattern containing specific peaks of high intensity at 14.0° (±0.1°), 17.4° (±0.1°), 18.4° (±0.1°), 21.4° (±0.1°) and 24.1° (±0.1°) 2θ, or characterised by an X-ray powder diffraction pattern containing specific peaks at 5.6° (±0.1°), 12.5° (±0.1°), 14.0° (±0.1°), 17.4° (±0.1°), 18.4° (±0 1°), 21.4° (±0.1°), 22.2° (±0.1°), 22.9° (±0.1°), 24.1° (±0.1°) and 24.5° (±0.1°) 2θ; or characterised by a differential scanning calorimetry curve to have an onset of melting which is in the range 127-132 °C."*

IX. The respondent's arguments, insofar as relevant to the present decision, may be summarised as follows:

Amendments, Article 123(2) EPC

The application as filed lacked a basis for the subject-matter of claims 2-4 and 6-8.

Sufficiency of disclosure

In view of a lack of clarity in the definition of the feature "substantially crystalline", the skilled person was unable to determine whether he was working within the scope of claim 1, leading to a lack of sufficient disclosure for the subject-matter thereof. Further a lack of sufficient disclosure arose since there was no evidence that the problem as set out in the patent had been solved across the scope of claim 1.

Novelty, Article 54 EPC

Although lacking any characterisation, the product of example 3 of D1 corresponded to a compound of formula (I) recited in claim 1 at issue. The reworking of this example according to D4 served as proof that the preparation thereof according to D1 inevitably led to the specific crystalline form of claim 1 at issue.

Admittance - new inventive step objection vis à vis claim 1

The objection that claim 1 lacked inventive step in view of D1 as closest prior art was to be admitted into the appeal proceedings.

Inventive step, Article 56 EPC - claim 5

Claim 5 did not enjoy the priority date of the contested patent. The effective date of said claim was thus the filing date of the application, and as a consequence D1 was prior art under Art 54(2) EPC. The subject-matter of claim 1 lacked inventive step in view of D1 as closest prior art.

X. The appellant's arguments, insofar as relevant to the present decision, may be summarised as follows:

Amendments, Article 123(2) EPC

The subject-matter of claims 2-4 and 6-8 was derivable from the application as filed.

Sufficiency of disclosure

The objection of the respondent with regard to the term "substantially crystalline" in claim 1 was at most related to Article 84 EPC, and did not lead to the conclusion that the subject-matter of claim 1 was insufficiently disclosed.

Novelty, Article 54 EPC

D4 did not serve as evidence that the skilled person, by carrying out the final step of example 3 of D1, would inevitably obtain a substantially crystalline compound as recited in claim 1 at issue. Consequently, D1 did not represent a direct and unambiguous disclosure of the crystalline form of claim 1 at issue.

Admittance - new inventive step objection vis à vis claim 1

The new objection was not part of written appeal proceedings and its submission during oral proceedings was too late. It raised complex new issues and was consequently not to be admitted into the proceedings.

Inventive step, Article 56 EPC - claim 5

The subject-matter of claim 5 found basis in example 3 of the priority document. The effective date of said claim was consequently the priority date, and D1 was not prior art pursuant to Article 54(2) EPC. D1 was thus irrelevant for the assessment of inventive step.

Reasons for the Decision

Main request

The set of claims of the main request corresponds to the claims as granted wherein claim 5 has been deleted.

1. Amendments, Article 123(2) EPC

1.1 Claim 1 at issue concerns a compound of formula (I) "in a substantially crystalline form", characterised by specific X-ray powder diffraction (XRPD) peaks. Claim 2, dependent thereon, concerns a compound of formula (I) of claim 1 that exists "in a substantially anhydrous form".

1.2 The respondent submitted that the application as filed lacked a basis for the subject-matter of claim 2, specifically with regard to the combination therein of the feature "in a substantially anhydrous form" with the feature of claim 1 according to which the compound of formula (I) was "in a substantially crystalline form" and exhibited a specific XRPD pattern. In the application as filed, the specific XRPD pattern was disclosed only in combination with the features "substantially pure and essentially in the anhydrous form" (page 5, lines 28-30). The same reasoning applied to the subject-matter of claims 3 and 4 which also lacked basis in the application as filed.

Furthermore, the application as filed lacked basis for the subject-matter of process claims 6-8, since there was no disclosure therein that the specific compound of claim 1 at issue could be obtained via said processes.

1.3 Any amendment to a European patent application or a European patent is subject to the mandatory prohibition on extension laid down in Article 123(2) EPC and can therefore be made only within the limits of what the 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 the documents as filed (see G 3/89, G 11/91 and G 2/10; also known as the "gold standard").

1.4 Claim 2 at issue corresponds to claim 2 as filed. The latter is dependent on claim 1 as filed. Claim 1 as filed is directed to a compound of formula (I) in a substantially crystalline form and differs from claim 1 at issue in that it lacks the XRPD peaks recited in the latter. The application as filed however clearly states that the compound of formula (I) of claim 1 as filed may exist in four different substantially crystalline forms, one of which corresponds to polymorphic form II of claim 6 as filed (application, page 3, lines 9-11). From a technical perspective therefore, the application as filed directly and unambiguously discloses to the skilled person that claim 2 as filed, in referring to compound (I) of claim 1 as filed, is to be applied individually to each of the polymorphic forms disclosed in the application for this compound, including polymorphic form II of claim 6 as filed.

1.5 A similar conclusion applies to dependent claims 3 and 4 at issue which correspond respectively to dependent claims 7 and 8 as filed. Both claims 7 and 8 as filed depend on claim 1 as filed. For the same reason as set out above, the application as filed discloses the combination of these claims with claims 1 and 2 as filed, in conjunction with the disclosure that one of the forms in which the compound of formula (I) may

exist corresponds to polymorphic form II of claim 6 as filed (application, page 3, lines 9-11). Furthermore, the application as filed also discloses that claims 7 and 8 as filed concern exclusively the characteristics of polymorphic form II (page 4, lines 31-32 and page 5, line 28 - page 6, line 3).

1.6 Similarly, it would be unambiguous to the skilled person that the subject-matter of claims 18-20 as filed, in referring to compound (I) of claim 1 as filed, was to be applied to each of the individual polymorphic forms disclosed in the application for this compound, including polymorphic form II as defined in claim 6 as filed.

1.7 It follows that the requirements of Article 123(2) EPC are met.

2. Sufficiency of disclosure

2.1 The respondent submitted that in view of a lack of clarity in the definition of the feature "substantially crystalline" in claim 1, the skilled person was unable to determine whether he was working within the scope of said claim, with the consequence that a lack of sufficient disclosure arose.

2.2 However, the assertion that the skilled person is unable to determine whether he is working within the claimed scope as such is not a valid basis for denying sufficiency of disclosure (see, e.g. T 593/09). A legitimate objection of lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts, that the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person

skilled in the art. In order to establish insufficiency, the burden of proof is upon the opponent to demonstrate that the skilled person, using common general knowledge, would be unable to carry out the invention.

2.3 In the present situation, while it may be the case that the expression "substantially crystalline" generates uncertainty with regard to the level of crystallinity required to fall within the scope of claim 1, it has not been demonstrated by the respondent that as a result of that uncertainty, the skilled person would be prevented from obtaining the polymorphic form II of claim 1. On the contrary, the patent, in example 2, discloses a method for the preparation of the desired polymorphic form II of claim 1 at issue. It was not brought into question by the respondent that by following this example, the skilled person would arrive at polymorphic form II recited in claim 1.

2.4 The feature "substantially crystalline" in claim 1 consequently represents a potential issue for discussion only under Article 84 EPC. Clarity is however only relevant in opposition (appeal) proceedings when – and then only to the extent that – an amendment introduces a lack of clarity (G 3/14). Since claim 1 of the main request is identical to claim 1 as granted, it is not open to objection under Article 84 EPC.

2.5 In a separate line of argumentation, the respondent submitted that the contested patent lacked data demonstrating that the problem as set out in paragraph [0002] thereof, namely the provision of improved chemical stability, solid state stability and shelf

life, had been solved across the scope of claim 1. Consequently, claim 1 was not sufficiently disclosed.

2.6 The problem set out in the contested patent and the effect(s) underlying it are not part of claim 1. The board acknowledges that in e.g. T 593/09 (reasons, 4.1.4), the **subjective** problem to be solved according to the patent, even though not part of the claims, had been taken into account when deciding on sufficiency of disclosure. However, the question in that case was not whether the claimed products objectively actually solved the technical problem, i.e. demonstrated the technical effects mentioned in the patent, but rather whether, in view of the ill-defined parameter present in the claim, products according to the claim could be selected by the skilled person **without undue burden**, such that a solution to the **alleged** problem set out in the patent would have been provided. In the present case, however, the skilled person is able to obtain polymorph II as defined in claim 1 without any undue burden, namely by following example 2 of the opposed patent (see point 3.3 above). Hence, the present case is different to that underlying T 593/09.

2.7 Incidentally, it is noted that some boards have held that an objection of insufficient disclosure cannot legitimately be based on the argument that the information in the patent does not enable a skilled person to achieve a non-claimed technical effect (e.g. T 1845/14, reasons 9.8; T 1311/15, reasons 5.2 and T 2001/12, reasons 3.4).

For both reasons, the appellant's argument cannot succeed.

2.8 It follows from the foregoing that the invention defined in claim 1 is sufficiently disclosed.

3. Novelty - Article 54 EPC

3.1 The respondent contested novelty of the subject-matter of claim 1 in view of D1 in conjunction with the data in D4.

3.2 D1 is an international patent application filed on 2 December 1999 and published on 15 June 2000 and validly entered the European regional phase. It has thus a filing date that is earlier than the priority date of the contested patent (2 June 2000) and was published in the interval between the priority date and the filing date (31 May 2001) thereof. It was undisputed that with regard to the subject-matter of claim 1 at issue, D1 is at least state of the art under Article 54(3) EPC and thus relevant to the assessment of novelty.

3.3 D1 discloses the preparation of a compound of structural formula (I) recited in claim 1 at issue (D1, example 3, step l), page 28, lines 1 - 13). This compound is said to be "prepared according to the method of example 1, step h), using the product of step k)" (D1, page 28, line 5). In said step h), it is stated that the resultant residue [of the step] "was purified (SiO_2, methanol:chloroform 3:47 as eluant) to afford the title compound (0.44g)". Therefore, only in the latter method is the way of isolating the product and the physical form of the product provided; no information is provided in D1 as to the method of isolation and the physical form (e.g. solid or oil) of the product obtained in step l) of example 3, which

corresponds to the compound of formula (I) of claim 1 at issue.

3.4 D1 (example 3) is therefore silent with regard to the method of isolation and the physical form of the product resulting therefrom, let alone whether said product was obtained in crystalline form, or specifically in polymorphic form II underlying claim 1 at issue.

3.5 In view of this, the respondent filed experiments in D4, according to which, in Method A, a reproduction of step l) of example 3 in D1 was attempted. According to said method, after quenching the reaction mixture, an organic phase was separated and a crude product was isolated. Chromatographic separation (methanol:chloroform 3:47) was performed, the resultant fractions were collected, and the solvent was removed by rotary evaporation at 40°C and 20 mbar followed by further drying at room temperature and 0.7 mbar, to yield a solid product (D4, page 3, "Experiment according to method A"). Characterisation of this solid yielded an XRPD peak pattern as well as a background halo signal typical of an amorphous solid, indicative of the simultaneous presence of the amorphous form (D4, figure 2.1).

3.6 It was not disputed by the appellant that the peaks in the XRPD pattern obtained in Method A of D4 were characteristic of the compound of formula (I) in the polymorphic form II of claim 1 at issue.

3.7 The respondent submitted that on the basis of the evidence provided by D4, the product of example 3 of D1 unambiguously disclosed the compound of formula (I) of claim 1 at issue. Although D1 did not explicitly

disclose the way the product was isolated, in particular the evaporation of the silica column eluate, this step, to the person skilled in the art, was implicitly disclosed therein, and inevitably provided the product having the XRPD pattern disclosed in D4.

3.8 The board does not agree. Method A of D4 differs from the method described in D1 in that it involves the removal of the chromatography solvent by rotary evaporation at 40°C and 20 mbar, followed by further drying at room temperature and 0.7 mbar. Contrary to this, D1 is entirely silent with respect to the drying process employed therein (page 21, lines 1-2). It can thus not be concluded that by following the method set out in D1, the skilled person would inevitably obtain a substance displaying the XRPD pattern shown in D4.

3.9 In fact, D2 teaches that whether polymorphic forms exist, and if so, which specific form is obtained, will depend on factors such as drying, grinding, temperature, concentration, agitation and pH (page 946, right hand column, final paragraph and figure 1: decision tree for polymorphs). It is furthermore taught that if the amorphous form is desired, it can be prepared in various ways, such as by freeze drying (D2, page 952, "Amorphous Forms", first paragraph), indicating that different ways of removing the solvent will have different consequences for the physical form of the product. Indeed, that these various factors were important in determining the final polymorphic form obtained was accepted by the respondent during opposition proceedings in arguing a lack of sufficient disclosure (notice of opposition, paragraph bridging pages 5 and 6). Consequently, since D1 is entirely silent with regard to how the product of example 3, step l) is isolated from the chromatographic eluant, it

cannot be assumed that said compound was isolated in solid form in D1, even less in the specific polymorphic form II shown in the XRPD pattern of the product according to Method A of D4. Therefore, for this reason alone, it cannot be concluded that carrying out the method step l) of example 3 in D1 will inevitably result in a compound of formula (I) in polymorphic form II corresponding to the subject-matter claim 1 at issue.

It follows that the subject-matter of claim 1 at issue is novel pursuant to Article 54 EPC.

4. Admittance - new inventive step objection vis à vis claim 1

4.1 During oral proceedings before the board the respondent, for the first time in appeal proceedings, submitted a new objection according to which the subject-matter of claim 1 at issue lacked inventive step over D1 as closest prior art. Thus, the priority document of the contested patent, British application 0013407.2, filed on 2 June 2000, disclosed neither the specific XRPD peaks of claim 1, nor the term "substantially". Claim 1 consequently did not enjoy the claimed priority date, the effective date thereof corresponding to 31 May 2001, the filing date of the application. D1, published on 15 June 2000, was consequently prior art under Article 54(2) EPC, and was thus relevant for the assessment of inventive step. The subject-matter of claim 1 differed from the disclosure in D1 in the provision of polymorphic form II. Since no technical effects had been demonstrated, the problem was the mere provision of polymorphic forms which, in line with decision T 777/08, did not involve an inventive step.

4.2 According to the respondent, this objection was originally submitted during opposition proceedings. The reference in the reply to the grounds of appeal to the first instance proceedings (page 1, point 2) was sufficient to justify taking it into account in appeal proceedings. The objection was not difficult to understand, and was of fundamental relevance for the subject-matter of claim 1.

4.3 This objection constitutes an amendment to the respondent's case during appeal proceedings. According to Article 13(1) RPBA 2007, the admittance thereof is at the discretion of the board.

4.4 The board does not accept the respondent's justification for the filing of said objection during oral proceedings. According to Article 12(2) RPBA 2007 the reply to the statement of grounds should contain the respondent's complete case, and *inter alia* should specify expressly all the facts and arguments relied on. Thus, submissions made during opposition proceedings do not automatically form part of appeal proceedings. A statement merely making general reference to submissions in preceding opposition proceedings cannot normally replace an explicit account of the legal and factual reasons underlying the specific objection. For this reason alone, the new inventive step objection needs not be admitted.

4.5 Oral proceedings before the board represents the latest possible stage in appeal proceedings. Submitting an entirely new objection of lack of inventive step with respect to claim 1 takes both the appellant and the board by surprise. It opens up complex new issues which have not been dealt with at all in written appeal

proceedings. These include the validity of the claimed priority in view of the term "substantially crystalline" and the recitation of specific XRPD peaks in claim 1, and the question of whether the alleged technical effects mentioned in paragraph [0002] of the patent have been achieved. These issues are such that the appellant in particular cannot be expected to deal with them without adjournment of the proceedings. Hence, also in view of Article 13(3) RPBA 2007, the new inventive step objection cannot be admitted.

4.6 For these reasons, the board decided not to admit into appeal proceedings the new inventive step objection based on claim 1.

5. Inventive step, Article 56 EPC - claim 5

5.1 Claim 5 at issue is directed to a mixture of a compound of formula (I) in polymorphic form II (by way of back-reference to claim 1) and polymorphic form III (by way of reciting the physical characteristics of this polymorphic form).

5.2 The respondent submitted that claim 5 at issue did not enjoy the priority date of the patent (2 June 2000, supra), such that the effective date of said claim was the filing date of the application (31 May 2001). D1 was state of the art pursuant to Article 54(2) EPC, relevant for the assessment of inventive step of the subject-matter of claim 5 pursuant to Article 56 EPC.

5.3 In contrast to the objection concerning the priority of claim 1, the objection against claim 5 had been raised during written appeal proceedings. More specifically, in point 7.1 of the reply to the statement of grounds of appeal, the respondent had already argued that the

mixture of polymorphic forms II and III could not benefit from the claimed priority. Therefore, unlike the objection concerning the priority of claim 1, admittance is not an issue. Furthermore, no objection against admittance has been submitted by the appellant.

5.4 According to the respondent, example 3 of the priority document did not constitute a disclosure of the subject-matter of claim 5 at issue. The context of example 3 in the priority document was merely to prepare polymorphic form III from the mixture of forms II and III, produced in an intermediate step. It was not comparable to the products of example 1 and 2 of the priority document, which resulted in the formation of pure polymorphic forms I and II, respectively. The intermediate preparation of the mixture in example 3 was not the subject-matter of the invention in the priority document. Said mixture resulted from a specific preparation procedure, the crystallisation conditions of which led only to a specific ratio of polymorphs II and III. Since this specific ratio and the specific crystallisation conditions employed in example 3 were absent in claim 5 at issue, the latter represented an intermediate generalisation of the disclosure of the priority document, which consequently failed to disclose the subject-matter of claim 5 at issue. Claim 5 thus did not enjoy the right of priority from the claimed priority date.

5.5 The respondent did not dispute that if the claim to priority were to be deemed valid, D1 would constitute state of the art pursuant to Article 54(3) EPC, and would consequently be irrelevant for the assessment of inventive step of claim 5 at issue.

5.6 The standard to be applied in deciding whether a claim enjoys the right to priority, the gold standard test (supra), is to be applied consistently to the provisions of Articles 54, 76(1), 87 to 89 and 123(2)EPC. Thus priority is to be acknowledged for claim 5 only if the skilled person can derive the subject-matter thereof, using common general knowledge, at least implicitly, but directly and unambiguously from the priority document as a whole.

5.7 The text of example 3 of the priority document, which is directed to the preparation of a compound of formula (I) in the form of polymorph III, reads as follows:

"*Ethanol (200µm) was added to 10mg of the compound of formula (I) and warmed to dissolution over a steam bath. The resulting solution was left to crystallise over night. XRPD and DSC confirmed that a mixture of Polymorphs II and III had been formed. This material was used to seed a larger scale preparation: Batch 4358K/A of the compound of formula (I) (191mg) was slurried in 1ml of a 50% aqueous solution of isopropanol. To this slurry, 15 mg of seeds of mixed Polymorph II/III were added. After 2 days complete conversion into Polymorph III had occurred as shown by XRPD.*"

5.8 This example explicitly discloses a mixture of polymorphic forms II and III. Furthermore, the appellant's argument that claim 5 represents an intermediate generalisation is not convincing. Example 3 does not mention a specific ratio of polymorph II to III. Although the solvent and the relative amount thereof is mentioned in example 3, the rate of cooling and the precise amount of crystallisation time ("over night") are not provided. The precise crystallisation

conditions are consequently not sufficiently specified to permit the conclusion that only a specific ratio of polymorphic forms II and III will necessarily result therefrom.

5.9 The board fails to see any other interpretation according to which the subject-matter of claim 5 could be understood as an intermediate generalisation of the disclosure of example 3 of the priority document. It follows therefore that claim 5 at issue enjoys the right to priority from example 3 of the priority document. In this regard, the question of whether further references in the priority document focus on pure polymorphic forms II or III is irrelevant.

5.10 Document D1 therefore does not represent state of the art pursuant to Article 54(2) EPC and is thus not relevant for the assessment of inventive step of claim 5 at issue.

Conclusion

6. The main request is allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

   claims 1 to 14 of the main request, filed with the statements of grounds of appeal.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated