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Datasheet for the decision of 22 October 2008

Case Number: T 0392/06 - 3.3.01

Application Number: 98810443.6

Publication Number: 0884312

IPC: C07D 251/68

Language of the proceedings: EN

Title of invention:
Triazinylaminostilbene compounds

Patentee:
Ciba Holding Inc.

Opponent:
3V Sigma S.p.A.
Kemira Germany GmbH

Headword:
Triazinylaminostilbene/CIBA

Relevant legal provisions:
EPC Art. 54, 100(b), 111(1), 123(2)(3)
RPBA Art. 12(2), 13(1)(3), 15(4)

Keyword:
"Main request: late filed evidence - admissibility (no)"
"Admissibiliy of objection under Article 100(b) (no)"
"Novelty (yes) - product not inevitable result of a disclosed process"

Decisions cited:
G 0004/95, G 0009/91, T 0793/93, T 0990/96, T 0327/92

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0392/06 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 22 October 2008

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 17 January 2006 revoking European patent No. 0884312 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: P. Ranguis
Members: G. Seufert
C.-P. Brandt

Summary of Facts and Submissions

I. The Appellant (Proprietor of the patent) lodged an appeal on 09 March 2006 against the decision of the Opposition Division dated 17 January 2006 on the revocation of the European patent No. 884 312, and filed a written statement on 26 May 2006 setting out the grounds of appeal.

II. In this decision the following numbering will be used to refer to documents:

(1) GB-A-1 293 804

(2) Expert opinion by Prof. Herrmann dated 15 March 2004 including:
Two experimental reports
Two evaluations of the content of water
X-ray diffraction patterns

(3) Expert opinion by Prof. Herrmann dated 30 May 2005 including:
Experimental report dated 4 and 5 April 2005
Evaluation of the content of water
Two X-ray diffraction patterns made on the same product

(4) Expert opinion by Prof. van Koten dated 24 May 2006 including:
4 experimental reports
Two X-ray diffraction patterns (unwashed solid)
Two X-ray diffraction patterns (washed solid)

(5) Expert opinion by Prof. Herrmann dated 20 November 2006 including *inter alia*:
Experimental report dated 17 and 18 October 2006
Two X-ray diffraction patterns (slurry and washed solid)

III. Opposition was filed by Respondents I and II (Opponents I and II) both requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC in combination with Article 52(1), 54 and 56 EPC) and insufficiency of disclosure (Article 100(b) EPC in combination with Article 83 EPC).

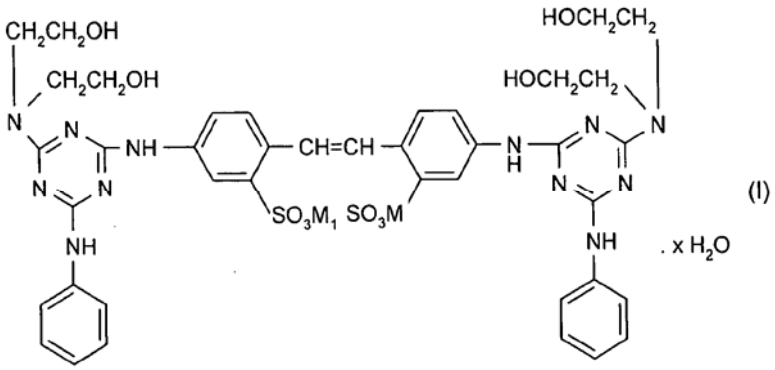
IV. The decision under appeal was based on the sole request consisting of the claims as granted. The Opposition Division held that the subject-matter of the patent was not novel with respect to the product obtained in following the steps I to IV of example I of document (1), in particular taking into account the data concerning the water content and the X-ray diffraction pattern provided by Opponent (I) together with the expert opinion by Prof. Herrmann dated 30 May 2005, document (3).

Furthermore, the Opposition Division held that the patent in suit did not give rise to objection under Article 100(b) EPC. The Opposition Division considered that the objection according to which the process as described in the patent in suit provided crystal forms having a different number of moles of crystallisation water to that disclosed in claim 1 was not relevant since the determination of the crystallisation water was a routine task for the person skilled in the art.

V. Annexed to the statement of the grounds of appeal, the Appellant submitted a main request and a first and secondary auxiliary. During oral proceedings before the Board, held on 22 October 2008, the Appellant filed a new main request consisting of 34 claims in response to

the observation by the Board that claims 1 and 4 of the main request submitted with the statement of the grounds of appeal are not clear (Art. 84 EPC) and claim 4 of this same main request is not supported by the application as filed (Art. 123(2) EPC). Independent claims 1, 2, 3, 4, 19, 20, 21 and 32 of the new main request read as follows:

"1. A hydrate of the 4,4-di-triazinylamino-2,2'-di-sulfostilbene compound having the formula:



(I)

in which
M and M_1 both represent sodium,
the hydrate is a crystal form which is designated as C form and characterised by an X-ray diffraction pattern which is essentially as in Figure 2 and in which x represents 14 to 20,
the hydrate is a crystal form which is designated as D form and characterised by an X-ray diffraction pattern which is essentially as in Figure 3 and in which x represents l0 to 14,
the hydrate is a crystal form which is designated as E form and characterised by an X-ray diffraction pattern which is essentially as in Figure 4 and in which x represents 16 to 26,

the hydrate is a crystal form which is designated as A form and characterised by an X-ray diffraction pattern which is essentially as in Figure 5 and in which x represents 1 to 6;
or a mixture containing one or more of the hydrates of the 4,4'-di-triazinylamino-2,2'-di-sulfostilbene compound having the formula (I), M and M_1 representing sodium;

or M and M_1 both represent potassium, the hydrate being characterised by an X-ray diffraction pattern which is essentially as set out in the accompanying Figure 8 and in which x represents 9 to 17,

or M and M_1 both represent lithium, the hydrates being characterised by an X-ray diffraction pattern which is essentially as set out in the accompanying Figures 9 to 11; or a mixture containing one or more of the hydrates of the 4,4'-di-triazinylamino-2,2'-di-sulfostilbene compound having the formula (I), M and M1 representing lithium and in which x represents 9 to 30.

2. A process for the production of the di-sodium salt of 4,4'-di-triazinylamino-2,2'-di-sulfostilbene possessing the (A) hydrate form by successively reacting cyanuric chloride with 4,4'-diaminostilbene disulphonic acid di-sodium salt, aniline and diethanolamine, adjusting the pH of the mixture to 9.0 to 9.5 with concentrated sodium hydroxide solution and evaporating the mixture to dryness.

3. A process for the production of the (C) hydrate crystal form by neutralization of the free acid of 4,4'-di-triazinylamino-2,2'-di-sulfostilbene possessing

the (A) hydrate form with dilute sodium hydroxide solution, homogenising and allowing to stand at room temperature; the (D) hydrate crystal form by treatment of the sodium salt of 4,4'-di-triazinylamino-2,2'-di-sulfostilbene possessing the (A) hydrate form aqueous sodium chloride solution, stabilizing and homogenising; and the (E) hydrate crystal form by treatment of the free acid of 4,4'-di-triazinylamino-2,2'-di-sulfostilbene possessing the (A) hydrate form with concentrated sodium hydroxide solution and homogenising.

4. A process for the production of a mixture of two or more of the novel hydrates of formula (I), wherein M and M_1 both represent sodium, the hydrate is a crystal form which is designated as C form and characterised by an X-ray diffraction pattern which is essentially as in Figure 2 and in which x represents 14 to 20, the hydrate is a crystal form which is designated as D form and characterised by an X-ray diffraction pattern which is essentially as in Figure 3 and in which x represents 10 to 14, the hydrate is a crystal form which is designated as E form and characterised by an X-ray diffraction pattern which is essentially as in Figure 4 and in which x represents 16 to 26, the hydrate is a crystal form which is designated as A form and characterised by an X-ray diffraction pattern which is essentially as in Figure 5 and in which x represents 1 to 6,
comprises mixing an aqueous solution of an inorganic salt electrolyte and the active substance of formula (I),
wherein M and M_1 both represent sodium, the hydrate is a crystal form which is designated as C form and

characterised by an X-ray diffraction pattern which is essentially as in Figure 2 and in which x represents 14 to 20, the hydrate is a crystal form which is designated as D form and characterised by an X-ray diffraction pattern which is essentially as in Figure 3 and in which x represents 10 to 14, the hydrate is a crystal form which is designated as E form and characterised by an X-ray diffraction pattern which is essentially as in Figure 4 and in which x represents 16 to 26, the hydrate is a crystal form which is designated as A form and characterised by an X-ray diffraction pattern which is essentially as in Figure 5 and in which x represents 1 to 6.

19. A process for the production of compounds according to claim 1, wherein M and M_1 both represent potassium, the hydrate being characterised by an X-ray diffraction pattern which is essentially as set out in the accompanying Figure 8 and in which x represents 9 to 17, or M and M_1 both represent lithium, the hydrates being characterised by an X-ray diffraction pattern which is essentially as set out in the accompanying Figures 9 to 11; or a mixture containing one or more of the hydrates of the 4,4'-di-triazinylamino-2,2'-di-sulfostilbene compound having the formula (I), M and M_1 representing lithium and in which x represents 9 to 30, by neutralising the free acid form of 4,4'-di-triazinylamino-2,2'-di-sulfostilbene with potassium or lithium hydroxide, respectively.

20. An aqueous formulation containing 30-50% by weight of active substance in the form of one or more of novel hydrates (I), or a mixture thereof, as defined in claim 1.

21. An aqueous formulation containing 30-50% by weight of active substance in the form of one or more of novel hydrate forms A, C, D and E of the formula (I), or a mixture thereof, as defined in claim 1.

32. A method for the fluorescent whitening of paper or textile material, comprising contacting the paper or textile material with an aqueous formulation according to any of claims 20 to 31."

VI. The submissions of the Appellant during the appeal proceedings may be summarised as follows:

The Appellant argued that the C form of the disputed patent is not the direct and inevitable result of the steps I-IV of example I of document (1). In the Appellant's own experiments, in particular in those attached to the expert opinion by Prof. van Koten dated 24 May 2006, document (4), and submitted with the statement of the grounds of appeal, the C form has never been obtained. The experimental data submitted by Respondent I on 30 May 2005, document (3), during the opposition proceedings contained too many deviations from the process disclosed in document (1) and the X-ray diffraction patterns were not measured directly after the preparation, but a week or more later. There was no reason for the skilled person to leave the product of step IV of document (1) standing for a longer period, in view of the fact that step IV was immediately followed by step V to obtain the alpha-crystalline form of document (1). Furthermore, the final treatment of the slurry, namely filtration and

washing with sodium chloride and sucking dry of the cake, has been omitted.

With regard to the additional experimental data provided by Respondent I with the reply to the statement of the grounds of appeal, document (5), the Appellant argued that there are again deviations from the process of document (1), especially in step IV, which Respondent I himself has considered as decisive for the formation of the crystal modification.

The Appellant further argued that the instructions of document (1) with regard to the various details are not sufficiently clear and leave room for interpretation. Thus, the C form cannot be considered as the inevitable outcome of the process described in document (1).

In support thereof decision T 793/93 was cited, where the Board held that "if there are reasonable doubts as to what may or may not be the result of carrying out the literal disclosure and instruction of a prior art document then the case of anticipation based on such a prior art document must fail".

VII. The submissions of the Respondents during the appeal procedure may be summarised as follows:

Respondent I contested the statement of the Appellant as to the relevance of the experimental report dated 30 May 2005, document (3). He argued that the specified deviations in the experimental data presented to the opposition division were small and not decisive for the formation of the crystal modification. It was not the details of the synthesis of the chemical product which

mattered, but the crystallisation step of the crude product from water according to the features exclusively disclosed in step IV of document (1). According to Respondent I the interruption of the experiment before the filtration and washing of the slurry was perfectly correct, because it is this intermediate slurry which anticipates the slurry claimed in the patent in suit. The time table with regard to the measurement of the X-ray diffraction patterns observed by the Appellant was correct. However, the formation of the C form is the final and unavoidable result of the soaking of the B form (or other crystal forms) in water and, therefore, its formation is a natural result determined by thermodynamic laws.

In any case the additional experimental report dated 17 and 18 October 2006, document (5), submitted with the reply to the statement of the grounds of appeal demonstrated the formation of the C form. An X-ray diffraction pattern was measured within a few hours after the product has been obtained both on the slurry obtained at step IV and on the wet crystals obtained after the filtration of the slurry.

In his late filed submission dated 21 October 2008 Respondent I further argued that the patent in suit does not comply with the requirement of Article 100(b) EPC, a ground which he raised for the first time in the appeal proceedings, due to the fact that the wavelength of the Cu-radiation employed in the measurement of the X-ray diffraction patterns was not reported in the disputed patent. In support he provided a further expert opinion by Prof. Krebs.

Respondent II adopted the argumentation of Respondent I in its entirety. Additionally, he argued that lack of novelty can also be shown without relying on experimental data. To support his view he cited decision T 990/96. In this decision the Board stated that it is common general knowledge that a chemical compound prepared according to a chemical process usually contains various impurities and it was not possible for thermodynamical reasons to obtain a product which is totally free of impurities. It was therefore common practice for the skilled person to purify the obtained compound. Conventional methods for purification of low molecular organic reaction products were common general knowledge. The Board concluded therefore that a document disclosing a low molecular chemical compound made this compound available to the public in all grades of purity. By analogy to the situation underlying decision T 990/96 Respondent II argued that compounds with the chemical formula (I) have been known for many years, but have not been analysed in suspension. The skilled person is aware of the fact that a compound can be present in various polymorphic forms. Thus, by merely reworking the process of document (1) and analysing the slurry obtained thereby, the skilled person will realise that various crystal forms can be obtained due to variations within the process described in document (1). Finding the most stable form will then be an easy task for the skilled person.

Furthermore, Respondent II contested the Appellant's statement as to the arbitrary interruption of the process of document (1). In his opinion the question

whether the skilled person would have had reasons to interrupt the process of document (1) at the stage where the slurry is obtained, is of no significance for the assessment of novelty. In support of his argument he referred to decision T 327/92, where the Board held that an intermediate, which existed only some 60 seconds before being further processed, destroyed the novelty of the patent proprietors claim, because all the technical characteristics required by the claim were met.

During oral proceedings Respondent II also requested the appointment of an independent technical expert in view of the contradictory experimental result of the Appellant and the Respondents.

VIII. During oral proceedings the representative of the Respondent I asked the Board whether one of the accompanying persons might use a personal computer to consult the documents involved in the proceedings. This request was contested by the Appellant on the ground that such a computer could be used to register the declaration of the parties and thereafter be used before a national court. The Board authorized this person accompanying Respondent I to use his Laptop to consult the documents contained therein after it was declared by the representative of the Respondent I that no registration of the oral proceedings would be made.

IX. The Appellant requested that the decision under appeal be set aside, the patent be maintained on the basis of the main request filed during oral proceedings, or any of the first or second auxiliary requests filed with letter dated 26 May 2006, the case be remitted to the

Opposition Division for the assessment of an inventive step, if novelty is acknowledged, not to admit the last submission of Respondent dated 21 October 2008 and not to allow the appointment of an independent expert.

Respondents I and II requested that the appeal be dismissed, the objection under Article 100(b) EPC be admitted into the proceedings, an independent expert be appointed as set out in the annex to the minutes of the proceedings and the case be remitted to the first instance for the assessment of an inventive step, if novelty is acknowledged.

X. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of late filed facts and evidence*

2.1 With fax dated 21 October 2008, i.e. the day before oral proceedings, referring for the first time during the appeal proceedings to the ground under Article 100(b) EPC, Respondent I submitted an expert opinion by Prof. Krebs contesting the significance of the X-ray diffraction patterns of the patent in suit.

2.2 To justify the late filing, the representative of Respondent I argued that the case had only been taken over by him in August 2008 and that the issue raised in the expert opinion has unfortunately been overlooked.

He further argued that he had only recently received this expert opinion and had sent it without delay to the Board, the Appellant and Respondent II. He further took the view that this late filed submission did not represent a new document, or new facts or evidence, but merely a further line of arguments on a ground, namely 100(b) EPC, which had already been raised before the Opposition Division.

2.3 Respondent II shared the opinion of Respondent I that the late filed submission represented merely new arguments and did not provide any new facts or evidence.

2.4 In accordance with Article 13(3) of the Rules of Procedure of the Boards of Appeal, amendments, which include new facts, new evidence or new requests, sought to be made after oral proceedings have been arranged shall not be admitted if issues are raised which cannot be dealt with without the adjournment of the oral proceedings.

2.5 The late filed submission by Respondent I represents the opinion of an expert contesting the significance of the X-ray diffraction patterns provided in the disputed patent on the grounds that depending on the wavelength of the employed Cu X-ray radiation, the X-ray diffraction patterns differ significantly. The expert opinion contains tables and diffraction patterns based on calculations carried out by the expert. This objection has never been raised before at any stage of the proceedings and is completely different from that related to the content of crystal water (see point IV above).

2.6 In the opinion of the Board such an expert opinion on a newly raised issue can hardly be considered as the presentation of merely new arguments, but provides new facts and evidence at a very late stage of the proceedings. It clearly left the Appellant no possibility to present a counter expertise. If the late filed submission was admitted postponement of the oral proceedings would have become necessary, which is contrary to Article 13(3) of the RPBA.

2.7 The Board also notes that taking over the case is not a serious reason for the late filing of the submission, in particular, as the representative of Respondent I has taken over the case in August 2008 and the submission was filed on 21 October 2008. The late filed submission was also not occasioned by any of the submissions on the part of the Appellant.

2.8 For these reasons, the late filed submission is not admitted into the appeal proceedings.

3. *Admissibility of the ground of opposition according to Article 100(b) EPC into the appeal proceedings*

3.1 During oral proceedings before the Board Respondent I raised the ground of opposition under Article 100(b) EPC. He argued that this ground has already been raised in the notice of opposition and has been discussed in the proceedings before the Opposition Division.

3.2 The Board notes that this ground of opposition was discussed in the decision under appeal (see point IV above). However, during the appeal proceedings before the Board neither Respondent I nor Respondent II in

reply to the statement of the grounds of appeal raised this ground of opposition. In accordance with Article 12(2) RPBA "the statement of the grounds of appeal and the reply shall contain a party's **complete case**. They shall set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld and should specify expressly **all** the facts, arguments and evidence relied on".

The first time this ground of opposition was raised, was in the late filed submission by Respondent I and for a completely different issue as the one previously submitted (see point 2 above). It results that up to the day before the oral proceedings the Board and the Appellant had every reason to believe that this ground of opposition was not being pursued by the Respondents and were thus taken by surprise by the submission of Respondent I.

Article 13(1) RPBA leaves it to the discretion of the Board of Appeal to admit and consider any amendment to a party's case after it has filed its grounds of appeal or reply. In view of the very late stage at which the ground under Article 100(b) EPC has been raised, thus taking the Board and the Appellant by surprise, the Board decided to exercise its discretion under Article 13(1) RPBA not to admit this ground of opposition into the procedure (see also G 4/95, OJ EPO 1996, 412, point 10, 1st paragraph).

The Board is also of the opinion that admitting such a ground at such a late stage would be contrary to a fair conduct of the oral proceedings (Article 15(4) RPBA).

Main request

4. *Amendments (Article 123(2) and (3) EPC)*

4.1 The amendments made to independent claim 1 as granted, namely the further specification of the hydrates in their crystal forms characterised by the X-ray diffraction patterns according to fig. 2-5, 8 and 9-11 and their water content, have a proper basis in the application as filed. These alternative crystal hydrate forms are supported by (a) claim 1 in combination with claims 2 and 9-12, (b) claim 1 in combination with claim 4 and (c) claim 1 in combination with claim 5 as originally filed. The amendments made to independent claim 4 are supported by claim 17 in combination with claims 2 and 9-12 as originally filed. The independent claims 2, 3, 19, 20, 21 and 32 are properly supported by the claims 15, 16, 33, 34, 35 and 46 as originally filed and the dependent claims 5-18, 22-31 and 33-34 are supported by 18-31, 36-45 and 47-48 as originally filed.
Additionally, the B form has been deleted from the list of alternative crystal forms.

4.2 Therefore all the amendments made to the claims as granted meet the requirement of Article 123(2) EPC.

4.3 The amendments lead to a restriction of the scope of the claims as granted, and therefore of the protection conferred thereby. The requirements of Article 123(3) EPC are therefore complied with.

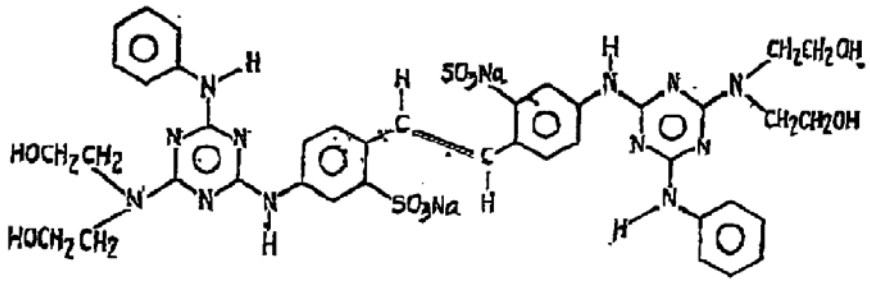
4.4 The compliance of the amended set of claims with the requirements of Article 123(2) and (3) EPC was not disputed by the Respondents.

5. *Novelty (Article 100(a) EPC)*

5.1 Both Respondents have disputed the novelty of the subject-matter of the patent in suit in view of the disclosure of document (1), in particular steps I to IV of example I of document (1). In support of his objection Respondent I relied upon experimental data provided with the expert opinion of Prof. Herrmann dated 30 May 2005, document (3), on which the Opposition Division based its decision, and further experimental data provided with a further expert opinion by Prof. Herrmann dated 20 November 2006 and annexed to the reply to statement of grounds of appeal, document (5).

5.2 The Board notes that it is a generally applied principle that for concluding lack of novelty, there must be a direct and unambiguous disclosure in the state of the art which would directly and inevitably lead the skilled person to subject-matter falling within the scope of what is claimed. Furthermore, before the Opposition Division as well as before the Board, it is the Opponent(s) who bears the burden of proof as regards demonstrating that the patent does not fulfil the requirement of the EPC.

5.3 Document (1) discloses the alpha-crystalline form of the compound of the formula (I)



I

characterised by a specific X-ray diffraction pattern. The preparation of the alpha-crystalline form is described as a sequence of five steps in example I of document (1). The chemical formula (I) of document (1) corresponds to the chemical formula (I) of claim 1 of the main request with M and M_1 both representing sodium without the water molecules. Document (1) does not explicitly refer to hydrates of formula (I) nor does it explicitly describe compounds with X-ray data according to any of the crystal forms referred to in claim 1 of the main request.

5.4 The question which needs to be answered is therefore whether document (1) implicitly discloses a compound of claim 1 of the main request as the direct and inevitable result of a process described in document (1) as alleged by the Respondents.

5.5 In the opinion of Respondent I the compound, more particularly the slurry, obtained in step IV of example I of document (1) before the filtration and washing of the product, is identical to the crystal C form of the patent in suit. As evidence in support thereof he relied upon the experiment carried out by Respondent I on 4 and 5 April 2005 attached to Prof. Herrmann's expert opinion dated 30 May 2005, document (3). In this

experiment the steps I-IV of example (I) have been repeated, in the opinion of Respondent I in strict adherence to the reaction condition specified in document (1). After the crystallisation step IV a sample of the slurry obtained before filtration, washing and drying has been taken. The sample was taken from the slurry, because in the opinion of Respondent I it is the intermediate slurry and not the washed and sucked dry compound of document (1) that anticipates the C form of the patent in suit. The water content of this sample has been determined and an X-ray diffraction pattern has been measured. A second diffraction pattern has been measured on part of the obtained compound at the Technical University Munich. The amount of water of hydration of the sample was 17,38 molecules, which falls within the range of 14 to 20 as claimed in claim 1 of the main request. The X-ray diffraction patterns in both measurements are clearly identical to the diffraction pattern of the C form of the disputed patent.
According to Respondent I the C form is the most stable form, which is also shown by the patent in suit. All the crystal forms described in the patent transform to the C-Form. Thus, the water slurry obtained in repeating example I of document (1) inevitably leads to the stable C form.

Respondent II shared the opinion of Respondent I that the subject-matter of the disputed patent is not novel. In addition he argued that lack of novelty of the claimed subject-matter can also be shown without relying on experimental data. To support his view he cited decision T 990/96.

5.6 With regard to decision T 990/96 cited by Respondent II the Board is of the opinion that the case underlying this decision cannot be compared to the present case. In T 990/96 there was no doubt that the compound to be purified was known per se in the art. The question, which has to be decided in the present case, is whether the crystal C form has actually been made available to the public within the meaning of Article 54 EPC, either explicitly or as the inevitable result of the process of document (1). T 990/96 is of no relevance for answering this question. The Board therefore sees no need to discuss this decision in further detail.

5.7 With regard to the experiment carried out by Respondent I, the Board agrees with Respondent I in that the X-ray diffraction pattern measured on the slurry sample appears to be essentially the same as that of the C form in fig. 2 of the patent in suit and the amount of crystal water of the sample is within the claimed range. The diffraction pattern measured in Munich equally appears to be identical with that of the C form.

5.8 The Board, however, also observes the following: Apparently, the X-ray diffraction pattern on the sample taken after the crystallisation and before the washing and drying steps has been measured not earlier than nine days after the preparation of the slurry (enclosure 2 of the expert opinion of 30 May 2005: creation of the diffraction pattern of "Camp.315" on 14 April 2005; according to the enclosure 1 of the same expert opinion "Camp.315" was prepared on 05 April 2005). The X-ray diffraction pattern measured in Munich on a part of the obtained compound took place not

earlier than one week after its preparation (page 7 of the expert opinion, characterisation of the diffraction pattern as (3V**120405**_01_nass"). The correctness of these observations with regard to the relevant dates of the measurements has been admitted by the Respondent I.

5.9 The Board also observes that according to the patent in suit the C form is obtained from the crystal B form by letting it stand in suspension at 25°C for two days. Using the same procedure the C form can be obtained from the A, D, E, F or G crystal forms (page 5, paragraphs [0035] to [0037] of the patent in suit). The C form is never directly obtained in the disputed patent.

5.10 The sample taken out of the slurry in the experiment provided by the Respondent was left **nine days** before an X-ray diffraction pattern was measured. The measurement on the part of the obtained compound, which was sent to Munich, took place **one week** after the preparation.

5.11 In the Board's opinion it should also be considered that the process disclosed in document (1) is a sequence of five steps. The slurry, which according to the Respondents takes away the novelty of the C form of the disputed patent, is obtained at the end of step IV **before** filtration, washing and sucking dry of the product occurs. The experiment of the Respondent of April 2005 therefore ended at that point. However, document (1) teaches the immediate filtration and washing of the slurry with 500 grams of a 5% sodium chloride solution, (document (1), page 5, lines 13-15: "When the slurry is uniform, it is filtered, the cake is washed with 500 grams of 5% sodium chloride solution

and the cake is then sucked dry"). In addition, the reaction sequence of document (1) does not end with step IV. Step IV is followed by step V in order to obtain the alpha-crystalline form claimed by document (1).

5.12 Thus, taking a sample of the slurry and leaving it standing for at least one week before measuring an X-ray diffraction pattern is against the proper reading of document (1). This is all the more important in view of the possibility that the C form measured by Respondent I may not have been the crystal form that has been originally formed in view of the aforementioned observation that the C form can be obtained from other crystal forms upon standing. A transformation into the C form upon standing for one week or more cannot be excluded.

5.13 In addition, the Board notes that reworking steps I-IV of example I of document (1) by the Appellant and the **immediate** measurement, i.e. within 20 and 35 minutes, of an X ray diffraction pattern of the compound obtained before and after the washing step shows the formation of the crystal B form, expert opinion of Prof. van Koten dated 24 May 2006, document (4).

5.14 It follows from the above that the experimental data provided by the Respondent I are not sufficient to prove beyond any reasonable doubt, that the process described in document (1) directly and inevitably leads to the crystal C form of the disputed patent (see T 793/93, point 2.1).

5.15 Respondent II has argued that the question whether the skilled person would actually have had a reason to interrupt the process after having obtained the slurry, is of no significance for the assessment of novelty. In his opinion the slurry is an intermediate, which is obtained during the process of document (1). Since the X-ray diffraction pattern and the water content of this intermediate are the same as those required for the C form by claim 1 of the main request, this intermediate destroys the novelty of the subject-matter of the patent in suit. In support of his arguments Respondent II referred to decision T 327/92.

5.16 The Board agrees with Respondent II that an intermediate, which has been obtained **directly and unambiguously** as a result of a process described in the prior art, even if the skilled person had no specific reason to interrupt the process at that particular point, can possibly destroy the novelty of claimed subject-matter. In the present case the slurry, which is then further processed, may be considered as an intermediate that has been obtained in the process of document (1). It is however indispensible in the Board's opinion and in accordance with T 327/92 that the **technical characteristics** of the claimed subject-matter and the intermediate slurry are the same for novelty to be destroyed. In the present case the Board is of the opinion that the Respondents failed to demonstrate the identity of the intermediate slurry of document (1) and the C form of the disputed patent. The X-ray diffraction patterns have been measured days after the preparation and the possibility that the form measured is not the same form as the one obtained in step IV cannot be excluded.

5.17 To further support his allegation that document (1) makes the C form of the patent in suit available to the public in the sense of Article 54 EPC, Respondent I has provided additional evidence submitted with his reply to the grounds of appeal. In a further experiment carried out by Respondent I on 17 and 18 October 2006 steps I-IV of document (1) have been repeated once more, document (5). Samples have been taken from the slurry as well as from the filtered and washed product and X-ray diffraction patterns of these samples have been measured, according to Respondent I immediately. Both diffraction patterns correspond to the X-ray diffraction pattern of the C form of the disputed patent.

5.18 The Board notes that the time that has passed between the measurements of the X-ray diffraction patterns and the preparation of the samples was still several hours. In the opinion of the Board it is, however, not necessary to examine the significance of this detail any further due to the fact the content of the crystal water of both samples obtained in the experiment of 17/18 October 2006 has not been determined. According to claim 1 of the main request, the C form is not only characterised by a specific X-ray diffraction pattern, but also by a specific amount of crystal water, i.e. the value of x is between 14 and 20. Without this data the additional evidence provided by Respondent I cannot prove identity between the intermediate slurry of document (1) and the C form of the patent in suit.

5.19 Respondent I argued that he considers the water content of the samples of 17/18 October 2006, document (5), to

be the same as in the sample obtained 04/05 April 2005, document (3). The diffraction patterns are basically identical and the preparation process was basically the same. Even, if there would be some change, he has no doubt that the change would lie within the claimed range. With regard to the Board's observation that in earlier experiments by the Respondent, namely those attached to the expert opinion of Prof. Herrmann of 15 March 2004, document (2), the C form was allegedly obtained with a crystal water content of 25.22, Respondent I argued this experiment should not be considered. It has already been rejected by the Opposition Division, because there were deviations from the process according to document (1). The Respondent further argued that the margin of error in the measurement of the water content is rather high.

5.20 The Board cannot follow the arguments of Respondent I. Firstly, the Board observes that in earlier experiments Respondent I has obtained crystal forms with the same diffraction pattern as the C form of the patent, whereby the water content lies outside the presently claimed range, document (2). In this context, it is of no relevance whether these experiments provided suitable evidence of the novelty destroying teaching of document (1). The diffraction patterns of these earlier experiments and those of 04/05 April 2005, document (3), are essentially that of the C form of the patent is suit. Apparently, a certain variation of the water content of the C form does not significantly alter the X-ray diffraction pattern. Thus, identity of the diffraction patterns cannot be considered as sufficient evidence for identity of the crystal water content. Secondly, the Board observes that the reaction

conditions between the experiments of 17/18 October 2006 and 04/05 April 2005 are similar, but not identical. Especially step IV, which leads to the formation of the crystal slurry, differs in at least one aspect. In the experiment of 2005 the formation of the crystals is achieved by letting the solution stand. Afterwards the product is stirred for 2 hours to break up the precipitate. In the experiment of 17/18 October the formation of the crystal takes place with stirring. Thus, the stirring for two hours at the end is not necessary.

5.21 It follows from the above that it cannot be said with certainty that the compound obtained in the experiment of 17/18 October 2006 has the same water content as the compound obtained on 04/05 April 2005. Without such data on the content of the crystal water, the experiment of October 2006 cannot prove that the subject-matter of claim 1 of the main request lacks novelty over document (1).

5.22 For the reasons set out above and contrary to the findings of the Opposition Division, the Board concludes, that the Respondents have failed to demonstrate credibly and without reasonable doubts that the slurry as well as the cake after filtration and washing obtained as intermediates in the process according to step IV of example I of document (1) is identical to any of the crystal forms according to claim 1 of the main request. Therefore, the Board finds that the subject-matter of claim 1 of the main request as well as the independent claims 2, 3, 4, 19, 20, 21 and 32 is novel over the disclosure of document (1) and thus complies with the requirement of Article 54 EPC.

6. *Request for an independent expert*

6.1 On the ground that the experimental data submitted by the Appellant and the Respondents yielded contradictory results, Respondent II requested during oral proceedings the appointment of an independent expert.

6.2 The Board has taken due account of the experimental data and expert opinions already provided by the parties and considers itself, on the basis of its own expertise, to be in a position to come to a conclusion in the present case. The Board based its decision on the fact that the Respondent's experimental data are insufficient to prove without doubt that the intermediate slurry obtained in document (1) anticipates the C form as defined in claim 1 of the disputed patent. The decision of the Board is, therefore, not based on the alleged contradictory results obtained by the parties.

6.3 Furthermore, an appeal procedure *inter partes* is to be considered as a judicial procedure (see in particular G 9/91, OJ EPO 1993, 408, point 18). In such a procedure, each party carries the burden of proof of any fact it alleges. The Respondents/Opponents on which rested the onus to provide evidence that the slurry or the cake obtained following steps I to IV of example 1 of document (1) was identical to the C form defined in claim 1 failed in that respect (see point 5 above). The Board has, therefore, not settled a contradiction between experiments from the Appellant and the Respondents, but has decided on the evidence submitted by the Respondents, which turned out to be incomplete.

The Board has no reason to substitute for the Respondents to compensate for their deficiency in the provision of the evidence which support their objection of lack of novelty in allowing an independent expert. For this reason, it is not necessary to appoint an independent expert.

6.4 Furthermore, commissioning of an independent expert would have made postponement of the oral proceedings necessary, which is contrary to Article 13(3) RBPA.

7. *Remittal*

According to Article 111(1) EPC, the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution. The Opposition Division had revoked the patent only for the reason of lack of novelty. The requirement of an inventive step has not yet been examined. Furthermore, the Appellant and both Respondents requested that the case be remitted to the first instance for assessment of an inventive step. In these circumstances, the Board considers it appropriate to remit the case to the Opposition Division for the assessment of inventive step on the basis of the main request filed during oral proceedings.

First and second auxiliary request

8. The main request having been considered to be novel and the Board having decided to remit the case to the first instance on the basis of this main request, there is no need to decide on these requests.

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 proceed with the opposition proceedings on the basis of the main request filed during oral proceedings for the assessment of inventive step.

The Registrar: The Chairman:

M. Schalow P. Ranguis