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Datasheet for the decision of 5 July 2013

Case Number: T 1772/09 - 3.3.01

Application Number: 02782507.4

Publication Number: 1330249

IPC: A61K31/496, C07D215/22, A61P25/18

Language of the proceedings: EN

Title of invention:
LOW HYGROSCOPIC ARIPIPRAZOLE DRUG SUBSTANCE AND PROCESSES FOR THE PREPARATION THEREOF

Patent Proprietor:
OTSUKA PHARMACEUTICAL CO., LTD.

Opponents:
Teva Pharmaceutical Industries Ltd.
Fermion Oy
Pharmaceutical Works POLPHARMA
EGIS Gyógyszergyár Nyrt
Ratiopharm GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 83, 54, 111(1)
EPC R. 115(2)
RPBA Art. 13, 15(3)

Keyword:
Late-filed documents: Admission (yes)
Main request: Added subject-matter (no); sufficiency of disclosure (no)
First auxiliary request: Added subject-matter (no); sufficiency of disclosure (yes); novelty (yes) - not inevitable result of prior-art process
Remittal to the department of first instance

Decisions cited:
T 0226/98, T 0225/93, T 0466/05, T 0749/98, T 1127/02

Catchword:
-

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Case Number: T 1772/09 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 5 July 2013

Appellant: (Patent Proprietor)	OTSUKA PHARMACEUTICAL CO., LTD. 9, Kandatsukasa-cho 2-chome Chiyoda-ku Tokyo 101-8535 (JP)
Representative:	HOFFMANN EITLE Patent- und Rechtsanwälte Arabellastrasse 4 81925 München (DE)
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Representative:	Gallagher, Kirk James D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent 2 (Opponent 2)	Fermion Oy P.O. Box 28 FIN-02101 Espoo (FI)
Respondent 3: (Opponent 3)	Pharmaceutical Works POLPHARMA Pelplinska Str. 19 83-200 Starogard Gdanski (PL)
Representative:	Gizinska-Schohe, Malgorzata European Patent Attorney Helmpertstrasse 11a 80687 München (DE)
Respondent 4: (Opponent 4)	EGIS Gyógyszergyár Nyrt 1106 Budapest Keresztúri út 30-38 (HU)
Representative:	Stolmár & Partner Blumenstraße 17 80331 München (DE)

Respondent 5: (Opponent 5)	Ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm (DE)
Representative:	Gallagher, Kirk James D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 July 2009 revoking European patent No. 1330249 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman:	C. M. Radke
Members:	G. Seufert
	L. Bühler

Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the decision of the opposition division revoking European patent No. 1 330 249.

II. The present decision refers to the following documents:

(1) US 5,006,528

(2) S. Aoki *et al.*, The Fourth Japan-Korea Symposium on Separation Technology, 6-8 October 1996, Waseda University International Conference Center, Tokyo, Japan, CR. 119, pages 937-940

(6) "Basic Principles of Particle Size Analysis" by A. Rawle, Malvern Instruments Ltd., pages 1-8

(7) EP 0 367 141 A

(15a) "Experimental results obtained in 2006", Copy of document (15) of the contested decision with amended reference numbers for the documents cited therein, pages 1-11, submitted by respondent 3 with reply to statement of grounds of appeal

(15b) "Further data from experimental results as obtained by Opponent 03 in 2006", pages 1-2, submitted by respondent 3 with reply to the statement of grounds of appeal

(15c) "Experimental results (D15c) - a Second Series of experiments", pages 1-20, submitted by respondent 3 with reply to the statement of grounds of appeal

(19) "Untersuchungsbericht Aripiprazol" by H.-G. Striegel, pages 1-4, dated 21 December 2006, filed by opponent 5 with notice of opposition

(20) "Untersuchungsbericht Aripiprazol" by Professor M. U. Schmidt, dated 23 December 2006, pages 1-17 including Annexes I and II, filed by opponent 5 with notice of opposition

(21) M. Rhodes, "Introduction to Particle Technology", John Wiley & Sons, Chichester (GB) 1998, pages 69 and 70

(29) "Particle distribution analyzers Mictrotrac [Nikkiso]", internet extract: http://www.nikkiso-b.co.jp/product_file/product1.htm, dated 20 July 2007, two pages

(30) International Standard ISO 13320-1, Particle size analysis - Laser diffraction methods, Part 1, General Principles, 1999, pages ii-v and 1-34

(31) M. W. Wedd, Determination of Particle Size Distributions using Laser Diffraction, 2003, http://www.erpt.org/032Q/Wedd-00.htm, pages 1-4

(32) "Experimental Report", submitted by the appellant with the statement of grounds of appeal, 7 pages including Annexes 1-3

(33a) EP 0 776 927 B

(33b) US 6,267,942 B

(33c) Copy of Microtrac Timeline with the part "Legacy of Microtrac Instrumentation, The Leeds & Northrup years (1972-1993)", one page

(36) "Untersuchungsbericht Aripiprazol", by Professor R. Boese, dated 31 May 2010, including Annexes I and II, 64 pages, filed by respondent 5 in reply to the statement of grounds of appeal

(37) "Projektbericht Aripiprazol" (Annex III of document (36)), by Professor R. Boese and C. Schauerte, pages 1-24

(38) "Laborbericht" Ratiopharm, dated 22 September 2008, 2 pages, filed by respondent 5 in reply to the statement of grounds of appeal

(39) Experimental report by S. Aoki, including Annexes 1 to 3, 31 pages, filed by the appellant with letter dated 25 October 2012

(40) "Final Report: Aripiprazol" by Professor J. Ulrich, including Annexes 1 to 3,

dated 12 October 2012, 101 pages, filed by the appellant with letter of 25 October 2012

(41) Declaration of Professor M. Antonietti, including Exhibits A and B, dated 29 January 2013, 16 pages filed by the appellant with letter of 7 March 2013

(42) Declaration by Nikkiso Co. Ltd, dated 7 February 2013, signed by Y. Kizawa, including brochure of Microtrac HRA, brochure of Nanotrac UPA, and pages 1 (brochure HRA) and 1 and 3 (brochure UPA) with annotations, a total of 23 pages, filed by the appellant with letter of 7 March 2013

III. Notices of opposition had been filed by respondents 1-5 (opponents 1-5) requesting revocation of the patent in suit in part (opponent 1) or in its entirety (opponents 2-5) on the grounds of lack of novelty and inventive step, insufficiency of disclosure and added subject-matter (Article 100(a), (b) and (c) EPC).

IV. The decision of the opposition division was based on a main request and an auxiliary request, both filed with letter of 7 April 2009.

The opposition division held that

- the claimed subject-matter was directly and unambiguously disclosed in the application as filed,
- the subject-matter of claims 1-7 of the main request and claims 5, 6 and 17 of the auxiliary request was not sufficiently disclosed due to the lack of information concerning the determination of the mean particle size,
- the subject-matter of claim 1 of the auxiliary request was sufficiently disclosed and

- the claimed subject-matter was novel but was anticipated by document (2) taking into account the experimental data in documents (19) and (20).

The opposition division also decided to admit documents (21) to (28) into the proceedings.

V. Independent claims 1 and 8 of the main request underlying the contested decision read as follows:

"1. Hydrate A of aripiprazole wherein said Hydrate has a powder x-ray diffraction spectrum which is substantially the same as the following powder x-ray diffraction spectrum shown in Figure 3;
particular infrared absorption bands at 2951, 2822, 1692, 1577, 1447, 1378, 1187, 963 and 784 cm^{-1} on the IR (KBr) spectrum;
an endothermic curve which is substantially the same as the thermogravimetric/differential thermal analysis (heating rate 5°C/min) endothermic curve shown in Figure 1; and
a mean particle size of 50 µm or less."

"8. Anhydrous Aripiprazole Crystals B having low hygroscopicity wherein said low hygroscopicity is a moisture content of 0.40% or less after placing said drug substance for 24 hours in a desiccator maintained at a temperature of 60°C and a humidity level of 100%,
a powder X-ray diffraction spectrum which is substantially the same as the following powder X-ray diffraction spectrum shown in Figure 5, and
particular infrared absorption bands at 2945, 2812, 1678, 1627, 1448, 1377, 1173, 960 and 779 cm^{-1} on the IR (KBr) spectrum; and
exhibiting an endothermic peak near about 141.5°C in thermogravimetric/differential thermal analysis (heating rate 5 °C/min) and

an endothermic peak near about 140.7°C in differential scanning calorimetry (heating rate 5°C/min)."

Further independent claims of the main request relate to the preparation of anhydrous aripiprazole crystals B, pharmaceutical compositions comprising them, methods for their preparation and the use of anhydrous aripiprazole crystals B in the manufacture of a medicament for certain diseases.

VI. With the statement of grounds of appeal the appellant defended the patent in suit on the basis of the main request underlying the contested decision, and filed first to fourth auxiliary requests replacing the auxiliary request previously on file. In addition, it filed documents (29)-(32).

VII. With their replies to the statement of grounds of appeal, respondents 3, 4 and 5 submitted documents (15a)-(15c), (33a)-(33c) and (36)-(38).

VIII. With letters dated 25 October 2012 and 7 March 2013, the appellant filed documents (39)-(42).

IX. Summons to oral proceedings were issued on 16 April 2013.

X. With letters dated 4 June 2013 and 11 June 2013 respondents 1 and 4 filed further documents.

XI. By letter of 4 July 2013, respondent 3 informed the board that it would not be attending the oral proceedings scheduled for 5 July 2013.

XII. At the oral proceedings, the appellant withdrew its first auxiliary request. The second to fourth auxiliary

requests were maintained in their respective order as first to third auxiliary requests.

The first auxiliary request is distinguished from the main request in that claims 1-7, directed to the hydrate A of aripiprazole, and claims 12-20, 24 and 25 have been deleted. The remaining claims have been renumbered.

The second auxiliary request differs from the first auxiliary request in that claim 3 has been deleted.

The third auxiliary request differs from the main request in that claims 8-44 directed to the anhydrous aripiprazole crystals B have been deleted.

XIII. The arguments of the appellant, to the extent that they are relevant for the present decision, can be summarised as follows:

- Admissibility of documents (39) to (42)

Documents (39) to (42) had been filed in direct response to the arguments and evidence provided by the respondents during the appeal proceedings and to the criticism with respect to the appellant's evidence provided with the statement of grounds of appeal. They could therefore not have been filed during the opposition proceedings. Furthermore, documents (39) and (40) were highly relevant with regard to the question of novelty.

- Amendments

Claims 2 to 7 of the main request found their basis in original claims 2, 6 and 8-11 in combination with

page 21, line 23 to page 22, line 25 and page 12, lines 8 to 11 of the description as originally filed. Claim 8 had its basis on pages 23 to 24 of the application as originally filed. The omission of the ^{1}H-NMR data did not extend the claimed subject-matter, since the ^{1}H-NMR spectrum was measured in solution and thus was not specific to a crystalline form. The use of the term "anhydrous" for the originally disclosed term "anhydride" was the correction of an obvious error, which was apparent to the skilled person in view of the chemical structure of aripiprazole. It also found a basis on page 4, lines 10 to 17, page 17, lines 10 to 19 and table 1 on page 85 of the application as originally filed.

- Sufficiency of disclosure

The information with regard to the determination of the particle size was sufficient for the skilled person to reproduce the invention. The reference to "Mictrotrack HRA" in the patent in suit clearly identified the instrument used for the measurement. At the relevant time there was only one Microtrac HRA model on the market, namely the Microtrac HRA 9320-X100, also named Microtrac X-100. The designation Microtrac HRA-X100 in document (33a) referred also to this model. Microtrac UPA in document (33b) was not a Microtrac HRA instrument and the Microtrac HRA-UPA in document (33a) was a complex machine connecting Microtrac HRA and Microtrac UPA by one computer. The Microtrac HRA instrument measured the particle size by laser diffraction, which resulted in a volume distribution and the corresponding volume mean. Since there was no indication in the patent in suit that the volume mean should be converted into other means, although this was in principle possible, there was no reason to assume

that anything else than the volume mean and, in particular, the De Brouckere mean D[4,3] as the only meaningful mean, was intended. Furthermore, the skilled person would refrain from such a conversion in view of the danger related to it. In addition, all laser diffraction instruments gave the same measurement results within error margins, since the underlying scientific principles were the same. Moreover, all manufacturers provided instrument validation to establish the quality of the instrument. Finally, the use of a volume mean was standard for pharmaceutical products for the reasons that pharmaceutical products were delivered in particular mass doses and, assuming constant density, this mass corresponded to a particular volume. In support, documents (6), (21), (30), (41) and (42) were cited.

The hygroscopicity in claim 8 of the main request was a clear parameter, for which the measurement was indicated on page 12 of the patent in suit. This method was used to determine the hygroscopicity in all the examples. The second step was not relevant for the uptake of water, but merely made sure that the results were not distorted by condensation water. Hence, no uncertainty existed as to how the parameter was determined.

- Novelty

The anhydrous aripiprazole crystals B according to claim 1 of the first auxiliary request were novel over document (2), since they were not the inevitable result of the processes disclosed therein. Document (2) provided no details with regard to those processes, and when reproducing them the skilled person had to select several parameters, such as the type of alcohol, the

amount of solvent mixture, the heating temperature and time and the cooling temperature for the preparation of the hydrate and the heating time necessary for the conversion of type 3 crystals into type 1 crystals. There was no common knowledge on which the skilled person could rely in this context. Document (19) failed to indicate those parameters, and in any case no such parameters were provided in document (2). Document (37) did not start from anhydrous type 1 crystals as required by document (2), since the starting material was an ethanolate. Furthermore, the appellant's own experimental data showed that depending on the conditions for the preparation of the type 3 crystals, the claimed compound with its low hygroscopicity might or might not be obtained. The different initial moisture content was of no consequence for the hygroscopicity, as apparent from examples 1 and 5 of the patent in suit and also from the table on page 46 of document (40).

XIV. The arguments of the respondents, to the extent that they are relevant for the present decision, can be summarised as follows:

- Admissibility of documents (39) to (42)

Documents (39) to (42) should not be admitted into the proceedings. These documents addressed issues which had been disputed from the beginning of the opposition proceedings. They could have been filed in the first-instance proceedings or at the latest with the statement of grounds of appeal. In particular, documents (39) and (40) had been filed more than two years after documents (36) to (38) had been filed by respondent 5, and had not left the respondents enough time for a proper evaluation. Furthermore, one of the

main points of criticism, namely that the experiments had not been carried out by an independent expert, had not even been addressed. Similar objections applied with respect to the admission of document (41), which was a declaration of a renowned expert, and document (42). Both documents could not be fully evaluated in the available time. Moreover, the supporting evidence in document (42) was in Japanese and could not be easily verified.

- Amendments

Granted claims 2 to 7 had no basis in the application as filed. In particular, a combination of original claim 7 with original claims 2 and 6 was not disclosed. There was also no direct and unambiguous disclosure for a combination of claim 7 with the information indicated on page 21, line 23 to page 22, line 25. Granted claim 8 had no basis in the application as originally filed, because the subject-matter of original claims 13, 16 and 18 to 20 was not disclosed in combination. The change of the term "anhydride" to the term "anhydrous" was not a correction of an obvious error, but the change of a "species" (anhydride) by a "genus" (anhydrous) and therefore extended the subject-matter beyond the content of the application as originally filed.

- Sufficiency of disclosure

The information in the patent in suit with respect to the particle size was not sufficient to allow the skilled person to reproduce the invention. The term "mean particle size" was not defined. There existed various means and various methods for its determination, leading to different results. With

regard to the instrument mentioned in the patent in suit, there existed several models. It was not disputed that Microtrac HRA instruments used laser diffraction as the measuring method. However, this did not mean that the mean particle size was necessarily the volume mean. Conversion into other means was possible and did not result in a high propagation of error. Furthermore, in order to be able to reproduce the measurement according to the patent in suit, it was necessary to specify the computer and the software connected to the instrument. It was equally necessary to identify the data analysis method. None of this information was disclosed in the patent in suit. In support, reference was made to documents (6), (21) and (30).

Concerning the hygroscopicity parameter, the patent in suit mentioned two different methods for its measurement, which left the skilled person in doubt as to its exact determination. Furthermore, this parameter was unreliable, because it changed with time and was dependent on preparation conditions. Nevertheless, no specific time for the hygroscopicity measurement was provided in the patent in suit and with regard to the preparation parameters the patent in suit mentioned only the heating time and temperature.

- Novelty

The claimed anhydrous aripiprazole crystals B were not novel over the disclosure of document (2), because they were the inevitable result of the processes disclosed therein, as shown in documents (15a) to (15c), (19) and (20) and (36) to (38). Moreover, hygroscopicity, which was the only distinguishing feature, was such an unclear parameter that it could not be used to distinguish the claimed compound from the prior-art

compound. Concerning the lack of information with respect to the reaction conditions in document (2), crystallisation belonged to the basic techniques of the skilled person and required no further detailed instructions. The alleged difference in starting material in document (37) was of no consequence, since this material was dissolved in the subsequent step. The appellant's experimental report (document (40)) was not suitable to disprove lack of novelty. The experiments had not been carried out by an independent expert. Samples A3 and B were not anhydrous aripiprazole according to document (2). The exact conditions of the hygroscopicity test were not disclosed and there was a time gap between the preparation of the samples and the experiments carried out by Professor Ulrich. Furthermore, the anhydrous crystals B obtained by the appellant had a high initial moisture content, in contrast to those disclosed in the patent and in document (37), and as a consequence also showed high hygroscopicity.

XV. Respondent 2 did not file any submissions or requests during the appeal proceedings.

XVI. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for consideration of the remaining grounds for opposition should the board find that the grounds under Article 100(b) and (a) EPC together with Article 54 EPC did not prejudice the maintenance of the patent on the basis of the main request of 7 April 2009 or of the first to third auxiliary requests filed as second to fourth auxiliary requests with the statement of grounds of appeal of 17 November 2009. In the alternative, it requested that the patent be maintained on the basis of the main

request of 7 April 2009 or, alternatively, of the first to third auxiliary requests filed as second to fourth auxiliary requests with the statement of grounds of appeal of 17 November 2009.

XVII. Respondents 1, 3, 4 and 5 requested that the appeal be dismissed. Respondent 1 further requested that documents (41) and (42) not be admitted into the appeal proceedings. Respondent 5 requested that the case be remitted to the department of first instance for consideration of the grounds for opposition under Article 100(a) EPC together with Article 56 EPC should the board find that the other grounds for opposition did not prejudice the maintenance of the patent on the basis of one of the requests on file. Respondent 5 further requested that documents (39) and (40) not be admitted into the appeal proceedings.

XVIII. At the end of the oral proceedings the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. Non-appearance at oral proceedings before the board

2.1 Respondent 2, which did not file any submissions or requests, and respondent 3, which had announced its non-attendence (see points XI and XV above), were not present at the oral proceedings before the board to which they had been duly summoned.

2.2 According to Rule 115(2) EPC, oral proceedings may continue in the absence of a duly summoned party that

does not appear. According to Article 15(3) of the Rules of Procedure of the Boards of Appeal (RPBA), the board is not obliged to delay any step in the proceedings, including its decision, by reasons only of the absence at the oral proceedings of any party duly summoned, which may then be treated as relying only on its written case. In deciding not to attend oral proceedings, respondents 2 and 3 chose not to avail themselves of the opportunity to present their observations and comments orally.

2.3 The contentious issues were apparent from the decision under appeal, the statement of grounds of appeal and the replies thereto. Respondents 2 and 3 must have expected that the board would decide on these issues at the oral proceedings. Hence, the board concludes that respondents 2 and 3 had an opportunity to present their observations and comments on the grounds and evidence on which the board's decision, arrived at during oral proceedings, is based. The board was, therefore, in a position to take a final decision at the oral proceedings despite the absence of the duly summoned respondents 2 and 3.

3. Admission of documents (39) to (42)

3.1 Respondents 1 and 5 objected to the admission of documents (39) to (42) into the appeal proceedings, arguing that their late filing was not justified (see point XIV above).

3.2 The board is not convinced by their arguments for the following reasons:

3.2.1 With the statement of grounds of appeal, the appellant had filed experimental data (i.e. document (32))

challenging the opposition division's finding that the claimed anhydrous aripiprazole crystals B were anticipated by document (2). Respondent 5, in particular, questioned the relevance of these data, on the grounds that it was not clear whether or not the experiments had been carried out by a qualified person, that the experiments in document (32) were allegedly not a proper reproduction of the teaching of document (2) and that the determination of the water content had not been carried out *lege artis*. In addition, respondent 5 submitted its own experimental data with documents (36) to (38). In reply, the appellant filed documents (39) and (40). The board is of the opinion that the filing of these documents is a legitimate attempt by the appellant to address the objections raised by respondent 5 and to verify the experimental data provided in documents (36) to (38). The board also notes that documents (39) and (40) were filed almost sixth months before the summons to oral proceedings. Nevertheless, none of the respondents informed the board that time was needed for an adequate reply. Nor did they request postponement of the oral proceedings. In this context, the board also notes that the respondents could not have relied on the fact that the board would exercise its discretion under Rule 13(1) RPBA in their favour and not admit documents (39) and (40). Their potential relevance for the question of novelty was not disputed.

3.2.2 Document (41) was submitted by the appellant in reply to the respondents' arguments concerning the feature "mean particle size" filed with their replies to the statement of grounds of appeal, and in response to the documents filed in support thereof. The board notes that Professor Antonietti merely reviewed those documents considered to be relevant for the question of

particle size determination, that is documents (6) and (21) relied on by the opposition division in the decision under appeal, documents (29) to (31) filed by the appellant with the statement of grounds of appeal and documents (33a) to (33c) filed by respondent 4 in reply to the statement of grounds of appeal, without providing new facts or evidence or raising new questions that could come as a surprise to the respondents or the board.

3.2.3 Document (42) is a short, easily understandable declaration by Mr Kizawa, General Manager, Sales und Marketing of Nikkiso, a manufacturer of Mictrotrac instruments including the instrument mentioned in the patent in suit for the determination of the particle size. It was filed in response to respondent 4's allegation that there existed several different Mictrotrac HRA instruments. The Japanese enclosures are merely attached to support Mr Kizawa's statements as to the range of particle sizes that can be measured and the measuring method. In this context, translation of the relevant terms were provided.

3.3 Hence, the board in exercising its discretion under Article 13(1) RPBA decided to admit documents (39) to (42) into the proceedings.

Main request

4. Amendments (Article 100(c) EPC)

Contrary to the opinion of respondents 3 and 5, the subject-matter of claims 2 to 7 and claim 8 of the main request has a basis in the application as originally filed. (Support for claims 2 to 7: claims 2, 6 and 8-11 as originally filed, in combination with the disclosure

on page 21, line 24 to page 22, line 25 and page 12, lines 8 to 11; support for claim 8: see point 6 below). In view of the negative outcome with respect to the issue of sufficiency of disclosure (see point 5 below), it is not necessary to go into more detail with respect to this issue.

5. Sufficiency of disclosure (Article 100(b) EPC)

5.1 Claim 1 of the main request is directed to a particular crystalline form of aripiprazole, namely hydrate A, which is defined by several parameters, including a mean particle size of 50 µm or less. Although the mean particle size is an essential feature of the claimed crystalline form (according to the respondents it is the sole distinguishing feature), claim 1 specifies neither the type of mean particle size nor the method according to which the particle size is to be determined.

5.2 Since the presently claimed product is defined by the use of parameters, it is of critical importance for sufficiency of disclosure that the person skilled in the art is provided with all the information necessary to accurately measure those parameters as intended by the appellant in order to reproduce the precise product that is claimed. In other words, the skilled person must know how to identify a product exhibiting the claimed properties.

5.3 The size of particles can be characterised by several means, such as number, length, surface and volume. There are simple means and moment means. Two of the most important moment means are the surface area moment mean or Sauter mean diameter (D[3,2]) and the volume or mass moment mean or De Brouckere mean (D[4,3]).

Furthermore, different methods are known for measuring particle size distributions, which give different means (see document (6), page 2, middle column, line 11 to page 3, right column, line 16). Means derived from a specific measurement can also be converted to various other means (document (6), page 3, right column to page 4, middle column, sections "Interconversion between number, length and volume/mass means" and "Measured and derived diameters").

5.4 The patent in suit is silent as to the specific type of mean particle size to be used for the definition of the claimed product. With respect to particle size measurement, it indicates on page 12, lines 15-16 that "0.1 g of the particles to be measured were suspended in a 20 ml n-hexane solution of 0.5g soy lecithin, and particle size was measured using a size distribution meter (Microtrack HRA, Microtrack Co)." The only example for the preparation of the claimed hydrate A (i.e. example 1) merely indicates a range for the mean particle size (see page 14, line 23 of the patent in suit: "mean particle size of 20-25 µm"). Hence even the repetition of this example could not provide the person skilled in the art with sufficient information on the type of mean particle size to be determined.

5.5 The board is not convinced that the indication "Microtrack HRA" is sufficient to clearly identify the instrument that was used for the particle size measurement. In document (33a) two models are mentioned: Microtrac HRA-UPA 100 and Microtrac HRA-X100 (see page 5, lines 54-58). In his declaration (document (42)), Mr Kizawa states that at the time of the filing of the patent only one Microtrac HRA instrument existed, namely the model "Microtrac 9320-X100" (also called Microtrac X100). In this context,

the board notes that the documents attached to this declaration cannot support Mr Kizawa's assertions, since their publication date is not clear and the appellant, when asked by the chairman of the board at the oral proceedings, was not able to provide the information sought. Furthermore, Mr Kizawa also states in his declaration that a complex instrument which connected Microtrac HRA with Microtrac UPA also existed, called Mictrotrac HRA-UPA 100. In the board's opinion, doubts therefore remain whether the instrument "Microtrack HRA" mentioned in the patent in suit necessarily refers to the instrument "**Mictrotrac HRA** X100" and not, for example, to the instrument "**Microtrack HRA** UPA100".

5.6 However, even assuming that the patent in suit refers to the Microtrac HRA X100 instrument, which - uncontested by all parties - measures the particle size by laser diffraction, the board cannot accept the appellant's conclusion that, as a consequence, the mean particle size according to patent was the volume mean particle size or, more precisely, the De Brouckere volume moment mean D[4,3].

5.6.1 It is not disputed that laser diffraction techniques initially generate a volume distribution (document (6), page 3, left column, last five lines of the second paragraph and penultimate paragraph; document (21), page 69, last line to page 70, first line, document (30), page 4, Section 4 "Principle"). They **can** therefore, as pointed out by the appellant, generate the De Brouckere mean or equivalent volume mean. However, it is equally indisputable that the initially generated volume distribution can be converted into a variety of other size distributions and means (documents (6), page 3, right column, line 17 to

page 4, middle column, line 18; document (21), page 70, lines 2 to 3). It has not been contested that Microtrac HRA instruments are capable of performing such conversions from the particle size distribution originally measured. In view of this possibility, the appellant's argument that the intended mean particle size was necessarily a volume mean and even more specifically the De Brouckere mean is not convincing. Hence, even if, by reference to the Microtrac HRA instrument, laser diffraction is identified as the measuring method, this is not sufficient to define which mean particle size is the intended or "true" mean particle size of the claimed crystalline form.

5.6.2 The board is also not convinced by the appellant's argument that the skilled person would not consider, and would in fact be discouraged from, converting the volume distribution into any other size distribution or mean, because of the propagation of error. As disclosed in document (6), page 3, right column, lines 40 to 51, calculating the mass or volume mean distribution with **laser diffraction** permits conversion into a number mean with a very low margin of error, i.e. less than 1%. The board acknowledges that the situation may be different when starting from a mean generated by a different method. For this reason, document (6) indicates that the skilled person must be aware of the "great dangers of interconversion" (see page 3, left column, last three lines or page 4, middle column, lines 5 to 10). However, as long as the skilled person is aware of the consequences such an interconversion may have on "derived" mean particle sizes, there is nothing preventing him from calculating other particle size distributions or means from the one initially generated. In particular, he would have no reason not to do so, if he is aware, as in the present case, that

the initial data can be transformed without unacceptable consequences.

5.6.3 Equally unconvincing is the appellant's argument that "the determination of particle size using the volume mean was the standard method for measurement of pharmaceutical particles having a particles size of 50 microns or less" (see document (41), point 25). Neither the appellant nor Professor Antonietti provided any support for this assertion. Moreover, the board fails to see a correlation between the administration of a particular dose of a medicament and the mean particle size of the medicament. The board accepts that under particular circumstances a specific volume mean (which might be a number volume mean or any other volume mean) may be of relevance in the administrations of a drug, for example when a substance is inhaled. However, it is completely irrelevant if the drug in a particular mass dose is dissolved before it is administered.

5.7 In the present case, where the particle size is one of the characterising parameters of the claimed product and might be its only distinguishing feature, the mere mention of the measuring instrument alone, without providing information as to the data analysis method such as the computer system or the model used for calculation, is not sufficient for a reliable reproduction of the particle size measurement. The influence of the operating conditions is apparent from document (30), which refers to a list of criteria which should be provided "in order that the measurement can be readily repeated by different operators in different laboratories" (see chapter 7 on pages 14 and 15). Among them are the instrument type, the software version, type of light scattering model applied, real and

imaginary part of complex refractory index if Mie theory is applied (see also page 18 of document (30)). With respect to all these conditions the patent is totally silent.

5.8 The board concurs with the appellant and Professor Antonietti that a person skilled in the art is in a position to measure a mean particle size using a particular laser diffraction instrument. It is also acknowledged that the skilled person, if he has all relevant information regarding the operating conditions and the data analysis method for one particular laser diffraction instrument by one manufacturer, is most likely in a position to reliably reproduce the measured result within error margins on this instrument or even on a laser diffraction instrument supplied by a different manufacturer. The decisive point in the present case, however, is that precisely this information is missing from the patent in suit.

The concept of validation is not relevant in this context. Validation merely permits the operator to confirm whether an instrument is performing according to certain standards, in other words, whether it is working correctly.

5.9 For the aforementioned reasons, the board concludes that the patent in suit does not contain sufficient information for the skilled person to correlate a mean particle size measured for any given batch of aripiprazole hydrate A with the intended parameter according to claim 1. He is therefore not in a position to reliably reproduce the aripiprazole hydrate A according to the invention. In the present case, this is not merely a question of uncertainty at the boundary

of claim 1, but affects the core of the claimed invention.

Hence, the ground for opposition pursuant to Article 100(b) EPC prejudices the maintenance of the patent on the basis of the main request.

First auxiliary request (i.e. the second auxiliary request filed with the statement of grounds of appeal)

6. Amendments (Article 100(c) EPC)

6.1 According to respondents 3 and 5, the subject-matter of claim 1 of the first auxiliary request (claim 8 of the main request and claim 8 as granted) was not supported by the application as originally filed (see point XIV above).

6.2 The board does not agree.

6.2.1 Claim 1 of the first auxiliary request finds its basis on page 23, line 19, to page 24, line 24 of the application as originally filed. The passage starts with the statement that ""Aripiprazole Anhydride Crystals B" of the present invention as used herein have the physicochemical properties given in (6)-(12) below" and continues with the description of those properties. Claim 1 contains only properties (7) to (11). However, property (12) is optional and the presence or absence of property (6) relating to ^{1}H-NMR data is of no consequence, because these data were measured in **solution**; they are specific to the molecule aripiprazole as such and therefore do not add any information to the naming of the compound as aripiprazole; in particular, they cannot further characterise "Aripiprazole Anhydride Crystals B", which

are a specific **solid** (crystalline) form. This is also apparent from the application as filed, as the ^{1}H-NMR data of all solid forms of aripiprazole referred to therein, including the hydrate A and the anhydrous crystals B, are identical (see page 22, lines 5-15, and page 23, line 24, to page 24, line 4). The board therefore concurs with the opposition division that the omission of these non-characterising data does not lead to an extension of subject-matter beyond the application as originally filed.

6.2.2 In view of the above, respondent 5's argument that the subject-matter is not clearly and unambiguously disclosed because there is no disclosure of a combination of originally filed claims 13, 16 and 18 to 20 is not convincing. Article 100(c) EPC refers to the content of the application as filed, which is not limited to the claims.

6.2.3 The board is also not convinced by the respondents' arguments with regard to the replacement of the term "anhydride" by the the term "anhydrous".

In organic chemistry, the term "anhydride" has a specific meaning. It characterises a product which is obtained by removing water from carboxylic acids and can be illustrated by the following equation:
$RC(=O)OH + R(C=O)OH \rightarrow R(C=O)O(O=C)R + H_2O$.
Aripiprazole has no such acid functionality. The skilled person would therefore immediately recognise that in the present context he cannot attribute the usual technical meaning to the term "anhydride". Moreover, the application as originally filed states on page 4, lines 10 to 17 that "The inventors of the present invention have discovered that this reduced-hygroscopic form of Aripiprazole is a crystalline

substance defined herein as **Anhydride** B. A particular process for the preparation of **this anhydrous** crystalline substance has also been discovered and comprises yet another aspect of the present invention" (emphasis added by the board). A further passage states on page 104, lines 6 to 9 that "The following examples used aripiprazole drug substance made by first milling or pulverizing the conventional hydrate of aripiprazol and then heating it to form the **anhydrous** form (**anhydride** B)" (emphasis added by the board). From these passages and in view of the recognisable fact that the term "anhydride" cannot have its usual technical meaning, it is clear for any skilled reader that this term was incorrectly used for the **anhydrous** form of the crystalline form B. The substitution of the term "anhydride" by the term "anhydrous" in claim 1 of the first auxiliary request does therefore not contravene Article 100(c) in conjunction with Article 123 EPC.

6.3 No further objections under Article 100(c) EPC were raised by the respondents against the first auxiliary request and the board sees no reason to raise objections of its own.

6.4 The board therefore concludes that no grounds for opposition pursuant to Article 100(c) EPC prejudice the maintenance of the patent in suit on the basis of the first auxiliary request.

6.5 Compared to the claims as granted, the first auxiliary request has been amended by deleting claims 1-7, 12 to 20, 24, 25 and 45 to 50 (see point XII above). These amendments do not give rise to objections under Articles 123(2) and (3) EPC. The respondents did not

raise any additional objections under Article 123 EPC with respect to this request.

7. Sufficiency of disclosure

7.1 Neither claim 1 nor any other independent claim of the first auxiliary request refers to a mean particle size. Hence, the conclusions drawn under point 5 above for the main request do not apply to the first auxiliary request.

7.2 Claim 1 of the first auxiliary request refers to anhydrous aripiprazole crystals B characterised by several parameters, including a "low hygroscopicity", which is defined as a moisture content of 0.40% or less after placing said drug substance for 24 hours in a desiccator maintained at a temperature of 60°C and a humidity level of 100%.

The patent in suit furthermore provides information with respect to the "Hygroscopicity Test Method". According to this method, the substance was placed for 24 hours in a dessicator at 60°C and 100% humidity. After 24 hours the substance (in a weighing bottle) was placed in a dessicator at room temperature and a humidity of 30% for a further 24 hours. The water content was then measured by the Karl Fischer method (page 12, lines 17 to 22).

7.3 With respect to the alleged insufficiency of disclosure the respondents essentially argued (see point XIV above) that the skilled person was not in a position to reproduce the invention in view of

(a) the inconsistency between the method for the determination of the moisture content in claim 1

and the method described on page 12 ("one-step" method vs "two-step" method) and

(b) the unreliability of the hygroscopicity parameter, which changed over time and was dependent on the manner of preparing the anhydrous crystals.

7.4 Concerning point (a), the board notes that the first step of the method described on page 12 is identical to the step disclosed in claim 1. As explained by the appellant, this was the step in which water uptake occurs. The following step merely made sure that the measurement was not distorted by condensation water. Hence, the first step is the one that was decisive for the absorption of water in the claimed crystals. The board has no reason to doubt this explanation. Nor have the respondents provided convincing counter-arguments. Claim 1 defines the conditions to which the crystals have to be subjected before their moisture content is measured and the method to do this is clearly described in the patent in suit. The board also does not agree with the respondents that the reference in the examples to merely the decisive step is an indication that the hygroscopicity measurement was not carried out according to the detailed method indicated in the description of the patent in suit. The board therefore sees no inconsistency between claim 1 and the description.

The reference to paragraph [0133] of the patent in suit as an allegedly yet further method for the measurement of the moisture content is equally unconvincing. This paragraph is concerned with the measurement of hygroscopicity of **tablets** (see paragraph [0132]).

Decisions T 225/93, T 466/05 and T 749/98 cited by respondent 5 in this context cannot support its case.

In the cases underlying these decisions several methods existed for the measurement of a parameter, leading to different results. Since there was no information in the respective patents as to the method to be used, the boards concluded that the invention was insufficiently disclosed. In the present case, however, the method for measuring the particle size is clearly indicated.

7.5 With regard to objection (b) under point 7.3 above, which was raised by respondent 3 in its written submissions, the board concurs with the opposition division that the point in time for the measurement of the moisture content is not important for carrying out the invention. Claim 1 is directed to anhydrous aripiprazole crystals B characterised by the parameters according to claim 1, which can be measured at any time to determine whether or not a sample falls within the scope of the claims. Respondent 3's argument with regard to the alleged unreliability of this parameter concerns the stability of the crystals over time (e.g. during storage). The question whether a compound is stable over time is, however, not relevant for sufficiency of disclosure, which is concerned with the question whether or not such a compound can be obtained according to the information and instructions given in the patent.

The board equally concurs with the opposition division that the addition as to how the anhydrous crystals B were prepared is irrelevant. The hygroscopicity, like the other parameters, is clearly measurable according to the method disclosed in the patent in suit. Hence, the claimed compound can always be distinguished from a compound of the prior art. Any additional preparation steps would not further limit the claim.

This case differs from the case underlying decision T 226/98, cited by respondent 3, where the board considered that the expression "as a pharmaceutical product" did not define a clear standard of purity. In addition, since purity standards may change over time, it remained obscure what was considered to be the required product quality. In the present case, the required product property, namely the hygroscopicity, is clearly defined and can be measured at any time.

Respondent 3 also argued that the instruction in the patent in suit for the preparation of anhydrous crystals B referring only to the heating step was insufficient. However, it has provided no evidence to support this allegation. On the contrary, respondent 3 provided experimental evidence (document (15c), examples N, S and T) reworking examples 2 to 4 of the patent in suit and was able to obtain the claimed anhydrous crystals by following the heating method described in the patent.

8. Novelty

8.1 According to respondents 3-5 the subject-matter of claim 1 was anticipated by the disclosure of document (2). In support of their assertion, documents (15a) to (15c), (19), (20) and (36) to (38) were provided. Furthermore, during the written proceedings, respondent 3 contested novelty of the claimed subject-matter in view of document (7), in particular example 1. In support, it relied on documents (15a) and (15b). The board observes that the disclosure of document (7) is identical to the disclosure of document (1), which, according to the decision under appeal, was not considered to anticipate anhydrous aripiprazole crystals B.

8.2 It is a general principle that lack of novelty must be shown by a direct and unambiguous disclosure in the prior art which inevitably leads the skilled person to subject-matter that falls within the scope of what is claimed.

8.3 According to document (15a), example 1 of document (7) was reproduced, resulting in compound A which was identified as a solvate, i.e. the ethanolate of aripiprazole (document (15a), page 3, penultimate paragraph). This compound has an X-ray diffraction pattern according to figure 1 (page 4 of document (15a)), which differs from the presently claimed pattern, and an endothermic peak in the DSC curve at 139°C. The latter coincides with the melting point given in example 1 of document (7). Compound A was then further dried at 80°C for 40 hours or, alternatively, at 100°C for 24 hours to yield compounds A1 and A2. Characterisation of A1 and A2 by means of X-ray diffraction patterns, thermogravimetric/differential analyses and/or hygroscopicity shows, according to documents (15a) and (15b), that compound A1 included anhydrous aripiprazole crystals B **and** the ethanolate of aripiprazole. Compound A2 allegedly corresponds in all physicochemical parameters to the anhydrous aripiprazole crystals B (pages 3 to 7 of document (15a) and 1 to 2 of document (15b)). The board notes that the melting point of the different compounds A, A1 and A2 is identical to the melting point given in example 1 of document (7), which is the only physicochemical parameter given in that document.

8.4 However, the further drying or heating steps described in document (15a) are not disclosed in document (7), as already noted by the opposition division. In fact, document (7) is entirely silent on drying or heating

conditions. Since depending on these steps different products, that is A, A1 or A2 can be obtained, the board, in agreement with the opposition division, can only conclude that anhydrous aripiprazole crystals B with all physicochemical parameters according to claim 1 of the first auxiliary request are not the inevitable outcome of the synthesis according to example 1 of document (7).

8.5 Document (2) is a study on crystal transformation of aripiprazole. It refers to three different aripiprazole crystalline forms, namely types 1, 2 and 3, which were characterised by their x-ray diffraction patterns and melting points. Concerning their preparation, the information given in document (2) is sparse: anhydrous type 1 was prepared by recrystallising aripiprazole from ethanol and could be converted into type 2 via heating at 130°C to 140°C for 15 hours. Both types of polymorphs could be transformed to hydrous crystals type 3 by recrystallisation from alcoholic solvent containing water up to 20%(v/v). Type 3 could be converted to type 1 by heating at 80°C (page 938, last paragraph). No further experimental details are provided in document (2). Nor does this document provide information as to the hygroscopicity of type 1 crystals.

8.6 In an attempt to demonstrate that a product falling within the scope of claim 1 of the first auxiliary request is the inevitable result of the disclosure in document (2), the respondents provided tentative reproductions of the teaching of document (2) (documents (15a) to (15c), (19) and (20), and (36) to (38)).

8.7 However, in view of the scant information as to the experimental details, the respondents were not in a position to reproduce the teaching of document (2) without having to arbitrarily select a number of parameters which are not disclosed in document (2), for example a) the type of the alcohol, b) the amount of water and c) the cooling regime for the preparation of the type 3 crystals or d) the heating time for the preparation of type 1 crystals from type 3 crystals. Hence, the conditions which have to be selected can vary significantly.

8.8 In their reproductions the respondents used a mixture of 80% ethanol and 20% water and various cooling regimes for the preparation of type 3 crystals. Subsequently, these crystals were heated at 80°C for 40 hours (page 8 of document (37)) or 48 hours (conditions for document (19) according to the table on page 9 of respondent 5's reply to the statement of grounds of appeal) or 8 hours (page 8 of document (15a)). However, neither ethanol, nor the presence of 20% water, the cooling regime or the heating time is mentioned in document (2). The board can also see no convincing reason why a skilled reader based on his common general knowledge would have chosen precisely those conditions when carrying out the teaching of document (2). It is not disputed that crystallisation techniques as such belong to the basic skills of a person skilled in the art. However, this argument is beside the point. The fact that the skilled person knows in general how to recrystallise a compound is not relevant in view of the fact that document (2) does not disclose the exact conditions of the crystallisation and the subsequent drying step and that these conditions may have an influence on the characteristics of the product obtained. The respondents' argument that

the skilled person only had to apply "usual cooling and drying conditions" is not convincing in the absence of any notion as to what is to be considered usual cooling and, in particular, drying conditions in the context of document (2).

8.9 Moreover, the appellant provided experimental evidence in order to demonstrate that even under the set of conditions similar to those selected by the respondents, that is a ratio of ethanol to water of 80:20, various cooling regimes and heating at a temperature of 80°C for 40 hours, a product with a hygroscopicity as defined in claim 1 is not the inevitable result (document (32) and more particularly documents (39) and (40)). According to the table on page 46 of document (40), only two out of twelve examples showed the hygroscopicity claimed.

8.10 According to the respondents, the appellant's experimental evidence was unreliable and inadequate to disprove lack of novelty over document (2).

8.10.1 One of the respondents' main arguments was based on the fact that two of the four samples prepared in document (39), namely samples A3 and B, did not correspond to the type 1 crystals disclosed in document (2), with the consequence that the recrystallisation in document (40) based on those samples was not carried out according to document (2).

The board is not convinced by this argument. According to document (2), aripiprazole type 1 crystals are prepared from hydrous type 3 crystals. The hydrous type 3 crystals are prepared from type 1 or type 2 crystals. These are **dissolved** in a alcohol/water solution and their crystalline properties lost. Hence,

the exact nature of the crystal structure of the starting material is, in the board's opinion, not decisive. Furthermore, the board notes that document (37) does not provide clear evidence as to the starting material either. The starting crystals in document (37), for which no X-ray diffraction pattern has been provided, is characterised by an ^{1}H-NMR and shows the additional signal for ethanol. Furthermore, DSC shows two signals at around 100°C and 139°C. This corresponds to the signals which were detected by respondent 3 for aripiprazole ethanolate (document (15a), page 4, line 1). The data are also in keeping with the results in document (39), which show that the crystallisation of aripiprazole from ethanol and drying the obtained product at 45°C for 6 hours (see the bottom paragraph on page 12, corresponding to the crystallisation and drying on page 4 of document (37)) yields an ethanolate.

8.10.2 The respondents also argued that hygroscopicity was a vague and unclear parameter as compared to the parameters commonly used to characterise a crystalline form, in particular the X-ray powder diffraction pattern which is the gold standard for identification of polymorphs. Hence, hygroscopicity should not be taken into account when assessing novelty. In support, decision T 1127/02 was cited.

The board does not agree. A definition of hygroscopicity is present in claim 1 and this parameter can be measured in accordance with the method described in the patent (see point 7.5 above). The board therefore sees no reason to disregard this clearly defined parameter in the assessment of novelty. Decision T 1127/02, which states that the lack of clarity might affect the decision on issues under

Article 100(a), such as novelty, cannot therefore support the respondents' case.

8.10.3 The board is also not convinced by the respondents' arguments that the appellant's data are less reliable because they were allegedly carried out by an employee of the appellant and not by an independent expert. The board notes that only the starting materials were prepared by the employee. Essential in the present context is, however, the preparation of the hydrous crystal form and the preparation of crystal type 1 from these hydrous crystals. These experiments were carried out by an independent expert, namely Professor Ulrich, as can be seen from document (40).

8.10.4 Furthermore, the respondents argued that the anhydrous crystals produced in document (40) were still wet, before the hygroscopicity was measured. According to the respondents, this was particularly apparent from the table on page 46, samples A1, A2, A3 and B of the "short dried" batch; (hereinafter named examples 9 to 12; for ease of reference the board refers to the samples of table 46 from top to bottom as examples 1 to 24). The lowest value for the water content in all examples was 0.06 wt.-%, which was above the content measured in document (37) and above the values described in Table 1 of the patent in suit (see page 16). Wet material, however, was prone to take up water. As a consequence, higher hygroscopicity values were measured in document (40). In other words, in its experimental evidence the appellant had not dried the the crystals for long enough to obtain the anhydrous form.

The board cannot dispute that the initial moisture content in the examples in table 46 of document (40) is

higher than in the examples of document (37), although the drying temperature and the drying time are precisely the same in both documents. Notwithstanding this discrepancy, there is however no clear correlation apparent between the initial moisture content and the moisture content after the hygroscopicity test, as asserted by the respondents. For example, the moisture content for example 11 was the highest and for example 12 the lowest in the "short dried" batch. Thus, according to the respondents, example 11 should be more prone to take up water than example 12. However, according to examples 15 and 16, exactly the opposite is observed. A similar observation can be made by comparing examples 17 and 19 with examples 21 and 23. Furthermore, examples 1 and 3 have the same initial moisture content. However, their moisture content differs considerably after the hygroscopicity test. In the absence of a clear correlation, the respondents' argument that the reason for the high hygroscopicity observed by the appellant was the high initial moisture content, is not convincing.

8.10.5 A further argument was that no explanation was given in document (40) as to how the hygroscopicity tests were performed. This argument cannot succeed in view of the information provided on page 3 of document (40) stating that the hygroscopicity test was carried out according to page 12, line 17-22 of the patent in suit. The same method was used in document (37).

8.10.6 With regard to the alleged time gap between the preparation of the aripiprazole crystals in document (39) and the recrystallisation experiments of the document (40) raised by respondent 4, the board fails to see the relevance of this point. In the absence of any evidence to the contrary, the board has

no reason to doubt the stability of the samples A1, A2, A3 or B.

8.11 Hence, in view of the discrepancy between the respondents' and the appellant's experimental data, for which no satisfactory explanation is apparent to the board other than that essential conditions are simply not so clearly and completely disclosed in document (2) that the skilled person can readily prepare a compound as presently claimed, the board is of the opinion that it has not been conclusively shown that the presently claimed anhydrous aripiprazole crystals B are the inevitable result of the disclosure of document (2). Accordingly, the subject-matter of the first auxiliary request is deemed to be novel pursuant to Article 54 EPC.

9. Remittal

In the decision under appeal the first instance revoked the patent on the grounds of insufficiency of disclosure for the subject-matter of claim 1 of the main request and lack of novelty of the subject-matter of claim 1 of the auxiliary request. Hence, no decision on inventive step has been taken. In these circumstances the board considers it appropriate to remit the case to the department of first instance for further prosecution on the basis of the first auxiliary request which was filed as second auxiliary request with the statement of grounds of appeal of 17 November 2009.

Second to third auxiliary requests (third to fourth auxiliary requests filed with statement of grounds of appeal)

10. Having come to the conclusion that the first auxiliary request complies with the requirements of Article 100(c) and (b) EPC and is novel over the prior art and having decided to remit the case, there is no need for the board 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 department of first instance for further prosecution.

The Registrar: The Chairman:

M. Schalow C. M. Radke

Decision electronically authenticated