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**Datasheet for the decision
of 24 January 2008**

Case Number: T 1210/05 - 3.3.01

Application Number: 97912445.0

Publication Number: 0944617

IPC: C07D 401/12

Language of the proceedings: EN

Title of invention:

Crystals of benzimidazole derivatives and their production

Patentee:

Takeda Pharmaceutical Company Limited

Opponent:

Krka, Tovarna Zdravil, d.d.

Headword:

2-(2-pyridylmethylsulfinyl)benzimidazole crystals/TAKEDA

Relevant legal provisions:

EPC Art. 100a), 54, 56, 111(1)

Relevant legal provisions (EPC 1973):

EPC Art. 100a), 54, 56, 111(1)

Keyword:

"Novelty (yes) - prior disclosure not proven beyond any reasonable doubt"

"Inventive step (yes) - non obvious solution"

Decisions cited:

T 0133/87, T 0005/89, T 0270/90, T 0472/92, T 0097/94,
T 0750/94, T 0574/00, T 0480/02, T 0496/02

Catchword:

-



Case Number: T 1210/05 - 3.3.01

DECISION
of the Technical Board of Appeal 3.3.01
of 24 January 2008

Appellant: Takeda Pharmaceutical Company Limited
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 15 July 2005
revoking European patent No. 0944617 pursuant
to Article 102(1) EPC 1973.

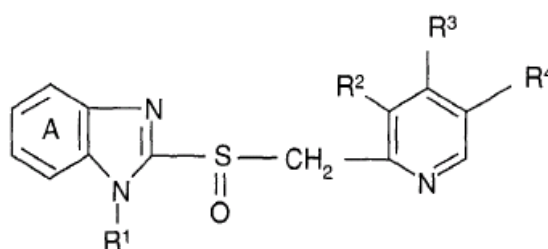
Composition of the Board:

Chairman: P. Ranguis
Members: J.-B. Ousset
R. T. Menapace
C. M. Radke
D. S. Rogers

Summary of Facts and Submissions

- I. The present appeal lies from the decision of the opposition division posted on 15 July 2005 revoking the European patent No. 0 944 617 filed on 13 November 1997 and claiming the priority of 14 November 1996.
- II. The patent in suit was granted with six claims. Claim 1, the sole independent claim, reading as follows:

"1. A method for producing a crystal of the compound of formula (I):



(I)

wherein the ring A may optionally be substituted by a substituent selected from halogen, C₁₋₇ alkyl, cyano, carboxy, alkoxycarbonyl having 1 to 4 carbon atoms in its alkoxy moiety, alkoxycarbonylalkyl having 1 to 4 carbon atoms in each of its alkoxy and alkyl moieties, carbamoyl, carbamoylalkyl having 1 to 4 carbon atoms in its alkyl moiety, hydroxy, C₁₋₅ alkoxy, C₁₋₇ hydroxyalkyl, C₁₋₇ halogenated alkyl, C₁₋₄ halogenated alkoxy, C₁₋₄ acyl, carbamoyloxy, nitro, C₁₋₄ acyloxy, aryl, aryloxy, C₁₋₆ alkylthio and C₁₋₆ alkylsulfinyl; R¹ represents hydrogen or an N-protecting group selected from a C₁₋₅ alkyl group, a C₁₋₄ acyl group, an alkoxycarbonyl group having 1 to 4 carbon atoms in its

alkoxy moiety, a carbamoyl group, an alkylcarbamoyl group having 1 to 4 carbon atoms in its alkyl moiety, a dialkylcarbamoyl group having 1 to 4 carbon atoms in each of its alkyl moieties, an alkylcarbonylmethyl group having 1 to 4 carbon atoms in its alkyl moiety, and an alkoxycarbonylmethyl group having 1 to 4 carbon atoms in its alkoxy moiety;

each of R^2 , R^3 and R^4 is (1) a hydrogen atom, (2) a C_{1-4} alkyl group which may optionally be substituted with halogen atom(s), or (3) a C_{1-8} alkoxy group which may optionally be substituted with halogen atom(s) or C_{1-4} alkoxy; wherein the crystal has a water content of not higher than 500 ppm and a C_{1-6} alcohol content of not higher than 200 ppm, which method comprises subjecting a solvate of the compound (I) with water and C_{1-6} alcohol, which solvate is obtained by recrystallization with the use of the water and C_{1-6} alcohol, to de-solvent treatment by being suspended, left standing or stirred in water, and then drying."

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

- (1) Copy of a poster presented and inspected at the oral proceedings before the first instance
- (2) Affidavit of Ms Kotar-Jordan dated of 13 February 2004
- (3) Affidavit of Ms Kramar dated of 13 February 2004
- (4) Eur. J. Pharm. Sci. 1996, 4, Suppl., S182
- (5) EP-A-0 302 720
- (6) Email from Mr K. Briggs, Senior publishing editor for the European Journal of Pharmaceutical Sciences of 23 April 2004
- (8) Minutes of the hearing of Ms Kotar-Jordan

recorded during oral proceedings before the opposition division on 16 June 2005.

- (9) Minutes of the hearing of Ms Kramar recorded during oral proceedings before the opposition division on 16 June 2005.

IV. The opponent (respondent) sought revocation of the patent in suit for lack of novelty in view of the content of the poster, document (1) - in particular the description of a specific method for preparing the polymorphic A-form of lansoprazole - which was allegedly presented to the public before the priority date, namely at the Third European Congress of Pharmaceutical Sciences, Edinburgh, 15-17 September 1996 (hereafter: "the Edinburgh Congress")

As evidence in support of this alleged disclosure the documents (2), (3) and (4) were filed.

Furthermore, the opponent also contested the inventive step in view of the document (5) in combination with document (1).

V. At the oral proceedings before the opposition division on 16 June 2005, Ms Kotar-Jordan and Ms Kramar were heard as witnesses (see documents (8) and (9)).

VI. In the decision under appeal it was held that document (1), under the subheading "Preparation of polymorph forms" disclosed the process of claim 1, and that it had been sufficiently proven that a poster identical to document (1) had actually been displayed to members of the public at the Edinburgh Congress. The opposition division decided that the witnesses, both employees of

the opponent and having provided testimony on the basis of their personal knowledge, had credibly answered the relevant questions. Their testimony together with documents (2) and (4) was considered to represent an unbroken chain of evidence sufficiently strong to make it probable beyond all reasonable doubt that document (1) was identical to the poster which had been presented at the Edinburgh Congress.

VII. Oral proceedings before the board took place on 24 January 2008.

VIII. In the course of the appeal proceedings, the following documents were *inter alia* submitted:

(13) Invoice from the Biro Stavek Company dated 18 September 1996

(14) English translation of document (13)

(18) Affidavit of Ms Kotar-Jordan dated 21 January 2008.

IX. The relevant arguments of the appellant may be summarized as follows:

- It was not disputed that a poster had been presented at the Edinburgh Congress. The sole question at issue is "what" was displayed on this poster. Following the jurisprudence related to prior use, the same standard of proof, namely "up to the hilt", had to be applied in the present case, since all the means of evidence in support thereof were within the power and knowledge of the opponent (see in particular T 472/92, OJ EPO 1998, 161).

- Ms Kotar-Jordan's testimony, document (8), in particular her statement "I prepared it, I know it" was the only direct evidence that a poster identical to document (1), was displayed during the Edinburgh Congress. The question was not whether Ms Kotar-Jordan was telling the truth or not but rather whether her assertions were corroborated or not. Indeed, everybody can be mistaken.

- Documents (2) to (4), (13), (14) and (18) were not corroborating evidence in that respect. In particular, document (4) did not disclose any process for preparing lansoprazole. The invoice, document (13), was silent on the content of the poster and there was no evidence that this invoice was the only one. The affidavit, document (18), merely showed that Ms Kotar-Jordan had attended several congresses where she presented various different posters about lansoprazole. From this it might be possible to infer that Ms Kotar-Jordan could be mixing up the events of various conferences in her mind.

- Concerning inventive step, the closest prior art was represented by document (5). In view thereof, the technical problem to be solved was to provide a process for preparing solvent-free crystals of the benzimidazole as defined in claim 1. The proposed solution of subjecting the solvate to a de-solvent treatment by being suspended, left-standing or stirred in water was not obvious in view of the prior art cited.

X. The respondent argued as follows:

- Document (1) is identical to a poster displayed during the Edinburgh Congress. The content of this poster disclosed the process according to the patent in suit. The standard of proof to be applied was the balance of probabilities and not the one in case of prior use, namely "beyond any reasonable doubt".

- Since the opposition division revoked the patent in suit, the appellant now had the burden of proof to demonstrate that the reasons given by the opposition division were not sound.

- As regards the question "what had been disclosed", the content of document (1) is clear and would immediately be understood by a person skilled in the art.

- The testimonies of Ms Kotar-Jordan and Ms Kramar, documents (8) and (9), were credible. In particular, the testimony of the former was clear and unambiguous when she stated that document (1) was identical to the poster displayed at the Edinburgh Congress. The situation differed in that respect from the one underlying the decision T 750/94 (OJ EPO 1998, 32).

- Ms Kotar-Jordan's testimony, document (8), was all the more credible as this was her first congress, a particularly memorable event for a young researcher.

- No further corroborating evidence was needed.

- If nevertheless required, corroborating evidence confirmed the accuracy of Ms Kotar-Jordan's testimony: Ms Kramar has confirmed that document (1) was identical to the poster displayed at the Edinburgh Congress; she remembered well the background of the poster (a picture of crystals). Document (4) distributed during the congress, as confirmed by document (6), has the same authors, the same title and related to the same subject-matter as document (1). This abstract did not mention all the details of the poster due to the constraints of the abstract format. Invoice, document (13), and its translation, document (14), related to the manufacture of a poster headed "Study of polymorphism.." and was sent shortly after the date of the Edinburgh Congress and showed that one poster had been made by an external manufacturer. Affidavit, document (18), showed that there was no confusion with the other presentations of Ms Kotar-Jordan, since it was the first time she was in Scotland and among all the posters of the list, document (1) was the only one having photographs of crystals as background. Although, as pointed out by the appellant, there were overlaps between the different authors of the different posters, document (1) was the only one having all these authors.

- The claimed subject-matter lacked novelty over document (5), given that the de-solvent treatment, according to the patent in suit, did not exclude a mixture of ethanol and water. If the board came to the conclusion, that the claimed subject-matter was novel, the case should be remitted to the first instance, because the decision of the first instance was silent on inventive step.

- The claimed subject-matter was not inventive. In example 4 of document (5) (see page 5, lines 31-34), the term "washed" included the expressions " stirred, suspended and left-standing" present in claim 1 of the patent in suit and there was a strong desire for the skilled person to remove any trace of solvent from the crystalline compound. To reach this goal, the suspension of the crystals in water was a technique commonly used in the laboratories and the obtained result was to be considered as a bonus effect. Example 1 of the patent in suit could not be used to show that the problem had been solved, because it did not fall within the scope of claim 1. A salt was indeed formed by addition of a solution of aqueous ammonia to the solvate and the wording of the claims did not embrace salts. The compound obtained from reference example 6 could not have been used directly without submitting it to a further crystallisation using ammonia in aqueous solution. This essential feature was not found in claim 1. Furthermore, the water content and the alcohol content were dependent on the drying conditions as mentioned on page 13, lines 22-29 of the description as originally filed. Since these conditions were absent in the wording of the claims, an inventive step for the whole claimed subject-matter could not be acknowledged.

XI. The appellant requested that the decision under appeal be set aside and the patent maintained as granted.

The respondent requested that the appeal be dismissed.

XII. At the end of the oral proceedings, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. *State of the art - Prior disclosure of a poster*
 - 2.1 Document (1) is a true copy of a poster that was presented and inspected at the oral proceedings before the first instance (not contested by the appellant). It refers to the preparation and characterization of two polymorphs and two pseudopolymorphs of lansoprazole (see introductory part).

The preparation of the polymorphic A-form may be performed by **three** methods, one of them consisting in stirring solvated crystals of lansoprazole (ethanolate/hydrate) in water at room temperature for two hours, the crystals then being removed by filtration and dried in vacuum (see document (1) under "Methods: Preparation of polymorphic forms", point 2).

The various forms of lansoprazole, namely polymorphic A-form and B-form, and pseudopolymorphic forms are characterized by thermal analysis, FT-IR spectroscopy, X-ray diffraction and scanning electron microscopy (see document (1), under "Results and Discussion").

- 2.2 It is not contested that the method of preparation mentioned above falls within the process defined in claim 1 of the patent in suit and the board concurs with the relevant finding in the decision under appeal.

Hence, the question of whether or not that method was made available to the public before the priority date of the patent in suit by display of a poster identical to document (1) at the Edinburgh Congress, is crucial for deciding on the present appeal as the underlying decision of the opposition division is primarily based on a finding that a poster identical to document (1) was so displayed.

2.3 The first point is to decide on whom lies the burden of proof in these appeal proceedings regarding the public availability of a poster identical to document (1).

2.3.1 The respondent contended that since the opposition division on the basis of a correct evaluation of the evidence had decided to revoke the patent due to prior disclosure, the burden of proof lies with the proprietor of the patent to demonstrate that the reasons given by the opposition division for revoking the patent were not correct.

2.3.2 The respondent thus appears to suggest that as the opposition division had decided that a poster identical to document (1) was displayed at the Edinburgh Congress, and that hence the patent lacked novelty, by challenging the finding of lack of novelty in appeal proceedings, the appellant has the burden of proving that a poster identical to document (1) was not displayed at the Edinburgh Congress. In other words the appellant has to prove a negative.

2.3.3 Before the opposition division it is the opponent who bears the burden of proof as regards demonstrating that the patent does not fulfil the requirements of the EPC.

Appeal proceedings do not result in a shift in the burden of proof in the way suggested by the respondent - that is towards a requirement that the appellant prove a negative. It is clear that in the case where the opposition division has revoked a patent, the appellant must argue before the board why this decision was wrong - (see Case Law, 5th ed. 2006, page 440, section 5.2, para.2). In the present case the appellant has so argued. Thus, the board is in a position to examine the issues of standard of proof required as regards prior public disclosure and then to evaluate the evidence on file.

- 2.3.4 Since according to the jurisprudence of the boards of appeal each party carries the separate burden of proof of any fact they allege (see T 270/90, OJ EPO 1993, 725), the burden of proof concerning the precise content of the poster displayed at the Edinburgh Congress lay and still lies with the respondent as the party which alleges the prior disclosure of a poster identical to document (1).

- 2.4 The second point is to decide the standard of proof to be applied in the present case.
 - 2.4.1 According to the jurisprudence of the boards of appeal, in prior public use cases, where practically all the evidence in support of an alleged prior public use lies within the power and knowledge of the Opponent, the latter has to prove his case "up to the hilt" (see T 472/92, OJ EPO 1998, 161, point 3.1).
 - 2.4.2 In this case the board holds that the standard of proof to be applied for ascertaining whether a disclosure was

made available to the public through displaying a poster during a congress is the same as for public prior use. Therefore, the opponent has the burden to prove beyond reasonable doubt that a poster identical to document (1) was displayed at the Edinburgh Congress (see T 97/94, OJ EPO 1998, 467, point 5.1, and T 472/92; T 574/00 dated 9 June 2004, point 2.2).

2.5 Turning to the question of whether the evaluation of evidence by the opposition division was actually in conformity with the relevant case law, the following has to be considered:

2.5.1 Each of the three elements of a public prior disclosure, namely its date, the circumstances in which it took place and its content, has to be proven. In the present case the key issue is whether on the poster displayed at the Edinburgh Congress, the following text appeared in relation to the preparation of lansoprazole:

"solvated crystals of lansoprazole (ethanolate/hydrate) were stirred in water at room temperature two hours, then crystals removed by filtration and dried in vacuum."

This text appears on document (1).

2.5.2 As to the reasoning for the finding of the opposition division that a poster identical to document (1) was displayed at the Edinburgh Congress, the board observes the following:

The relevant content of document (1), the affidavits of the witnesses Ms Kotar-Jordan and Ms Kramar, documents

(2) and (3), as well as their oral testimony (documents (8) and (9)), and the abstract, document (4), are not in contradiction with each other. However, that is not sufficient for meeting the required standard of proof.

2.5.3 With the exception of Ms Kotar-Jordan's testimony, document (8), none of this evidence refers to the critical passage of document (1). Ms Kramar, who was not involved in the design and the preparation of a poster for the Edinburgh Congress (second page of document (9)), could not remember the detailed wording of it (last page of document (9)). Document (4) is a supplement to the European Journal of Pharmaceutical Sciences which was distributed at the Edinburgh Congress (see document (6)). Although document (4) has the same title and lists the same authors as document (1), it does not refer to any poster and is silent on the method by which two of polymorphs and more pseudopolymorphs of 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl]-1H-benzimidazole were prepared (see document (4), two first paragraphs). Furthermore, document (4) makes no mention of FT-IR spectra, the subject-matter of Figures 3, 4 and 8 of document (1).

Documents (2) and (3) do not enable the board to determine any features of the poster displayed at the Edinburgh Congress. The respective assertions of Ms Kotar-Jordan and Kramar set out therein, namely:

"I displayed during the afore-mentioned Congress the attached poster of KRKA, entitled "Study of Polymorphism of a Novel Antiulcer Drug" in a poster session for participants" and

"During the afore-mentioned Congress the attached poster of KRKA, entitled "Study of Polymorphism of a Novel Antiulcer Drug" was displayed in a poster session for participants of the Congress"

are unsubstantiated allegations.

2.5.4 Under these circumstances, documents (2) to (4) and the testimonies of Ms Kotar-Jordan and Kramar, documents (8) and (9), cannot, contrary to the statements in the paragraph bridging pages 6 and 7 of the Reasons of the decision under appeal, be considered as corroborative evidence supporting a finding that a poster identical to document (1) was displayed at the Edinburgh Congress. Equally, documents (4) and (2) and the oral testimony of Ms Kotar-Jordan, document (8) do not constitute an unbroken chain of evidence in respect of the fact in question (see page 11 of the opposition division's decision).

2.5.5 Hence, the finding of the opposition division rests exclusively on the testimony of Ms Kotar-Jordan, document (8). This remains so even when taking into account that she could produce, from her possession, the original of a poster of which document (1) is a copy, on which the critical method for preparing lansoprazole was expressly described in the relevant context set out. No independent evidence (in writing or by other persons) is available to support Ms Kotar-Jordan's testimony.

2.5.6 This does not mean that her written and oral testimony was per se insufficient. However, there must be good

reasons for treating this evidence alone as having established the facts beyond any reasonable doubt.

2.5.7 As to these reasons the following is found in the decision under appeal:

"Mrs Kotar-Jordan has clearly stated that it was the original poster, which was presented at the Congress. She was also the appropriate person to testify on this issue since she drafted the poster and was in the possession of the poster all the time. The Opposition Division does not have any indications which would put doubts on the credibility of Mrs Kotar's testimony."

(page 8)

and

"..both witnesses provided testimony on the basis of their personal knowledge. They credibly answered the questions as to the date, the subject and the circumstances for the presentation to the public of the poster D1. **Under these circumstances, the Opposition Division is of the opinion that Mrs. Kotar's testimony could only then be refused, if it thought, that Mrs. Kotar was lying. However, the Opposition Division does not have any indications for this**" (page 10).

2.5.8 The Board finds this reasoning to be faulty. It starts by accepting as true the matter that has to be proven by the testimony whose credibility is to be evaluated. Furthermore, it is certainly not the case that a person only does not tell the truth if he is being dishonest. A person can be honestly mistaken in his recollection of an event, particularly if the event took place some time ago. It is worth noting that the Edinburgh Congress took place more than seven years before

Ms Kotar-Jordan's affidavit, document (2), and more than eight years before she was heard as a witness. Hence, the board does not agree with the opposition division's conclusions that Ms Kotar-Jordan's testimony must be true as there was no evidence that she was lying.

2.6 It follows from these considerations that it has not been sufficiently proven, i.e. beyond all reasonable doubt, that a poster with the content of document (1) (in particular a specific method for preparing the form A of lansoprazole - see point 2.1, above) was displayed to the public at the Edinburgh Congress (or at any other place or date before the priority date of the patent in suit). Thus, the finding in the decision under appeal, that a poster identical to document (1), belongs to the state of the art within the meaning of Article 54(2) EPC, cannot stand. The conclusion of the board is based upon an objective assessment of the facts, evidence and arguments and did not necessitate a hearing of the witnesses by the board itself.

2.7 As the board held it appropriate and no party objected, to decide itself on this issue (Article 114(1) EPC), the further evidence adduced by the parties during the appeal proceedings has to be considered.

2.7.1 The invoice, document (13), is for the "Design for a poster on STUDY OF POLYMORPHISM ... 1 80 m in length" (see document (14)). Document (13) is dated 18 September 1996. This may be an indication that a poster with that title and dimensions was prepared for display at the Edinburgh Congress.

It should be noted that document (13) alone does not show that only one single poster was made by the Biro Stavek Company for the Edinburgh Congress. No conclusions can be drawn from document (13) as to the content of the poster, in particular whether it described the relevant method for preparing the A-form of lansoprazole. Therefore, the invoice is not, either on its own or in combination with other evidence adduced by the opponent, sufficient to establish the identity of document (1) with a poster displayed at the Edinburgh Congress (cf. point 2.5.3, above).

2.7.2 The same is true for Ms Kotar-Jordan's second affidavit, document (18). Here, she states that between September 1996 and August 1997 seven more posters, of which she was a co-author, were shown at international symposia, the majority of them relating to lansoprazole. This document cannot, therefore, serve as corroborating evidence in respect of the exact content of a poster displayed at the Edinburgh Congress.

2.7.3 Therefore, the further evidence submitted by the opponent does not persuade the board that a poster identical to document (1) was disclosed at the Edinburgh Congress.

2.7.4 That being so, the documents and affidavits submitted by the proprietor in support of his position on this issue need not be considered.

2.8 In conclusion, it cannot be established beyond reasonable doubt that the poster displayed at the Edinburgh Congress had the content of document (1);

hence the content of document (1) is not considered as prior art under Article 54(2) EPC.

3. *Novelty - document (5)*

- 3.1 Document (5) discloses a method for the production of 2-(2-pyridylmethylsulfinyl)benzimidazole compounds of formula (II) by oxidation of the corresponding 2-(2-pyridylmethylthio)benzimidazole of formula (I) with hydrogen peroxide in the presence of vanadium compounds (see page 2, lines 27 to 62).

The desired compound (II) produced by the reaction described above is usually separated out as crystals from the reaction mixture, so that the crystals can be collected by filtration after decomposition of the excess of hydrogen peroxide remaining after the reaction by addition of an aqueous solution of sodium thiosulfate, but the crystals may also be collected by extraction with a solvent such as chloroform if necessary, followed by concentration.

The crystals thus collected can be purified if necessary by a routine method such as recrystallization and chromatography (see page 4, lines 24 to 30).

According to Example 4, purification is achieved by multi-crystallisation steps using a mixture of ethanol-water.

- 3.2 The claimed subject-matter as defined in claim 1, differs from the disclosure of document (5) in that the solvate with water and C₁-C₆ alcohol is suspended, left standing or stirred in water. The respondent's contention that the wording of claim 1 did not exclude

the use of ethanol in addition to water is at variance with a proper understanding of claim 1 and is unfounded.

3.3 In view of the above, the claimed subject-matter is novel over document (5) within the meaning of Article 54 EPC.

4. *Request for remittal*

4.1 At the oral proceedings before the board, the respondent requested the case to be remitted to the first instance in order to have his case examined by two instances in respect of inventive step, since this had not been discussed before the opposition division.

4.2 In exercising its discretionary power under Article 111(1) EPC, the board takes into account the circumstances of the case and the issue of procedural economy. Article 111(1) EPC does not give the parties the right to have each request examined by two instances (see T 133/87 dated 23 June 1988, not published, point 2 and T 5/89, OJ EPO 1992, 348, point 5.5).

4.3 The board observes, first, that the present situation has not changed with respect to that prevailing before the first instance, in that the claims according to the appellant's main request are those granted and document (5) was cited against inventive step in the statement of the grounds of opposition. The respondent was not, therefore, confronted with a fresh case. Furthermore, the respondent had to expect that inventive step could be discussed on the basis of document (5), since the main line of the appellant's attack was against the

acceptance of the content of document (1) as forming part of the state of the art.

4.4 In view of the above and for reason of procedural economy, the board finds it appropriate to exercise its discretion **not** to allow the request of remittal submitted by the respondent so that the case can be expected to be ready for a final decision at the conclusion of the oral proceedings (see Article 15(6) of the Rules of Procedure of the Boards of Appeal, OJ EPO 2007, 536).

5. Inventive step

5.1 The board concurs with the parties that document (5) represents the closest prior art, since it relates to a method for producing 2-(2-pyridylmethylsulfinyl)benzimidazole compounds (see page 2, line 3 of document (5)).

5.2 Thus, starting from document (5), the technical results or effects successfully achieved by the claimed subject-matter are to be determined for defining the objective technical problem to be solved.

5.2.1 According to the patent in suit, when the process of preparation of 2-(2-pyridylmethylsulfinyl)benzimidazole compounds as described in document (5) is followed, water and ethanol can hardly be eliminated from the end product and the resulting crystals inevitably contain a fair amount of water and ethanol. These solvents turned out to be difficult to remove by vacuum drying without detracting from the stability of the compound (see page 2, paragraphs [0004]-[0006] of the patent in suit).

Thus, although this is not stated in the text of document (5), the benzimidazole compound provided by the process of document (5) is a solvate containing one molecule of water and one of ethanol per molecule of benzimidazole (see page 2, lines 30-31 of the patent in suit).

5.2.2 Example 1 of the patent in suit relates to the production of 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridine-2-yl]methylsulfinyl]benzimidazole. In order to render clearer the distinguishing step between this example and the comparative example disclosed in the patent in suit, i.e. Comparative Example 1, the board has artificially divided the process of example 1 into three steps:

- 13.0 g of 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridine-2-yl]methylsulfinyl]benzimidazole monohydrate, monoethanolate obtained according to **Reference Example 6 (see page 7 of the patent in suit)**, was dissolved in a solution heated at about 60°C made of 75 ml of ethanol-water mixture (9:1) and 70 µl of 25% aqueous ammonia solution. Insolubles were removed by filtration and the filtrate was ice-cooled to give wet crystals of 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridine-2-yl]methylsulfinyl]benzimidazole monohydrate, monoethanolate solvate.

- The obtained wet crystals were suspended in 53 ml of water and the suspension was stirred. The

emerged crystals were recovered by filtration,
washed with water,

- and then were dried in vacuum to give 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridine-2-yl]methylsulfinyl]benzimidazole as white needles, having a water content of 0.01% and an ethanol content: 63 ppm.

5.2.3 The patent in suit also contains a Comparative Example 1 which differs from its Example 1 in that the second step of suspension in water is not carried out. Following this process 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridine-2-yl]methylsulfinyl]benzimidazole is obtained as white needles. Water content: 0.12%. Ethanol content: 360 ppm.

5.2.4 Comparative Example 1 of the patent in suit is not within the teaching of document (5) and, therefore, appears "at first glance" not to be a basis for determining the technical problem to be solved.

However, in the present case, Comparative Example 1 of the patent in suit derives from the product obtained according to Reference Example 6 of the patent in suit (see point 5.2.2), which is, in fact, Example 4 of document (5). Due to the drying treatment disclosed in Comparative Example 1 of the patent in suit (40°C for 20 hours under vacuum), it is clear that the resulting product of Comparative Example 1 **cannot** have more water and ethanol than that of Reference Example 6, (i.e. Example 4 of the document (5)). Thus the product obtained according to Example 4 of document (5) contains at least as much water and ethanol as the

2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridine-2-yl]methylsulfinyl]benzimidazole obtained according to Comparative Example 1 of the patent in suit.

It is also pointed out, that Comparative Example 1 and Example 1 of the patent in suit differ only in that in Example 1 the crystals were suspended in water. The noticeable effect obtained (see respective contents of water and ethanol in the solvate) can thus be attributed exclusively to this difference which distinguishes the closest prior art from the currently claimed subject-matter. Therefore, Comparative Example 1 of the patent in suit provides a basis for assessing if there is an improvement provided by the claimed process (see T 496/02, not published in the OJ EPO, dated 11 January 2005, point 4.5.2 and T 480/02, dated 28 March 2007, not published in the OJ EPO, point 3.6). Example 1 in that respect shows that a dramatic decrease of the water and ethanol contents in the 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridine-2-yl] methyl sulfinyl]benzimidazole is obtained by suspending the monoethanolate, monohydrate solvate in water as compared to Comparative Example 1 of the patent in suit.

- 5.2.5 The respondent contended that a single example in the patent in suit cannot be used to show that the technical problem underlying the present patent has been solved, since a salt is formed by addition of aqueous ammonia for the making of the solvate. The wording of the claims relates only to the free base and not the salts thereof. He also disputed the fact, that the claimed process solved the technical problem

without using an aqueous solution of ammonia (see point 5.2.2, above).

- 5.2.6 However, the presence of a very minor amount of ammonia, i.e. 70 microliters of a 25% aqueous solution of ammonia (see point 5.2.2) when crystallizing the solvate does not mean, in the absence of evidence, that a salt of the compound is formed and if it is so, this salt would not be formed in a considerable amount.

Hence the respondent's contention that the technical problem alleged in the patent in suit was not solved in the absence of the aqueous ammonia solution is not substantiated.

- 5.2.7 Finally, the respondent submitted that the water content and the alcohol content in the final product are dependent of the drying conditions as mentioned on page 13, lines 22-29 of the originally filed description. Since the wording of the claims is silent on these conditions the respondent concluded, that the technical problem alleged by the appellant could not be solved over the whole scope of the claims.

- 5.2.8 Even if the board accepted that the content of water and ethanol varies depending on the conditions used in the suspending and drying procedures, this is a matter of the difference in the degree of desolvation. In view of the significant decrease of the amounts of water and ethanol (see Example 1 of the patent in suit and point 5.2.2) and in view of the upper limits mentioned for these amounts in claim 1, the board is satisfied that there exists a broad range of conditions for which the degree of desolvation is improved, so that the

respondent's contention that, in the absence of the specification of the process conditions, the problem is not solved over the whole claimed area, is not convincing.

5.2.9 In view of the above, the technical problem addressed and successfully solved by the claimed subject-matter in view of document (5) as the closest prior art is to be seen in the provision of a process for the transformation of solvate crystals of compounds of formula (I) (see point II above) containing water and C₁₋₆ alcohol, into crystals having a water content of not higher than 500 ppm and a C₁₋₆ alcohol content of not higher than 200 ppm.

5.3 It remains to be decided whether or not the claimed solution is obvious in view of the prior art cited.

5.3.1 The prior art does not give any guidance to suspend a solvate hydrate and ethanolate of compound of formula (I) in water. Still less does it give any hint that such a process step would have solved the technical problem defined above.

5.3.2 Moreover, starting only from document (5), that is to say without knowing the teaching of the patent in suit, the person skilled in the art would not find therein any hint that the compounds obtained in this document are solvates and not pure crystalline forms of the 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridine-2-yl]methylsulfinyl]benzimidazole obtained after drying, since document (5) nowhere mentions the formation of solvates (see point 5.2.1 above). He would thus not

even envisage to suspend the said crystals in water to solve the problem underlying the patent in suit.

5.3.3 The respondent argued that in Example 4 of document (5) the term "washed" embraced the features of claim 1, "stirred, suspended and left-standing". Since there was a general trend to remove any trace of solvent from the crystalline compound, it would have been obvious for the person skilled in the art to suspend crystals in water, all the more given the fact that the suspension of the crystals in water was a technique commonly used in the art. Hence, the obtained result is to be considered as a bonus effect.

5.3.4 The board observes that the term "washed" used in Example 4 of document (5) relates to the washing of the crystals with **ice-cooled ethanol-water mixture (8:2)**. Therefore, already for this reason the argument of the respondent is at variance with the facts. Furthermore, the respondent's allegation that it was common general knowledge to suspend crystals in water is unsubstantiated. To the contrary, it is surprising that the suspension of a solvate hydrate in water causes the removal of the water contained in said solvate.

5.3.5 For these reasons, document (5) does not render claim 1 of the patent as granted obvious. It follows that the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC. The same applies to dependent claims 2 to 6.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained unamended.

The Registrar

The Chairman

M. Schalow

P. Ranguis