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**Datasheet for the decision
of 19 June 2015**

Case Number: T 0517/14 - 3.3.01

Application Number: 08002626.3

Publication Number: 1930011

IPC: A61K31/663, A61P19/10, C07F9/38

Language of the proceedings: EN

Title of invention:
Crystalline form of ibandronate sodium

Patent Proprietor:
Teva Pharmaceutical Industries Ltd

Opponents:
Hexal AG
Helm AG

Headword:
Ibandronate sodium, Form T/TEVA

Relevant legal provisions:
EPC Art. 100(b), 54, 56, 61, 76(1), 88, 117, 125
EPC R. 52, 53
EPC 1973 Art. 60(1), 60(3), 72, 74, 87
EPC 1973 R. 20

Keyword:
Right of priority - assignment
Main request, allowable

Decisions cited:

G 0003/92, G 0003/99, G 0001/13, J 0019/87, J 0012/00,
J 0002/01, J 0004/10, T 0206/83, T 1008/96, T 0005/05,
T 0062/05, T 0788/05, T 0493/06, T 0382/07, T 0777/08,
T 1933/12, T 0160/13, T 0205/14



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Case Number: T 0517/14 - 3.3.01

**D E C I S I O N
of Technical Board of Appeal 3.3.01
of 19 June 2015**

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 9 January 2014
revoking European patent No. 1930011 pursuant to
Article 101(3) (b) EPC.**

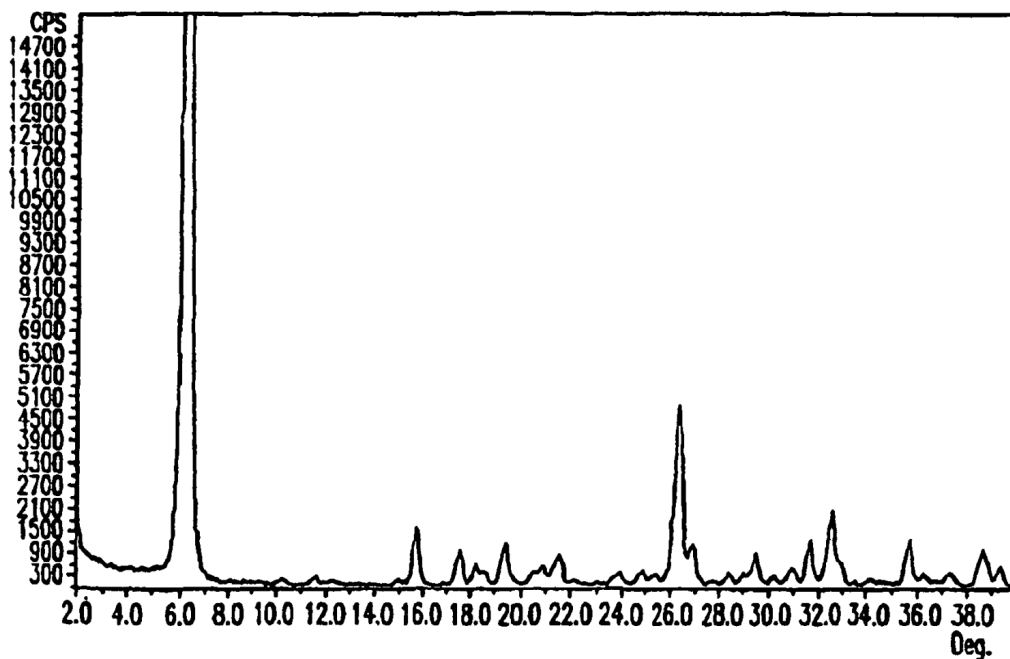
Composition of the Board:

Chairman A. Lindner
Members: L. Seymour
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 930 011 was filed as patent application number 08 002 626.3, as a divisional application of the parent application EP-A-1 713 489, based on international application WO 2006/024024, filed on 23 August 2005, and claiming priority from US applications No. 60/604,026 of 23 August 2004 (P1) and 60/690,867 of 16 June 2005 (P2). The claims as granted read as follows:

- "1. A crystalline form of ibandronate sodium characterized by x-ray reflections at 6.2, 15.7, 26.3, 32.6, and 35.6 ± 0.2° 2θ.
2. The crystalline form of ibandronate sodium of claim 1, characterized by further x-ray reflections at 17.6, 19.4, 26.9, 31.7, and 38.7 ± 0.2° 2θ.
3. The crystalline form of ibandronate sodium of claim 2 having a powder x-ray diffraction diagram as shown below:



4. A pharmaceutical composition comprising the ibandronate sodium as defined in any one of the preceding claims."
- II. The following documents, cited during the opposition/ appeal proceedings, are referred to below:
- (1) EP-B-0 252 504
 - (2) WO 2006/081963
 - (10) S Byrn et al., *Pharmaceutical Research*, 1995, 12(7), 945 - 954
 - (21b) Letter of appointment and conditions of employment of Ms Revital Lifshitz dated 3 August 1998 and confidentiality agreement dated 16 August 1998
 - (21c) Terms of employment of Mr Thomas Bayer dated 6 January 2004 and undated confidentiality agreement (Appendix B)
 - (21d) Letter setting out the conditions of employment of Ms Judith Aronhime dated 16 December 2004, first confidentiality agreement dated 24 April 1994, and second confidentiality agreement dated 19 December 2004 (Appendix B)
 - (22a) Expert opinion of Mr Tal Band, dated 21 May 2012
 - (22f) Israel, Patents Law 5727-1967, official translation

- (22g) Israel, Patents Law 5727-1967, unofficial translation retrieved from WIPO website, covering amendments enacted until 1999
- (23a) Expert opinion of Mr Patrick J. Birde dated 15 February 2012
- (23b) Expert opinion of Mr Robert C. Millonig and Ms Gaby L. Longsworth dated 23 April 2012
- (29) US-A-4 927 814
- (34) EPAR (European public assessment report) Scientific Discussion for Bondronat, revision 8, published on the EMA (European Medicines Agency) website on 14 May 2004
- (42) Stability data annexed to patentee's letter dated 23 September 2013
- (43) Annex B to letter dated 20 September 2013, submitted during opposition against parent patent EP-B-1 713 489 (see appeal case T 205/14)
- (44) A Kleeman et al., Pharmaceutical Substances: Syntheses, Patents, Applications, Thieme, 3rd edition, 1999, page 973, "Ibandronate sodium monohydrate"
- (46) Experimental reports submitted as documents (39), (40), (52), (53) and (53a) during opposition proceedings against parent patent EP-B-1 713 489 (note: partly also in the present proceedings as documents (19), (20), (39) and (40))

(48) Federal Supreme Court of Germany (BGH), decision of 16 April 2013, X ZR 49/12, "Fahrzeugscheibe"; see also GRUR 2013, 712

(49) Declaration of Dr. Christian Lehmann dated 14 May 2015

- III. The appeal lies from the decision of the opposition division revoking the patent. The decision was based on a main request (claims as granted), auxiliary requests 1 and 2 filed with letter dated 20 September 2013, and auxiliary request 3 filed during oral proceedings before the opposition division. The subject-matter of the main request and of auxiliary requests 1 and 2 were found not to meet the requirements of Article 56 EPC. Auxiliary request 3 was not admitted into the proceedings.
- IV. The appellant (patentee) lodged an appeal against this decision. With its statement of grounds of appeal dated 9 May 2014, the appellant submitted auxiliary requests 1 and 2, which were identical to those on which the decision under appeal was based (see previous point III).
- V. The respondent (opponent 1) submitted its reply with letter of 5 August 2014.
- VI. Opponent 2 did not take an active part in the appeal proceedings, or file any requests in writing.
- VII. Oral proceedings were held before the board on 19 June 2015.
- VIII. The appellant's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

In relation to the question of entitlement to priority, the appellant argued that, no matter whether Israeli or US law applied to the validity of the transfer, it had provided clear and convincing evidence, namely, in the form of documents (21b) to (21d), (22a), (22f), (22g), (23a), and (23b), which showed that it was entitled, as an employer and successor in right to the three applicants of the US provisional applications (P1) and (P2), to the right of priority deriving from said applications. With respect to Israeli law, it was established that the right of priority derived from the US provisional applications (P1) and (P2) had been acquired by operation of section 132 of the Israeli Patents Law 5727-1967, or by factual circumstances implying such a transfer, namely, through the fulfillment of contractual obligations, in the absence of a formal requirement for the transfer of the right of priority. There was no evidence on file that disproved the findings of the expert opinions that the appellant had provided. It was also clear from the decision of the German Federal Supreme Court filed as document (48) that Article 87 EPC did not require a formal and separate assignment as provided by Article 72 EPC for European patent applications. A transfer by conduct from the transferor to the transferee implying such a transfer under the circumstances was sufficient.

With respect to the question of choice of national law, the appellant argued that it had provided evidence for succession in title under both Israeli and US national law. In any case, it would be unreasonable and unpredictable to ask an applicant to comply with the law of each and every signatory state for which an application claiming priority of a first application

was filed. It would be a reasonable solution to apply, in analogy to Article 60(1) EPC, the law of the country of employment in case of an employment relationship. In the alternative, also the application of the law of the state of the filing of the first application could be justified. The appellant's evidence supported both choices.

The appellant further submitted that the objection under Article 100(b) EPC was unfounded since a synthetic organic chemist would have no difficulty in preparing a simple organic molecule such as ibandronic acid. Suitable methods had also been readily retrievable from standard reference works such as the Merck index. The additional attack under Article 100(b) EPC based on the scope of the claims had been raised for the first time at oral proceedings before the board and should be dismissed as being late-filed and lacking in substantiation.

With respect to the issue of inventive step, the appellant defined the problem to be solved, starting from document (34) as the closest prior art, as lying in the provision of a polymorphically stable form of ibandronate sodium, that could be produced in a consistent and reliable manner. The solution proposed in claim 1 of the main request related to the crystalline form of ibandronate sodium defined by the combination of five X-ray reflections that were characteristic of the form referred to in the patent in suit as form T. The data presented in document (42) demonstrated that this subject-matter successfully solved the problem posed. The respondent's attack on the breadth of claim 1 was unsubstantiated.

The solution claimed was not rendered obvious by any of the documents in the proceedings.

In this context, the appellant disputed the respondent's reading of document (34). Polymorphic stability related to the propensity to convert into an alternative crystalline or amorphous form under stress, storage or during processing. This was different from the stability referred to in section 7.1 of document (34), which clearly related to chemical and physical stability. The skilled person would have learned from the single paragraph of document (34) dealing with polymorphism that ibandronate sodium monohydrate existed in two polymorphic forms A and B, which had similar solubility and dissolution characteristics. The skilled person would therefore conclude that it did not matter whether either or both polymorphs were present in the tablet. It could not even be excluded that the two forms might interconvert. The last sentence of said paragraph merely expressed a desired outcome, without any certainty that this would actually be achieved. Under circumstances, such as the present, where different polymorphic forms had been found not to influence the relevant performance characteristics, such as solubility and intrinsic dissolution properties, no further testing of the polymorphic stability would be necessary, as outlined in document (49). Therefore, no expectation could be derived from document (34) that forms A or B would exhibit stability towards polymorphic conversion. Furthermore, in document (34), the forms A and B were not characterised, nor was a complete synthesis provided. In seeking to produce the drug substance, the skilled person would not know what conditions to use in the final crystallisation step. The required screening procedure represented a research project with

unpredictable outcome with respect to achieving a polymorphically stable product. Therefore, document (34) alone could not render the claimed subject-matter obvious.

The remaining documents relied on by the respondent would also be of no assistance in this respect:

Document (44) related to the entry from 1999 for "ibandronate sodium monohydrate" from the handbook "Pharmaceutical Substances", and only constituted a very general reference. It could be derived from the entry "Formulation(s)" that, at the time, Bondronat had only been authorised as an infusion concentrate. Therefore, the skilled person would have no reason to use document (44) as a source of information regarding the solid drug form. Moreover, the scheme depicting the synthesis of this substance did not include any specific conditions or solvents for the salt-formation step. The cross-reference to document (1) would also be of no help in this respect. In consulting the latter, the skilled person would have established that it only specifically disclosed a method for making ibandronic acid, but not salts thereof.

Even were the skilled person to have considered document (1) with respect to suitable conditions for recrystallisation, he would not have arrived at the claimed subject-matter. In particular, as had been demonstrated in the experimental reports submitted as document (46), an adaptation of Example 7 of document (1) to the synthesis of ibandronate sodium did not yield present form T. Moreover, the solvent systems generally suggested in the description of document (1), namely, water/methanol or water/acetone, allowed for countless possible variations in the manner of

performing the recrystallisation. The examples of the patent in suit demonstrated that said solvent systems could be used to obtain numerous different polymorphic forms, many of which had been found to lack polymorphic stability. The skilled person would have had no expectation of being able to produce a polymorphic form exhibiting the present advantageous properties. In this respect, the conditions used in document (43), which had yielded form T, were only one of numerous possibilities that the skilled person could have contemplated. Consequently, there was no avenue in the prior art directing the skilled person in an obvious manner to the claimed subject-matter as a solution to the problem posed.

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

In relation to the question of entitlement to priority, the respondent argued that Article 87 EPC required a separate and express assignment of the right of priority executed by the applicants of the provisional US applications (P1) and (P2) and the appellant. It was recognised that a first filing created two distinguishable rights, namely, the right to the grant of a patent and the right of priority. The latter could be transferred independently of the former. Evidence to the effect that the appellant had acquired the right to the grant of a patent derived from the provisional applications (P1) and (P2) was therefore not sufficient to prove that it had also acquired the rights of priority derived from the first filings. According to decision T 62/05, a transfer of a right of priority had to be proven in a formal way, that is, by way of an assignment declaration in writing signed on behalf of

the parties to the transaction. The appellant had failed to provide evidence for such an assignment which met the required standard of proof. The contractual arrangements submitted by the appellant (documents (21b), (21c), and (21d)) only showed that obligations of the individual inventors and employees towards the employer existed. There was, however, no evidence that the inventors and employees had fulfilled their obligations to transfer their rights of priority derived from the US provisional applications (P1) and (P2) to the appellant. Moreover, it was not clear from the contractual arrangements which of the affiliates of the corporate group of the appellant was to be seen as the transferee.

As to the applicable law, the respondent concurred with decision T 62/05 which applied Article 72 EPC. It had been the aim of the legislator when drafting the EPC not to burden the EPO with questions of substantive national law. Moreover, the interpretation of contractual arrangements was at issue and not deficiencies as to formal requirements under national law. This had also been the case in cases T 1008/96 and T 62/05. The EPO was competent to assess the content of contracts.

An objection under Article 100(b) EPC was raised relating to the fact that the patent in suit did not disclose how to obtain the starting material, ibandronic acid. The reference in paragraph [0005] of the patent in suit was erroneous. This deficiency could only be remedied by means of a comprehensive search of the prior art, contrary to decision T 206/83. The appellant had not demonstrated that the synthesis of ibandronic acid belonged to the common general knowledge. The additional objection based on the

breadth of the claims had been raised during the present opposition proceedings and also during the parallel appeal case T 205/14. This objection could not therefore come as a surprise to the appellant and should therefore be admitted into the proceedings.

Turning to the issue of inventive step of the main request, the respondent identified the Bondronat 50 mg tablet together with all available information on its components as the closest prior art. For the sake of convenience, references in this respect were limited to document (34), since this contained the most relevant information, in particular, with respect to the drug substance ibandronate sodium monohydrate.

The respondent disputed the appellant's definition of the problem to be solved as lying in the provision of ibandronate sodium in a stable polymorphic form. In this context, the respondent firstly criticised the breadth of claim 1 as covering multiple crystalline forms. Five peaks were not sufficient to uniquely characterise form T. It must therefore be concluded that the alleged property was not exhibited over the whole scope claimed. The respondent further criticised that the evidence provided by the appellant in document (42) was not suitable for demonstrating the polymorphic stability of form T, since important details relating to test conditions had not been specified, such as the temperature employed upon exposure to humidity. The problem to be solved could therefore merely be seen as lying in the provision of a crystalline form of ibandronate sodium. In the absence of any unexpected property, the solution proposed could not be regarded as involving an inventive step.

Moreover, even were it to be assumed that polymorphic stability had been demonstrated for the full scope claimed, the solution proposed would be obvious:

The drug substance disclosed in document (34), "ibandronic acid, monosodium salt, monohydrate", was described on page 13 as being "a very stable compound" and "a fine crystalline powder". Furthermore, according to this document, a second polymorphic form B had been identified; however, the manufacturing processes exclusively afforded polymorph A, and, even if form B was present, this would not affect the tablet performance. In view of this disclosure, it would have been clear to the skilled person that the relevant properties of the drug substance had been investigated according to standard procedures, as set out in Figure 1 of document (10), and that both polymorphs A and B, or at least the former, exhibited polymorphic stability under the conditions encountered during tableting and storage. The distinction made by the appellant between polymorphic stability, on the one hand, and chemical and physical stability, on the other, was artificial and incorrect, as supported by numerous prior art documents, including document (10).

Therefore, from the teaching of document (34), the skilled person would be aware of the existence of polymorphically stable forms of ibandronate monosodium monohydrate. This could not be regarded as an unexpected property in the sense of decision T 777/08. In seeking to obtain such forms, the skilled person would turn to document (1), since this described the synthesis of ibandronic acid, and procedures for the formation of the salts thereof. He would be reaffirmed in his expectation of success by document (44), and its disclosure of a scheme for the synthesis of ibandronate

sodium monohydrate, together with cross-reference to document (1). In applying the teaching of the latter to the synthesis of the former, the skilled person would conduct a routine polymorph screening within the framework of the solvent systems taught, in particular, acetone/water as employed Example 7. As demonstrated in document (43), through only slight modification of the procedure described in Example 7, the skilled person would arrive at the crystalline form T of ibandronate sodium, without the exercise of inventive skill.

- X. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request), or on the basis of auxiliary requests 1 or 2 filed with the statement of grounds of appeal dated 9 May 2014.

The respondent (opponent 1) requested that the appeal be dismissed.

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

Reasons for the Decision

1. The appeal is admissible.
2. *Entitlement to priority*
 - 2.1 The patent in suit was filed as a divisional application claiming benefit under Article 76(1) EPC of the priority of its parent application (see point I above). Therefore, the appellant's entitlement to the priorities from US applications No. 60/604,026 of

23 August 2004 (P1) and 60/690,867 of 16 June 2005 (P2) has to be investigated with respect to the parent application.

2.2 The respondent contested the entitlement of the patent in suit to the priorities from US applications (P1) and (P2), and argued that the appellant had failed to prove to the required standard that, on the date of filing of the parent application WO 2006/024024, the rights of priority derived from the US provisional applications (P1) and (P2), both filed in the name of the three inventors, had been validly transferred to the respondent. As a consequence, the date of filing of the international application WO 2006/024024 was the effective date for determination of the relevant state of the art (Article 76(1) EPC), and document (2) had to be regarded as constituting state of the art within the meaning of Article 54(3) EPC and was thus novelty destroying.

2.3 With respect to the presently relevant parent application EP-A-1 713 489, published as WO 2006/024024, the applicable provisions of the EPC 1973 and of the EPC in force as of 13 December 2007 are determined in accordance with the decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000 and with Article 2 of the Decision of the Administrative Council of 7 December 2006 amending the Implementing Regulations to the European Patent Convention 2000 (OJ EPO 2007, Special Edition No 1, 89, 197).

2.4 Pursuant to Article 87(1) EPC 1973, a right of priority, that is, the right to claim priority for a

European patent application from the filing date of an eligible "first application" (or "previous application" in Article 88 EPC), originates in the applicant of said first application. Therefore, in principle, the applicant has to be the same for the first application and for the subsequent application for which the right of priority is invoked. Where the first application has been filed jointly by two or more applicants, the right of priority belongs to them jointly (T 788/05, point 2 of the reasons).

However, pursuant to Article 87(1) EPC 1973, the right of priority may also be invoked by the "successor in title" of the person who has filed the first application. By reference to the "successor in title", it is recognised that the right of priority, being a legal right, may be transferred from the original applicant to a third person (T 62/05, point 3.6 of the reasons; see also T 5/05, point 4.2 of the reasons; T 788/05, point 2 of the reasons; T 382/07, point 9.1; T 1933/12, points 2.3 and 2.4 of the reasons; Grabinski, in: Benkard (Ed.), EPÜ, 2nd edition 2012, Art. 87 No. 3; Bremi, in: Singer/Stauder (Ed.), Europäisches Patentübereinkommen, 6th edition 2013, Art. 87 No. 53).

It is generally accepted that the right of priority is transferable independently of the corresponding first application which can remain with the original applicant. Furthermore, the right of priority may be transferred to a third person for one or more countries only (T 62/05, point 3.6 of the reasons; see also Grabinski, in: Benkard (Ed.), EPÜ, 2nd edition 2012, Art. 87 No. 3; Bremi, in: Singer/Stauder (Ed.), Europäisches Patentübereinkommen, 6th edition 2013, Art. 87 No. 53). It is thus an independent right up and

until it is invoked for one or more later applications to which it becomes an accessory. The right of priority has thus to be distinguished from the right to the patent deriving either from substantive law or from the status of being the applicant of the first application.

The board does not share the respondent's view that the characterisation of the right of priority as a right independent of the right to the priority application implies that the valid transfer of a priority right inevitably requires a separate and express assignment declaration. The requirements for a valid transfer of rights of priority is a matter distinct from the characterisation as an independent legal right. Article 87 EPC 1973 is silent on the requirements for a valid transfer of rights of priority. It neither requires an express assignment in writing nor excludes a transfer by operation of law or by conduct of the parties concerned implying such transfer. This issue will be addressed in more detail below (see point 2.7).

- 2.5 The reference to the "successor in title" in Article 87(1) EPC 1973 is also interpreted as requiring a transfer of the right of priority before the filing of the subsequent application (implicit in T 493/06, point 11 of the reasons; Grabinski, in: Benkard (Ed.), EPÜ, 2nd edition 2012, Art. 87 No. 4; Breimi, in: Singer/Stauder (Ed.), Europäisches Patentübereinkommen, 6th edition 2013, Art. 87 No. 53 and 54; Ruhl, Unionspriorität, 2000, p. 100 No. 262; Teschemacher, Anmeldetag und Priorität im europäischen Patentrecht, GRUR 1983, 695, p. 699; see at national level: document (48), point 11 of the reasons; Patents Court, decision of 12 June 2009, Edwards Lifesciences AG v Cook Biotech Incorporated [2009] EWHC 1304 (Pat), point 95 of the reasons; Patents Court, decision of 23 June 2010, KCI

Licensing Inc & Ors v Smith & Nephew Plc & Ors [2010] EWHC 1487 (Pat), point 54 of the reasons; see also Wieczorek, Die Unionspriorität im Patentrecht, 1975, p. 142). The board is aware of diverging opinions (see Moufang, in: Schulte (Ed.), Patentgesetz mit Europäischem Patentübereinkommen, 9th edition 2014, §41 No. 28; German Federal Patent Court, decision of 28 October 2010, 11 W(pat) 14/09, B1PMZ 2011, 255, point B.2)a)cc) of the reasons). This divergence is, however, not relevant for the outcome of the present decision (see below point 2.8).

- 2.6 If entitlement to priority is challenged, a successor in title, who desires to take advantage of the priority of a first application and who asserts that priority is rightly claimed from the first application, has to prove its entitlement to that right, which includes a valid transfer of the right of priority (T 1008/96, point 3.3 of the reasons; T 493/06, point 8 of the reasons). In the present case, the burden of proof is therefore on the appellant to establish that
- a) before the date of filing of the international application WO 2006/024024 (see the proviso in point 2.5 above)
 - b) the right of priority derived from the US provisional applications (P1) and (P2) had been transferred to it
 - c) by the three original applicants and inventors
 - d) in accordance with the requirements of the relevant law.
- 2.7 Before assessing the evidence on file, the relevant law that governs the requirements for a valid transfer of the right of priority for the filing of a European patent application under Article 87(1) EPC 1973 has to

be determined. Neither Articles 87 EPC 1973 and 88 EPC, nor Rules 52 and 53 EPC set out any such requirement.

- 2.7.1 Decision **T 62/05** (points 3.8 and 3.9 of the reasons) considered that the transfer of right of priority had to be proven in a formal way and that it was therefore appropriate to apply an equally high standard of proof as required by Article 72 EPC 1973.

The present board cannot follow this reasoning, which was relied upon by the respondent.

The standard of proof defines the degree of persuasion that is required in order to convince the deciding body of the existence of an alleged fact. The standard applied by the boards of appeal is "balance of probabilities" which amounts, in practice, to proof on preponderant balance of evidence. The seriousness of the consequences of alleged facts should not make any difference to the standard of proof to be applied in determining these facts. Article 72 EPC 1973 does not concern the issue of standard of proof, but sets out formal requirements for a valid assignment of a European patent application and thereby limits the means of giving or obtaining evidence for the determination of such a transfer. Relying on Article 72 EPC 1973 would thus establish an exclusionary rule of evidence, in that it excludes all evidence which is not in the form as required by Rule 20 EPC 1973. Having regard to Article 117 EPC and the principle of free evaluation of evidence, such an exclusionary rule of evidence should not be extended beyond its scope of application.

Article 72 EPC 1973 constitutes harmonised law with respect to the formal requirements for a transfer of a

validly filed European patent application and overrules as *lex specialis* national law which, in general, governs legal acts related to property interests in such applications (Article 74 EPC 1973). No reason is apparent for applying Article 72 EPC 1973 by analogy in the context of a transfer of right of priority preceding a subsequent filing:

As regards its material scope, Article 72 EPC 1973 is concerned with the transfer of a European patent application and the associated rights, foremost the right to the grant of a patent to which the applicant is assumed to be entitled (Article 60(3) EPC 1973). The right of priority derived from a first application only becomes an accessory to subsequent applications for which it was rightfully invoked. Until then, the right of priority is a distinguishable right that is transferable independently of the corresponding first application. Thus, applying Article 72 EPC 1973 to the transfer of a right of priority in view of a subsequent European patent application would, in the case of a European first filing, ignore the fact that the priority right is a right independent of the right to the first application and, in the case of a non-European first filing, that Article 72 EPC 1973 does not govern the relationship between the applicant of a European patent application and a different applicant of a distinct first application. Indeed, the provisions concerning a transfer of rights, namely Article 72 EPC 1973 in conjunction with Rule 20 EPC 1973, and the related provisions (Articles 60(3) EPC 1973 and 61 EPC) serve another purpose. They define the conditions under which the EPO may take into account questions of substantive law and procedural acts by a person **other than the registered applicant** (J 2/01, OJ EPO 2005, 88, point 3 of the reasons).

Neither the systematic context (Articles 61 EPC, and 60(3), 72, and 74 EPC 1973), nor the preparatory work to Article 72 EPC 1973, which is silent with respect to the question of transfer of the right of priority, leave room for applying Article 72 EPC 1973 in a way which goes beyond its clear wording. The board therefore concurs with the decision of 16 April 2013 of the German Federal Supreme Court (filed as document (48), point 13 of the reasons) that Article 87 EPC does not require a formal and separate assignment as provided by Article 72 EPC.

- 2.7.2 The board further considered the question whether the silence of the EPC with respect to the requirements for a valid transfer of a right of priority implies that there are no formal requirements for such a transfer under the EPC. It would thus be possible to establish a transfer of a right of priority using any kind of evidence within the meaning of Article 117 EPC. It would be sufficient to demonstrate such a transfer by way of conduct of parties to a contract implying the transfer in the circumstances of the case. However, this would exclude the possibility of a transfer by operation of law which can only be established by reference to a (comprehensive) legal system. Also, the board's assessment of the evidence adduced will inevitably need to be made by reference to defined formal and material requirements. As an example, the question whether it is sufficient to have a declaration by the transferor only or whether an employee may transfer all its future rights in an invention to an employer cannot be resolved under the EPC. It has to be born in mind that the EPC does not establish a fully harmonised patent system, although a high degree of harmonisation between the EPC and national laws has

indeed been achieved. Neither the interpretation of the EPC nor the application of Article 125 EPC, which refers to procedural law only, constitute a proper basis for further harmonisation to the extent that the EPC does not clearly provide for harmonised law itself. For these reasons, the board did not take silence as a conscious choice of the legislator that the transfer of a right of priority is free of requirements as to form and content.

- 2.7.3 Since the provisions of the EPC do not lend themselves to an autonomous determination of the requirements for the transfer of right of priority, the validity of such transfer is a **matter of national law**. The board concurs in this respect with decision T 1008/96, point 3.3 of the reasons. The board also notes that other decisions have relied on national law when assessing the validity of a transfer of the right of priority (see T 160/13, point 1.1 of the reasons; J 19/87, point 2 of the reasons; implicit in T 493/06, points 9 to 11 of the reasons).

The respondent argued that it had been the intention of the legislator not to burden the EPO with questions of substantive national law. While it is true that it was held with respect to the purpose of Article 60(1) and (3) EPC 1973 that the EPO should not be concerned with questions of entitlement in terms of substantive law and should have no power to determine disputes as to whether or not a particular applicant is legally entitled to apply for and be granted a European patent in respect of the subject-matter of a particular application (J 2/01, OJ EPO 2005, 88, point 2.6 of the reasons, citing G 3/92, OJ EPO 1994, 607, point 3 of the reasons), this reasoning cannot be extended beyond the context of Article 60(1) and (3) EPC 1973. The EPC

does not, as a matter of principle, bar the organs of the EPO from applying substantive national law governing an incidental question which is decisive for the outcome of the proceedings before the EPO (see for example G 3/99, OJ EPO 2002, 347, point 9 of the reasons; G 1/13, points 2.3.3, 5.1, 6 to 8 of the reasons). In the board's judgment, the assessment of whether the applicant of a European patent application is "successor in title" within the meaning of Article 87(1) EPC 1973 of the right of priority deriving from an earlier application is the exclusive concern of national law.

The above cases did, however, not address the issue of the choice of the applicable national law. Indeed, the determination of the applicable national law seems to have been straightforward in view of the circumstances of the respective cases:

- In case J 19/87, the inventor, resident of the UK, filed a UK patent application. He then assigned his rights to the invention and to the UK patent application, together with the right to file further patent applications in respect of the invention and the right to claim priority from the UK application to a company with place of business in the UK. This company, in turn, assigned back the rights in the invention and the UK application and agreed that the first assignment was void. The inventor then filed a European patent application claiming priority from the UK patent application. All circumstances relevant to the transfer of right of priority (residence, place of business, state of of the first filing, assignment contracts) thus related to UK law, and the board

was safe in applying this national law to the question of entitlement to the priority.

- In case T 1008/96, the European patent application resulting in the patent in suit claimed the priorities of two Italian utility model applications. The patent proprietor, a company with place of business in Italy, alleged that the applicant of the two Italian utility model applications, an Italian resident, had assigned these applications to it. One of the opponents produced an Italian Court decision according to which the transferor was still the owner of the first of the two priority applications after the date of the alleged assignment. Again, all circumstances relevant to the transfer of right of priority (residence, place of business, state of first filing, assignment contracts) were connected with Italy and thus with Italian law. The legal situation under Italian law appears not to have been backed up by detailed evidence and the decision was taken based on the evaluation of the conflicting evidence on file.

- In case T 493/06, the entitlement to priority of an international patent application which constituted state of the art within the meaning of Articles 54(3) and (4) EPC 1973 was contested. This application to which one of the opponents was co-applicant claimed priority of five UK patent applications. Two of these were filed in the name of a professional representative, having its place of business and residence in the UK, who had acted as trustee. An assignment document was produced relating to the transfer from the trustee to the opponent, a company with place of business in the

UK. Also in this case, the factual circumstances were connected to the UK, implying the application of UK national law.

- Finally, case T 160/13 concerned the transfer within a corporate group. The patent in suit was filed as an international application by an affiliate with place of business in France and claimed the priority of a German utility model application, which had been filed by an affiliate with place of business in Germany. Here, the place of business of the transferor, the state of filing of the first application and the assignment declaration by the transferor (e-mails sent by an employee of the German affiliate) were factual elements connected to German territory. Only the place of business of the transferee tended to the application of a law other than German law. Unfortunately, in this case, neither the opposition division nor the board justified their explicit choice of German law.

2.7.4 In none of the above decisions was the law of the state for which protection was sought **by the subsequent filing** considered to be relevant. Indeed, in the case of a subsequent European patent application this would require harmonised law. The above decisions, however, provide no guidance as to whether, in the assessment of the validity of a transfer of the right of priority, the law applicable to the **legal relationship between the transferor and the transferee** of the right of priority, such as corporate agreement, employment contract, or universal succession, should apply, or the law of the **state of filing of the first application**. Whereas this point of law was not at issue in the cases referred to above, it is relevant to the present

decision: The applicants of the US provisional applications (P1) and (P2) were employees of the appellant working in Israel. Thus, whereas the first filings point to US law, the employment relationship is connected to Israel.

- 2.7.5 Articles 87 EPC 1973 and 88 EPC and Rules 52 to 53 EPC are silent on the choice of law to be made with respect to the assessment of the validity of a transfer of rights of priority. Nevertheless, in the absence of harmonised law, the board must determine the applicable national law, since this is essential for reaching a decision as to whether said transfer has been properly established and proven by the party bearing the burden of proof in this respect.

In the board's judgment, the following considerations militate in favour of the law applicable to the legal relationship between the transferor and the transferee of the right of priority, and against the law of the state of filing of the first application:

- In view of the potential legal implications of the date of (first) priority in the assessment of patentability or validity of a patent application or patent, it is imperative that applicants and the public at large be provided with legal certainty and predictability with respect to the rules of law governing the subject of claiming priority, including the assessment of validity of a transfer of the right of priority.

Many factors may be envisaged that might influence the choice of state for the filing of a first application. A first applicant intending to transfer its priority right might not therefore

anticipate that the law of the state of filing of the first application might govern its relationship with a transferee and that they might have to comply with this law even when there is no connection between the state of first filing and their legal relationship.

On the other hand, the transferor and transferee of the right to priority will be familiar with the law that governs their legal relationship and thus be aware of any formal requirements regarding the transfer of the right of priority. The application of this law will not hamper legal certainty, since, in the event that the entitlement to the priority becomes relevant, the applicable law can be ascertained and verified on the basis of the evidence that the applicant or proprietor will have to provide.

- The law of the state of filing of the first application is relevant for the determination of a regular first application (Article 87(2) EPC 1973). The fate of such first application does not, however, prejudice the right of priority claimed for a subsequent application (Article 87(3) EPC 1973). Moreover, the transferability of the right of priority as such is determined by Article 87(1) EPC 1973, independently of the law of the state of filing of the first application. Therefore, there is no connection between this law and the question of a valid transfer.

- Finally, the board also notes that Article 60(1), second sentence, EPC 1973 provides a conflict-of-law rule for the determination of the entitlement to the invention in an employment relationship.

According to this provision, the law of the state in which the employee is mainly employed is applicable, or, alternatively, the law of the state in which the employer has its place of business to which the employee is attached. Albeit not applicable to the right to priority, this conflict-of-law rule reflects the understanding of the legislator that mutual obligations of employer and employee in relation to the transfer of an intellectual property right arising from the employee's efforts shall be governed by the law of the state to which the employment relationship is most closely connected. Moreover, this choice of law follows on from Article 60(1), first sentence, EPC 1973, which uses the term "successor in title" without defining it and thereby leaving its determination to national law.

2.7.6 For the above reasons, the board concludes that, in the present case, the law of the state of the employment relationship between the three original applicants and the appellant determines the transfer of the right of priority. At the time of filing of the international application WO 2006/024024, the original applicants were employees of the appellant (see point 2.8.1 below). Both the state where the original applicants were employed and the place of business of the appellant, to which the original applicants were attached, are Israel. Therefore, Israeli law applies.

2.8 Turning to the evidence before it, the board had to evaluate whether it provided proof that

- a) before the date of filing of the international application WO 2006/024024

- b) the right of priority derived from the US provisional applications (P1) and (P2) had been transferred to the appellant
- c) by the three original applicants and inventors
- d) in accordance with the requirements of Israeli law.

2.8.1 Documents (21b), (21c), and (21d) provide conclusive evidence that the three inventors and applicants of the US provisional applications (P1) and (P2), Ms Revital Lifshitz, Mr Thomas Bayer and Ms Judith Aronhime, were employees of the appellant. These documents also show that the employment relationship existed at the time when the invention can be presumed to have been made, namely, before the filing of the US provisional applications (P1) and (P2). Even though the letter setting out the conditions of employment of Ms Judith Aronhime (document (21d)) has a date which is after the filing date of the US provisional application (P1), reference is made in said letter to her appointment as of 1 August 2004. Furthermore, the first confidentiality agreement between the appellant and Ms Judith Aronhime was signed on 24 April 1994. This shows that Ms Judith Aronhime was an employee of the appellant even before her appointment to her position as of 1 August 2004.

2.8.2 The invention giving rise to the US provisional applications (P1) and (P2), as well as to the international application WO 2006/024024, qualifies as a service invention under Chapter 8 of the Israeli Patents Law 5727-1967, which is applicable in the present case (reference is made herein to the English translations filed as documents (22f) and (22g)). The expert opinion of Mr Tal Band of 21 May 2012 (document (22a), point 7 of the opinion) provides proof for this

factual and legal aspect. The board sees no reason to doubt the conclusion reached in this opinion.

2.8.3 The appellant argued that it had acquired the right of priority derived from the US provisional applications (P1) and (P2) by operation of section 132 of the Israeli Patents Law 5727-1967. In support of its contention, the appellant relied on the opinion of its expert, Mr Tal Band (document (22a)).

Section 132 of the Patents Law 5727-1967 reads as follows:

"Inventions in consequence of service

- (a) An invention by an employee, arrived at in consequence of his service and during the period of his service (hereafter: service invention) shall, in the absence of an agreement to the contrary between him and his employer, become the employer's property, unless the employer relinquishes the invention within six months after the day on which notification under section 131 was delivered to him.
- (b) If, in his notification under section 131, the employee stated that - in the absence of a contrary reply from the employer within six months after delivery of the employee's notification - the invention will become the employee's property, and if the employer made no contrary aforesaid reply, then the invention shall not become the employer's property."

Mr Tal Band provided the following opinion on the legal effects of section 132 of the Israeli Patents Law 5727-1967 (documents (22a), points 8 to 10):

"8. Once an invention is deemed to be a service invention, and in the absence of any agreement to the contrary between the employer and the employee, Section 132 of the Patents Law provides that the invention shall become the property of the employer. Israeli law does not require any written instrument of assignment in such circumstances to transfer the ownership rights in the service invention from the employee (or employees) to the employer. The full ownership of a service invention inherently vests in the employer by virtue of the law, once the invention is arrived at by the employee.

9. The employer's ownership of a service invention would inherently entail, under Israeli law, the right to file a patent application on the invention. The employer's ownership of a service invention further entails the right to claim priority from an application filed on the invention abroad (i.e. in any country which is "a Member State", as defined in Section 1 of the Patents Law), by the employees, for and on behalf of the employer. Accordingly, it is my opinion that, under Israeli law, the right to claim priority from such an application inherently vests in the employer, without any need for a written instrument of assignment of the specific right of priority from the employees to the employer.

10. I was advised by Teva, and accordingly it is my factual assumption for the purpose of this expert opinion in connection with the ending passage of Section 132(a) above, that Teva never renounced the invention. It is also my understanding, and accordingly my factual assumption for the purpose of this expert opinion, that none of the three inventors in the

present case gave Teva a notification that would render Section 132(b) applicable."

2.8.4 The board has no reason to doubt the above conclusions by the appellant's expert. It is true that an opinion by an expert who has represented a party "in numerous proceedings" (see documents (22a) last sentence of the second paragraph) may, upon free evaluation of the evidence, carry less weight than a court decision, another independent authority under the national law, or an expert commissioned by the board under Article 117(1) (e) EPC together with Rule 117, first sentence, EPC. Nevertheless, an opinion of a party's expert is a means of evidence under Article 117(1) EPC. In the present case, the respondent did not file any contrary evidence. Of course, both the legal and evidentiary burden of proof rested on the appellant to establish its right to claim priority from the US provisional applications (P1) and (P2). The respondent could therefore limit itself to casting doubt on the credibility of the evidence adduced by the appellant. However, in doing so, it ran risk that, in the absence of further evidence disproving the conclusions in the appellant's expert opinions, the board could decide in favour of the appellant, if the respondent's challenge to the evidence before the board did not give rise to substantiated doubts as to the veracity of this expert opinion.

2.8.5 The board cannot make out any flaws in the opinion of Mr Tal Band.

The finding that, under Israeli law, the full ownership of a service invention belongs to the employer, by virtue of the law and without any need for a written instrument of assignment, is confirmed by the wording

of section 132 of the Patents Law 5727-1967. Since the invention that gave rise to the US provisional applications (P1) and (P2) qualified as a service invention within the meaning of section 132 of the Patents Law 5727-1967 (see point 2.8.3 above), the right to the invention passed to the appellant under said provision. Moreover, the factual assumptions in the opinions that the appellant had not relinquished the invention giving rise to the US provisional applications (P1) and (P2), and that the invention had not remained with one of the inventors under section 132(b) of the Patents Law 5727-1967, have never been contested by the respondent.

The second step in the chain of argument, namely, that the employer's ownership of a service invention further entails the right to claim priority from an application filed by the employees for and on behalf of the employer, was also not reasonably put into doubt. It is true that the right of priority is not mentioned in section 132 of the Patents Law 5727-1967. However, it follows from section 140 of the Patents Law 5727-1967 that the aim of section 132 is to vest the employer with the rights to obtain worldwide protection for service inventions made by his employees. The respondent did not invoke any other provision or legal authority which would support the view that the right of priority was excluded from the operation of section 132 of the Patents Law 5727-1967 and which would have put into question the expert's conclusion that the employer's ownership of a service invention further entails the right to claim priority from an application filed on the invention abroad.

The respondent argued that section 140 of the Patents Law 5727-1967 merely created an obligation of the

employee to act in the interest of the employer and therefore required with respect to the transfer of the right of priority an express written assignment executed by the employee. The board does not agree.

Section 140 of the Patents Law 5727-1967 reads as follows:

"If a person made a service invention and if the ownership of it passed, in whole or in part, to his employer under section 132 or by agreement, then he must do everything required of him by the employer in order to obtain protection for the invention to the employer's benefit in any place whatsoever, and he must sign any document required therefor; if he does not do so, then the Registrar may permit the employer to do so after he has given the employee an opportunity to state his arguments."

It follows from the wording of this provision that the employee's obligation to sign a document is only stated with respect to a corresponding requirement in the law of the state of the filing of a patent application. It cannot be read into section 140 of the Patents Law 5727-1967 that a valid transfer of the right of priority requires a declaration of assignment executed by the inventor. Apart from the fact that section 140 does not make any reference to the right to priority, such an interpretation would create an additional hurdle for the employer in obtaining patent protection for service inventions and thus run counter to the aim of this provision. Since the Patents Law 5727-1967 does not provide elsewhere for formal requirements for the transfer of the right of priority, the transfer of the right of priority arising from a first filing by an employee-inventor does not, under Israeli law, require

any written document signed by the employee in accordance with section 140 either. It is therefore reasonable to conclude from sections 132 and 140, with respect to a service invention, that the right of priority arising from a first filing by an employee-inventor - albeit being a right separate of the right to the invention - will devolve to the employer as a necessary correlate of the employer's entitlement to seek worldwide protection for the invention.

2.8.6 For the above reasons, the board was satisfied that the appellant had discharged its burden of proof and provided convincing evidence for the fact that the right of priority derived from the US provisional applications (P1) and (P2) had been transferred to the appellant before the date of filing of the international application WO 2006/024024.

2.9 The board was not persuaded by the respondent's counter-arguments:

2.9.1 The respondent brought forward the argument that, with respect to a transfer of the right of priority, a distinction had to be made between the obligation to assign the rights and the separate act of assignment. They maintained that the contractual arrangements in documents (21b), (21c) and (21d) merely created obligations. Such obligations could not be regarded as proof for a subsequent valid transfer of rights. With respect to the right of priority, the fulfillment of the contractual obligations of the inventors and original applicants therefore required a separate assignment. According to the respondent, the appellant had failed to provide proof for such assignment.

It is true that, with respect to Rule 20 EPC 1973, a distinction is made in the jurisprudence of the boards of appeal between an obligation to assign a right and the assignment itself (J 4/10, point 5.4 of the reasons; J 12/00, points 2 and 14 of the reasons). This jurisprudence pertains, however, to Article 72 EPC 1973, which is not applicable in the present case. Such a distinction has no bearing on the transfer of a right of priority if, according to the applicable national law, the right is transferred by operation of law (e.g. merger or succession), or if an assignment does not require specific formalities and thus can be implied from the circumstances. This is, for example, the case under German and Swiss national law (T 160/13, point 1.1 of the reasons; document (48), points 12 and 14 of the reasons; Breimi, epi Information 1/2010, page 18, left-hand column, second complete paragraph).

In the present case, the applicable Israeli law on service inventions does not require particular formal requirements to be fulfilled; in particular, it does not require a separate and express assignment. Even if, for the sake of argument, section 132 of the Patents Law 5727-1967 regarding service inventions were to be disregarded, a transfer of the right of priority can nevertheless, in the absence of formal requirements under Israeli law, be agreed orally between the employee and the employer, or even be manifested by way of circumstances implying such transfer. Thus, even when considering the contractual arrangements (documents (21b), (21c) and (21d)), in particular the agreement that no proprietary or other right to a service invention remained with the employees, and the obligations under section 140 of the Patents Law 5727-1967 only, the circumstances were such that the filing of the international application WO 2006/024024

claiming priority from the US provisional applications (P1) and (P2) in the name of the appellant (except for the United States of America and Barbados) would, in the board's judgement, imply a mutual agreement between the inventors and the appellant on the transfer of the right of priority to the latter.

2.9.2 The respondent also pointed to differences in the extent of the respective contractual obligations of the three inventors and employees (documents (21b), (21c) and (21d)). It is true that the degree of detail on which the rights and duties are stated varies among the respective arrangements. However, even the less detailed contractual agreements (that is, the confidentiality agreement dated 16 August 1998 and signed by Ms Revital Lifshitz, document (21b), and the first confidentiality agreement dated 24 April 1994 and signed by Ms Judith Aronhime, document (21d)) state that **all** rights in a invention arrived at by the employee in the course of or in connection with the employment, exclusively belong to the employer without **any** proprietary or other right remaining with the employee. Thus, all contracts confirm and reflect what is set forth in section 132 of the Patents Law 5727-1967. The further obligation to sign any document as required by the employer in order to obtain patent protection is not to be found in the confidentiality agreements referred to above. However, such obligation existed already under section 140 of the Patents Law 5727-1967. Therefore, the contractual arrangements neither contradict nor do they depart from the regulation on service inventions enshrined in Chapter 8 of the Patents Law 5727-1967. Since the appellant provided conclusive evidence, which was not countered by any evidence filed by the respondent, that the right of priority derived from the US provisional

applications (P1) and (P2) had been transferred to the respondent before the date of filing of the international application WO 2006/024024 by operation of section 132 of the Patents Law 5727-1967, the alleged differences in the contractual arrangements are not relevant for the present decision and would in any case not lead to a different conclusion.

2.9.3 According to the respondent, it was not clear from the confidentiality agreements (that is, in the case of Ms Revital Lifshitz, the confidentiality agreement dated 16 August 1998 included in document (21b); in the case of Mr Thomas Bayer, the undated Appendix B entitled "Safeguarding Trade Secrets, protection of intellectual Property and Non Compete Agreements" included in document (21c); and in the case of Ms Judith Aronhime, a first confidentiality agreement dated 24 April 1994 and Appendix B dated 19 December 2004 entitled "Letter of undertaking to maintain confidentiality, intellectual property and non-competition", both included in document (21d)) who the potential transferee of a right of priority was. The relevant passages referred to "the Company and/ or ... the Subsidiary Companies" or to "Teva Group" or "Teva" which were, in a nutshell, defined as any corporation controlled by Teva Pharmaceutical Industries Ltd. or Teva, respectively. The board, however, agrees with the opposition division that there is no doubt that the employment agreements were concluded between the appellant and the respective inventors and applicants of the US provisional applications (P1) and (P2). Therefore, the appellant was employer within the meaning of Chapter 8 of the Patents Law 5727-1967. Whether the appellant could have transferred its rights to affiliated companies is

relevant only with respect to the designation of Barbados, but not for the case under consideration.

2.9.4 The respondent also pointed to an incoherence in dates as regards the opinion of Mr Tal Band signed on 21 May 2012 (document (22a)) and the reference to an opinion of Mr Tal Band in the earlier opinions of Mr Patrick J. Birde dated 15 February 2012 (document (23a)) and of Mr Robert C. Millonig and Ms Gaby L. Longsworth dated 23 April 2012 (document (23b)). Moreover, document (23a) refers to an "Expert Opinion of Adv. Tal Band, dated 14 February 2012". The existence of different versions of an expert opinion is as such not sufficient to cast the opinion into doubt. What matters is whether or not the versions are contradictory or incoherent. No contradictory statement can be found in documents (23a) and (23b) from which it might be inferred that Mr Tal Band deviated in his later opinion of 21 May 2012 (document (22a)) from his earlier opinion referred to in documents (23a) and (23b). Therefore, the board has no reason to doubt his opinion.

2.10 Consequently, the board holds that the international application WO 2006/024024 enjoys the earliest priority date of 23 August 2004.

3. *Novelty (Articles 52(1), 54 EPC), main request*

The only novelty objection raised by the respondent during the present appeal proceedings related to document (2). Its case in this respect rested solely on the issue of whether the patent in suit was entitled to claim the priority from application (P1). In view of the conclusion on this issue, as detailed above in point 2, and in view of the fact that the respondent

did not contest that the subject-matter claimed has a basis in application (P1), document (2) is not regarded as constituting state of the art within the meaning of Article 54(3) EPC.

4. *Sufficiency of disclosure (Article 100(b) EPC),
main request*

4.1 The respondent's objected to the fact that the patent in suit did not provide a correct reference to a prior art document disclosing the preparation of the starting material ibandronic acid, required for the synthesis of the claimed crystalline form of ibandronate sodium (see patent in suit, paragraphs [0003], [0005], [0042], [0078] and [0163]).

However, the board cannot agree that said erroneous reference results in a lack of sufficiency of disclosure. At the priority date of the patent in suit, ibandronic acid was a well-known therapeutic moiety, particularly to the skilled person seeking to investigate solid-state forms of its salts. The synthesis thereof was also readily retrievable from standard reference books, such as document (44) (see scheme, step 1, and reference to document (1)). The present situation is not therefore comparable with that underlying the decision T 206/83 (see OJ EPO 1987, 5): In that decision, it is apparent that the compounds in question were not traceable in a straightforward manner (see point V.b), and it was held under the circumstances that "reliance on the contents of Chemical Abstracts to rectify insufficiency might be tantamount to leave the skilled reader to carry out a search in the whole state of the art, which would be an unacceptable burden on the public" (see point 6).

From the above it follows that a case for lack of sufficiency of disclosure has not been established. Consequently, it is concluded that the ground of opposition under Article 100(b) EPC does not prejudice the maintenance of the main request.

- 4.2 During oral proceedings before the board, the respondent raised, for the first time, an objection under Article 100(b) EPC based on the allegation that claim 1 covered a multitude of crystalline forms, and that the patent in suit provided insufficient information to allow these to be obtained. Pursuant to Article 13(1) RPBA, this represents an amendment to the respondent's case that may be admitted and considered at the board's discretion.

The respondent argued that this objection could not have come as a surprise to the appellant since a similar line of argumentation had been put forward during the appeal case T 205/14 concerning the parent patent. However, the subject-matter claimed in the present case relates to an independent crystalline form, characterised by different X-ray reflections. Therefore, the board cannot see any reason why the appellant should have expected the same objections to be raised as in the parent case. Moreover, if the parallels between the two cases were so evident, the question arises as to why this objection was not raised in a more timely manner. No explanation in this respect was given by the respondent.

Finally, the respondent pointed to the minutes of oral proceedings before the opposition division (page 5, top paragraph) in order to support its contention that the additional objection had been raised previously. However, this passage relates to inventive step and not

sufficiency, and to the distinct question as to whether a technical effect was observed for the whole scope claimed.

Consequently, the board decided not to admit this amendment of the respondent's case into the proceedings.

5. *Inventive step (Articles 52(1) and 56 EPC), main request*

5.1 Claim 1 relates to a crystalline form of ibandronate sodium characterised by five X-ray powder diffraction (XRPD) reflections; in dependent claim 2, five further peaks are defined; and in dependent claim 3, the full diffractogram is depicted (see above point I).

5.2 The board considers, in agreement with the parties, that document (34) represents the closest state of the art. Document (34) is the EPAR Scientific Discussion document for Bondronat, in the version published after approval of the 50 mg film-coated tablet (see excerpt from attached e-mail exchange). It comprises three sections relating to different drug products, namely, "an ampoule in two strengths (1 mg/1 ml and 2 mg/2 ml) containing a concentrate for solution for infusion" (pages 2 to 9); "the additional dosage presentation 6 mg/6 ml" (pages 9 to 12); and "Bondronat 50 mg, film coated tablet" (pages 12 to 14). The final section concerns an additional indication (pages 14 to 29). In each of these sections, the drug substance used is identified as being "ibandronic acid, monosodium salt, monohydrate" (see e.g. page 2, "Dosage form"; pages 10 and 12, "Composition"; page 15, last paragraph).

The relevant passages of the section relating to the "Bondronat 50 mg, film coated tablet" are reproduced below (see pages 12 to 14).

5.2.1 **"Drug substance ... Manufacture:**

"The synthesis comprises seven steps.

...

No catalysts are used. As solvents acetone, ethanol, methanol, diethylcarbonate, diisopropylether and methylethylketone are used.

...

The substance is a very stable compound as demonstrated by long-term studies. Only under extreme conditions in stress studies (i.e. oxidative conditions), a small increase of phosphate and phosphite was observed."

5.2.2 **"Stability of the Drug Substance**

This is well-known from the first authorisation of the solution for infusion.

Several stress tests were undertaken to induce degradation of the active ingredient. Only in the presence of hydrogen peroxide decomposition occurred, indicated by slightly increasing contents of phosphate, phosphite and two unknown impurities.

Three batches were stored as recommended in the ICH guideline on "Stability Testing of New Drug Substances and Products" (25°C/60 r.h. and 30°C for five years, 40°C and 40°C/75% r.h. for six months). Additionally, results of four batches are included in the stability report as supportive data. All results comply with the specification. ..."

5.2.3 **"Product Development and Finished Product**

The development of this tablet is standard. The active substance is very stable. It is used as a fine crystalline powder and is freely soluble in water, so the tablets dissolve very rapidly in aqueous media: Dissolution >85% after 15 minutes. The film-coating has no effect on the dissolution rate.

A second polymorphic [sic] form (B) has been identified, but it has similar solubility and intrinsic dissolution properties to polymorph A and is not expected to affect the tablet performance, if present in the tablets. The manufacturing processes are expected to produce tablets containing exclusively polymorph A."

5.2.4 **"Stability of the Product**

The active ingredient has been proven to be a very stable compound and this is also reflected in the stability of the product, which has been demonstrated by studies under ICH conditions. Furthermore, during development several batches have been monitored using three different TLC systems and one HPLC method. No significant increase in any degradation product was observed. The limits applied for unspecified impurities also are in line with ICH topic Q3B. ..."

5.3 The problem to be solved in the light of document (34) can be seen as lying in the provision of a polymorphically stable form of ibandronate sodium (cf. e.g. patent in suit, paragraphs [0012], [0016]).

The solution as defined in claims 1 to 3 relates to a crystalline form of ibandronate sodium characterised by

a number of XRPD peaks (claims 1 and 2) and the corresponding complete XRPD diagram (claim 3).

- 5.4 In order to render it plausible that the problem defined in point 5.3 has been successfully solved, the appellant relied on the data submitted in document (42). Therein, it is demonstrated that ibandronate sodium form T is stable to conversion into other solid-state forms over extended periods of time at various relative humidities, and when subjected to grinding, pressure and heating.

Criticism was raised by the respondent concerning missing details of the measurement conditions. However, the board cannot see that this puts into question the validity of the results obtained. For example, in Figure 1 of document (42), there is no reason to doubt that, in the absence of any other indication, the diffractograms in question were measured at a constant, ambient temperature.

The respondent further objected that the five peaks specified in claim 1 were not sufficient to characterise the unique crystalline form designated "form T" in the patent in suit, and that a multitude of forms were embraced, for which it was *a priori* not plausible that they would solve the problem posed. However, the respondent did not further substantiate this objection, and, in the absence of evidence to the contrary, the board is satisfied that the problem posed has been solved.

- 5.5 It remains to be investigated whether the proposed solution would have been obvious to the skilled person in the light of the prior art.

5.5.1 As outlined above in point 5.2, throughout document (34), the drug substance used in formulating the drug products, both as infusion concentrates and as tablets, is identified as being as being "ibandronic acid, monosodium salt, monohydrate". The term "monohydrate" would be understood by the skilled person to designate a crystalline solid incorporating one mole of water for every mole of ibandronate sodium (cf. e.g. document (10), page 946, left-hand column, second complete paragraph, third sentence). The stability of this drug substance is also repeatedly emphasised in document (34), as tested under various conditions, such as oxidative stress, and under storage at high humidity and temperature (see above points 5.2.1 to 5.2.4).

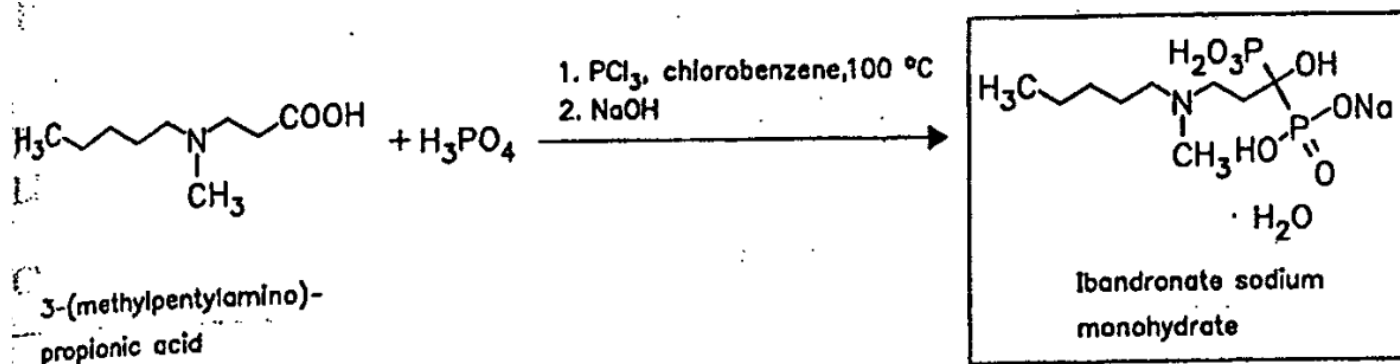
In the first paragraph of the section "Product Development and Finished Product" (above point 5.2.3), the active substance is described as being "a fine crystalline powder". In the following paragraph, it is disclosed that a second crystal form, designated form B, exists, but that "the manufacturing processes are expected to produce **tablets containing exclusively polymorph A**" (emphasis added). In view of this statement, the skilled person is given a clear indication that form A of ibandronate sodium monohydrate had been subjected to stress conditions mimicking those encountered during the tableting process, and had been found to exhibit polymorphic stability under these conditions.

With respect to form B, this is disclosed as having "similar solubility and intrinsic dissolution properties to polymorph A". However, contrary to the submissions of the respondent, there is no basis provided for inferring equivalence of the two forms in any other properties. Indeed, the preference expressed

in document (34) for form A rather suggests otherwise (see document (10), page 948, sentence bridging left- and right-hand columns).

Consequently, it is concluded that document (34) teaches the existence of a preferred polymorphic form of ibandronate sodium monohydrate with good tableting properties and of high stability, including polymorphic stability. Document (34) therefore provides the skilled person with a strong incentive to seek to obtain such a crystalline monohydrate as a solution to the problem posed.

- 5.5.2 In view of the fact that document (34) itself does not provide any useful details with respect to the conditions used to obtain ibandronate sodium monohydrate (cf. above point 5.2.1), the skilled person would have sought further information in the literature relating to methods of preparing this drug substance. In this respect, document (44), which is a standard reference book for information on pharmaceutical substances, would be a first point of reference for the skilled person seeking further relevant information. Under the entry for ibandronate sodium monohydrate, the following scheme is disclosed, together with a reference to document (1):



Reference(s):

EP 252 504 (Boehringer Mannh.; appl. 9.7.1987; D-prior. 11.7.1986).

Based on this disclosure in document (44), the skilled person is directly pointed to document (1), and would regard this as a promising avenue to pursue, in the expectation of being able to obtain the target drug substance in accordance with methods taught by this document.

5.5.3 The following analysis refers to the English language family member of document (1), namely, document (29), in keeping with the submissions of the parties. The corresponding passages in German are to be found in document (1): page 2, lines 24 to 41 and 50 to 54; page 5, lines 47 to 53; examples 7 and 9A; and claims 1 and 3.

Document (29) relates to diphosphonate compounds of formula (I) and pharmaceutically acceptable salts thereof (column 1, lines 42 to 66 and claim 1). Ibandronic acid is disclosed as a preferred example thereof (column 2, lines 21 to 27; example 9A; claim 4). With respect to the conversion of diphosphonate compounds into their salts, the following is stated in column 5, line 67 to column 6, line 11:

"The free diphosphonic acids of general formula (I) can be isolated as the free acids or in the form of their mono- or dialkali metal salts. The alkali metal salts can usually be readily purified by reprecipitation from water/methanol or from water/acetone.

As pharmacologically acceptable salts, there are preferably used the alkali metal or ammonium salts which can be prepared in the usual way, for example by titration of the compounds with inorganic or organic bases, for example sodium or potassium hydrogen carbonates, aqueous solutions of sodium or potassium hydroxide or aqueous solutions of ammonia or of amines, for example trimethyl or triethylamine."

The reaction conditions for salt formation are illustrated in Example 7 as follows:

"500 mg of the diphosphonic acid prepared according to Example 1 are suspended in 5 ml water, dissolved with 2.68 ml 1N aqueous sodium hydroxide solution, concentrated somewhat and brought to crystallisation by pouring into acetone. There are thus obtained 440 mg (78% of theory) of the disodium salt of 1-hydroxy-3-(N,N-dipentylamino)-propane-1,1-diphosphonic acid in the form of the monohydrate. The melting point is above 300° C."

- 5.5.4 In view of the fact that Example 7 is the only embodiment to provide a detailed reaction procedure for salt formation, the most obvious initial course of action for the skilled person, seeking to apply the teaching of document (1) to the synthesis of ibandronate sodium monohydrate as disclosed in document (44), would be to follow the procedure of this example accordingly.

Evidence for the outcome of such an adaptation can be found in the experimental data submitted as document (46). Therein it is demonstrated that, by following the reaction procedure of Example 7, employing ibandronic acid as starting material, the requisite amount of sodium hydroxide, and a reasonable variation of crystallisation conditions within the framework specified, ibandronate sodium monohydrate is consistently obtained, having an XRPD pattern corresponding to that depicted in Figure 18 of the patent in suit, designated as form QQ ibandronate sodium. It is further disclosed in the patent in suit that this form exhibits polymorphic stability (see paragraph [0038]).

Therefore, the board concludes that, in following the avenue presented by the combined teachings of documents (44) and (1), the skilled person would identify a crystalline form of ibandronate sodium that solves the problem posed, but is different from that now claimed. In view of the teaching of document (34), as set out above in point 5.5.1, the skilled person would have no cause to expect to be able to obtain a further crystalline form with similarly favourable properties, nor is a method suggested in the prior art as to how this was to be achieved.

5.5.5 The respondent additionally argued that, as disclosed in document (43), only slight modifications to the procedure described in Example 7 of document (1) would be required in order to obtain form T of ibandronate sodium. However, as explained above in point 5.5.4, a faithful adaptation of Example 7 was consistently found to yield form QQ of ibandronate sodium monohydrate. Once the skilled person departs from the the procedure specifically disclosed, he is presented with any number

of potential modifications within the solvent systems suggested, without any guidance as to how to achieve the desired property of polymorphic stability, or any reasonable expectation of being able to do so. Indeed, from the examples of the patent in suit, it is apparent that, when working with the solvent systems generally suggested in document (1), namely, water/methanol or water/acetone, numerous different polymorphic forms are obtained. It was not disputed by the respondent that many of these lack polymorphic stability. The facts of the present case therefore differ from those underlying decision T 777/08 (OJ EPO 2011, 633), since, therein, the specific polymorph claimed was found to be an arbitrary choice from a group of equally suitable candidates for solving the problem posed (see Headnote, point 2).

- 5.6 In view of the above considerations, the board concludes that the subject-matter of claim 1 of the main request involves an inventive step. The same applies to the remaining claims, relating to dependent claims, and a pharmaceutical composition thereof.

Accordingly, the subject-matter of the main request (claims as granted) meets the requirements of Articles 52(1) and 56 EPC.

Since this request is considered to be allowable, it is not necessary to comment on the lower-ranking auxiliary requests.

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

A. Lindner

Decision electronically authenticated