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Datasheet for the decision of 11 April 2013

Case Number: T 0612/09 - 3.3.04

Application Number: 99949913.0

Publication Number: 1115417

IPC: A61K 38/12

Language of the proceedings: EN

Title of invention:
Use of daptomycin

Patent Proprietor:
Cubist Pharmaceuticals, Inc.

Opponents:
Plate Schweitzer Zounek
Sölch, Günter

Headword:
Daptomycin/CUBIST PHARMACEUTICALS

Relevant legal provisions:
EPC Art. 111(1), 123(2)

Keyword:
"Main request - added subject-matter (yes)"
"Auxiliary request - added subject-matter (no), part-range directly and unambiguously disclosed"
"Remittal (yes)"

Decisions cited:
T 0002/81, T 0201/83, T 0240/95, T 0473/98, T 0727/00, T 1170/02

Catchword:
See points 10 to 20.

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0612/09 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 11 April 2013

Appellant: (Patent Proprietor)	Cubist Pharmaceuticals, Inc. 65 Hayden Avenue Lexington, MA 02421 (US)
Representative:	Fisher, Adrian John Carpmaels & Ransford One Southampton Row London WC1B 5HA (GB)
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Representative:	Mitcheson, Thomas 3 New Square Lincoln's Inn London WC2A 3RS (GB)
Respondent II: (Opponent 2)	Sölch, Günter Nordring 27 D-83624 Otterfing (DE)
Representative:	Keller, Günter Lederer & Keller Patentanwälte Unsöldstraße 2 D-80538 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 19 January 2009 revoking European patent No. 1115417 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: R. Morawetz
G. Alt

Summary of Facts and Submissions

I. The appeal of the proprietor (hereafter "appellant") lies against the decision of the opposition division posted on 19 January 2009, whereby European patent No. EP 1 115 417 was revoked.

II. The patent at issue has the title "Use of daptomycin". It was granted on European application No. 99949913.0 which originated from international application PCT/US1999/022366 published as WO 00/018419.

III. The application as filed (reference is made to the published application WO 00/18419) comprised 65 claims. Only claims 39, 42, 49 and 52 are of relevance to the present decision. These claims read as follows:

"39. Use of daptomycin for the manufacture of a medicament for treating a bacterial infection in a patient in need thereof, wherein a dose for said use is 3 to 75 mg/kg of daptomycin at a dosage interval of once every 24 hours to once weekly.

42. The use according to claim 39, wherein the dose is 10 to 25 mg/kg.

49. Use of daptomycin for the manufacture of a medicament for treating a bacterial infection in a patient in need thereof, wherein a dose for such use is 3 to 75 mg/kg of daptomycin at a dosage interval of once every 24 hours.

52. The use according to claim 49, wherein the dose is 10 to 25 mg/kg."

IV. The patent was opposed by opponents 1 and 2 (hereafter "respondent I" and "respondent II" or "respondents") under Article 100(a) EPC 1973 for lack of novelty (Article 54 EPC 1973) and lack of inventive step (Article 56 EPC 1973), under Article 100(b) EPC 1973 for insufficiency of disclosure and under Article 100(c) EPC 1973 on the ground that the claims as granted contained subject-matter extending beyond the content of the application as filed (Article 123(2) EPC 1973). In addition opponent 1 (respondent I) opposed the patent under Article 100(a) EPC 1973 for lack of patentability (Article 52(4) EPC 1973).

V. The decision of the opposition division was based on a main request filed as auxiliary request with the proprietor's letter of 18 October 2007 and an auxiliary request filed as second auxiliary request with the proprietor's letter of 10 October 2008. The opposition division decided that both the main request and the auxiliary request contravened Article 123(2) EPC since neither the dose range from "3 to 10 mg/kg of daptomycin" nor the dosage interval of "once every 48 hours" in conjunction with a dose of "3 to 10 mg/kg of daptomycin" could be derived directly and unambiguously from the application as filed.

VI. Claim 1 of the main request before the opposition division (which corresponds to the main request before the board) reads as follows (amendments compared to claim 39 as filed indicated in bold by the board):

"1. Use of daptomycin for the manufacture of a medicament for treating a bacterial infection in a

human patient in need thereof, wherein a dose for **said treating** is **3 to 10 mg/kg** of daptomycin, **wherein said dose is repeatedly administered in** a dosage interval of once every 24 hours **or once every 48 hours**."

VII. Claim 1 of the auxiliary request before the opposition division (which corresponds to the auxiliary request before the board) reads as follows (amendments compared to claim 49 as filed indicated in bold by the board):

"1. Use of daptomycin for the manufacture of a medicament for treating a bacterial infection in a **human** patient in need thereof, wherein a dose for **said treating** is **3 to 10 mg/kg** of daptomycin, **wherein said dose is repeatedly administered in** a dosage interval of once every 24 hours."

VIII. Oral proceedings before the board were held on 10 April 2013. At the end of the oral proceedings the debate was closed. The parties were informed of the board's decision by a communication on 11 April 2013.

IX. The arguments of the appellant can be summarised as follows:

Main request
Amendments (Article 123(2) EPC)

The disclosure of the two ranges of 3 to 75 mg/kg and 10 to 25 mg/kg of daptomycin in claims 39 and 42 as filed provided a basis for the new range of 3 to 10 mg/kg of daptomycin at a dosage interval of once every 24 hours to once weekly in accordance with decision T 2/81, headnote 2, first sentence and point 3

of the reasons.

As to the combination of the sub-range with the dosage interval of once every 48 hours, page 10, lines 12 to 14 disclosed that daptomycin was administered to a human patient in a dose of 3 to 12 mg/kg every 24 to 48 hours. As it was well established that two ends of a disclosed range were themselves disclosed, "every 24 to 48 hours" was a direct and unambiguous disclosure of every 24 hours and every 48 hours. The skilled reader would unequivocally and instantly recognise that, if a dosage interval of 48 hours was applicable to the broader range of 3 to 12 mg/kg, it was necessarily also applicable to the narrower range of 3 to 10 mg/kg.

Auxiliary request
Amendments (Articles 100(c) and 123(2) EPC)

Repeated administration of daptomycin was implicit in the reference to a dosage interval because an interval required administration more than once. Repeated administration was also implicit in the reference to once every 24 hours.

In accordance with the principles developed in decision T 2/81 claims 49 and 52 provided a basis for the dose of 3 to 10 mg/kg of daptomycin at a dosage interval of once every 24 hours. Moreover, in the light of page 10, lines 14 to 15 of the description and the examples, the skilled person would understand that this range was applicable to human patients. Example 4 looked at toxicity, that daptomycin was a potent antibiotic had been established in the prior art.

Alternatively, the two sentences on page 10, lines 12 to 15 provided a basis for claim 1. In accordance with decision T 201/83 the second sentence provided basis for adopting 10 mg/kg as the upper limit of the dosage range, in combination with a dosage interval of 24 hours. The values of 3, 4, 5, 6, 7, 8, 9 and 10 mg/kg daptomycin had been explicitly disclosed for a dosing interval of 24 hours. The value of 10 mg/kg could be separated from the other values disclosed as they were qualitatively all the same. This corresponded to a quantitative selection. The skilled person was not confronted with technical information which was not derivable from the application as filed. That in the case underlying decision T 201/83 the value was disclosed in an example was to the disadvantage of the then appellant because the board in this case had first to establish that the value could be separated from the remaining features disclosed in combination for that example.

Remittal

A proprietor was normally entitled to have the issues of patentability considered by two instances. The *obiter dictum* in the decision under appeal was made by the opposition division without taking into consideration the proprietor's submissions made in its letter of 10 October 2008.

X. The arguments of the respondents can be summarised as follows:

Main request
Amendments (Article 123(2) EPC)

In the case underlying decision T 2/81 the upper and lower limits claimed were selected from the upper and lower limits of two ranges claimed and included the preferred range. The claimed range of 3 to 10 mg/kg lay outside the preferred range of 10 to 25 mg/kg and therefore decision T 2/81 was not applicable.

The range of 24 to 48 hours was disclosed as one specific preferred embodiment in combination with a dosage range of 3 to 12 mg/kg daptomycin. From page 9, lines 7 to 13 the skilled person understood that the dose and the dosage interval of the method had to be safe and efficacious and that longer dosing intervals could provide for the administration of higher doses of daptomycin. The skilled person would be cautious to deviate from the dosage range that was explicitly disclosed because the dose and the dosing interval were intimately connected. Thus a dosage range of 3 to 10 mg/kg in combination with the dosage interval of once every 24 hours or once every 48 hours had not been originally disclosed.

Auxiliary request
Amendments (Articles 100(c) and 123(2) EPC)

The word "repeatedly" could not be found in the application as filed. The intake of the drug could be conducted with intermissions, creating new subject-

matter.

Point 4.3 of decision T 1170/02 confirmed that it was not allowed to combine the lower limit of the general range with the lower limit of the preferred range to create a new range. Even if the part-ranges lying within the overall range on either side of the narrower range were apparent from claims 49 and 52 as filed, the range of 3 to 10 mg/kg daptomycin was not directly and unambiguously disclosed in combination with human patients. Example 4 provided no efficacy data and no toxicology data above a dose of 6 mg/kg daptomycin once every 24 hours.

Also the disclosure on page 10 did not provide a basis. Decision T 201/83 was not applicable because in the present case the selected value with which the range was amended did not come from a specific example but from a list of values. If one specific value was taken from an example the skilled person recognized that the invention worked with this specific value. The selection of this value was therefore not arbitrary in contrast to the present situation, where the value was arbitrarily taken out of context and hence represented a qualitative choice.

Remittal

If the patent was in fact invalid the delay caused by a remittal would speak against a remittal because of the potential injustice to the respondents. There was no reason to consider that the opposition division had not considered the appellant's submissions in its *obiter*

dictum. Better justice would be done by having the board reconvened at a later point in time.

XI. The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution on the basis of the claims of the main or the auxiliary request which were before the opposition division.

XII. Both respondents requested that the appeal be dismissed. The first respondent also requested that, if the board should set aside the decision under appeal, it should proceed to deal with the additional grounds of opposition itself and revoke the patent, rather than remit the case to the first instance.

Reasons for the Decision

Main request
Amendments (Article 123(2) EPC)

1. Claim 1 is drawn up in the so-called Swiss-type format and concerns a dosage regime for treating a bacterial infection with the antibiotic daptomycin (see section VI above). According to the decision under appeal - which dealt with the same claim 1 which is at issue here - neither the dose range from "3 to 10 mg/kg of daptomycin" nor the dosage interval of "once every 48 hours" in conjunction with a dose of "3 to 10 mg/kg of daptomycin" could be derived directly and unambiguously from the application as filed.

2. According to Article 123(2) EPC the European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. In order to determine whether or not an amendment introduces new subject-matter it has to be established whether the overall change in the content of the application or patent results in the skilled person being presented with technical information which is not clearly and unambiguously set out in the application as filed, even when account is taken of matter which is implicit to a person skilled in the art (Case Law of the Boards of Appeal of the European Patent Office, 6th edition 2010, section III.A.1).

3. The board considers that the question whether or not claim 39 in combination with claim 42 discloses the dose of 3 to 10 mg/kg of daptomycin can be left open if it is manifestly apparent that the combination of that dose with a dosing interval of once every 48 hours for human patients cannot be derived directly and unambiguously from the application as filed.

4. The application as filed discloses on page 10, lines 12 to 14 the administration of daptomycin to a human patient in a dose of **3 to 12 mg/kg** every 24 to 48 hours. According to established case law of the Boards of Appeal the range "every 24 to 48 hours" is a direct and unambiguous disclosure of the two specifically named end points, i.e. "every 24 hours" and "every 48 hours" (cf Case Law of the Boards of Appeal of the European Patent Office", 6th edition 2010, section I.C.4.2.2, in particular decision T 240/95 of 6 July 1999, point 4.2 of the reasons). The question to be addressed is

whether the skilled person would have understood that the upper endpoint of the dosing interval, i.e. "every 48 hours", applies also to a dose of **3 to 10 mg/kg** of daptomycin.

5. The appellant asserts that the skilled reader would "unequivocally and instantly recognise" that if a dosage interval of 48 hours is applicable to the broader range of 3 to 12 mg/kg of daptomycin it must necessarily also be applicable to the narrower range of 3 to 10 mg/kg of daptomycin. No further argument why this would be the case was submitted by the appellant.

6. The board notes that the present invention addresses the problem of skeletal muscle toxicity at high doses of the antibiotic daptomycin. Whilst the dosing interval appeared to be the key determinant of muscle toxicity, C_{max} and/or AUC were found to be the key pharmacokinetic parameters associated with eradication of infection (see page 7, line 14 to page 9, line 4 of the application as filed). Based on these results the invention provides methods for administering the antibiotic daptomycin that minimize skeletal muscle toxicity. The application as filed discloses moreover that each of the dose and the dosage interval for the method is one that is safe and efficacious and further that longer dosing intervals can provide for administration of higher doses of daptomycin (see page 9, lines 7 to 13 of the application as filed). The board concludes therefrom that the application as filed discloses a functional relationship between the dosing interval and the dose of daptomycin both in terms of efficacy in treating the bacterial infection and in terms of safety as regards the problem of skeletal

muscle toxicity caused by the antibiotic. In the absence of any disclosure in the application as filed that a dose of 3 to 10 mg/kg of daptomycin is not only safe but also efficacious to treat a bacterial infection in a human patient if only administered once every 48 hours, the board sees no sound reason to accept the appellant's assertion that the skilled person would "unequivocally and instantly recognise" that the dosage interval of "every 48 hours" disclosed as the endpoint of a dosage interval for a dose range of 3 to 12 mg/kg daptomycin must necessarily also be applicable to lower doses of daptomycin and in particular to the range of 3 to 10 mg/kg daptomycin.

7. Accordingly, there is no clear and unambiguous disclosure in the application as filed for the feature "once every 48 hours" in combination with the further feature of claim 1 concerning the dosage regime claimed namely the dose of "3 to 10 mg/kg of daptomycin". Therefore the main request does not meet the requirements of Article 123(2) EPC.

Auxiliary request
Amendments (Articles 100(c) and 123(2) EPC)

8. Claim 1 of this request likewise concerns a dosage regime for treating a bacterial infection with the antibiotic daptomycin and differs from claim 1 of the main request in that the alternative "or once every 48 hours" is deleted (see section VII above). The decision under appeal dealt with the same claim 1 which is at issue here.

9. Claim 1 includes the feature "wherein said dose is repeatedly administered" which was present in claim 1 as granted and objected to by respondent II under Article 123(2) EPC (Article 100(c) EPC). The board shares the opposition division's view that the introduction of this feature into claim 1 does not contravene Article 123(2) EPC. Claim 49 as filed discloses that daptomycin is used "*at a dosage interval of once every 24 hours*" (see section III above). The board considers that from the indication of a "dosage interval" and of "once every 24 hours" the skilled person would understand directly and unambiguously that the dose of daptomycin is administered more than once, in other words, repeatedly. The board is not persuaded by respondent II's argument that "*repeatedly once every 24 hours*" can also mean "*that a drug is administered once every 24 hours for one week, then the intake of the drug is interrupted for one week followed by another week of taking the drug once every 24 hours. In other words the intake of the drug at a dosage interval of once every 24 hours can be conducted repeatedly, i.e. with* ***intermissions***." First of all the board notes that claim 1 reads: *"wherein said dose is repeatedly administered in a dosage interval of once every 24 hours"* and does not read "*repeatedly once every 24 hours*". Neither the wording of claim 1 nor the skilled person's common understanding regarding the administration of antibiotics warrant the interpretation advocated by respondent II. The introduction of the feature "*wherein said dose is repeatedly administered*" therefore does not result in new technical information which was not present in the application as filed.

10. According to the decision under appeal claim 1 however contravened Article 123(2) EPC because the dose range from "3 to 10 mg/kg of daptomycin" could not be derived directly and unambiguously from the application as filed. The opposition division held that the principles developed in decisions T 2/81 (cf OJ EPO 1982, 394) and T 201/83 (cf OJ EPO 1984, 481) were not applicable to the present case (see point 3.6 of the decision under appeal). The board comes to a different conclusion than the decision under appeal for the reasons set out below.

11. Firstly, the board agrees with the appellant that the principles developed in decision T 2/81, *supra*, are of relevance to the present case. In the case underlying decision T 2/81, *supra*, the application disclosed a range "*from 1 ppb to 10 ppm, preferably from 0.05 to 5 ppm.*". The question before the then competent board was whether the range from 0.05 to 10 ppm could be regarded as disclosed. The board held (see decision T 2/81, *supra*, point 3 of the reasons) as follows: "*The end-points are specifically named, and the two part-ranges of the general* [range] *lying outside the preferred range would be unequivocally and immediately apparent to the person skilled in the art. The simple sub-combination of these part-ranges of the concentration values as claimed would not merit novelty as "selection", so that the restriction does not represent any new subject-matter within the meaning of Article 123(2).*" As pointed out by the appellant, the board reached the claimed range of 0.05 to 10 ppm in two steps. In the first step, it considered that the two part-ranges of the general range lying outside the preferred range (i.e. 1 ppb to 0.05 ppm and 5 ppm to 10 ppm) would be unequivocally and immediately apparent to

the person skilled in the art. It then considered that no new matter was introduced by combining the preferred range (0.05 to 5 ppm) with the upper part-range (5 ppm to 10 ppm). According to the headnote 2 of decision T 2/81, *supra*,: "*The disclosure of a quantitative range of values (e.g. for concentrations or temperatures) together with an included preferred narrower range also directly discloses the two possible part-ranges lying within the overall range on either side of the narrower range. Hence a simple combination of the preferred narrower range and one of these part-ranges is also unequivocally derivable and is supported by the disclosure.*"

12. The respondents submitted that the principles developed in decision T 2/81, *supra*, were not applicable to situations where the range resulted from the combination of the lower limit of the general range with the lower limit of the preferred range, thus excluding the preferred range (see decision T 1170/02 of 1 March 2006, point 4.3 of the reasons).

13. However, the board agrees with the appellant that only the first step of the analysis carried out in decision T 2/81, *supra*, (see point 11 above) is necessary to arrive directly and unambiguously at the range of 3 to 10 mg/kg of daptomycin. In the present case, claim 49 as filed discloses the use of daptomycin for the manufacture of a medicament for treating a bacterial infection in a patient in need thereof, wherein a dose for such use is 3 to 75 mg/kg of daptomycin at a dosage interval of once every 24 hours. According to dependent claim 52 as filed the dose is 10 to 25 mg/kg. Applying the principles of decision T 2/81, *supra*, to the

present case, the two part-ranges lying within the overall range on either side of the narrower range and hence also directly and unambiguously disclosed to the person skilled in the art are i) a dose of 3 to 10 mg/kg of daptomycin and ii) a dose of 25 to 75 mg/kg of daptomycin. Claim 49 in combination with claim 52 as filed thus disclose the following four ranges of daptomycin doses - 3 to 75 mg/kg, 10 to 25 mg/kg, **3 to 10 mg/kg** and 25 to 75 mg/kg - at a dosage interval of once every 24 hours for treating a bacterial infection in a patient in need thereof. The board notes that this finding is in line with earlier case law, see e.g. decision T 727/00 of 22 June 2001, points 1.1.3, 1.1.4 and 2.1.2 of the reasons.

14. Claim 1 under consideration is directed to a dosage regime based on one of these four ranges for treating a **human** patient. The respondents submitted that the range of 3 to 10 mg/kg daptomycin was not directly and unambiguously disclosed in combination with human patients.

15. As pointed out above (see point 2), the relevant question to be addressed is whether or not restricting the dosage regime to human patients results in the skilled person being presented with technical information which is not clearly and unambiguously set out in the application as filed. The present invention addresses the problem of skeletal muscle toxicity at high doses of daptomycin (see page 5, lines 2 to 3 of the application as filed) and discloses that once-daily dosing can minimize daptomycin muscle toxicity, while potentially optimizing its antimicrobial efficacy (see page 8, lines 2 to 3, Figure 3 of the application as

filed). The disclosed methods can be used for human patients in clinical applications and in veterinary applications (see page 9, lines 9 to 10). The skilled person learns from the application as filed (see page 10, lines 12 to 15) that in a preferred embodiment daptomycin is administered to a human patient in a dose of 3 to 12 mg/kg every 24 to 48 hours and in an even more preferred embodiment, daptomycin is administered at a dose of 3, 4, 5, 6, 7, 8, 9, 10 or 12 mg/kg once every 24 hours. Furthermore, according to example 4 daptomycin is administered to human subjects at a dose of 4 mg/kg every 24 hours or at a dose of 6 mg/kg every 24 hours without any signs of muscle toxicity. The application as filed therefore points the skilled person to the use of a dose of 3 to 10 mg/kg of daptomycin for the treatment of a bacterial infection in human patients. The board concludes therefrom that the subject-matter of claim 1 does not present the skilled person with technical information which could not be derived clearly and unambiguously from the application as filed.

16. Secondly, the board agrees with the appellant that also the line of reasoning developed in decision T 201/83, *supra*, is of relevance to the present case. According to point 12 of the reasons of decision T 201/83 "*(…) an amendment of a concentration range in a claim for a mixture, such as an alloy, is allowable on the basis of a particular value described in a specific example, provided the skilled man could have readily recognised this value as not so closely associated with the other features of the example as to determine the effect of that embodiment of the invention as a whole in a unique manner and to a significant degree*".

17. In the case underlying decision T 201/83, *supra*, the fact that the value was disclosed in an example was insofar of relevance as the board had first to establish that the value disclosed in the context of an example could be considered separately from the other features disclosed in the example. This board cannot however derive from decision T 201/83, *supra*, the requirement that the value on which a sub-range is to be based has necessarily to be disclosed in an example. Rather it appears that what is required is that for the skilled person the value has to be recognisable as a singularity, as in decision T 201/83, *supra*, within or at the end of a range of possibilities which may mark an end-point for a particular sub-range (cf. decision T 201/83, *supra*, points 8 and 9 of the reasons).

18. In the present case page 10, lines 12 to 14 of the description as filed discloses that: "*In a more preferred embodiment, daptomycin is administered to a human patient in a dose of 3 to 12 mg/kg every 24 to 48 hours.*" Furthermore, page 10, lines 14 to 15 of the application as filed discloses that "*In an even more preferred embodiment, daptomycin is administered in a dose of 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12 mg/kg once every 24 hours.*" The board considers that this latter disclosure makes the dose of 10 mg/kg of daptomycin every 24 hours recognisable as a point within several possibilities. Therefore, in view of the observations above (see point 17) it can be used as the end-point to define a sub-range. From the following paragraph on page 10 it is moreover clear that the dosage regime applies to the treatment of a bacterial infection.

19. The respondents assert that the extraction of the value 10 mg/kg of daptomycin would correspond to a qualitative choice. However, a qualitative choice would require a selection from a variety of several possibilities wherein the selected possibility is qualitatively distinct from the other possibilities. In the present case the dose range of 3 to 12 mg/kg of daptomycin, each of the doses of the list of doses of 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12 mg/kg of daptomycin and hence also the dose of 10 mg/kg of daptomycin have been disclosed in connection with a dosing interval of 24 hours for the treatment of a bacterial infection in humans. Thus the range to be amended, i.e. 3 to 12 mg/kg of daptomycin, the value used for restricting the original range, i.e. 10 mg/kg of daptomycin, and the amended range, i.e. 3 to 10 mg/kg of daptomycin are all qualitatively identical. Therefore the restriction of the dose range from 3 to 12 mg/kg of daptomycin every 24 to 48 hours to 3 to 10 mg/kg of daptomycin every 24 hours is in the present case to be considered as a quantitative rather than a qualitative limitation of a dose range, i.e. it is a limitation that is directly and unambiguously derivable from the application as filed and that does not represent the skilled person with new technical information. Thus, the board concludes that page 10, lines 12 to 18 of the description as filed also provides a basis for claim 1 of the auxiliary request.

20. For the reasons indicated above (see points 8 to 19) the board decides that the auxiliary request complies with the requirements of Article 123(2) EPC (Article 100(c) EPC).

Remittal

21. As is clear from the wording of Article 111(1) EPC, and as the case-law of the Boards of Appeal has demonstrated, the decision whether or not to remit a case to the department of first instance is to be taken in the board's discretion according to the facts and circumstances of a particular case (see generally "Case Law of the Boards of Appeal of the European Patent Office", 6th edition 2010, VII.E.10 at pages 862 to 869). In the present case the decision of the opposition division was based only on one of the grounds of opposition in Article 100(c) EPC namely that the subject-matter of the European patent extends beyond the content of the application as filed. The opposition division did not decide on the other grounds of opposition relied on by the respondents - lack of novelty, lack of inventive step and insufficiency of disclosure (see section IV above) - although it did include in its written decision a short passage headed "*Obiter dictum*" in which it commented on some of those grounds.

22. Thus the first particular circumstance of this case which the board notes is that several of the grounds of opposition were not debated at the oral proceedings before, and not decided by, the opposition division. Those grounds were the subject of written proceedings and thus the parties are aware of each others' arguments thereon and each had an opportunity to make its case thereon in writing. It remains the fact however that these grounds have not been the subject of complete proceedings at first instance. This is a factor which the board considers would, on its own,

favour remittal.

23. The next particular circumstance of this case is the *obiter dictum* of the opposition division. Such *obiter dicta* are sometimes included in first instance decisions in order to avoid remittal (see decision T 473/98, OJ EPO 2001, 494 and "Case Law etc", *op. cit.*, VII.E.10.6, pages 868 to 869). In the present case the board notes, with no criticism of the opposition division, that the *obiter dictum* is short and precise and can be no more than a brief summary of the division's views on the grounds on which it did not decide (in fact, the *obiter dictum* states only that the claimed priorities appear to be invalid, that certain documents are thus part of the state of the art and that, regardless of the prior art to be considered, there is no inventive step due to the absence of certain data). Further, the appellant alleges that the opposition division did not consider its written submissions of 10 October 2008 in its *obiter dictum* while the respondents submit there is no reason to suppose that was the case. The board cannot make any conclusion as to whether or not the opposition division did or did not consider that particular submission - the point is entirely one of conjecture on both sides. In fact, it is impossible for the board (and indeed the parties) to know what submissions the opposition division did or did not have in mind when preparing its *obiter dictum*. All that can be said about the *obiter dictum* is that it is so short that it might be unsafe to conclude that it represents the opposition division's entire reasoning on the grounds it did not decide. The board concludes that the *obiter dictum* carries no weight as a factor either for or against

remittal.

24. As regards the parties' own views, the appellant requested remittal arguing that a patent proprietor was normally entitled to have issues considered by two instances whereas the respondents argued that the delay resulting from a remittal would cause them potential injustice. The first respondent requested the board to deal with the further grounds of opposition itself rather than remit. While the board does not accept that there is an entitlement, either normally or generally, to consideration of all issues at two instances, it would no doubt be preferable, other considerations apart, to ensure this happens in most if not all cases in the interest of justice. However, other and practical considerations cannot be ignored, and particularly not questions of delay which may in themselves cause injustice. If in the present case, in which the appeal has been pending since January 2009, the board could be satisfied that the further issues could be decided at appeal level with a real prospect of thereby being finalised sooner, then that factor would be weighed against the non-completion of those issues at first instance (see point 22 above). Unfortunately however, the board cannot be so satisfied.

25. As already mentioned, the present appeal was filed in January 2009. The oral proceedings were held on 10 April 2013 and the decision issued on 11 April 2013. The appeal proceedings thus lasted a little over four years. While it gives the board no pleasure to say so, four years is currently the average time taken to dispose of the appeals in its list of pending cases.

26. Against that background the board, in considering the respondents' argument that better justice would be done by the board itself reconvening at a later point in time, has to ask when that point in time would, or should, be? Quite clearly it could not, at the very earliest, be before any of the board's currently scheduled oral proceedings in other cases, and thus not in 2013. If, on the one hand, it should be before oral proceedings have taken place in all, or some, of the other cases in the board's list of pending cases, then clearly there would be a possible argument that the board was giving unfair preference to this case, in which oral proceedings on the issue giving rise to the appeal have already taken place and that issue has been decided, over other cases which have also been pending for four years and in which oral proceedings have not yet taken place. If, on the other hand, the board were now to treat this case as a newly-filed appeal for the purpose of the undecided issues, the parties might, indeed in the currently prevailing conditions probably would, have to wait another four years for a final decision. In the board's opinion, neither of those solutions would lead to better justice, and certainly not necessarily to an earlier final decision, as the respondents argued.

27. The board understands that currently the time taken to dispose of opposition proceedings is (as happened in the present case) about two years so assuming that, after a remittal, the opposition division gives this case no particular preference, the parties would have a decision in half the time they might have to wait for a decision from the board. Of course, if one or more parties were then to appeal, a further long wait for a

final decision might then ensue - just how long would depend on the length of the board's list of pending cases at that future point in time. But, in the absence of a further appeal, the likelihood must be that the parties will achieve a final decision sooner if there is a remittal and that is significant. Thus the board considers, not without regret, that the question of delay and the possible injustice delay may cause points, on balance, in favour of remittal.

28. Thus the particular circumstances of this case (see points 22 and 24 to 27 above) indicate that it would be appropriate for the board to exercise its discretion in favour of remitting the case to the first instance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the auxiliary request (filed as second auxiliary request with the proprietor's letter of 10 October 2008).

The Registrar The Chairman

P. Cremona C. Rennie-Smith