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**Datasheet for the decision  
of 6 September 2016**

**Case Number:** T 0489/13 - 3.3.07

**Application Number:** 06707141.5

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**IPC:** A61K9/20, A61K9/22, A61K9/36,  
A61K31/4412, A61P35/00

**Language of the proceedings:** EN

**Title of invention:**

PHARMACEUTICAL COMPOSITION COMPRISING AN OMEGA-CARBOXYARYL  
SUBSTITUTED DIPHENYL UREA FOR THE TREATMENT OF CANCER

**Patent Proprietor:**

Bayer HealthCare LLC

**Opponents:**

Altmann, Andreas  
Teva Pharmaceutical Industries Ltd.

**Relevant legal provisions:**

EPC Art. 54, 56, 111(1)  
RPBA Art. 12, 13

**Keyword:**

Novelty - main request (yes)

Inventive step - main request (no)

Late-filed evidence - admitted (no)

Auxiliary request 1 - admitted (yes)

Remittal (yes)



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Case Number: T 0489/13 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 6 September 2016**

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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
14 December 2012 concerning maintenance of the  
European Patent No. 1868579 in amended form.**

**Composition of the Board:**

**Chairman**            J. Riolo  
**Members:**            R. Hauss  
                             P. Schmitz

## Summary of Facts and Submissions

- I. European patent No. 1 868 579 was granted with twenty claims.

**Claim 1 as granted** reads as follows:

*"1. A pharmaceutical composition which is a tablet comprising the p-toluenesulfonic acid salt of 4{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-phenoxy}-pyridine-2-carboxylic acid methyl amide as active agent in a portion of at least 55% by weight of the composition."*

Hereinafter, the term "sorafenib" will refer to the amide compound named in claim 1 (i.e. the free base), and the term "sorafenib tosylate" will refer to its p-toluenesulfonic acid salt.

- II. Two notices of opposition were filed, opposing the patent under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was insufficiently disclosed and extended beyond the content of the application as filed.
- III. The patent proprietor requested the maintenance of the patent in amended form, filing an amended main request and several auxiliary requests. The claims of the **main request** differed from the claims as granted solely in the wording of a dependent claim.
- IV. The documents cited during the opposition proceedings included the following:
- D1: WO 03/068 228 A1
  - D4: Ritschel, Bauer-Brandl: Die Tablette, 2nd edition, ISBN 3-87193-228-0, pages 64, 65, 514-521 (2002)
  - D6: Drugs of the Future 27(12), 1141-1147 (2002)

D7: Clinical Cancer Research 10 (Suppl.), 6388s-6392s  
(2004)

D12A: Sorafenib-Vergleich DS BAY43-9006

D12B: Sorafenib-Vergleich DS BAY54-9085

D12A and D12B showing experimental data were filed by the patent proprietor with the letter replying to the notices of opposition.

- V. The appeal by opponent 1 lies from the decision of the opposition division, announced on 23 November 2012 and posted on 14 December 2012, finding that the patent as amended in the form of the main request met the requirements of the EPC.

According to the decision under appeal, the claims of the main request did not contain subject-matter extending beyond the content of the application as filed (Articles 100(c) and 123(2) EPC).

As far as disclosure was concerned, a person skilled in the art would be capable of preparing tablets according to the claims, of determining tablet hardness and of deciding whether a tablet was an immediate-release tablet (Article 100(b) EPC).

The claimed subject-matter was novel, since none of the cited prior-art documents disclosed a working example describing a sorafenib tosylate tablet, or any relative weight ranges for the active agent (Articles 100(a), 52(1) and 54 EPC).

Document D1 was regarded as the closest prior art. The subject-matter of claim 1 of the main request differed from the disclosure of document D1 in that the tablet contained the active agent at a concentration of at least 55% by weight. The technical problem to be solved was the provision of a new sorafenib pharmaceutical

form with improved release properties. The comparative data filed with the patent proprietor's letter of 30 January 2012 showed that sorafenib tosylate tablets according to the patent in suit had improved disintegration and dissolution properties when compared to equivalent sorafenib (free base) tablets. None of the cited prior-art documents disclosed or suggested that sorafenib tosylate tablets with at least 55% by weight of active agent would have improved release properties when compared to the equivalent sorafenib (free base) preparation (Articles 100(a), 52(1) and 56 EPC).

- VI. Opponent 1 (hereinafter, the appellant) lodged an appeal against that decision.
- VII. With the reply to the statement setting out the grounds of appeal, the patent proprietor (hereinafter, the respondent) submitted a main request and eight auxiliary requests. With a further letter dated 24 February 2015, the respondent submitted a corrected version of the fourth auxiliary request and new auxiliary request 3a.

The **main request** was identical to the main request of the first-instance proceedings (see points I and III above).

Claim 1 of the **first auxiliary request** reads as follows (the difference in comparison with claim 1 of the main request is underlined):

*"1. A pharmaceutical composition which is an immediate release tablet comprising the p-toluenesulfonic acid salt of 4{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-phenoxy}-pyridine-2-carboxylic acid methyl*

*amide as active agent in a portion of at least 55% by weight of the composition."*

VIII. Opponent 2 did not file an appeal, nor did it make any substantive submission during the appeal proceedings.

IX. The following documents were filed for the first time during the appeal proceedings:

D13: WO 2005/000284 A2

D14: Affidavit by Dr. Schückler of 5 September 2013

D14a: Bayer Product Report MRC-01045 of 26 June 2000

D15: Affidavit by Prof. Dr. Schubert-Zsilavec of  
20 August 2014

D16: M. Aulton (ed.), *Pharmaceutics: The Science of Dosage Form Design*, New York 1988, pages 246, 247, 249, 250

D17: Drug release of sorafenib tablets

D18: Compressibility plot of sorafenib tablets

D19: Disintegration time vs hardness of sorafenib  
tablets

D13 was filed by the appellant with the statement setting out the grounds of appeal. D14 and D14a were filed by the respondent with the reply to the statement of grounds. D15 and D16 were filed by the appellant with letters of 3 September 2014 and 14 April 2016. D17 to D19, reporting test results, were filed by the respondent with letter of 3 August 2016.

X. In a communication issued in preparation for oral proceedings and advising the parties of the board's preliminary opinion, the board mentioned the following points:

- On the issue of novelty, document D1 did not contain a specific disclosure of sorafenib tosylate in tablets at a concentration of over 55% by weight.



- With regard to the assessment of inventive step, the question as to which technical features distinguished the composition according to claim 1 of the main request from the disclosure of document D1 appeared to be a point of contention between the parties. The board was inclined to take the view that the sole difference was the drug load of at least 55%, in which case the comparative tests illustrated in documents D12A and D12B could not be pertinent, since they concerned a comparison between tablets containing sorafenib (free base) as opposed to sorafenib tosylate, rather than between tablets containing different concentrations of sorafenib tosylate. As it appeared credible that high drug loads facilitated administration and patient compliance, the technical problem to be solved might be seen in the provision of tablets of sorafenib tosylate permitting easy administration of a given dosage.

- The board saw no reason not to admit, *inter alia*, the first auxiliary request into the proceedings.

XI. Oral proceedings before the board were held on 6 September 2016.

XII. The appellant's arguments may be summarised as follows:

*Main request - novelty over document D1*

The composition defined in claim 1 of the main request lacked novelty over the disclosure of document D1, in particular claim 22 of D1, which individualised sorafenib tosylate, in combination with page 26 of that document disclosing tablets as an oral dosage form. The concentration range indicated in claim 1 could not establish novelty, because document D1 implicitly disclosed a concentration range of more than zero up to 100% of active agent, compared to which the claimed

concentration range of at least 55% by weight was neither narrow nor removed.

*Admission of documents D17 to D19*

Documents D17 to D19 (showing graphs) and the corresponding description of the respondent's comparative tests had been filed at a late stage of the appeal proceedings and were not *prima facie* relevant for the assessment of inventive step, since the comparative tests did not relate to the sole technical feature regarded by the board as distinguishing the composition of claim 1 of the main request from the disclosure of the closest prior art D1, viz. the drug load of at least 55% by weight.

*Main request - inventive step*

Document D1 disclosed tablets containing sorafenib tosylate as the active agent. If the claimed concentration range of at least 55% by weight of active agent was regarded as a distinguishing feature of the tablet according to claim 1, the objective technical problem was the provision of a tablet containing sorafenib tosylate permitting easy administration of a given dosage.

The person skilled in the art would have been aware that relatively high daily doses of sorafenib were to be administered (as disclosed in, *inter alia*, documents D6 and D7) and would thus naturally have sought to prepare tablets having a high drug load, to reduce the size or number of tablets required.

As apparent from document D4 (an extract from a textbook on tablet formulation), the technical solution of choosing a high drug load was a straightforward routine measure. Within that general context, the specific value of 55% by weight chosen for the lower

concentration limit was arbitrary and was not in itself linked to any surprising technical effect.

The respondent had not shown that there existed a prejudice in the art against formulating tablets of sorafenib tosylate at high drug loads, or that the person skilled in the art envisaging such tablets would have been deterred by an expectation of failure.

*Admission of auxiliary requests*

Since the various auxiliary requests pursued different lines of development of the claimed subject-matter, none of them was to be admitted into the proceedings, due to a lack of convergence. This criterion was to be applied irrespective of when the requests were filed.

XIII. The respondent's arguments may be summarised as follows:

*Main request - novelty over document D1*

More than one selection step was required within the disclosure of document D1, which mentioned many different compounds and routes of administration, in order to arrive at the subject-matter of claim 1 of the main request. Since document D1 listed various different oral dosage forms and did not mention that sorafenib tosylate was preferred, or that it was even suitable for oral administration, that document did not provide a direct and unambiguous disclosure of sorafenib tosylate tablets. The appellant's argument concerning overlapping concentration ranges was not applicable, because document D1 did not disclose any value at all for the concentration of the active agent. That total lack of disclosure did not correspond to

an implicit suggestion to work in the entire concentration range of more than zero up to 100%.

*Admission of documents D17 to D19*

Documents D17 to D19 had been prepared in response to the appellant's arguments commenting on the test results shown in documents D12A and D12B. The data reported in documents D17 to D19 were relevant to the issue of inventive step of the main request because they showed that, in comparison with other forms of sorafenib, the tosylate salt was exceptional as it provided particularly favourable properties in respect of compressibility and drug release. Satisfactory tablets with a drug load of at least 55% could only be provided with the tosylate salt, since difficulties were encountered when using other forms of sorafenib. The comparison with other forms of sorafenib was relevant, as the starting-point for the assessment of inventive step should be claim 21 of document D1 relating to sorafenib (free base) and its salts, rather than claim 22 relating to the tosylate salt.

*Main request - inventive step*

Clinical studies on humans, as mentioned for instance in document D7, which had been published after document D1, still used sorafenib (free base) and not the tosylate salt for oral administration. Therefore the assessment of inventive step should start from the embodiment of document D1 relating to sorafenib (claim 21 in D1), not sorafenib tosylate (claim 22 in D1).

Starting from document D1, the objective technical problem was thus the provision of a sorafenib dosage form for oral administration which presented improved

pharmaceutical properties while ensuring good patient compliance.

Based on a comparison of the dissolution of tablets containing sorafenib and sorafenib tosylate (D12A, D12B as discussed in the letter of 20 November 2013 on pages 13 to 14), and on the statements in the patent in suit mentioning satisfactory release properties and hardness of the tablets of the invention, it could be concluded that the technical problem was solved.

Using a high drug load in a solid oral dosage form in order to achieve the desired ease of administration meant less flexibility for the formulator regarding the optimisation of properties with the help of excipients. Therefore the person skilled in the art would not have had a reasonable expectation of success when considering the development of tablets containing a high load of sorafenib tosylate. It was surprising that tablets containing high loads of sorafenib tosylate had acceptable tablet characteristics in terms of their dissolution properties and hardness, in particular since other salt forms of sorafenib and the free base did not provide such satisfactory results. Moreover, since these difficulties had not been recognised in the prior art, the skilled person would have had no incentive to consider sorafenib tosylate tablets.

*Admission of auxiliary request 1*

The same request had been filed with the respondent's reply to the grounds of appeal and had been present also in the first-instance proceedings. Thus there existed no reason for the board not to admit it into the proceedings.

XIV. The appellant (opponent 1) requested that the decision under appeal be set aside and that the patent be revoked.

He also requested that none of the respondent's auxiliary requests be admitted into the proceedings, and that document D14, pages 9, 12, 73 and 74 of document D14a and documents D17 to D19 not be admitted into the proceedings.

The appellant furthermore requested that the case not be remitted to the opposition division, but be decided by the board.

XV. The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained on the basis of the main request as filed with the reply to the statement setting out the grounds of appeal.

As an auxiliary measure, it requested that the patent be maintained on the basis of one of auxiliary requests 1 to 3, 3a or 4 to 8, wherein auxiliary requests 1 to 3 and 5 to 8 had been filed with the respondent's reply to the statement setting out the grounds of appeal, and auxiliary requests 3a and 4 had been filed with letter of 24 February 2015.

The respondent also requested that, if the decision under appeal were to be set aside, the case be remitted to the opposition division for a decision on the merit of the auxiliary requests.

Furthermore, the respondent requested that documents D13, D15 and D16 not be admitted into the proceedings.

XVI. Opponent 2 (party to the proceedings as of right pursuant to Article 107 EPC) did not submit any request.

## **Reasons for the Decision**

1. Main request - novelty over D1
  - 1.1 Document D1 concerns aryl ureas with angiogenesis-inhibiting activity. More specifically, independent claim 22 of D1 is directed to a method of treating diseases mediated by the VEGF-induced signal transduction pathway comprising administering sorafenib tosylate. It is mentioned in the description that the compounds according to D1 may be administered orally (D1: page 25, bottom paragraph) and that compositions intended for oral use may be in the form of tablets (D1: page 26, first full paragraph). By combination, D1 thus discloses tablets as a dosage form of sorafenib tosylate. The document remains silent, however, regarding the concentration of sorafenib tosylate to be used in a tablet formulation.
  - 1.2 The appellant contended that, nevertheless, the concentration range of at least 55% by weight as specified in claim 1 of the main request could not establish novelty over a concentration range of more than zero to 100%, implicitly disclosed in document D1.
  - 1.3 The board considers that the appellant's argument must fail, if only because the mere fact that no specific value or concentration range is mentioned in document D1, i.e. the absence of any information on that point, cannot be equated with a direct and unambiguous implicit disclosure of a range of from more than zero to 100%. Rather, it must be concluded that document D1 simply does not provide any information

with regard to the concentration and cannot therefore anticipate the range of at least 55% by weight.

1.4 As a consequence, the subject-matter of claim 1 of the main request is novel over document D1 (Articles 100(a), 52(1) and 54 EPC).

2. Main request - inventive step and admission of documents D17 to D19

*Problem-and-solution approach*

2.1 Inventive step is assessed according to the problem-and-solution-approach, employed as a rule by the boards for assessing inventive step. This involves

(a) identifying a suitable starting point for the inventor in the prior art, in line with the purpose and technical features of the claimed subject-matter,

(b) assessing the technical effects achieved by the claimed subject-matter when compared with that starting point,

(c) defining the objective technical problem on the basis of the technical effects actually achieved,

(d) examining whether or not the skilled person, having regard to the state of the art within the meaning of Article 54(2) EPC, would have suggested the claimed combination of technical features in order to solve the objective technical problem.

Within the framework of the problem-and-solution approach, an alleged advantage in the form of a technical effect can be taken into account when determining the objective technical problem only if said effect is reflected in the technical features of the claim and is based on a feature distinguishing the



claimed subject-matter from the disclosure of the starting point in the prior art.

*Patent in suit*

- 2.2 Sorafenib and its salts were known to be of potential use in the treatment of proliferative diseases. The patent in suit aims to provide an oral dosage form of sorafenib which, while suitable for providing effective plasma levels of the active agent, is easy to administer and therefore facilitates patient compliance. A tablet should not be too large for comfortable swallowing, and it should not be necessary to administer more than two tablets at a time (see paragraphs [0002] to [0005] of the patent in suit).
- 2.3 Claim 1 of the main request is directed to tablets comprising at least 55% by weight of sorafenib tosylate.

*Starting point in the prior art*

- 2.4 It was common ground between the parties that document D1 was suitable as a starting point for the assessment of inventive step. The board sees no reason for selecting a different starting point.

*Distinguishing feature*

- 2.5 As established in section 1 above, the feature distinguishing the tablets according to claim 1 of the main request from the disclosure of document D1 (see claim 22 and page 26, first full paragraph of D1) is the drug load of at least 55% by weight.
- 2.6 The respondent contended that document D1 did not provide a direct and unambiguous disclosure of sorafenib tosylate in tablets, since sorafenib tosylate

was not the only compound disclosed in D1 and not even in independent claim 21 (directed to a method of treatment comprising administering sorafenib or a pharmaceutically acceptable salt thereof), and the document did not mention that sorafenib tosylate was suitable for oral administration in tablets.

2.7 The board does not find the respondent's arguments convincing.

Firstly, sorafenib tosylate is individualised in independent claim 22 of document D1. Thus this embodiment is disclosed directly, without requiring a selection from a group of compounds.

Secondly, document D1 provides a general disclosure of possible dosage forms, in particular tablets. Tablets are, in any case, known in the art to be typically the most preferred commercial dosage form and one which can feasibly be prepared with known techniques. Hence, in the absence of any statement to the contrary indicating a reason why sorafenib tosylate should not be formulated or administered in tablet form, the person skilled in the art reading document D1 would understand that the embodiment relating to sorafenib tosylate can be combined with the general disclosure relating to tablets. That combination only requires one selection among the dosage forms mentioned in D1.

2.8 Hence, the board considers that document D1 discloses tablet forms of sorafenib tosylate by combination of claim 22 with the general disclosure in the description on page 26 (first full paragraph), and that the sole feature distinguishing the tablets according to claim 1 of the main request from those of document D1 is the drug load of at least 55% by weight.

*Technical effects achieved*

2.9 As regards the technical effects achieved by the claimed subject-matter when compared with the disclosure of document D1, several were mentioned in the present case, viz.

- ease of administration and patient compliance and
- improved properties obtained specifically with the tosylate salt form at high drug loads.

2.10 Ease of administration and patient compliance

2.10.1 It was known from the prior art that the recommended oral daily dose of sorafenib can be in the range of several hundred milligrams, e.g. 400 mg twice daily (see document D6: page 1144, column 2, page 1145, column 1 and document D7: abstract; "BAY-43-9006" mentioned in those documents being another name for sorafenib). The drug will thus provide a certain bulk of solid powder to be administered, whether as free base or in the form of the tosylate salt.

2.10.2 It is therefore credible that formulating the tablets with a high drug load facilitates administration and, consequently, patient compliance, since smaller and/or fewer tablets will then be needed for administering a given dose of the drug.

2.11 Improved properties obtained specifically with the tosylate salt form at high drug loads

2.11.1 The respondent argued that, in addition to ease of administration, surprisingly improved pharmaceutical properties were obtained with sorafenib tosylate at high drug loads of at least 55% by weight; in particular, good dissolution properties and tablet hardness sufficient for commercial use.

- (a) In that context, reference was made to documents 12A and 12B and to paragraphs [0008] and [0098] of the patent in suit.
- (b) The respondent furthermore referred to documents D17 to D19 and submitted that the graphs presented in those documents, together with the description of the corresponding experiments provided with letter of 3 August 2016, showed that sorafenib tosylate was exceptional in its physico-chemical properties and that the formulation of tablets with high drug loads of over 55% by weight which were satisfactory in respect of dissolution and hardness was possible only with sorafenib tosylate but not with other forms of sorafenib.

2.11.2 ad (a)

Paragraph [0098] of the patent in suit refers to the hardness of an example formulation of sorafenib tosylate tablets described in the preceding paragraphs, but not in the context of comparative tests (see example 1 in paragraphs [0090] to [0099]). Thus, that passage does not relate to an assessment of the technical effects achieved by the claimed subject-matter when compared with the prior art, and is therefore not relevant. The same applies to paragraph [0008] of the patent specification; this merely states, without any supporting data, that the tablets according to the invention surprisingly show various favourable properties.

Documents 12A and 12B and the corresponding test report (provided in the respondent's letters replying to the notice of opposition and to the grounds of appeal) describe a comparison between the properties of similarly composed tablets containing sorafenib

tosylate (BAY 54-9085) in one case and sorafenib (BAY 43-9006, comparative sample) in the other. The board observes that such a comparison is not based on the sole technical feature distinguishing the claimed tablets from the disclosure of document D1, viz. the concentration of sorafenib tosylate in the tablet. For that reason, the results observed in that comparison cannot be used as a basis for defining the objective technical problem. In other words, the inventive step cannot be based on the selection of sorafenib tosylate, since the starting point in the prior art already uses sorafenib tosylate.

ad (b)

Documents D17 to D19 were filed by the respondent at an advanced stage of the appeal proceedings, viz. with letter of 3 August 2016 about a month before the date of the oral proceedings.

According to Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA), any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion. Thus the admission of documents D17 to D19 is subject to the board's discretion.

Documents D17 to D19 and the respondent's letter of 3 August 2016 provide data obtained in experiments investigating the influence of different salt forms of sorafenib (tosylate, hydrochloride, sulfate, trifluoroacetate and oxalate) on tablet properties (drug release, hardness, disintegration time), compared to free base.

The respondent argued that these data were submitted in response to the appellant's arguments. In addition to the principal argument that documents D12A and D12B did

not provide a comparison of tablets which differed in the concentration of sorafenib tosylate, the appellant had also argued that it was in any case not surprising that a salt form of sorafenib provided more favourable dissolution properties than the poorly soluble free base, and that the comparison was not conclusive because it was based on tablet samples which differed not only in the form and amount of active agent but also in the concentration of microcrystalline cellulose employed as an excipient. The new tests tried to address these objections.

Irrespective of whether the test results of D17 to D18 were provided in direct response to new arguments, the board observes that the new data still do not provide a comparison between tablets containing different concentrations of sorafenib tosylate and that these data are thus not *prima facie* relevant for determining the objective technical problem.

Nor indeed do those tests show, as argued by the respondent, that sorafenib (free base) or its salts other than the tosylate are unsuitable for use in tablet formulations containing at least 55% by weight of active agent. The data associated with D17 to D19 may suggest that different forms of sorafenib behave differently, which is in itself not surprising, but there is no evidence of the differences being critical or even significant.

Since documents D17 to D19 are therefore not considered *prima facie* relevant for assessing the inventive step of the main request, the documents were not admitted into the proceedings pursuant to Article 13(1) RPBA.

- 2.11.3 It follows from the considerations under points 2.11.1 and 2.11.2 that the alleged technical effect of

surprisingly improved properties cannot be taken into account in the formulation of the technical problem.

- 2.12 The technical effect which must be considered in the definition of the technical problem is ease of administration of a given dosage.

*Technical problem and solution*

- 2.13 Thus the technical problem to be solved, based on the drug load of at least 55% required by claim 1, is the provision of tablets of sorafenib tosylate permitting easy administration of a given dose.

- 2.14 It was not contested by the appellant that the tablet composition according to claim 1 of the main request is indeed a solution to that technical problem (see also the considerations under points 2.10.1 and 2.10.2 above).

*Obviousness of the solution*

- 2.15 Faced with the aforementioned technical problem, it is in principle straightforward and routine for the person skilled in the art to seek to administer a required dose either with small tablets and/or with few tablets, which can obviously be achieved by selecting high drug loads per tablet. For instance, document D4, which is a textbook on tablet development, mentions that in the case of tablets which are to be swallowed it will generally be the aim of the formulator to achieve small tablet sizes. For amounts from 150 mg active ingredient per tablet, typical drug loadings are well over 50% by weight (D4: page 68, last complete paragraph and page 65: table 2/1).

- 2.16 No technical prejudice against using high drug loads of sorafenib or its salts in tablets is known from the available prior art.
- 2.17 Under these circumstances, the board concludes that the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.
3. Admission of the first auxiliary request
- 3.1 The first auxiliary request was filed with the respondent's reply to the statement setting out the grounds of appeal. Pursuant to Article 12(1), 12(2), and 12(4), second half-sentence, RPBA, it is thus, in principle, to be taken into account in the proceedings.
- 3.2 Moreover, the board sees no reason not to admit this request into the proceedings under Article 12(4), first half-sentence, RPBA, since the same request was also previously present, and was not rejected, in the first-instance proceedings (see the first auxiliary request filed with letter of 18 September 2012).
- The appellant's objection concerning an alleged lack of convergence can, in any case, not apply to the first auxiliary request, which in claim 1 is restricted to immediate release tablets and thus has a narrower scope than the main request. The further independent claims refer to the composition of claim 1 and are identical in both requests.
4. Remittal (Article 111(1) EPC)
- 4.1 A further limiting feature has been introduced into claim 1 of the first auxiliary request, specifying that the claimed tablet is an immediate release formulation (see point VII above).



- 4.2 During oral proceedings before the board it was discussed whether the auxiliary requests were to be admitted into the proceedings and, if they were admitted, how they would change the discussion on inventive step. As became apparent in a preliminary discussion of the first auxiliary request, the focus of the discussion would shift to the feature of immediate release as the alleged basis of an invention. In that context, the respondent submitted that only sorafenib tosylate, as opposed to other forms of sorafenib, was suitable to provide satisfactory immediate release tablets with the claimed high concentration of active agent.
- 4.3 Since the substantive basis for the discussion of inventive step of the first auxiliary request has changed in comparison with the main request, the board finds it appropriate to remit the case to the opposition division to permit consideration of the case by two instances.
5. Admission of further documents
  - 5.1 At the outset of the oral proceedings before the board, the appellant requested that document D14 and certain parts of document D14a not be admitted into the proceedings, while the respondent requested that documents D13, D15 and D16 not be admitted.
  - 5.2 Since the parties did not subsequently rely on those documents in the discussion of inventive step of the main request which determined the present outcome, a decision on their admission into the proceedings is not required.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated