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# Datasheet for the decision of 17 February 2022

**Case Number:** T 0851/19 - 3.3.07

**Application Number:** 06707141.5

**Publication Number:** 1868579

**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

**Opponent:**
Altmann, Andreas

**Headword:**
Tablets comprising Sorafenib Tosylate / BAYER HEALTHCARE LLC

**Relevant legal provisions:**
EPC Art. 56
RPBA 2020 Art. 13(2)

**Keyword:**

Representation - change of professional representative
Inventive step - (no)
Late-filed auxiliary requests - admitted (no)

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**Case Number: T 0851/19 - 3.3.07**

# D E C I S I O N
# of Technical Board of Appeal 3.3.07
# of 17 February 2022

| | |
|---|---|
| **Appellant:** (Opponent 1) | Altmann, Andreas<br>Herzog Fiesser & Partner<br>Patentanwälte<br>Isartorplatz 1<br>80331 München (DE) |
| **Representative:** | Elkington and Fife LLP<br>Prospect House<br>8 Pembroke Road<br>Sevenoaks, Kent TN13 1XR (GB) |
| **Respondent:** (Patent Proprietor) | Bayer HealthCare LLC<br>100 Bayer Boulevard<br>Whippany, NJ 07981 (US) |
| **Representative:** | Weickmann & Weickmann PartmbB<br>Postfach 860 820<br>81635 München (DE) |
| **Former opponent:** (Opponent 2) | Teva Pharmaceutical Industries Ltd.<br>5 Basel Street<br>Petach Tikva 49131 (IL) |
| **Representative:** | Lederer & Keller Patentanwälte<br>Partnerschaft mbB<br>Unsöldstraße 2<br>80538 München (DE) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 11 January 2019 concerning maintenance of the European Patent No. 1868579 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | D. Boulois |
| **Members:** | E. Duval |
| | Y. Podbielski |

## Summary of Facts and Submissions

I. European patent 1 868 579 (hereinafter "the patent") was granted on the basis of 20 claims.

Claim 1 of the patent as granted related to a pharmaceutical composition which is a tablet comprising sorafenib tosylate as active agent in a portion of at least 55% by weight of the composition.

Sorafenib tosylate stands for the *p*-toluenesulfonic acid salt of 4{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-phenoxy}-pyridine-2-carboxylic acid methyl amide.

II. The following documents are cited in this decision:

D1: WO 03/68228 A1
D4: Ritschel, W.A., Bauer-Brandl, A., "Die Tablette", Editio Cantor Verlag Aulendorf, 2002, pp. 64-65 and pp. 514-521
D5: WO 03/090720 A1
D6: "BAY-43-9006", Drugs of the Future, 2002, 27(12) pp. 1141-1147
D7: Ahmad, T. and Eisen, T., "Kinase Inhibition with BAY 43-9006, In Renal Cell Carcinoma" Clinical Cancer Research, 2004, vol. 10, pp. 6388-6392
D12: Experimental data: Sorafenib-Vergleich DS BAY43-9006 (A) and BAY54-9085 (B)
D13: WO 2005/000284 A2
D15: Affidavit by Prof. Dr. Schubert-Zsilavecz of 20 August 2014
D17: Drug release of sorafenib tablets
D18: Compressibility plot of sorafenib tablets

D19: Disintegration time vs hardness of sorafenib tablets
D20: Mangilal et al., "Formulation and evaluation of sorafenib tosylate, immediate release film coated tablets for renal cancer", Wipps, vol. 4, issue 06, 2015, pp. 841-858
D21: Lowinger et al., "Design and discovery of Small Molecules targeting Raf-1 kinase", Current Pharmaceutical Design, 2002, 8, pp. 2269-2278

III. Two oppositions were filed against European patent 1 868 579 (hereinafter "the patent") on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

IV. The opposition division, in a first interlocutory decision posted on 14 December 2012, found that the patent as amended in the form of the main request, filed on 30 January 2012, met the requirements of the EPC. Claim 1 of this main request was identical to claim 1 as granted.

V. This first decision of the opposition division was set aside by the Board in decision T 489/13. The Board's decision was based on the same main request and on auxiliary request 1 filed on 20 November 2013. Claim 1 of auxiliary request 1 read as follows:

"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."

VI. The Board came in particular to the following conclusions:

(a) The main request did not meet the requirements of inventive step. Starting from document D1, the technical problem was the provision of tablets of sorafenib tosylate permitting easy administration of a given dose. The claimed solution did not involve an inventive step in light of D4.

(b) Regarding auxiliary request 1, as a result of the addition of the feature "immediate release" to claim 1, the substantive basis for the discussion of inventive step had changed. Accordingly, the Board decided to remit the case to the opposition division for further prosecution.

VII. The opposition division took a (second) interlocutory decision, posted on 11 January 2019, and finding that, on the basis of same auxiliary request 1, the patent met the requirements of the EPC.

VIII. In particular, the opposition division decided that:

(a) D17-D21 were admitted into the proceedings.

(b) Starting from the closest prior art D1, the subject-matter of claim 1 of auxiliary request 1 differed mainly by the high load of the tablet of more than 55 wt% and the fact that the pharmaceutical composition was an immediate release tablet. The problem was to provide immediate release tablets of sorafenib tosylate having an exceptional high load. The claimed solution was not obvious in light of D1 and D4.

IX. The present appeal was filed by opponent 1 (the appellant) against this second decision of the opposition division.

X. With its reply to the appeal, filed on 14 August 2019, the patent proprietor (the respondent) defended its case on the basis of the same auxiliary request 1 (i.e. filed on 19 September 2017 and identical to auxiliary request 1 filed on 20 November 2013), and alternatively on the basis of auxiliary requests 2-9 filed on 19 September 2017.

XI. Opponent 2 withdrew its opposition by letter dated 22 September 2020.

XII. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA issued on 11 November 2021.

XIII. By letter dated 11 January 2022, the respondent additionally filed auxiliary requests 1A and 6A.

XIV. Oral proceedings took place before the Board on 17 February 2022. During the oral proceedings, the respondent withdrew auxiliary requests 2, 5, 7 and 9. The requests of the parties at the end of the oral proceedings were the following:

The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety. The appellant further requested that D17-D19 not be admitted into the proceedings. They also requested that auxiliary requests 1A and 6A not be admitted into the proceedings.

The respondent requested that the appeal be dismissed, i.e. that the patent be maintained on the basis of auxiliary request 1 filed on 19 September 2017, or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 3, 4, 6 or 8 filed on 19 September 2017 or of auxiliary request 1A or 6A filed on 11 January 2022. The respondent further requested that documents D13, D15, D20 and D21 not be admitted into the proceedings.

Since opponent 2 withdrew its opposition, they were not party any more to the appeal proceedings.

XV. Claim 1 of auxiliary requests 1A, 3, 4, 6, 6A and 8 differed respectively from claim 1 of auxiliary request 1 (see V. above) by the following limitations:

Claim 1 of auxiliary requests 1A resulted from the addition of the feature "showing a hardness of more than 80 N".

Claim 1 of auxiliary request 3 specified that the composition comprised "a filler in a portion of from 3 to 20%, a disintegrant in a portion of from 5 to 12%, a binder in a portion of from 0.5 to 8%, a lubricant in a portion of from 0.2 to 0.8% and a surfactant in a portion of from 0.1 to 2% by weight of the composition".

Claim 1 of auxiliary request 4 specified that the composition comprised "microcrystalline cellulose as a filler in a portion of from 3 to 20%, croscarmellose sodium as a disintegrant in a portion of from 5 to 12%, hypromellose as a binder in a portion of from 0.5 to 8%, magnesium stearate as a lubricant in a portion of from 0.2 to 0.8% and sodium lauryl sulfate as a

surfactant in a portion of from 0.1 to 2% by weight of the composition".

In claim 1 of auxiliary request 6, the content in sorafenib tosylate was amended to "at least 75% by weight of the composition".

Claim 1 of auxiliary request 6A combined the amendments of auxiliary requests 1A and 6.

Claim 1 of auxiliary request 8 combined the amendments of auxiliary requests 4 and 6.

XVI. The arguments of the appellant may be summarised as follows:

(a) Transfer of the appellant's representation

The letter dated 12 August 2019 did not imply any withdrawal of the appeal, but only announced a change of representation.

(b) Admittance of documents D13, D15 and D17-D21

The opposition division did not correctly exercise its power of discretion when admitting D17-D19 into the proceedings despite their lack of relevance. Hence D17-D19 should not be admitted into the appeal proceedings.

D13, D20 and D21 had been admitted into the proceedings by the opposition division. Accordingly, the Board's power to hold inadmissible evidence which could have been presented or was not admitted in the first instance proceedings (under Article 12(4) RPBA 2007) did not apply here.

(c) Admittance of auxiliary requests 1A and 6A

Auxiliary requests 1A and 6A constituted an amendment to the respondent's case in the sense of Article 13(2) RPBA 2020 which was not justified by any exceptional circumstances.

(d) Inventive step

The closest prior art D1 disclosed immediate release tablets comprising sorafenib tosylate. The immediate release was not a distinguishing feature, because it was disclosed on page 26 of D1 in the context of tablets. In any case, the tosylate salt was not a distinguishing feature over D1. Hence, the data in D12 and D17-D19 did not reveal any combined effect of using a high drug load with an immediate release form of tablet.

The technical problem was the provision of a tablet with an improved patient compliance. The claimed solution was a tablet having a drug load of greater than 55% by weight.

It was known that the recommended oral daily dose of sorafenib was a high dosage such as 400 mg twice a day. It was straightforward for the person skilled in the art to seek to administer a required dose with few tablets or small tablets by selecting high drug loads per tablet. D4 taught such high drug loads in the context of any kind of tablets and therefore also for immediate release tablets, which represented the most common type of oral tablets. There was no prejudice in the prior art and no technical difficulties in combining the feature "immediate release" with the feature "high drug load" of sorafenib tosylate.

Accordingly, auxiliary request 1 did not satisfy the requirements of inventive step.

Auxiliary requests 3 and 4 set out specified amounts of well-known tablet excipients, shown e.g. in D1 (see page 26), without any demonstrated unexpected advantage. Consequently, these requests added nothing to inventive step.

Auxiliary requests 6 and 8 raised the drug content to at least 75% by weight, which was obvious for the same reasons as auxiliary request 1. D4 showed that even higher drug loads were common in tablets.

XVII. The arguments of the respondent may be summarised as follows:

(a) Transfer of the appellant's representation

The wording of the appellant's letter dated 12 August 2019 was ambiguous and might imply a withdrawal of the opposition or the appeal. It was questionable whether Dr Mullen was duly authorised to represent the appellant.

(b) Admittance of documents D13, D15 and D17-D21

D13 was late filed and not *prima facie* highly relevant. The provision of D20 after remittal of the case from the Boards of Appeal was a procedural abuse. As to D21, it was also *prima facie* not highly relevant. Hence these documents should not be admitted into the proceedings.

The opposition division had correctly found the tests reported in D17-D19 to be relevant in the assessment of

inventive step, and rightly admitted D17-D19 into the proceedings.

(c) Admittance of auxiliary requests 1A and 6A

Auxiliary requests 1A and 6A each consisted of a sole claim which was a combination of granted claims or claims of auxiliary request 1 and 6, and thus were under investigation from the beginning of the opposition proceedings. They did not require any investigative effort and had been filed more than one month before the oral proceedings in direct reaction to the Board´s preliminary opinion.

(d) Inventive step

D1 disclosed sorafenib free base, sorafenib salts and sorafenib tosylate as equivalently suitable active agents. These active agents could be administered by means of different administration modes and dosage forms. The passage of D1 relating to solid, rapidly released forms (see page 26, lines 19-20) was in no way linked to tablets. The claimed invention differed from D1 in that the sorafenib tablet:
- had a drug load of at least 55% by weight, and
- was an immediate release tablet.
The technical problem was the provision of solid dosage forms of sorafenib as active agent that have improved release characteristics, bioavailability and stability and simultaneously account for an improved patient compliance.

The skilled person formulating solid dosage forms such as tablets was confronted with the contradicting requirements of achieving a certain hardness but also a fast disintegration. In a high load tablet, these

requirements could no easily be balanced by excipients. The skilled person could not foresee that sorafenib tosylate would be ideally suitable to provide stable tablets having the required drug load and release profile as compared to e.g. sorafenib free base or other sorafenib salts (as shown in D12a, D12b and D17-D19). Hence auxiliary request 1 met the requirements of inventive step.

Regarding auxiliary requests 3 and 4, the properties achieved by the claimed high loading, immediate release tablet when choosing the tosylate salt of sorafenib were surprising considering the unusually low amount of disintegrant specified in claim 1.

The lower limit of 75 wt% sorafenib tosylate defined in claim 1 of auxiliary requests 6 and 8 was four times higher than the amounts used in D13. D13 thus taught away from the claimed invention.

## Reasons for the Decision

1. Transfer of the appellant's representation

Dr Andreas Altmann filed an opposition against the patent in suit. Dr Altmann is both the opponent and a professional representative. In a letter dated 12 August 2019, signed by Dr Altmann, the following was stated: "The representation in the above-mentioned appeal procedure by our law firm has been finished. All further correspondence shall be sent [...] to Elkington and Fife LLP [...]". On the day of the oral proceedings Dr Mullen, a European patent attorney with Elkington and Fife LLP, who had also signed the appellant's submissions of 28 November 2019 and had been announced

to attend the oral proceedings, appeared as representative for the appellant.

The respondent questioned that Dr Mullen was duly authorised to undertake the representation for the appellant. The wording of the letter dated 12 August 2019 where it was stated that "The representation in the above-mentioned appeal procedure by our law firm has been finished" was in the respondent's view not unambiguous and might imply a withdrawal of the opposition or the appeal.

The Board cannot follow this argument. An opposition or an appeal can only be withdrawn if such a request is expressed by the opponent or appellant in unambiguous terms. The above-mentioned letter clearly does not lend itself to such an interpretation. Furthermore, one of the usual ways of transferring representation from one attorney or law firm to another is precisely what has happened in this case: that one attorney or firm indicates that they lay down representation and give the details of the new representatives to the EPO. Dr Mullen confirmed during the oral proceedings that he was duly authorised to represent the appellant. The Board has no reason to doubt that.

2. Admittance of documents D13, D15 and D17-D21

2.1 The appellant objected to the admittance of D17-D19 into the appeal proceedings. The respondent submitted that D13, D15, D20 and D21 should not be admitted into the proceedings either.

For the following reasons, the Board takes the view that all of these documents are part of the appeal proceedings.

2.2 D17-D21 were all presented during the first instance proceedings and admitted by the opposition division (see the decision under appeal, points 3.3.1-3.5 of the reasons). The opposition division referred explicitly to D20 and D17 in its reasoning on the issues of sufficiency of disclosure and inventive step (see points 5 and 6.4 of the reasons). The appellant and respondent refer to D20-D21 and D17-D19 respectively in their grounds of appeal (see e.g. page 6 and 16) and reply thereto (see pages 8-10).

Consequently, since D17-D21 are neither evidence which could have been presented in the first instance proceedings (i.e. but was not), nor evidence which was not admitted, the discretionary power to hold such evidence inadmissible under Article 12(4) RPBA 2007 does not apply to these documents. Accordingly, these documents are to be taken into account in the appeal proceedings.

2.3 D13 and D15 were filed during the earlier appeal proceedings leading to decision T 489/13. Both decision T 489/13 (see point 5 of the reasons) and the appealed decision (see point 3.2.1 of the reasons) leave their admittance undecided. Hence there is no decision not to admit D13 or D15 in the proceedings.

Consequently, as for documents D17-D21, the discretionary power to hold such evidence inadmissible under Article 12(4) RPBA 2007 does not apply to D13 and D15. The Board considers that D13 and D15 are to be taken into account in the appeal proceedings.

3. Auxiliary request 1, inventive step

3.1 Auxiliary request 1 is the appellant's highest ranking request.

3.2 Claim 1 of auxiliary request 1 pertains to immediate release tablets comprising at least 55 wt% sorafenib tosylate. The objective of the invention is to provide a pharmaceutical sorafenib composition which should be applied no more than three times a day in order to achieve an effective plasma level of sorafenib. The tablet should not be too large, to provide good swallowing, and no more than two should have to be taken at the same time (see paragraph [0005] of the patent).

3.3 Both parties consider D1 to be a suitable starting point for the assessment of inventive step.

D1 discloses aryl ureas with angiogenesis inhibiting activity, in particular sorafenib tosylate (see claim 22 of D1). D1 further mentions that the compounds shown therein may be administered orally (see page 25, bottom paragraph) and that compositions intended for oral use may be in the form of tablets (see page 26, first full paragraph). As established in T 489/13 (see points 1.1 and 2.5-2.8), sorafenib tosylate is individualized in claim 22 of D1, such that its combination with the general disclosure relating to tablets only requires one selection among the dosage forms mentioned in D1. Thus, D1 discloses tablet forms of sorafenib tosylate.

However, the Board does not share the appellant's opinion that D1 discloses, in combination, the features pertaining to *immediate release* tablets comprising sorafenib tosylate. The first full paragraph on page 26

of D1 generally discusses compositions intended for oral use. This paragraph mentions in particular tablets, including coated tablets with delayed disintegration and adsorption (see lines 15-19). This passage is followed by the statement "These compounds may also be prepared in solid, rapidly released form". This statement logically pertains to alternatives to the delayed release tablet mentioned earlier. However, D1 does not clearly and unambiguously disclose that this alternative is a rapid release tablet, but only that it is, more generally, a solid, rapidly released form.

3.4 Thus, the subject-matter of claim 1 differs from the disclosure of D1 by the drug load of at least 55% by weight and in that the tablet is an immediate release tablet.

3.5 Turning to the technical effect associated with these differences, the respondent contends that the highly loaded tablet formulation of the invention allows for the preparation of small, easy to swallow dosage forms resulting in a high patient compliance. In addition, the tablets show immediate release characteristics associated with good bioavailability, high stability and sufficient hardness.

3.5.1 The Board accepts, and the appellant does not contest, that formulating the tablets with a high drug load of at least 55 wt % sorafenib facilitates administration and, consequently, patient compliance, since smaller and/or fewer tablets will then be needed for administering a given dose of the drug (see T 489/13, point 2.10 of the reasons).

The claimed tablets necessarily exhibit an immediate release since this is a feature of claim 1.

3.5.2 The Board however does not consider that the above differentiating features credibly lead to any improvements with respect to the further characteristics alleged by the respondent (namely bioavailability, stability or hardness).

In order to demonstrate that these effects are achieved by the claimed invention, the respondent relies on D12a, D12b and D17-D19. D12a and D12b show the dissolution behavior of highly loaded tablets comprising sorafenib free base and sorafenib tosylate, and differing additionally by the amount of microcrystalline cellulose. D17-D19 report the drug release properties, hardness and disintegration time of tablets comprising different sorafenib forms/salts.

However, the comparisons made in D12a, D12b and D17-D19 relate to the effect of choosing sorafenib tosylate over other forms of sorafenib. The closest prior art D1 already discloses sorafenib tosylate. Thus, D12a, D12b and D17-D19 do not suitably show any technical effect associated with the distinguishing features over the closest prior art, namely the drug load and the immediate release.

3.6 Accordingly, the technical problem starting from D1 is the provision of tablets of sorafenib tosylate leading to improved patient compliance.

3.7 Obviousness

3.7.1 The skilled person starting from the sorafenib tosylate tablets of D1 and seeking ways to improve patient

compliance would turn to higher drug loads as a straightforward solution to the problem, since this would allow the administration of the required dose either with smaller tablets or with fewer tablets. A drug load of at least 55 wt% would be considered by the skilled person as a matter of routine considering the common general knowledge reflected in D4, a textbook on tablet development (see page 64, last complete paragraph; page 65, table 2/1). Following D4, in the case of tablets which are to be swallowed, it will generally be the aim of the formulator to achieve small tablet sizes. D4 further mentions that for active agent contents of 350-550 mg (which encompasses the recommended oral daily dose of sorafenib of around 400 mg, see D6, page 1144, column 2; page 1145, column 1; and D7, abstract), typical drug loadings extend well above 55 wt%.

3.7.2 Furthermore, immediate release tablets and how to formulate them are part of the common general knowledge. Immediate release is the most common form of tablet, and it is well-known that such a formulation allows release of the active agent in a rapid manner. The closest prior art D1 (see page 26, lines 19-20) suggests solid, rapidly released forms, which corresponds to the definition of "immediate release" in the patent (see paragraph [0027]) as a delivery of the compound in a rapid manner. In this respect, the much narrower parametric feature appearing later in the same paragraph of the patent ("forms having a Q-value (30 minutes) of 75% due to USP-release method with device 2 (paddle, 75 rpm, in 0.1M HCl + 1% sodium dodecylsulfate)") is neither the commonly accepted definition of an immediate release form nor is it a feature of claim 1. The respondent's contention that "immediate release" should be so narrowly interpreted

in light of the description amounts to an attempt to read into claim 1 features which it does not comprise.

3.7.3 The Board cannot share the respondent's position that there is any prejudice against, or any technical difficulty in, formulating the tablet with both a high drug load and as an immediate release form. On the contrary, immediate release tablets use fewer excipients relative to other tablet forms because they do not require anything to retard the release of the drug. Thus the skilled person would all the more consider immediate release forms in the case of high drug loads since these allow for lower amounts of excipients. Furthermore, the general teaching of D4 regarding high drug loads is not limited to any particular tablet type, and there is no reason to assume that this teaching should not be applicable to immediate release tablets.

3.7.4 Lastly, the respondent's position is that the prior art does not give the skilled person any motivation to choose the tosylate salt of sorafenib to provide immediate release tablets having the claimed high drug load. An inventive step over D1 can however not be based on the choice of sorafenib tosylate, or on any technical effect associated with the choice of this salt, since sorafenib tosylate is already disclosed in the closest prior art D1, and is even the sole specific salt of sorafenib shown therein.

3.8 Accordingly, the subject-matter of auxiliary request 1 does not meet the requirements of inventive step.

4. Auxiliary requests 1A and 6A, admittance

The respondent filed auxiliary requests 1A and 6A by letter dated 11 January 2022, thus after notification of the summons to oral proceedings dated 3 May 2021. Auxiliary requests 1A and 6A correspond respectively to auxiliary requests 1 and 6 with an additional limitation to compositions with a hardness of more than 80 N.

Under Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The filing of auxiliary requests 1A and 6A represents a change in the respondent's case. The respondent argues that these new requests result from combinations of claims of the granted patent or of auxiliary requests 1 or 6, and thus were under investigation from the beginning of the opposition proceedings. However, the respondent does not contest that the limitation of the claimed subject-matter to a hardness of more that 80 N represents a change of case. Indeed, the respondent did not, at any earlier point in the appeal proceedings, discuss the relevance of this particular feature to inventive step.

Furthermore, the respondent did not justify the late filing of auxiliary requests 1A and 6A. The respondent submitted that this late filing was in direct reaction to the Board's preliminary opinion, in particular the considerations pertaining to D13 (see the communication under Article 15(1) RPBA, paragraph 2.3). However, this

communication did not contain any argument or objection which had not been raised by the parties before. Hence, the Board can identify no exceptional circumstances in the present case to justify the late filing of auxiliary requests 1A and 6A.

Accordingly, auxiliary requests 1A and 6A were not admitted into the appeal proceedings.

5. Auxiliary requests 3, 4, 6 and 8, inventive step

5.1 Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 1 by the presence of 3-20% filler, 5-12% disintegrant, 0.5-8% binder, 0.2-0.8% lubricant and 0.1-2% surfactant. In claim 1 of auxiliary request 4, these excipients are limited respectively to microcrystalline cellulose, croscarmellose sodium, hypromellose (i.e. hydroxypropylmethylcellulose), magnesium stearate and SDS.

D1 mentions all of the above specific excipients (see page 26, first full paragraph), albeit not in combination together with the features of a sorafenib tosylate tablet. D1 is silent about the amounts of these excipients.

The respondent did not demonstrate that these further limitations result in any additional technical effect over the sorafenib tosylate tablets known from D1. Accordingly, the technical problem is still the provision of tablets of sorafenib tosylate leading to improved patient compliance.

Neither the selection of these well-known excipients which are already shown in D1, nor the arbitrary choice of the amounts specified in claim 1 without any

associated effect, involves any inventive step. The respondent argued, during the oral proceedings, that the skilled person would not consider the low amounts of disintegrant specified in claim 1, namely 5-12 wt%. However, the respondent did not show that this amount of disintegrant, or any of the amounts specified in claim 1 either, depart from the usual amounts which the skilled person would consider in the course of routine work. On the contrary, the range for the amount of disintegrant is subsumed by the range shown in e.g. D5 (see bottom of page 3, 5-40 wt%). In addition, the choice of tablets with a high load in active ingredient would necessarily entail the choice of low amounts of excipients.

Accordingly, the subject-matter of claim 1 of auxiliary requests 3 and 4 does not involve an inventive step.

5.2 Auxiliary requests 6 and 8 correspond to auxiliary requests 1 and 4, wherein the drug load is amended to at least 75% by weight.

This limitation does not modify the assessment of inventive step. The drug loads considered in D4 (see page 65, table 2/1, 350-550 mg active ingredient for a tablet weight of 400-650 mg) extend well above the value of 75 wt% of claim 1. The fact that particular examples of D13 use a much lower amounts of active ingredient does not modify this assessment based on D1 and D4. Accordingly, the subject-matter of claim 1 of auxiliary requests 6 and 8 lacks an inventive step for the same reasons as auxiliary requests 1 and 4.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:


B. Atienza Vivancos D. Boulois

Decision electronically authenticated