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# Datasheet for the decision of 4 October 2021

**Case Number:** T 0689/19 - 3.3.01

**Application Number:** 04758053.5

**Publication Number:** 1610780

**IPC:** A61K31/427, A61K31/506, A61P35/02

**Language of the proceedings:** EN

**Title of invention:**
CYCLIC PROTEIN TYROSINE KINASE INHIBITORS

**Patent Proprietor:**
Bristol-Myers Squibb Holdings Ireland

**Opponents:**
Sandoz Farmacêutica Lda.
Mylan, LDA
Zentiva k.s.

**Headword:**
Dasatinib in the treatment of chronic myelogenous leukemia/ BRISTOL

**Relevant legal provisions:**
EPC Art. 105(1)(a), 111(2), 56

**Keyword:**

Intervention of the assumed infringer - admissible (yes)
Res judicata - decision on sufficiency binding
Inventive step - (yes)

**Decisions cited:**

G 0004/91, G 0010/91, G 0001/94, G 0001/97, G 0003/04, G 0002/19, R 0001/08, T 0079/89, T 0843/91, T 0934/91, T 0021/89, T 1063/92, T 0153/93, T 0167/93, T 0460/95, T 0863/96, T 0598/98, T 0817/00, T 0694/01, T 1459/06, T 0898/07, T 1545/08, T 0584/09, T 0223/11, T 1713/11, T 0950/13, T 0308/14, T 0439/17, G 0001/03, T 0488/16, T 1018/03

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**Boards of Appeal**

**Chambres de recours**

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

**Case Number: T 0689/19 - 3.3.01**

# D E C I S I O N
# of Technical Board of Appeal 3.3.01
# of 4 October 2021

| | |
|---|---|
| **Appellant 1:**<br>(Opponent 2) | Sandoz Farmacêutica Lda.<br>Avenida Professor Doutor Cavaco Silva, 10E<br>Taguspark<br>2740-255 Porto Salvo (PT) |
| **Representative:** | Eder, Michael<br>df-mp Dörries Frank-Molnia & Pohlman<br>Patentanwälte Rechtsanwälte PartG mbB<br>Theatinerstrasse 16<br>80333 München (DE) |
| **Appellant 2:**<br>(Opponent 4) | Mylan, LDA<br>Avenida D. João II<br>Edifício Atlantis, N° 44C - 7.3 e 7.4<br>1990-095 Lisboa (PT) |
| **Representative:** | Elkington and Fife LLP<br>Prospect House<br>8 Pembroke Road<br>Sevenoaks, Kent TN13 1XR (GB) |
| **Appellant 3:**<br>(Opponent 5) | Zentiva k.s.<br>U kabelovny 130<br>10237 Praha 10 (CZ) |
| **Representative:** | Ellis, Robin Patrick<br>Reddie & Grose GmbH<br>Hopfenstraße 8<br>D-80335 München (DE) |

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|---|---|
| **Respondent:**<br>(Patent Proprietor) | Bristol-Myers Squibb Holdings Ireland<br>Hinterbergstrasse 16<br>6312 Steinhausen (CH) |
| **Representative:** | Mewburn Ellis LLP<br>Aurora Building<br>Counterslip<br>Bristol BS1 6BX (GB) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 24 January 2019 concerning maintenance of the European Patent No. 1610780 in amended form.** |

**Composition of the Board:**

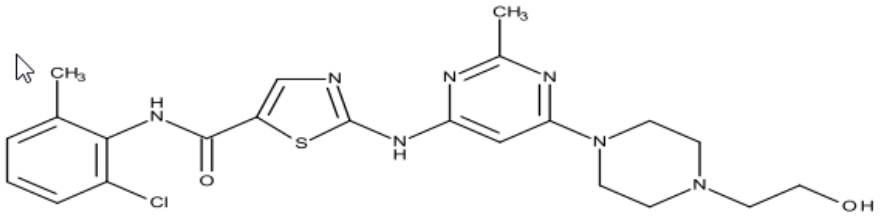
| | |
|---|---|
| **Chairman** | A. Lindner |
| **Members:** | M. Pregetter |
| | L. Bühler |

## Summary of Facts and Submissions

I. European patent No. 1 610 780 is based on European patent application No. 04758053.5, filed as an international application published as WO2004/085388.

The claims of the patent as granted read as follows:

"1. Use of the compound of formula IV or a salt thereof:



IV

for the manufacture of a medicament for the oral treatment of cancer, wherein the cancer is chronic myelogenous leukemia (CML), gastrointestinal stromal tumor (GIST), acute myelogenous leukemia (AML), mastocytosis, germ cell tumor, small cell lung cancer (SCLC), melanoma, pancreatic cancer, prostate cancer or pediatric sarcoma.

2. The use of claim 1, wherein the chronic myelogenous leukemia (CML) or the gastrointestinal stromal tumor (GIST) is resistant to STI-571.

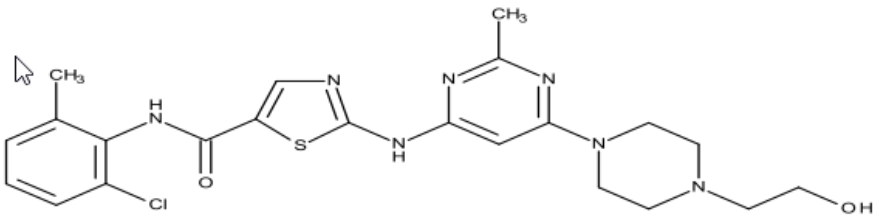
3. The use of claim 1, wherein the compound of formula (IV) is adapted to be administered once daily for 5 consecutive days, followed by 2 days when there is no treatment.

4. The use of claim 1, wherein the compound of formula (IV) is adapted to be administered 1 to 4 times per day.

5. The use of claim 1, wherein the cancer is chronic myelogenous leukemia (CML).

6. The use of claim 1, wherein the cancer is prostate cancer.

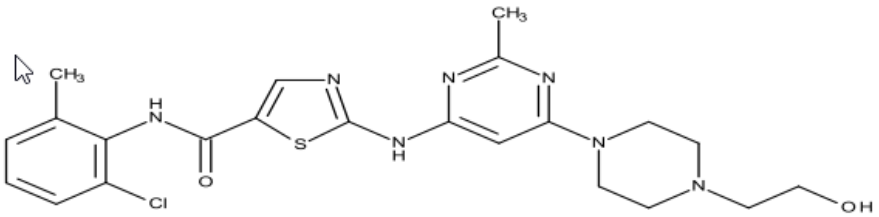
7. Use of the compound of formula IV or a salt thereof:



IV

for the manufacture of a medicament for the oral treatment of cancer, wherein the cancer is resistant to STI-571.

8. Compound of formula IV or a salt thereof:



IV

for use in the oral treatment of cancer, wherein the cancer is chronic myelogenous leukemia (CML), gastrointestinal stromal tumor (GIST), acute myelogenous leukemia (AML), mastocytosis, germ cell tumor, small cell lung cancer (SCLC), melanoma,

pancreatic cancer, prostate cancer or pediatric sarcoma.

9. The compound of claim 8, wherein the chronic myelogenous leukemia (CML) or the gastrointestinal stromal tumor (GIST) is resistant to STI-571.

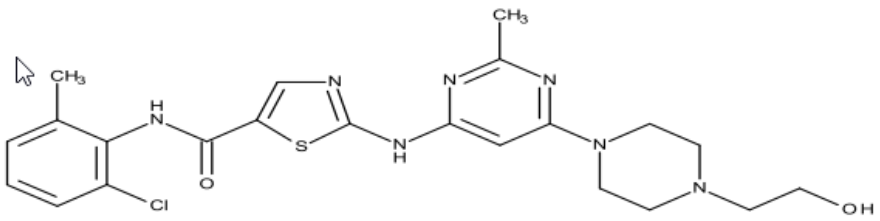
10. The compound of claim 1, wherein the compound of formula (IV) is adapled [sic] to be administered once daily for 5 consecutive days, followed by 2 days when there is no treatment.

11. The compound of claim 1, wherein the compound of formula (IV) is adapted to be administered 1 to 4 times per day.

12. The compound of claim 1, wherein the cancer is chromic [sic] myelogenous leukemia (CML).

13. The compound of claim 1, wherein the cancer is prostate cancer.

14. Compound of formula IV or a salt thereof:




IV

for use in the oral treatment of cancer, wherein the cancer is resistant to STI-571."

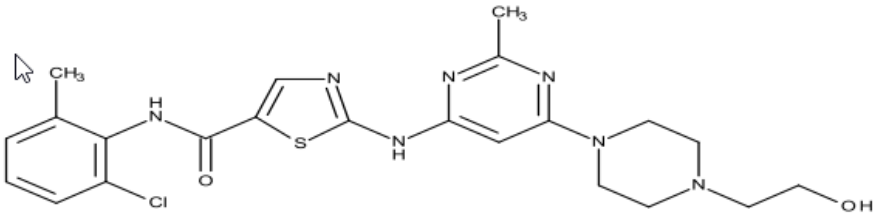
II. The patent was opposed by Apotex Inc. under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

The opposition division came to the conclusion that the subject-matter of the claims under consideration met the requirements of Article 123(2) EPC, but that the claimed subject-matter was not sufficiently disclosed.

III. The patent proprietor appealed against this decision. In decision T 950/13, issued on 3 February 2017, the board adopted the opposition division's finding regarding the requirements of Article 123(2) EPC. Furthermore, it found that the subject-matter of auxiliary request 2a, submitted with the statement of grounds of appeal, was sufficiently disclosed (point 5 of the reasons). When justifying the remittal to the opposition division, the board drew attention to the fact that the decision then under appeal dealt solely with the grounds of added matter and lack of sufficiency of disclosure, but had not decided on other grounds for opposition such as inventive step (point 6). It remitted the case to the department of first instance for further prosecution (order).

The claims of auxiliary request 2a read as follows:

"1. Use of the compound of formula (IV) or a salt thereof:

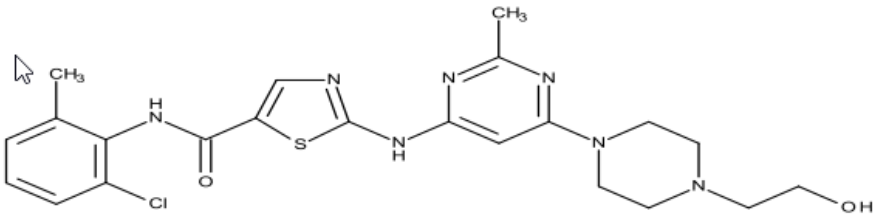


IV

for the manufacture of a medicament for the oral treatment of cancer, wherein the cancer is chronic myelogenous leukemia (CML).

2. The use of claim 1, wherein the compound of formula (IV) is adapted to be administered once daily for 5 consecutive days, followed by 2 days when there is no treatment.

3. Compound of formula IV or a salt thereof:



IV

for use in the oral treatment of cancer, wherein the cancer is chronic myelogenous leukemia (CML).

4. The compound of claim 3 for the use of claim 3, wherein the compound of formula (IV) is adapted to be administered once daily for 5 consecutive days, followed by 2 days when there is no treatment."

IV. On 8 August 2017 a first intervention was filed by Sandoz Farmacêutica Lda (intervener 1, opponent 2).

On 14 September 2017 Apotex Inc. withdrew its opposition.

On 7 March 2018 Teva B.V. filed an intervention, which was withdrawn on 25 September 2018.

On 12 October 2018 a further intervention was filed by Mylan, LDA (intervener 3, opponent 4).

On 29 November 2018 a further intervention was filed by Zentiva k.s. (intervener 4, opponent 5).

V. The opposition division found that the patent and the invention to which it relates, based on auxiliary request 2 (which comprises the set of claims underlying the order of decision T 950/13 and a description adapted thereto), met the requirements of the EPC. In particular, it was found that the interventions were admissible, the requirements of Article 123(2) EPC were met, issues relating to sufficiency of disclosure were *res judicata*, documents (19) and (20) were not to be admitted, inventive step was to be acknowledged and the description had been adapted to be in line with the set of claims of auxiliary request 2.

VI. All the remaining interveners appealed against this decision.

VII. With its reply to the statements of grounds of appeal, the respondent re-submitted two sets of claims as auxiliary requests 2a and 2b, auxiliary request 2a being the set of claims on which the decision of the

opposition division was based.

VIII. The following documents, cited during the opposition and appeal proceedings, are referred to below:

(1) WO00/62778

(2) L. J. Lombardo et al., Journal of Medicinal Chemistry, vol. 47, 2004, pages 6658 to 6661

(5) Buchdunger et al., Biochim. Biophys. Acta, 2001, 1551, M11-M18

(12) Affidavit of Filipe Teixeira Baptista of 3 August 2017 on behalf of Sandoz Farmacêutica Lda., including Exhibits 1 to 3

(16) Affidavit of Filipe Teixeira Baptista of 1 October 2018 on behalf of Sandoz Farmacêutica Lda.

(18) Warmuth et al., Blood, 2003, 101(2), 664-72

(19) Decision 2017 FC 296 of the Federal Court of Ottawa, docket T-1100-15

(20) Decision 2017 FC 190 of the Federal Court of Appeal, docket A-106-17

(21) Affidavit of Petra Fernandes of 12 October 2018 on behalf of Mylan LDA.

(22) Portuguese Law No. 62/2011 of 12 December 2011 (English translation)

(23) Letter dated 10 October 2018 instituting arbitration proceedings against Mylan LDA.

(27) Letter dated 22 November 2018 instituting arbitration proceedings against Zentiva k.s.

(33) Affidavit of Filipe Azoia of 3 December 2018 on behalf of Zentiva k.s.

(38) Affidavit of Petra Fernandes of 11 November 2020 on behalf of Mylan LDA.

(40) Buchanan et al., Bioorg. Med. Chem. Lett. 1999, 9, 2353-8

IX. Oral proceedings before the board took place on 4 October 2021.

X. The appellants' arguments, insofar as they are relevant to the present decision, may be summarised as follows:

*Admissibility of the interventions*

The appellants argue that the Portuguese arbitration proceedings under Portuguese Law No. 62/2011 were infringement proceedings within the meaning of Article 105 EPC. As evidenced by the letters initiating arbitration proceedings against the appellants and by the expert declarations of Portuguese lawyers filed by the appellants, Portuguese Law No. 62/2011 established the only legal remedy to enforce a patent protecting reference medicines, and Portuguese arbitration proceedings were intended to establish whether a third party was commercially active within the patent proprietor's right to exclude. Neither the fact that Portuguese arbitration proceedings were set off by a request for a marketing authorisation for a generic medicine nor a possible purpose of prevention had any

relevance to the issue of whether the arbitration proceedings were intended to determine infringement. Decision T 223/11 related to a different situation, as Portuguese Law No. 62/2011 took effect only later.

*Binding effect of T 950/13*

The appellants argued that they were entitled under Article 105 EPC to submit any arguments and evidence, and even could raise new grounds for opposition in line with decision G 1/94. Moreover, they were not parties in case T 950/13 and therefore not bound by that decision. Consequently, they could also raise those grounds of opposition considered in decision T 950/13. Decision T 694/01 relied on by the opposition division concerned a fundamentally different situation. At the time the intervention was filed in T 694/01, the board had given a final decision on the format of the claims, and the case had been remitted to the opposition division to consider only the adaptation of the description. In the present case, all options regarding the final format of the claims remained open. Therefore the rationale of decision T 694/01 did not apply. For these reasons, the interveners' right under Article 105 EPC to make their full case against the patent had to prevail over the binding effect of a decision as stipulated in Article 111(2) EPC. Consequently, they should be heard on objections of added matter and lack of sufficiency of disclosure. In any event, the board in T 950/13 had not taken a decision on added matter and this ground of opposition was still open for discussion.

*Inventive step*

Starting from either document (5) or (18), the difference between the claimed subject-matter and these documents was the use of the compound of formula IV (dasatinib) as active agent. The technical problem was an alternative treatment for CML. This problem had not been plausibly solved across the whole scope of the independent claims. The finding of a lack of plausibility in T 950/13 for an embodiment that fell within the scope of the independent claims was also applicable to effects relating to inventive step. The claims under consideration thus had to be conceptually split into a part relating to the treatment of imatinib-resistant CML and a part covering the remaining CML patients. The problem had not been plausibly solved for the first part, therefore no inventive step could be acknowledged.

However, even when considering that the problem had been solved, no inventive step was present. Starting from document (5), the person skilled in the art would have looked for documents disclosing protein kinase (PTK) inhibitors. While document (1) contained no evidence that its compounds inhibited PTKs, it would nevertheless have provided an incentive for the person skilled in the art to investigate its compounds. Dasatinib was one of the compounds exemplified in document (1) and thus one of the compounds available to the skilled person. Bcr-Abl inhibition assays were available. Performing screening tests was within the skills of the person skilled in the art. Furthermore, it was not uncommon for a PTK inhibitor to inhibit more than one PTK since these kinases had similar ATP binding sites. Document (5) identified on page M12 key structural aspects of imatinib and explicitly stressed

the importance of a methyl-substituted benzyl amide group. Such a group could also be found in dasatinib. The person skilled in the art would thus have considered dasatinib and would have arrived at the claimed subject-matter.

Starting from document (18), the person skilled in the art would have taken into account the following. Document (18) aimed at overcoming the resistance problems encountered with imatinib. As a potential solution two alternative compounds were introduced that were identified to be dual-specific PTK inhibitors for Src and Bcr-Abl. A person skilled in the art looking for further dual Src/Bcr-Abl inhibitors would have considered document (1), which exemplifies compounds that are Src inhibitors. There was thus a reasonable expectation of success. A person skilled in the art would have screened the compounds of document (1). Appellant 3 identified similarities in the pharmacophores of dasatinib and the two exemplified dual-specific PTK inhibitors of document (18). Furthermore, the homology of the binding pockets had to be borne in mind.

Appellant 2 considered document (1) to represent a valid starting point. It disclosed dasatinib (Example 455). The distinguishing feature was the use for the treatment of CML. The technical problem was providing a treatment for CML. The solution to this problem had not been made plausible and therefore the claim under consideration could not involve an inventive step. Should the problem be seen as the provision of a further use of dasatinib, the following applied: the screening for kinases, including Bcr-Abl, formed part of the common general knowledge, and therefore the claim lacked inventive step for the same reasons as

when starting from documents (5) or (18) as closest prior art.

*Admission of document (40)*

Document (40) was well known to all the parties to the proceedings since it had served as closest prior-art document in the parallel proceedings leading to T 488/16. It was a short document and no new arguments had been presented. The document had merely been submitted to show how thiazoles could interact with Src kinases. The newly-appointed representative had realised only very late into the appeal proceedings that document (40) had not been submitted for the case at hand.

*Article 84 EPC*

Appellant 1 argued that the deletion of the dependent claims defining imatinib-resistant cancers lent a different meaning to the (unchanged) independent claims. The subject-matter of these independent claims was very generic. In view of the finding of lack of plausibility of the treatment of the imatinib-resistant cancers in T 950/13, the issue of claim interpretation arose. This lack of plausibility, notwithstanding the disclosure in paragraph [0079] of the patent in suit, led to a lack of support for important parts of the independent claims. The requirements of Article 84 EPC were thus not met.

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

*Admissibility of the interventions*

The respondent argued that, due to the disruptive nature of interventions, "proceedings for infringement" within the meaning of Article 105(1)(a) EPC required a substantive legitimate interest for a party to intervene. In line with decision T 223/11, the arbitration proceedings under Law No. 62/2011 were preventive in that they related to the granting of marketing authorisations, which merely opened up the possibility of patent rights being infringed in the future. The arbitration proceedings were triggered by a request for a marketing authorisation for a generic drug. The proprietor of a patent protecting the reference drug was obliged under Law No. 62/2011 to institute arbitration proceedings to safeguard its patent rights. This was however long before the company applying for a marketing authorisation for a generic drug could enter the market and infringe the patent rights, and thus also long before patent rights could be enforced against such company. The purpose of the arbitration proceedings was to prevent infringement proceedings. According to decision T 439/17, proceedings which merely served to prepare an infringement claim did not have the character of infringement proceedings. Accepting arbitration proceedings under Law No. 62/2011 as infringement proceedings would go against the rationale of Article 105 EPC and create a unique situation in the pharmaceutical field. Manufacturers of generics who could have opposed the patent from the outset could force proprietors of pharmaceutical patents to initiate proceedings that would allow an intervention. Manufacturers of generics could thus choose the start of the arbitration proceedings at will and thereby also control their intervention in opposition proceedings.

Finally, the respondent argued that the arbitration proceedings did not necessarily lead to a decision on the merits as to existence of infringement. Such decision would require a patent proprietor to make a corresponding claim. However, no such claim had been made in any of those Portuguese arbitration proceedings when the interveners' notices of intervention were filed.

*Binding effect of T 950/13*

The respondent argued that pursuant to Article 111(2) EPC and the principle of *res judicata* the grounds of opposition of Articles 83 and 123(2) EPC were not open for discussion in view of decision T 950/13 and its *ratio decidendi*. The binding effect enshrined in Article 111(2) EPC did not depend on whether claims could still be changed or not. A new ground of opposition within the meaning of decision G 1/94 could only be a ground that had not yet been considered and decided upon by the board. Any possible conflict between an intervener's right and the requirements of Article 111(2) EPC would have to be decided in favour of Article 111(2) EPC, such that an intervener would have to accept a case remitted to the opposition division from a board of appeal as it stood at the time the intervener joined the ongoing opposition proceedings, in line with decision T 694/01. Not only the opposition division but also the board was bound by decision T 950/13. Finally, the facts underlying said decision and the objections raised by the appellants were also the same.

*Inventive step*

Document (5) disclosed a successful clinical trial relating to CML, mentioned imatinib resistance, and contained a paragraph relating to the structural basis of STI-571 (imatinib) specificity (page M17). The difference between the claimed subject-matter and the disclosure of document (5) was the use of dasatinib. The technical problem was one of the following:
(a) providing an alternative treatment for CML,
(b) providing an improved first-line treatment for CML, and (c) providing a second-line treatment in imatinib-resistant CML. In T 950/13 the board had concluded that dasatinib was suitable for the treatment of CML. It was not appropriate to split the claim into two parts. Especially in the treatment of cancer it was a given fact that not all patients responded to one treatment. However, in the present case it was not disputed by any parties that the claims "worked". Document (5) itself gave no suggestion as to why and how the structure of the active agent could be changed. The structures of imatinib and dasatinib were very different. For example, the methylated phenyl group was in the middle of imatinib, whereas in dasatinib it was on the periphery. Moreover, the lead structure of document (5) was depicted in figure 1A and did not include this methylated phenyl group. Furthermore, according to the finding in T 488/16, document (1) did not make it plausible that any of its compounds had an inhibitory effect on any PTK. Consequently, the person skilled in the art would not have turned to document (1). As document (1) did not provide the person skilled in the art with a group of compounds that had a clearly envisaged technical effect, said skilled person would have neither any motivation to screen the compounds of document (1) nor any expectation of success.

Document (18) was more remote from the claimed invention in that it concerned dual inhibition of PTKs and thus required the person skilled in the art to look for a compound that inhibited two specific PTKs, which was less probable for any given compound than inhibition of one specific PTK. Furthermore, document (18) made it clear that the primary target for treating CML was Bcr-Abl. The structures of imatinib, PP1 and CGP76060, the three active agents discussed in document (18), were remote from the structure of dasatinib. Concerning the similarities in binding pockets of the PTKs, imatinib itself provided proof that the inhibition of one PTK (in the case of imatinib Bcr-Abl) was not linked to the inhibition of a further PTK (such as Src). Bcr-Abl and Src belonged to different kinase families.

Document (1) was not a possible starting point for the person skilled in the art as it did not disclose a medical use in an enabling form.

The subject-matter of auxiliary request 2a involved an inventive step.

The board could join T 116/18 in referring questions to the Enlarged Board of Appeal concerning post-published evidence and plausibility.

*Admission of document (40)*

Neither exceptional circumstances, a change of representative not representing such circumstances, nor cogent reasons had been presented by appellant 3 to justify the admission of document (40). Document (40), submitted 9 years after commencement of the opposition

proceedings, should thus not be admitted.

*Article 84 EPC*

The attack under Article 84 EPC was late-filed, as it was not presented until the late stages of the oral proceedings. Apart from the fact that Article 84 EPC was not available for claims that were already present in the patent as granted, the deletion of dependent claims 2 and 5 (of the set of claims considered to contravene Article 83 EPC in decision T 950/13) did not change the meaning of independent claims 1 and 3 of auxiliary request 2a and thus could not lead to a lack of clarity.

XII. The final requests of the parties, as far as relevant to the present decision, were as follows:

The appellants (opponents 2, 4 and 5) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the interventions be rejected as inadmissible. Alternatively, they requested that the appeals be dismissed, implying that the patent be maintained based on the set of claims of auxiliary request 2a filed on 11 June 2013 underlying the contested decision, or that a patent be granted based on the set of claims of auxiliary request 2b filed with the reply to the statements of grounds of appeal.

## Reasons for the Decision

1. *Interventions - admissibility*

1.1 Exhibit 3 to document (12), and documents (23) and (27) prove that arbitration proceedings under Portuguese Law No. 62/2011 of 12 December 2011 (hereinafter Law No. 62/2011, see exhibit 1 to document (12), document (22), and exhibit 1 to document (33)) were initiated on 10 May 2017 against intervener 1 (opponent 2), on 10 October 2018 against intervener 3 (opponent 4) and on 22 November 2018 against intervener 4 (opponent 5). The notices of intervention were filed on 8 August 2017 (intervener 1/opponent 2), 12 October 2018 (intervener 3/opponent 4) and 29 November 2018 (intervener 4/ opponent 5). Therefore all the notices of intervention were filed within the three-month period referred to in Rule 89(1) EPC. At the time of the interventions, opposition proceedings were pending after remittal of the case by decision T 950/13. Together with the notices of intervention, written reasoned statements setting out the extent of the intervention and the grounds in support were filed, and the required fees were paid (Rule 89(2) EPC). Therefore the formal requirements of Rules 89 and 76 EPC are met, which is not contested. However, it is a matter of dispute between the parties whether arbitration proceedings instituted under Law No. 62/2011 are "proceedings for infringement" within the meaning of Article 105(1)(a) EPC that could give rise to an admissible intervention.

1.2 It should be noted that Law No. 62/2011 has meanwhile been amended by Law No. 110/2018 of 10 December 2018 (entry into force on 9 January 2019). However, the later amendments to Law No. 62/2011 are not relevant for assessing the admissibility of the interventions.

1.3 It has not been contested that Articles 2 and 3 No. 1 of Law No. 62/2011 confer on arbitration tribunals exclusive jurisdiction in disputes, including requests for preliminary injunctions, arising from industrial property rights related to so-called reference medicines and generic medicines (documents (12), (21), and (33), Judgment no. 460/15.5YHLSB.L1-8 of 5 May 2016 of the Court of Appeal of Lisbon, referred to in document (16), page 2). Thus Law No. 62/2011 has instituted a special regime for the settlement of disputes arising from industrial property rights related to marketing authorisations for medicines which rules out the jurisdiction of national courts, in particular the jurisdiction of the Portuguese Intellectual Property Court. The mandatory versus voluntary nature of the arbitration proceedings is thus not at issue. The dispute is about whether these proceedings, in view of their subject and nature, qualify as "infringement proceedings" within the meaning of Article 105 EPC.

1.4 Article 105 has to be read in conjunction with Article 64 EPC (G 4/91, OJ EPO 1993, 339, corrected translation, 707, point 1 of the Reasons). The (exclusive) rights conferred by a European patent and, correspondingly, the acts that constitute an infringement of these rights are defined in the national law of the contracting states. The national law also specifies the procedures and remedies for the enforcement of patent rights. Consequently, an autonomous interpretation of what constitutes "infringement proceedings" should avoid interfering with national legislation by adopting a definition that is tailored to some, but not all, national systems. Moreover, the legislative intent has to be taken into

account. The purpose of Article 105 EPC is to avoid parallel proceedings (infringement proceedings, nullity proceedings or declaratory proceedings for non-infringement) before national courts of the contracting states while centralised opposition and opposition appeal proceedings are still pending. This ensures efficient use of the judicial system and avoids contradictory decisions (see G 4/91, points 3 and 4 of the Reasons; G 1/94, OJ EPO 1994, 787, point 7 of the Reasons). Of course, the possibility of intervening in opposition proceedings after the opposition period has expired or during subsequent appeal proceedings, and of thereby acquiring the status of a party to the proceedings, is exceptional (see G 2/19, OJ EPO 2020, 87, point B.II.4 of the Reasons). However, the conditions set forth in Article 105(1) EPC strike the proper balance of interest (see G 4/91, point 8 of the Reasons: "*The problem which could arise out of late intervention in respect of delay of the proceedings was considered during the preparatory work but it was not accepted as a reason for rejecting such intervention even at the appeal stage of the proceedings*."). The board therefore agrees with decision T 1713/11 that it should take into account the legislative intent when examining the admissibility of an intervention without creating further preconditions for an intervention (T 1713/11, point 2.2 of the Reasons). When considering both the context and the purpose of Article 105 EPC, the definition of "proceedings for infringement" cannot depend on the nature of the proceedings (civil, administrative or penal), nor on the remedies available in these proceedings (T 1713/11, point 2.5 of the Reasons). In the board's opinion, it does not matter whether these proceedings are set off in the present case by a request for a marketing authorisation either. What matters is that the exclusive rights conferred by

a European patent are invoked in these proceedings and their enforcement is sought. Indeed, "infringement" means contravention of the rights conferred by a patent on its owner, which are rights to exclude (prevent) third parties from making use of the subject-matter of a patent without the authorisation of the patent proprietor. The board therefore concurs with the definition given in decision T 1713/11 that "proceedings for infringement" within the meaning of Article 105(1)(a) EPC are (national) proceedings "meant to establish whether a third party is commercially active in an area that falls within the patentee's right to exclude" (T 1713/11, point 2.6 of the Reasons).

1.5 In the board's judgement, it follows from the wording of the letters dated 10 May 2017, 10 October 2018 and 22 November 2018 which were sent on behalf of the respondent (exhibit 3 to document (12), documents (23) and (27)) that the arbitration proceedings instituted under Law No. 62/2011 against interveners 1, 3 and 4 aimed *inter alia* at establishing whether the interveners had committed acts falling within the patent proprietor's right to exclude of the patent in suit. The relevant passages read as follows:

"*The object of these proceedings is the exercise of the rights to which BMS is entitled, arising from the Portuguese parts of European Patent no. 1 711 481, European Patent no. 1 610 780 and European Patent no. 1 885 339, notably those under Article 101 of the Industrial Property Code, in relation to generic medicines with the active substance dasatinib, ...*
*...*
*You are furthermore informed that, under the present arbitration, a decision will be sought to* inter alia

*prevent the Defendant from practising any activities that infringe such rights or to avoid that said infringement continues, should it have already been committed, and, in the latter case, it will be further requested that the Defendant be convicted to the payment of a compensation for any damage caused due to such infringement.*"

1.6 Two affidavits provided by the parties also deal in greater detail with the nature and aim of the arbitration proceedings instituted under Law No. 62/2011. The parties' experts opine that arbitration proceedings are the only remedy for enforcing industrial property rights, in particular patent rights, against applicants for marketing authorisations for generic medicines, and that these proceedings aim at obtaining a decision on the merits as to the existence or not of infringement of industrial property rights (see documents (16) and (38), referring also to Article 101 of the Portuguese Industrial Property Code relied on in the letters instituting the arbitration proceedings). There is no evidence on file to disprove the conclusions by the intervener's experts, and the board fails to see a reason why it should disregard this evidence.

1.7 In the board's judgement, the arbitration proceedings instituted under Law No. 62/2011 against interveners 1, 3 and 4 thus constituted "proceedings for infringement" within the meaning of Article 105(1)(a) EPC.

1.8 The respondent's arguments did not persuade the board for the following reasons:

1.8.1 As regards the disruptive nature of interventions and the required substantive legitimate interest for a

party to intervene, the legislator took these aspects into consideration when adopting Article 105 EPC. In line with T 1713/11 (point 2.2 of the Reasons), the board holds that the conditions for interventions pursuant to Article 105(1) EPC establish a substantive legitimate interest and that no further preconditions for an intervention should be created by way of interpretation of Article 105 EPC. As long as opposition proceedings are pending, there is a legitimate interest in having the validity of a European patent determined within centralised opposition proceedings before the European Patent Office, rather than in one or more national proceedings (G 4/91, OJ EPO 1993, 339, corrected translation, 707, points 3 and 4 of the Reasons; G 1/94, OJ EPO 1994, 787, point 7 of the Reasons). The outcome of opposition proceedings must have a bearing on the national proceedings. This is the case if exclusive rights conferred by the European patent which is under consideration in opposition or opposition appeal proceedings are invoked in the national proceedings.

1.8.2 As regards the argument that the initial stage of arbitration proceedings according to Law No. 62/2011 was preventive, the board holds that the arbitration proceedings nevertheless fall under the notion of "infringement proceedings". As discussed above, the respondent's letters instituting such proceedings (exhibit 3 to document (12), and documents (23) and (27)) as well as the available expert declarations (documents (16) and (38)) show that these proceedings aim at prevention, cessation and/or compensation. The board cannot conclude from the evidence on file that these remedies are subject to distinct proceedings initiated at different points in time. But even if the arbitration proceedings according to Law No. 62/2011

are preventive (i.e. directed against impending infringement), this would not, in the board's judgement, be decisive. Neither the wording nor the purpose of Article 105(1)(a) EPC limits "infringement proceedings" to lawsuits against occurring acts of infringement of patent rights. In the board's judgement, all proceedings that are, in substance, directed to the enforcement of exclusive rights conferred by a patent, including proceedings which aim at preventing infringement of a patent, are encompassed by the term "infringement proceedings" (see T 1459/06, point 1 of the Reasons). The definition in point 2.6 of the Reasons of decision T 1713/11 appears to be more limited in that it refers to the issue of whether a third party "is commercially active". However, T 1713/11 is concerned with the question of whether a distinction should be made between criminal and civil proceedings, and not between a situation where a patent is being infringed and a situation where such infringement is imminent. The rationale of decision T 1713/11 is that, in point 2.6 of the Reasons, it gives an autonomous interpretation and definition of "infringement" by making the link to the proprietor's right to exclude. To the extent that, in the present case, rights conferred by the opposed patent had been asserted in order to prevent imminent infringement, the arbitration proceedings according to Law No. 62/2011 amount in substance to infringement proceedings within the meaning of Article 105(1)(a) EPC and give rise to an admissible intervention. This finding is also in line with decision T 439/17. The purpose of the national proceedings in this case was to obtain and/or preserve evidence of facts relevant for possible infringement proceedings. Such proceedings for obtaining and/or preserving evidence do not aim at preventing third parties from making use of the

subject-matter of a patent (T 439/17, point 7 of the Reasons). Therefore such proceedings do not constitute infringement proceedings.

1.8.3 As regards decision T 223/11, the board notes that this decision is not relevant since it deals with national proceedings before the Portuguese Administrative Court which had been instituted before the promulgation of Law No. 62/2011. The board furthermore holds that it has no power, when assessing the admissibility of an intervention, to consider the facts and circumstances of the national proceedings as if it were in the place of the national authority and to anticipate the outcome of the national proceedings. The board has only to determine whether or not the national proceedings are "infringement proceedings" within the meaning of Article 105(1)(a) EPC, that is, whether they are founded on the patent proprietor's rights to prevent third parties from making use of the subject-matter of the opposed patent. It is therefore irrelevant whether the national law provides for an exemption to the rights conferred by a patent and whether this exemption applies in the circumstances at hand in the national proceedings.

1.8.4 Nor is the board persuaded by the respondent's argument that arbitration proceedings instituted under Law No. 62/2011 could not be infringement proceedings because applicants for a marketing authorisation for a generic medicine are not able to put the generic product on the market until such authorisation is given. However, the rights conferred by a patent are not limited to offering for sale or selling a generic medicine. Rather, the patentee's right to exclude as defined according to the national law will encompass acts preparatory to the marketing such as making or

importing and storing the medicine (see e.g. Article 28 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, which is binding on all contracting states).

1.9 In view of the above, the board holds that the arbitration proceedings according to Law No. 62/2011 constitute infringement proceedings within the meaning of Article 105(1)(a) EPC to the extent that they are directed to the enforcement of patent rights (and not merely rights stemming from supplementary protection certificates or from the protection of undisclosed test or other data submitted as a condition for the approval of marketing a pharmaceutical product). The opposition division was therefore correct to hold the interventions admissible. The interveners thus acquired status as opponents 2, 4 and 5 respectively and were entitled to appeal under Article 107 EPC (G 3/04, OJ EPO 2006, 118, point 4 of the Reasons).

2. The appeals by the intervening opponents are admissible.

3. A*dmission of document (40)*

Document (40) was late-filed, and its filing constitutes an amendment to appellant 3's appeal case.

Article 13(2) RPBA stipulates that 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.

The change of a party's representative and/or the presence of this document in a related file do not

represent such exceptional circumstances.

Consequently, the board decided not to admit document (40) into the proceedings, in accordance with Article 13(2) RPBA.

4. *Decision T 950/13 - binding effect (Article 111(2) EPC) and* res judicata

4.1 All the interventions were filed after decision T 950/13 had been issued following an appeal by the patent proprietor against the decision of the opposition division dated 1 February 2013 revoking European patent no. 1 610 780. Decision T 950/13 remitted the present case to the opposition division for further prosecution of outstanding issues raised by the opposition filed on 21 January 2011. The board in case T 950/13 found that the subject-matter of claim 1 directed to the use of dasatinib in the manufacture of a medicament for the treatment of chronic myelogenous leukemia (CML) was sufficiently disclosed. Although the application did not contain experimental evidence for dasatinib's Bcr-Abl kinase-inhibitory activity, the board was satisfied that the application disclosed at least a plausible technical concept for the treatment of CML by dasatinib, taking into account the known causative link between the Bcr-Abl oncogene and CML, the inhibition of Bcr-Abl kinase as an effective way to treat the disease, and dasatinib's functional equivalence to imatinib as a Bcr-Abl kinase inhibitor. As a consequence, the board took into account the post-published evidence (L. J. Lombardo et al., Journal of Medicinal Chemistry, vol. 47, 2004, pages 6658 to 6661, designated document (2)), which was held to confirm the Bcr-Abl kinase-inhibitory activity of dasatinib (T 950/13, points 3.3 to 3.7 of the Reasons). Arguments

provided by the opposition division and opponent were addressed in points 3.3 to 3.6, 3.9 and 3.10 of the Reasons. The board therefore held that the subject-matter of claims 1 and 4 of the main request was sufficiently disclosed. However, the board held that the subject-matter of claim 2 of the main request, which was directed to the use of dasatinib for the manufacture of a medicament for oral treatment of CML resistant to imatinib, was not sufficiently disclosed (points 3.13 and 3.14 of the Reasons). This finding also applied to claim 2 of then-auxiliary request 1, which was directed to the same therapeutic use as claim 2 of the main request. This claim had been deleted in auxiliary request 2a. Claim 1 of this request being identical to claim 1 of the main request, the board held that the ground of opposition according to Article 100(b) EPC did not prejudice maintenance of the patent on the basis of auxiliary request 2a (point 5 of the Reasons). The board also upheld the opposition division's finding that the claims of auxiliary request 2a, which (except for a minor correction) corresponded to the claims of auxiliary request 3 considered by the opposition division, complied with Articles 123(2) and (3) EPC.

4.2 In their notices of intervention and on appeal, the appellants argued that the medical use claimed in the main request was not sufficiently disclosed. They asked that this ground be reconsidered, and argued that the application did not disclose a plausible concept of treatment but a mere allegation without proof that dasatinib treats the same cancers as imatinib. Appellant-opponents 2 and 5 also raised objections of added matter (Article 123(2) EPC). The appellants thus raised grounds on which a decision had been taken in case T 950/13. Relying on decision G 1/94, they argued

that they had the right to challenge the findings of decision T 950/13. Relying on Article 111(2) EPC and the principle of *res judicata*, the respondent denies such right of interveners and appellants.

4.3 According to the established case law of the boards of appeal, *res judicata* is a generally accepted principle which means that a matter which has been judicially determined in a final manner between parties by a tribunal of competent jurisdiction cannot become the subject of subsequent proceedings between the same parties or their successors (T 934/91, OJ EPO 1994, 184, point 3 of the Reasons; T 153/93, point 2 of the Reasons; T 167/93, OJ EPO 1997, 229, points 2.2 to 2.5 of the Reasons). Decisions of the boards of appeal are *res judicata* both in form and substance, because there is no means of redress as to substance against them (G 1/97, OJ EPO 2000, 322, point 2(a) of the Reasons; T 694/01, OJ EPO 2003, 250, point 2.10 of the Reasons). This also applies to interlocutory decisions remitting the case for further prosecution (T 694/01, point 2.10 of the Reasons). The fact that the *res judicata* effect may be challenged by way of a petition for review (Article 112a EPC) does not call into question the final character of a decision of a board of appeal in the absence of a decision pursuant to Article 112a(5), second sentence, EPC re-opening the proceedings before the board of appeal (R 1/08, point 2.1 of the Reasons; T 584/09 of 1 March 2013, points 14 and 15 of the Reasons). Hence a board's decision is an absolute bar to subsequent proceedings on the same matter between the same parties (or their successors). The order and the reasons for the decision determine the extent to which the decision is final (T 460/95, OJ EPO 1998, 587, point 2 of the Reasons). The "same matter" refers to all issues of fact and law which have been finally

settled (T 694/01, OJ EPO 2003, 250, point 2.10 of the Reasons; T 167/93,OJ EPO 1997, 229, point 2.5 of the Reasons; see also T 843/91, OJ EPO 1994, 832, headnote and point 3.4.2 of the Reasons; T 153/93, point 2 of the Reasons; T 308/14, catchword and point 1.3).

4.4 The binding effect of a decision is governed by Article 111(2) EPC. Pursuant to this provision, a department whose decision was appealed against is bound by the *ratio decidendi* of the board of appeal's decision if the case is remitted to the department for further prosecution. The *ratio decidendi* is the ground or the reason for making it, in other words the point in a case which determines the outcome of the judgment (T 934/91, OJ EPO 1994, 184, point 2 of the Reasons). The same binding effect applies to the board in the case of a subsequent appeal against a further decision of the department of first instance following remittal (self-binding effect, T 79/89, OJ EPO 1992, 283, point 3 of the Reasons; T 21/89, point 3.1 of the Reasons).

4.5 The principle of *res judicata* and that of the binding effect pursuant to Article 111(2) EPC are not identical, but complementary. The binding effect of the *ratio decidendi* pursuant to Article 111(2) EPC is limited to proceedings regarding the same application or patent following a remittal of the case after a (first) decision of a board of appeal. The department dealing with the case in the subsequently resumed proceedings and the board dealing with a possible second appeal arising from these proceedings are bound by the *ratio decidendi* of the first decision. This binding effect extends to matter which is not finally settled (*res judicata*), but encompassed by the *ratio decidendi* (see as an example T 817/00, point 3.2 of the Reasons: an objection of lack of novelty rejected by

the first decision was reintroduced, after remittal, as an objection of lack of inventive step, a ground for opposition which had not been considered in the first decision). On the other hand, it only applies "in so far as the facts are the same" (see as an example T 1018/03, points 2.1 and 2.2 of the Reasons: further features were introduced into the claims after remittal in order to overcome inventive-step objections raised in the second appeal). The principle of *res judicata* is not limited to a situation of remittal for further prosecution but also applies in such a situation. Matter which has become *res judicata* is not open for reconsideration following remittal. Since this principle applies to all issues of fact which have been finally settled, it precludes a change of facts as contemplated by Article 111(2) EPC (T 843/91, OJ EPO 1994, 832, headnote and point 3.4.2 of the Reasons; T 1063/92, point 2.5 of the Reasons; T 153/93, points 2 and 3 of the Reasons). New facts, evidence or arguments seeking to cast doubt upon settled issues of fact cannot be considered. An example of this situation is decision T 308/14 (see headnote and points 1.2 and 1.3 of the Reasons): the first decision contained the finding of fact that the weight-average molecular weight in a claim was clear in terms of Article 84 EPC since, taking into account the evidence on file, it did not depend on the measurement method applied. Based on new documents introduced after remittal, the opposition division held that there was insufficiency arising out of ambiguity, namely the ambiguity of the weight-average molecular weight when measured according to different methods. The board held that this contravened the principle of *res judicata* which extended to any finding of fact that led to the decision remitting the case. See, however, the diverging decision T 1545/08 (points 11 and 12 of the Reasons).

4.6 The appellants are correct in stating that the principle of *res judicata* was narrowly defined in decision T 167/93 (OJ EPO 1997, 229, point 2.5 of the Reasons). However, decision T 167/93 was not concerned with the situation of an intervention after remittal of the case by a board of appeal, but with a cross-procedural *res judicata* effect (see T 167/93, point VI of the Facts and Submissions and points 2.6 to 2.10 of the Reasons). The definition of *res judicata* given in decision T 167/93 also deals with this situation. It is based on the doctrine of estoppel (T 167/93, point 2.5 of the Reasons) which operates as a defence of a party in subsequent separate proceedings between the same parties if facts or issues which have previously been judicially determined in a final manner are raised again. The doctrine appears not to relate specifically to circumstances as in the present case, i.e. the effect of a decision of an appeal board on a third party joining the resumed opposition proceedings after partial settlement of the issues between the parties to the appeal. In the present situation, it is important to take into account that opposition and opposition appeal proceedings require a decision on the form in which a patent can be maintained. Such a decision not only binds the parties to these proceedings, but its effect is *erga omnes* (T 598/98, point 1.7 of the Reasons). The nature of opposition and opposition appeal proceedings therefore does not support the view that a matter finally settled by an appeal decision remitting the case to the opposition division for further prosecution only binds the parties to the appeal proceedings and does not prejudice an intervener that only becomes a party to the opposition proceedings subsequent to the remittal of the case. The result of applying the principle of *res judicata* depending on the

party status in the appeal proceedings leading to remittal would be absurd. The adjudged matter had to be accepted by the initial parties, and the opposition division had no power to re-open such matter in respect of those parties, whereas interveners would be allowed to disregard the final findings of the decision remitting the case to the opposition division and start opposition proceedings anew. However, in opposition proceedings it is not possible to take separate decisions for different parties on the form of the patent to be maintained. It is also not possible, as suggested by appellant-opponent 2, to conceptually separate the opposition proceedings into two different parts, the first one being the original opposition and the second one opposition proceedings including the interveners. A European patent can only be the subject of one common opposition procedure (Article 99(3) EPC; T 863/96, point 2). The filing of oppositions by different opponents or interveners does not lead to separate opposition proceedings for each party, not even conceptually (T 694/01, OJ EPO 2003, 250, point 2.19). In the absence of pending opposition proceedings, assumed infringers may also not initiate opposition proceedings on their own by filing a notice of intervention. They can only intervene in opposition and opposition appeal proceedings initiated by another party. For these reasons, the rationale of T 167/93 cannot, in the board's opinion, be extended to the situation at hand. The principle of *res judicata* must have effect for all parties to the resumed opposition proceedings, even those that were not party to the previous appeal proceedings. Also, the opposition division and, on subsequent appeal, the board are bound by the substance of a remitting decision in that they are prevented from re-opening the settled issues (see

T 694/01, OJ EPO 2003, 250, point 2.10 of the Reasons; T 308/14, catchword).

4.7 In view of the above, the board considered whether the object and purpose of Article 105(1) EPC might justify and constitute an exception to both the principle of *res judicata* and the binding effect under Article 111(2) EPC.

4.7.1 Article 105(1) EPC on the one hand and the principle of *res judicata* and Article 111(2) EPC on the other hand involve conflicting considerations. As set out above, the purpose of Article 105 EPC is to ensure efficient use of the judicial system by preventing parallel national proceedings and to avoid contradictory decisions on the validity of European patents in the EPO and national courts. The principle of *res judicata* and Article 111(2) EPC, on the other hand, serve legal certainty, i.e. the general interest of the public that legal disputes be terminated within reasonable time. However, these principles also prevent re-litigation of issues of fact or law that have already been determined by a court, and thereby avoid a waste of judicial resources and inconsistent decisions. Whereas the purpose of Article 105 EPC speaks in favour of allowing the assumed infringer to make their full case against the opposed patent and make use of all available means of attacking the patent, the principle of *res judicata* and Article 111(2) EPC contradict this. These principles appear irreconcilable and the question is therefore which principle should prevail.

4.7.2 The appellants relied on decision G 1/94 (OJ EPO 1994, 787, point 13 of the Reasons) and argued that the Enlarged Board of Appeal had acknowledged an intervener's right to defend its case in full even at

the appeal stage of proceedings. Decision G 1/94 is concerned with an intervention of the assumed infringer when the proceedings have reached the appeal stage, and is confined to the finding that such intervention is admissible "*during pending appeal proceedings and may be based on any ground for opposition under Article 100 EPC*". Both the procedural situation and the point of law considered in decision G 1/94 differ from the factual and legal issues in the present case. As regards the procedural situation, it is clear from the reference to "pending appeal proceedings" that decision G 1/94 considered a situation where a presumed infringer intervenes before a decision is taken at the appeal stage. It thereby built on and added to decision G 4/91 (OJ EPO 1993, 339, corrected translation, 707) in which the Enlarged Board held that a notice of intervention filed during the two-month period for appeal provided by Article 108 EPC has no legal effect if no appeal is filed by a party to the opposition proceedings before the opposition division (G 4/91, headnote 4 and point 7 of the Reasons). The admissibility of an intervention thus requires that no final decision has been taken either by the opposition division in the absence of an appeal (G 4/91, headnote 2 and 3) or by a board of appeal in the event of such appeal. The statement that interveners should not be prevented from making use of all available means of attacking the patent has to be read in this context. This statement does not extend to a situation in which opposition appeal proceedings have been determined and completed in part or in full by the issuing of a decision. It is also to be noted that the order and the headnote of decision G 1/94 refer to a "new ground for opposition" and not to "all available means of attacking the patent" as stated in point 13 of the Reasons. The narrow order appears to address a

potential conflict with decision G 10/91 mentioned in said passage. From this reference it can be inferred that the Enlarged Board of Appeal, in addition to the admissibility of an intervention during appeal proceedings as such, addressed as a further procedural issue an exception to the constraint on introducing new grounds in appeal proceedings as established by decision G 10/91 (OJ EPO 1993, 420, headnote 3 and point 18 of the Reasons, requiring the approval of the patent proprietor). But even if the introduction of a new ground for opposition is merely seen as exemplifying the absence of any limitations to the introduction of new matter, this ruling is still confined to the situation that no decision has been taken on appeal. Indeed, the Enlarged Board of Appeal also held that the case should be remitted to the department of first instance for further prosecution should a new ground for opposition be introduced in "ordinary" appeal proceedings (G 1/94, point 13 of the Reasons). For this reason, and because the Enlarged Board of Appeal had refrained from commenting on further aspects of an intervention during the appeal proceedings, the rationale of decision G 1/94 cannot be extended to the issues of the present case and cannot support the appellants' view that G 1/94 establishes a right of the interveners to present the full case in opposition proceedings after remittal under Article 111(1) EPC which prevails over the principle of *res judicata* and the binding effect according to Article 111(2) EPC.

4.8 Allowing interveners in opposition proceedings after a remittal under Article 111(1) EPC for further prosecution to make "use of all available means of attacking the patent" (G 1/94, OJ EPO 1994, 787, point 13 of the Reasons) and, in particular, to challenge

issues which have been finally determined in the remitting decision of an appeal board would lead to a situation which cannot be reconciled with the provisions of the EPC and generally applicable principles of procedural law, and cannot be justified by the interest in enabling the validity of a European patent which is the subject of infringement proceedings before a national court to be determined centrally within opposition proceedings before the EPO.

4.8.1 As discussed in decision T 694/01 (OJ EPO 2003, 250, point 2.18 of the Reasons), an intervention in opposition proceedings after remittal would *de facto* constitute a means of appeal against the board's remitting decision if interveners were allowed to raise factual and legal issues finally settled therein. However, only parties to the proceedings leading to the contested decision who are adversely affected thereby have the right to initiate appeal and review proceedings and can become a party thereto (Articles 107 and 112a(1) EPC; G 2/19, OJ EPO 2020, 87, point B.II.4 of the Reasons; G 3/04, OJ EPO 2006, 118, point 6 of the Reasons). If the assumed infringer validly intervenes in the opposition proceedings after remittal by an appeal board, he acquires the status of an opponent (Article 105(2) EPC) and thus a party to these proceedings, but nothing more. Lacking party status in the appeal proceedings which lead to the remittal prior to the intervention, an intervener joining the resumed opposition proceedings has no standing to challenge, by whatever means of redress, the matter finally adjudged between the other parties in the appeal decision (see G 2/19, OJ EPO 2020, 87, points B.II.4 and 5 of the Reasons). Although this has not been argued by the appellants, the board also notes, for sake of completeness, that neither the wording nor the object

and purpose of Article 105 EPC suggests that an intervener in opposition proceedings after remittal by a board of appeal retroactively acquires the status of an appellant to the previous appeal proceedings (see G 3/04, OJ EPO 2006, 118, points 5 and 6 of the Reasons, which denies such a status even in the event of an intervention being filed during pending appeal proceedings). These remain proceedings *inter alios*. But even if such a creative interpretation of Article 105 EPC was accepted in order to give full effect to the legislative purpose of Article 105 EPC, such interpretation could only pave the way for a petition for review under Article 112a EPC as the sole available means of redress against a final decision by a board of appeal. The creation of an additional remedy aimed at reviewing a decision of a board of appeal would in any case exceed the application of general procedural principles (Article 125 EPC) and the powers of the boards of appeal (see G 1/97, OJ EPO 2000, 322, point 3(a) of the Reasons; T 402/01 of 4 October 2005, point 1.2 of the Reasons; T 883/06, point 2 and 3 of the Reasons).

4.8.2 However, the appellants did not claim a right to review decision T 950/13, but argued that there could be no restriction on the matter raised in an intervention, even when filed in opposition proceedings following a remittal, since an intervener was not restricted to the grounds of the opposition(s) instituting the proceedings. Such approach, which gives an absolute character to the right to expand on the factual and legal framework of the initial opposition, cannot be accepted. Exceeding the framework of an initial opposition is not the same as re-opening issues raised therein and decided by the board of appeal. In the latter case, the opposition division would have to

disregard a decision of a board of appeal which sets aside the opposition division's previous decision, and decide on the matter again. The opposition division would thus become judge in its own cause. This is without doubt irreconcilable with fundamental principles of procedural law. Even leaving aside the fact that submissions by the interveners which call into question the decision *de facto* aim at the revision of a board's decision contrary to G 1/97 (OJ EPO 2000, 322, point 6 of the Reasons), the appellants' approach is also unacceptable as it either leads to contradicting decisions within the same opposition procedure or a waste of time and resources. The board therefore agrees with decision T 694/01 that there "*is nothing in the EPC to suggest that the intervention of an assumed infringer opens a new stage of proceedings which invalidates binding results of the proceedings to date*" (T 694/01, OJ EPO 2003, 250, point 2.18 of the Reasons).

4.9 In the event of an assumed infringer intervening in opposition proceedings after remittal to the opposition division for further prosecution, the intervener must for the above reasons accept the case as it stands when joining it (T 694/01, OJ EPO 2003, 250, point 2.20 of the Reasons). In such a case, opposition proceedings within the meaning of Article 105 EPC exist only to the extent that the examination of the grounds for opposition has not been completed by the issuing of a decision of the board of appeal. The extent to which opposition proceedings are completed is determined by the principle of *res judicata* and the binding effect pursuant to Article 111(2) EPC (see above). An assumed infringer can validly intervene in opposition proceedings resumed after remittal of the case under Article 111(1) EPC to the extent that these proceedings

are still existing, and is not entitled to intervene in matters finally adjudicated which are no longer part of the opposition proceedings (T 694/01, point 2.20 of the Reasons; T 898/07, point 3.1 of the Reasons).

4.10 In the case at hand, the grounds of opposition of added matter and sufficiency of disclosure have been finally determined in decision T 950/13. These grounds are therefore not open to an intervention and can be considered neither by the opposition division nor by the board on appeal. As set out above, due to the principle of *res judicata*, it is not possible to change the facts underlying the decision T 950/13 even if this change is acceptable in view of the *ratio decidendi*.

4.11 *Referral*

According to Article 112(1)(a) EPC, a referral should be made if a board considers that a decision of the Enlarged Board of Appeal is required to ensure uniform application of the law or when a question of fundamental importance arises.

It is thus clear that a referral to the Enlarged Board is a matter of discretion. Whilst it is clear that the point of law of the scope of interventions filed in resumed opposition proceedings after remittal for further prosecution that has been argued in this case is important, it is equally evident that the question of law can be answered on the basis of the detailed analysis in decision T 694/01. Accordingly, a decision on this point by the Enlarged Board is not required. As set out in detail above, the finding is not in conflict with decision G 1/94 (OJ EPO 1994, 787) relied on by the opponents, as said decision is concerned with a procedurally distinct situation. Moreover, it has been

explained why the board considers that there are no decisions conflicting with decision T 694/01. Therefore there is also no need for a referral in order to ensure uniform application of the law.

For these reasons there is no necessity to refer a question in this regard to the Enlarged Board of Appeal as suggested by appellant 2.

5. *Inventive step*

The patent in suit aims at treating certain types of cancer, in particular chronic myelogenous leukemia, by oral administration of a compound of formula IV (paragraphs [0001], [0007] and [0079]). The compound of formula IV is known as "dasatinib".

5.1 *Documents (5) or (18) as closest prior art*

5.1.1 The decision under appeal and all appellants rely, *inter alia*, on either document (5) or (18) as closest prior art.

Document (5) is entitled "Bcr-Abl inhibition as a modality of CML therapeutics". The disclosure of this document thus focuses on the treatment of chronic myelogenous leukemia, especially in the context of Bcr-Abl inhibition. After discussing Bcr-Abl as a therapeutic target in the treatment of chronic myelogenous leukemia (page M11, right-hand column, first paragraph), the document goes on to describe the design of a potent, selective and orally active protein kinase inhibitor class based on a central phenylamino-pyrimidine template (see Figure 1A and paragraph bridging pages M11 and M12). Two further advantageous groups are identified, see Figures 1B and 1C, which are

included in the most promising compound, STI-571 (imatinib). Then the *in vitro* and *in vivo* profile of imatinib and clinical studies (relying on oral administration) carried out with imatinib are discussed, followed by details concerning resistance to imatinib (chapters 4 to 6). The structural basis of imatinib specificity is linked to the distinctive inactive conformation of the activation loop of Abl (page M17, left-hand column, second paragraph). In the "Conclusions" hopes for a new generation of specific, targeted therapies in oncology following the development of imatinib are expressed.

Document (18), in the context of CML and other Bcr-Abl+ leukemias, discusses possible strategies to prevent or overcome imatinib mesylate resistance. To this end mutations at the inhibitor binding pocket of Bcr-Abl or mutations destabilising the inactive conformation of Abl are effected. Two compounds, PPI (a 4-amino, 3-aryl substituted 1H-pyrazolo[3,4-d]pyrimidine) and CGP76030 (a 4-amino, 5-aryl substituted 7H-pyrrolo[2,3-d]pyrimidine), known to be Src kinase inhibitors, were found to inhibit Bcr-Abl in a concentration-dependent manner (abstract). Dual-specific Src/Abl kinase inhibitors are thus identified as having a potential role in the treatment of advanced or imatinib mesylate-resistant Philadelphia chromosome-positive leukemias (last paragraph).

5.1.2 It is common ground that the difference between the subject-matter of claims 1 or 3 of auxiliary request 2a and the disclosure of these two documents is the use of dasatinib as active agent.

Furthermore, it is common ground between the appellants and accepted as one possibility by the respondent that

the technical problem is the provision of an alternative treatment for CML.

5.1.3 As a next step, it needs to be determined whether this problem has been solved over the whole scope claimed.

The appellants pointed to the finding of T 950/13 regarding the lack of plausibility of the treatment of CML which is resistant to imatinib (T 950/13, reasons 3.14). The direct consequence of this finding was, according to the appellants, that the subject-matter of the claims encompassed variants which did not plausibly solve the technical problem.

The board draws attention to the primary finding of T 950/13, namely that the subject-matter of claims 1 and 4 of the then-main request, which is identical to the subject-matter of claims 1 and 3 respectively of auxiliary request 2a, is sufficiently disclosed. These claims define the treatment of CML with dasatinib. The board in T 950/13 found that there was a plausible technical concept to support this treatment. The fact that the board went on to find that such a plausible technical concept was not disclosed for the treatment of a specific patient group, i.e. patients suffering from a cancer resistant to imatinib treatment, does not change this general finding.

According to G01/03 (OJ EPO 2004, 413, point 2.5.2), the inclusion of non-working embodiments is of no harm if there are a large number of conceivable alternatives and the specification contains sufficient information on the relevant criteria for finding appropriate alternatives over the claimed range with reasonable effort. In T 950/13, the board did not state that the imatinib-resistant patient could not be treated,

rather, it concluded that there was no technical concept for such a treatment in the application as filed. In the context of the discussion of inventive step, the following applies. A lack of a plausible disclosure for one group of patients in the application as filed does not automatically lead to the finding that the treatment does not work for this group of patients. It seems to be paramount to distinguish in this respect between the concepts of lack of disclosure and non-working embodiments.

While a plausible technical concept might not be disclosed in the application as filed for a specific embodiment (in the present case imatinib-resistant patients), this does not automatically imply that this specific embodiment has to be classified as a non-working embodiment, or, seen in the context of the problem-solution approach, as an embodiment that does not solve the technical problem.

In the case at hand, the board identified (the disclosure in the application as filed of) a technical concept for the general treatment in T 950/13. No such technical concept could be identified in the application as filed for the specific embodiment concerning imatinib-resistant patients. However, the reasons underlying the failure of a treatment are not necessarily linked to the reasons for not accepting the disclosure of a technical concept. From this, it follows directly that a lack of disclosure of this concept does not automatically equate with a failure of treatment. As such automatic equating is not possible, a finding that the problem has not been solved over the whole scope requires confirmation of the existence of non-working embodiments. In the case at hand, the appellants have not identified any non-working

embodiments.

Regarding the issue of whether the problem has been solved over the whole scope, a closer look at the problem under consideration might be necessary in certain situations and/or technical fields. It requires a case-by-case assessment to establish whether a problem relating to the treatment of diseases, i.e. in the field of second medical uses, has been solved. In the case of the treatment of cancers, CML being one, a 100 percent "success" of the treatment would most probably not be expected by the medical practitioner. Even the term "success" might require some interpretation. "Success" in the treatment of cancer spans from total remission to slowing down of progression. Instead, in the case of cancer, the medical practitioner would expect to be confronted with a proportion of patients, possibly even with a substantial proportion of patients, who do not respond to a treatment that has been shown to "work" in principle. As a consequence, the medical practitioner would change the medication for the given patient, but would not doubt that the treatment might provide benefits to other patients. However, such considerations are not crucial for the present case.

In sum, the lack of a plausible disclosure regarding the imatinib-resistant patients cannot be equated with a finding that the claimed subject-matter includes non-working embodiments. No non-working embodiments have been identified by the appellants.

Consequently, the problem is to be considered as solved over the whole scope of the claims.

5.1.4 It remains to assess whether its solution would have been obvious to the person skilled in the art.

All the appellants referred to document (1) as rendering the claimed subject-matter obvious. They argued that the structures of the compounds of documents (5) and (18) that were responsible for their activity (pharmacophores) would provide an incentive for the person skilled in the art to seriously contemplate the compounds of document (1). Furthermore, document (18) identified Src kinases and pointed to dual or multiple kinase inhibitors. Screening activities were within the competences of the person skilled in the art.

Document (1) relates to certain cyclic compounds and their use in treating protein tyrosine kinase (PTK)-associated disorders such as immunological and oncological disorders (page 1, lines 9 to 12). The section discussing the background of the invention lists various families of PTKs. This section goes on to mention "a wide variety" of oncological and immunological disorders and finally focuses on Lck, a cytoplasmic/non-receptor PTK of the Src kinase family, and its activity in relation to T cells. The inhibitors of the PTKs are described as cyclic compounds of formula I, which is a Markush formula with Q, a 5-membered heteroaryl ring, a 6-membered heteroaryl ring or an aryl ring in central position (page 3, line 2 to page 8, line 7). Preferred compounds have a thiazole in central position (page 13, line 18). Methods of preparation of the compounds of formula I are described in Schemes A to E and I to XI (page 14, line 4 to page 39, line 8). One of the cyclic compounds is dasatinib (example 455). In total, 580 compounds are exemplified and characterised by their HPLC retention

time. For some of the compounds, information concerning the solid state and colour is given. Under the heading "utility", inhibition of members of the Src family is linked to diseases relating to immunological disorders, and inhibition of HER1 or HER2, which are receptor PTKs, is linked to anti-angiogenic uses such as the treatment of cancer and diabetic retinopathy (page 39, line 10 to page 40, line 9). A list of potential diseases to be treated is given on page 40, line 19 to page 43, line 25. It is stated that the compounds described in the examples have been tested in one or more of the enzyme assays (using Lck, Fyn, Lyn, Hck, Fgr, Src, Blk, Yes, Her1, Her2) and have "shown activity" (page 50, line 1 to page 51, line 30). The treatment of chronic myelogenous leukemia or the inhibition of Bcr-Abl is not disclosed. None of the exemplified compounds has been shown to have any activity for inhibiting any of the PTKs mentioned.

A close structural similarity in the sense of a common, or at least related, pharmacophore has not been shown to be present between dasatinib and imatinib or between dasatinib and PPI or CGP76030. Steric aspects of the molecules and aspects relating to electronic distribution within the molecules that would lead to accommodation in the kinase binding site despite the presence of different ring systems and substituents have not been invoked by the appellants. Concerning the ring systems and substituents as such, the following has been found. Document (1) identifies the thiazole group of dasatinib as a preferable element. In addition, dasatinib has a benzamide group in its peripheral parts and non-fused heterocyclic rings in the form of piperazine and pyrimidine. Document (5) clearly identifies the phenylamino-pyrimidine core of imatinib and points to a (centrally located) benzamide

group as being advantageous. PPI and CGP76030 share fused heterocyclic ring systems with amino and phenyl substitution. Neither a phenylamino-pyrimidine core nor a fused heterocyclic ring system with amino and phenyl substitution can be found in dasatinib. Thus the person skilled in the art would not have been pointed towards dasatinib for reasons related to structural similarity.

Concerning the functional aspects, the following applies. Document (1) lists various PTKs, belonging to both main families of PTKs. A Markush formula and several (580) specific compounds are disclosed. However, none of the compounds has been linked via its inhibitory activity to any of the kinases mentioned. Consequently, the person skilled in the art would have been faced with a screening project for "pairing" any of the compounds with one or more of the kinases mentioned. In the absence of any guidance as to which structure/compound might inhibit which PTK, such a screening project goes beyond the routine activities performed by a skilled person when trying to find alternative compounds inhibiting specific (either Bcr-Abl or dual Bcr-Abl and Src) kinases for the treatment of CML. The disclosure of document (1) can at best be seen as an invitation to perform a research programme.

As mentioned under point 5.1.1 above, document (18) relates to dual-specific Src and Abl kinase inhibitors. The two exemplified compounds are said to have been originally characterised as Src kinase inhibitors. The passage goes on to state that both compounds inhibited Bcr-Abl in a concentration-dependent manner by overlapping binding modes (abstract). It is thus clear that document (18) does not depart from the teaching that it is the Bcr-Abl inhibition as such that is responsible for the treatment of CML. The Src kinase

specificity comes in (merely) in the context of imatinib mesylate resistance. The person skilled in the art, being thus made aware that a Bcr-Abl inhibition was paramount for successful treatment of CML, would not have further investigated the compounds disclosed in document (1) despite the vague mention of Src kinase inhibition in this document.

5.1.5 The subject-matter of auxiliary request 2a is a non-obvious alternative over the teaching of documents (5) and (18).

5.2 *Document (1) as closest prior art*

5.2.1 The disclosure of document (1) is discussed in point 5.1.4 above.

The most promising starting point in document (1) is dasatinib. However, this compound has not been linked to any activity (in the present case, inhibition of one or more specific PTKs) or the treatment of any disease.

5.2.2 Consequently, the technical problem when starting from document (1) can be seen as identifying a medical use for dasatinib.

5.2.3 In view of the many PTKs listed in document (1) and the very general nature of the disclosure failing to link any of these PTKs to diseases or classes of diseases, it amounts to a research programme to identify such a medical use.

5.2.4 Carrying out a research programme is beyond the routine tasks of the person skilled in the art. Consequently, the person skilled in the art would not have arrived at the subject-matter of auxiliary request 2a starting

from document (1).

5.3 The subject-matter of auxiliary request 2a involves an inventive step (Article 56 EPC).

Having come to this conclusion, it is not necessary to examine the more ambitious technical problems identified as problems b) and c) by the respondent.

5.4 *Referral*

As post-published evidence is not crucial to the decision, issues relating to T 116/18 and a possible referral relating to such issues do not have to be dealt with.

6. *Article 84 EPC*

Despite the issue of whether aspects relating to Article 84 EPC are open for discussion (see G 3/14), the board provides herein, in favour of appellant 1, its conclusion on appellant 1's objection.

Article 84 EPC stipulates that the claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

The claims of auxiliary request 2a differ from the claims as granted, *inter alia*, by the deletion of dependent claims relating to CML resistant to STI-571, which are numbered 2 and 9 in the set of claims as granted.

Support for the subject-matter of the independent claims of auxiliary request 2a and for the subject-

matter of the dependent claims referred to above can be found in paragraph [0079], which is present in the patent as granted and in the description found by the opposition division to be compliant with Article 84 EPC for the set of claims of auxiliary request 2a.

The board fails to see how the deletion of a dependent claim can affect the support by the description for the independent claim (on which this deleted claim depended). Furthermore, the interpretation of the independent claims is not affected by the presence or absence of any dependent claims. This is in line with the board's conclusion, see point 5.1.3 above, that the problem of providing an alternative treatment for CML has been solved. The requirements of Article 84 EPC are met.

Having come to this conclusion, issues relating to the admission of the objection and the applicability of G 3/14 do not need to be addressed.

The objection by appellant 1 is rejected.

## Order

## For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated