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**Datasheet for the decision
of 4 June 2018**

Case Number: R 0009/17

Appeal Number: T 0488/16 – 3.3.01

Application Number: 00922102.9

Publication Number: 1169038

IPC: A61K 31/426, C07C 237/40,
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C07D 277/56, C07D 409/12,
C07D 417/12

Language of the proceedings: EN

Title of invention:
CYCLIC PROTEIN TYROSINE KINASE INHIBITORS

Patent Proprietor:
Bristol-Myers Squibb Holdings Ireland

Opponents:
Isenbruck Bösl Hörschler LLP
APOTEX INC.
Actavis Group PTC ehf
Generics [UK] Limited

Headword:
-

Relevant legal provisions:
EPC Art. 112a(2)(c)
EPC R. 106

Keyword:

Admissibility of petition: yes

Right to be heard fundamentally violated: no

Petition for review: clearly unallowable

Decisions cited:

R 0008/15, R 0007/16

Catchword:

-



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Grande Chambre de recours

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Case Number: R 0009/17

D E C I S I O N
of the Enlarged Board of Appeal
of 4 June 2018

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Decision under review:

**Decision of the Technical Board of Appeal
3.3.01 of the European Patent Office of
1 February 1017.**

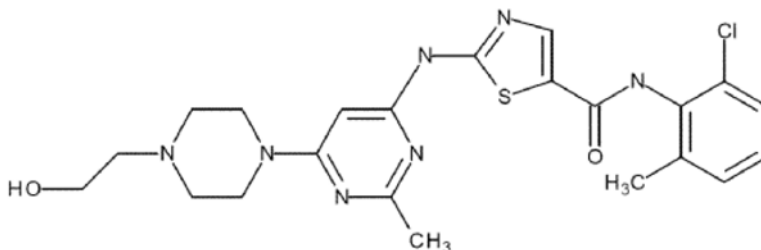
Composition of the Board:

Chairman: C. Josefsson
Members: W. Van der Eijk
W. Sieber

Summary of Facts and Submissions

- I. The petition for review concerns decision T 488/16 of 1 February 2017 of Board of Appeal 3.3.01(notified on 24 July 2017), in which the appeal of the patent proprietor, Bristol-Myers Squibb Holding Ireland, against the decision of the Opposition division to revoke European patent 1169038, was dismissed.
- II. During the opposition proceedings the three requests on file of the patent proprietor (further: the Petitioner) were found not to be allowable. The main request was found to be insufficiently disclosed, the first auxiliary request was not allowed because it contained subject-matter which extended beyond the content of the application as filed, and the second auxiliary request was found to lack an inventive step.
- III. In the appeal the Petitioner only filed a main request, which was identical to the second auxiliary request, which was not allowed by the opposition division. As a result, the sole issue in appeal was whether the Opposition division erred in not allowing the second auxiliary request.
- IV. The main request in appeal consists of 1 claim. This claim reads as follows:

1. The compound of formula:



or salts thereof.

This chemical compound is known under the name dasatinib, and will further be referred to by that name.

- V. During the opposition proceedings the patentee had argued that the technical problem solved by the claimed invention was the inhibition of protein tyrosine kinase (PTK). This effect was disclosed in the application as filed and was confirmed by post published evidence (documents (9) and (10)). The opponents had argued that this technical effect was not made plausible in the application as filed. They further argued that post-published evidence filed by the Petitioner, in order to demonstrate that dasatinib did indeed have the alleged technical effect, should not be taken into account.
- VI. The opposition division came to the conclusion that the technical effect alleged by the patentee was not made plausible in the application as filed. According to the opposition division it did not matter how the technical problem to be solved by the invention was exactly formulated. In this context it stated (p.16, first paragraph) "Whether the problem to be solved is formulated as the provision of alternative cancer agents or as alternative PTK inhibitors as formulated by the patentee during the oral proceedings is of

little importance for the present case since the opposition division came to the conclusion that neither of these problems can be considered to be plausibly solved." This statement by the opposition division should be seen against the background that the main request also claimed the use of dasatinib for treatment of specific diseases. The opposition division further agreed with the opponents that the post published evidence could not be taken into account.

The opposition division then reformulated the technical problem to be solved to a less ambitious one, namely the mere provision of alternative low molecular organic compounds. The solution to this problem was not seen as involving an inventive step.

VII. In the appeal, the Petitioner challenged the findings of the opposition division and submitted documents (36) and (37), which dealt with the question of what the application conveyed to the skilled reader. These documents were filed in support of the appellant's position that the opposition division erred in its assessment of what was plausibly disclosed in the application as filed. The Board admitted these documents into the proceedings as they were seen as an appropriate and legitimate attempt to address the objections raised by the opposition division.

VIII. However, the Board did not follow the argumentation of the Petitioner and confirmed the findings of the opposition division. In 4.19 of the reasons the Board concluded: "For the reasons set out above, the Board concurs with the opposition division and the respondents that the post-published documents (9) and (10) are the first disclosure showing that at least for

certain thiazole, in particular dasatinib, the purported technical problem has actually been solved. In accordance with established case law, these documents are therefore not taken into consideration in the assessment of inventive step."

- IX. The petition for review is based on Article 112a(2)(c) EPC in that a fundamental violation of the Petitioner's right to be heard under Article 113 EPC has occurred. The Petitioner alleges that the Board did not consider and take into account its arguments with respect to two central aspects of its case:
- I. the skills and general knowledge of the person skilled in the art on the filing date;
 - II. the technical problem to be considered for the evaluation of inventive step.
- X. According to the Petitioner, the right to be heard not only includes the right to make submissions on the grounds and evidence upon which a decision is to be based, but also that these submissions are considered. The Petitioner argues that the reasoning in the written decision demonstrates that the Board did not properly consider its arguments and submissions on the above mentioned issues, and that the decision therefore does not comply with Article 113 EPC. The Petitioner also argues that because this violation only became apparent in the written decision, it had no opportunity to make an objection under Rule 106 EPC.
- XI. The Enlarged Board summoned the Petitioner at its request to oral proceedings on 4 June 2018. Annexed to the summons was a communication of the Enlarged Board. In this communication the Enlarged Board expressed its

provisional opinion, namely that the petition seemed to be admissible but that the two objections seemed to be unfounded and that the petition therefore might be rejected as being clearly unallowable. In its reply dated 4 May 2018 the Petitioner reacted to the communication and further developed its argumentation. During oral proceedings before the Enlarged Board the Petitioner also orally presented its case and filed Illustration A and Illustration B.

At the end of the oral proceedings the Enlarged Board announced its decision.

Reasons for the Decision

1. Admissibility

The petition fulfils all the formal requirements for being admissible and the Petitioner is adversely affected by the decision under review. With respect to the obligation under Rule 106 EPC to raise an objection during the appeal proceedings, the Enlarged Board agrees with the Petitioner that the exception mentioned in the last part of this rule applies. As the alleged violation only became apparent in the written decision, the Petitioner could not have raised an objection during the appeal proceedings. The petition is therefore admissible.

2. General

This petition takes issue with the written decision of a Technical Board of Appeal. It alleges that it follows

from the reasoning of the written decision that the Board did not consider its submissions with respect to two central aspects of its case. The Petitioner is right in stating that the right to be heard not only includes the right to make submissions but also the right that these submissions are considered and taken into account. It is the established jurisprudence of the Enlarged Board that the reasoning of a decision should deal with the arguments of a party. See in this regard recently R7/16, para. 3.1.2: "The right to be heard not only implies that a party is given the opportunity to present its views but also that its arguments are taken into account and considered. The reasoning in a decision should be such that a party can establish that the deciding body actually considered its arguments and can understand why – in the case of an adverse decision – its arguments were found not to be convincing. Assessing the completeness of the reasoning would usually be beyond the scope of scrutiny under Article 113 (1) EPC. For compliance with the right to be heard, reasons may be incomplete, but as long as they allow drawing the conclusion that the Board, in the course of the appeal proceedings, substantively assessed a certain point as being part of the procedure and that it found to be relevant, there will be no violation of Article 113 (1) EPC (R8/15 of 18 July 2016, Reasons, points 2.2.2 and 2.2.3)."

In light of the above, the Enlarged Board has to consider whether the two alleged violations are well founded.

3. First complaint: the skills and knowledge of the person skilled in the art on the filing date

3.1 The complaint

3.1.1 The Petitioner complains that the Board regarded itself as having sufficient expertise to assess the application from the point of view of the notional skilled reader and cast aside the Petitioner's expert evidence in relation to the views of the person skilled in the art. In doing so, the Board failed to define who in its view the skilled reader is and what his skills and common general knowledge are, but nevertheless introduced a surprising conclusion as to how this person would read the application. The Petitioner therefore had no opportunity to comment thereupon, whereas at the same time its submissions on this topic have not been considered or taken into account. The Petitioner in this context particularly complains about the way the Board dealt with the expert evidence provided by the Petitioner in documents (36) and (37).

3.1.2 In 4.14 of the petition, the line of argument which has allegedly not been considered is recapitulated as follows: "It is thus a central point of Petitioner's case that the relevant notional person of average skill in the art would have understood from the application as filed that activity testing of all of the 580 Example compounds had taken place. This is because the patent is addressed to those with an interest in finding and using new protein tyrosine kinase inhibitors and the corresponding notional person of average skill in the art would not assume that the patentee would (contrary to the explicit statements in the application as filed) synthesize 580 novel compounds from scratch merely to enrich chemistry.

Further, as explained by Professor Parang (document (37) §26-29), the skilled person would observe in the application as filed an evolution in the Example compounds which is consistent with the progression of a typical, SAR based, optimization program in which further compounds are chosen for synthesis based on the observed activity of their predecessor."

- 3.1.3 Furthermore, the petitioner complains that the Board incorrectly referred to D10, one of the post-published documents, as evidence for concluding that the technical effect was not made plausible to the notional person skilled in the art at the filing date. This is all the more objectionable, as the Board otherwise concluded that D10 could not be used as evidence to confirm the technical effect of dasatinib.

3.2 Evaluation of the complaint

- 3.2.1 The Enlarged Board notes that the Board in its decision considered the following:
- a. in item XI (pp. 5-6) the Board summarised the arguments of the Petitioner with respect to the teaching of the application as filed, including documents (36) and (37), and the use of post-published evidence.
 - b. it admitted documents (36) and (37), although late filed, into the proceedings, as an appropriate and legitimate attempt to deal with the findings of the opposition division (see 3.1 of the reasons);
 - c. it then explained (as a preliminary remark) in point 4.6.1 of the reasons that expert evidence on the issue of how a person skilled in the art would read a document is not normally necessary, as it is not an

issue where expert technical expertise is usually required. Normally the Board would be able to answer that question on the basis of its own knowledge. Furthermore, the Board stated that expert opinion is subject to free evaluation by the Board. What matters are the substantiation and persuasiveness of the expert opinion. The Board finally drew the conclusion that such opinions have no particular authority and must be evaluated by the Board.

d. in points 4.6.2 to 4.6.5, the Board continued discussing the content of documents(36) and (37) and explained why it was not convinced by it. In general it seems the Board agreed with most of what was expressed in the opinions. However, according to the Board, the opinions did not address the basic problem (which was already explained in point 4.5 of the reasons): namely that the assertion on p. 50 of the application as filed (This sentence reads: "Compounds described in the following Examples have been tested in one or more of these assays and have shown activity") was not backed by any data, either to support the claim that the claimed compound (dasatinib) had shown PTK inhibition or to explain under what conditions the assays were carried out. The Board's finding was - concurring with the opposition division - that without such data it had not been made plausible to the person skilled in the art that the posed problem had actually been solved. See for example point 4.6.4 of the reasons, last paragraph: "However, in the complete absence of any data, no conclusion can be drawn as to whether or not the examples reflect a progression in the direction of improved PTK inhibitory activity. Nor is any conclusion possible as to whether or not a suitable pharmacophore reflected by the formula in Figure 4 of Professor

Parang's declaration, which includes dasatinib, had indeed been found at the filing date of the application."

There is no definition by the Board of the skills and general knowledge of the skilled person. The Board stated: "In the Board's opinion, the skilled reader can be expected to react in a way common to all persons skilled in the art, which means that any acceptance as to whether or not a particular assertion is correct must be based on verifiable facts, be it information provided in the patent application or available to the skilled person as common general knowledge." (point 4.6.2 of the reasons).

- 3.2.2 In the view of the Enlarged Board, the above summarised reasoning of the Board does not support the position of the Petitioner that its arguments were not considered.

The Board, contrary to what the Petitioner alleges, did consider the arguments and evidence from the Petitioner, including documents (36) and (37), and explained why it was not convinced by it (see points 4.6.2 - 4.6.5 of the reasons). With respect to the two expert opinions, the Board explained that it did not fundamentally disagree with them, but found that they did not address the essential problem in the case at hand. This central problem was already formulated by the opposition division, namely that the application did not provide verifiable facts that backed up the assertions made on p. 50 of the application. The conclusion of the Board that the expert evidence did not show why any person skilled in the art would accept

such statements in the absence of verifiable facts, is not proof that the expert opinions were not considered.

3.2.3 It is clear that the Petitioner filed (36) and (37) in order to overcome the problem raised by the opposition division. The Petitioner had an opportunity to argue its case, the respondents presented their views and the Board drew its own conclusion. This conclusion is formulated in the reasoning in a manner that makes it understandable why the Board is of the view that the Petitioner was not successful in rebutting the findings of the opposition division. During the oral proceedings the Petitioner argued with reference to Illustration B, that the approach of the Board was incorrect, because it had failed to deal with the question of plausibility at the right "level", that is the level of the person skilled in the art in the particular case as defined by the Petitioner, and did not properly evaluate what this person would understand from the application. This criticism goes into the merits of the decision. As indicated above, the Petitioner was heard on this issue and the Board took note of and considered the arguments of the parties, including the Petitioner. Whether the Board made mistakes in its evaluation of these arguments and adopted a wrong approach for assessing plausibility cannot however be judged in review proceedings.

3.2.4 The Enlarged Board is also not convinced that the Petitioner was objectively taken by surprise by this reasoning. It cannot be inferred from the decision that the Board introduced a new ground for dismissing the appeal that could not have been commented upon by the parties. The respondents had argued and the opposition

division found that because of the lack of verifiable data to back up the assertion on p.50 of the application, the alleged technical effect of the invention was not made plausible to the skilled person. The Board comes to the same conclusion for basically the same reasons. In conclusion, there was no new ground introduced on which the parties could not comment.

3.2.5 The Enlarged Board is further of the view that the Board was not obliged to share its thinking with the parties before taking a decision. Both the Petitioner and the respondents had every opportunity to discuss the issue which, as all parties could be aware, was central to the outcome of the appeal. Neither the Petitioner nor the respondents were hindered from making the arguments they wanted to make. The Petitioner was however not entitled to know whether it was successful in convincing the Board. It is established jurisprudence that there is no obligation for a Board to give advance indications of the reasons for its decision. It is sufficient if the parties were aware of the decisive issues and had an opportunity to make their views known. In inter partes appeals there is furthermore an obligation for the Board to remain neutral and not to give helpful information or hints to one of the parties. Also, in light of this obligation, the Enlarged Board does not see a violation of the right to be heard by the Board in this respect.

3.2.6 Finally, the Petitioner complains about the reference to D10 in the reasoning. This complaint is based on a sentence in the third paragraph of point 4.5 of the reasons: "As pointed out by the respondents, such a

reading also appears to be in conflict with the appellant's post-published evidence according to which certain compounds of the example were inactive at a specific concentration". This sentence does not in the view of the Enlarged Board show that the Board based a decisive argument for rejecting the appeal on a surprising use of document (10). Firstly, the sentence refers to an argument made by the opponents, of which the Petitioner was aware and could have commented upon. Secondly, the sentence, when read in context, appears to provide a supporting argument for a conclusion already drawn, on the basis of the Board's reading of the already quoted passage on p. 50 of the patent description.

The first complaint therefore is unfounded and thus clearly unallowable.

4. Second complaint: the technical problem to be considered for the evaluation of inventive step

- 4.1 The complaint

According to the Petitioner the Board did not deal with its point that the objective problem to be considered was the provision of a PTK inhibitor and that different standards apply with respect to plausibility for the provision of a compound having a valuable property such as PTK inhibition and for the provision of a compound for a medical use. The Petitioner suggests that the Board actually looked at a more ambitious problem, namely the medical use of the compound dasatinib for treating PTK related disorders or diseases. Thereby the Board missed the point that the only claim on file did

not refer at all to a medical use, it just claimed dasatinib. The Petitioner added that, in case it were assumed that the Board had the same problem in mind as the Petitioner, the decision is "defective to an extent that the Petitioner cannot ascertain whether the Board has based its decision on facts the Petitioner had no possibility to comment upon" (point 4.3 of the submission of 4 May 2018) and "The observations made and conclusions reached by the Board at this point of the written reasons of the decision do not justify the findings that no PTK inhibitory activity at all (of dasatinib) has been made plausible." (petition, point 5.20) Petitioner criticises the decision as being inconsistent and interrupted by illogical steps, with as a consequence that it does not allow the Petitioner to understand how the Board reached its conclusion.

4.2 Evaluation of the complaint

- 4.2.1 The Petitioner is correct that in appeal, unlike in the opposition proceedings, only the compound dasatinib was claimed and not its medical use. In opposition proceedings, a point of discussion had been whether different standards for plausibility of the solution for these technical problems would apply. However, as in appeal only the compound was claimed, there was no need for the Board to deal with that issue. The only question to be answered was whether the alleged effect of the claimed compound (PTK inhibition) was made plausible and whether the opposition division had erred in fact or in law in this matter.
- The opposition division had stated in its decision (page 16, lines 1-5): "Whether the problem to be solved is formulated as the provision of alternative anti-

cancer agents or as alternative PTK inhibitors as formulated by the patentee during the oral proceedings is of little importance for the present case since the opposition division came to the conclusion that neither of these problems can be considered to be plausibly solved."

This conclusion was challenged by the Petitioner, discussed between the parties in appeal and is a central part of the reasoning of the Board (points 5.1-5.5 of the reasons).

4.2.2 In its petition the Petitioner refers to several quotes from the decision in which the technical problem is formulated in different ways. It sometimes refers just to the PTK inhibition activity and sometimes makes the link with the treatment of PTK related disorders. However, the Enlarged Board is not convinced that this points to a procedural violation by the Board. Point 5.4 of the reasons of the decision starts with: "At the oral proceedings before the Board, the appellant argued that dasatinib showed a clear improvement in PTK inhibitory activity [...]." At the end of point 5.4 it reads: "Accordingly, the appellant formulated the problem as the provision of an improved PTK inhibitor and considered it solved by the compound dasatinib." These formulations seem to indicate that the Board had understood the technical problem as seen by the Petitioner.

In point 5.5 of the reasons the Board explains why it believes that the application as filed does not contain evidence that this problem is successfully solved. It is true that the Board in this paragraph also refers to the usefulness of dasatinib for the treatment of

cancer. However, at the end of point 5.5 the conclusion of the Board is in line with the problem formulated in point 5.4: "The Board therefore concurs with the opposition division and the respondents that the effect on which the appellant relied (i.e. any PTK inhibitory activity) cannot be taken into account in formulating the technical problem."

4.2.3 The Enlarged Board is therefore of the view that the Petitioner did not succeed in demonstrating that the Board had a different problem in mind than the appellant and ignored its arguments. Furthermore, the Enlarged Board cannot possibly see that the Board was of the view that the technical problem as formulated by the Petitioner was solved but that the more ambitious problem of the medical use of dasatinib was not, and that the negative decision for the Petitioner was caused by a confusion of the two problems. In conclusion, the Enlarged Board is of the view that the Petitioner did not make a convincing case that the Board ignored its argumentation with respect to the technical problem to be considered.

4.2.4 As regards the criticism that the reasons do not justify the decision and the written decision is inconsistent and interrupted by illogical steps, the Enlarged Board is of the view that this criticism goes into the substance of the decision. In petition for review proceedings however the Enlarged Board is not entitled to review the quality or correctness of the reasoning of a decision. Such a review would imply that the Enlarged Board has to go into the merits of the decision under review. The Enlarged Board therefore cannot deal with the substance of the remarks made by

the Petitioner in its reply to the communication of the Enlarged Board, where under the headings of "verifiable facts vs. has been tested", "verifiable facts vs. verifiable data" , "application of the concept of verifiable facts" , "individualized compounds", "activity" and "test" the incorrectness and inconsistency of the reasoning of the Board is criticised. Even if the criticism of the Petitioner that the reasoning is defective were correct - which the Enlarged Board cannot evaluate- that would not in itself prove that a violation of the right to be heard has occurred. Such a violation can only be assumed to exist if the reasons demonstrate that a point central to a party's case has been overlooked or not considered. In this context reference is made to the already quoted decision R 7/16, where with respect to the reasoning of a decision the jurisprudence of the Enlarged Board has been summarised.

The Enlarged Board, after having carefully reviewed the entire proceedings and the totality of the reasons of the decision, has found no indications that central elements of the submissions of the Petitioner have been ignored or not considered. Nor was the Enlarged Board able to find proof that the Board based its decision on grounds or evidence that were not in the proceedings and on which the Petitioner was thus unable to comment upon.

In the light of the above also the second objection is not founded and therefore clearly unallowable.

5. In summary, as both complaints are not founded the petition must be rejected as being clearly unallowable.

Order

For these reasons it is unanimously decided that:

**The petition for review is rejected as being clearly
unallowable.**

The Registrar:

The Chairman:

P. Cremona

C. Josefsson