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Datasheet for the decision of 6 May 2026

Case Number: T 0715/24 - 3.3.04

Application Number: 16724512.5

Publication Number: 3288980

IPC: C07K16/28, A61K39/395, A61P35/00

Language of the proceedings: EN

Title of invention:
Treatment of PD-L1-positive melanoma using an anti-PD-1 antibody

Patent Proprietor:
Bristol-Myers Squibb Company

Opponents:
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Kraus & Lederer PartGmbB
Pajaro Limited
Greiner, Elisabeth
Pohlman, Sandra M.

Headword:
Anti-PD-1 monotherapy/BRISTOL-MYERS SQUIBB

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - extension beyond the content of the application as filed (yes)

Decisions cited:
G 0002/10

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Case Number: T 0715/24 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 6 May 2026

Appellant: (Patent Proprietor)	Bristol-Myers Squibb Company Route 206 and Province Line Road Princeton, NJ 08543 (US)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
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Respondent III: (Opponent 3)	Pajaro Limited 12 New Fetter Lane London EC4A 1JP (GB)
Representative:	Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)

Respondent IV: (Opponent 4)	Greiner, Elisabeth Theatinerstraße 16 80333 München (DE)
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Respondent V: (Opponent 5)	Pohlman, Sandra M. Fünf Höfe Theatinerstraße 16 80333 München (DE)
Representative:	Pohlman, Sandra M. df-mp Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted/electronically transmitted on 13 March 2024 revoking European patent No. 3288980 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	D. Luis Alves
	R. Romandini

Summary of Facts and Submissions

I. The patent proprietor (appellant) filed an appeal against the opposition division's decision to revoke European patent No. 3 288 980, entitled "*Treatment of PD-L1-positive melanoma using an anti-PD-1 antibody*".

II. Five oppositions had been filed, invoking the grounds for opposition under Article 100(a) EPC, in combination with Articles 53(c), 54 and 56 EPC, and under Article 100(b) and (c) EPC.

III. In its decision, the opposition division considered a main claim request and 20 auxiliary claim requests. It held, *inter alia*, that claim 1 of auxiliary request 20 related to subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

IV. With its statement setting out the grounds of appeal, the appellant filed sets of claims of a main request and 29 auxiliary requests. The main request is identical to auxiliary request 20 considered in the decision under appeal. The other requests were newly filed. Further, the appellant filed documents D78 and D79.

V. In its letter dated 7 October 2024, the appellant made further submissions and filed document D80.

VI. Opponent 3 (respondent III), opponent 4 (respondent IV) and opponent 5 (respondent V) submitted replies to the appeal.

VII. The appellant made further submissions by letter dated 21 November 2025.

VIII. The board sent a summons to oral proceedings and a communication pursuant to Article 15(1) RPBA in which it set out its preliminary view on the appeal.

IX. Oral proceedings were held as scheduled, in the presence of the appellant and respondents III, IV and V. Respondents I and II did not attend, as announced by letters dated 4 May 2026 and 8 April 2026, respectively.

At the oral proceedings, the appellant withdrew auxiliary request 1, renumbered auxiliary request 2 to auxiliary request 1, and withdrew all lower-ranking requests.

At the end of the oral proceedings, the chair announced the board's decision.

X. Claim 1 of the **main request** reads:

"1. A composition comprising nivolumab for use in treating a melanoma in a patient:

(i) wherein the patient is identified as having a PD-L1 positive melanoma tumor by measuring a PD-L1 cell surface expression on the melanoma tumor; and

(ii) wherein the patient is to be administered a flat dose of 480 mg of nivolumab as monotherapy once every four weeks, wherein the patient is not administered a combination of nivolumab and an anti-CTLA-4 antibody or an antigen-binding portion thereof that specifically binds to a human CTLA-4."

In claim 1 of **auxiliary request 1** (filed as auxiliary request 2), the wording of part (ii) reads:

"(ii) wherein the patient is to be administered a flat dose of 480 mg of nivolumab as monotherapy once every four weeks, wherein the monotherapy comprises administering the patient nivolumab without another anti-cancer agent."

XI. The appellant's arguments of relevance to this decision may be summarised as follows.

Main request
Claim construction - Claim 1

Claim 1 was to be construed to mean that the patient is administered nivolumab but is not administered a CTLA-4 antibody. It did not exclude administering other anti-cancer agents. Thus, the term "monotherapy" did not have its usual meaning. This arose from the plain wording of the claim, as well as paragraph [0040] of the description of the patent as granted. If monotherapy were given its usual meaning, the subsequent negative feature would be redundant. This is not how the skilled person would have interpreted the wording of the claim. Since the negative feature made it clear that the term "monotherapy" was not to be given its usual meaning, the question then was what meaning it should be given. The skilled person would read this term in line with the definition provided on paragraph [0040] of the description, which presented several embodiments rather than merely providing a confirmatory statement. This paragraph too made it clear that "monotherapy" in claim 1 was not to be given its usual meaning.

The negative feature, namely that the patient is not administered an anti-CTLA-4 antibody, applied for the whole duration of the claimed treatment. Thus, no antibodies to CTLA-4 were administered at the same point in time as, or before or after nivolumab.

According to the case law, a single interpretation of the claim should be adopted. This should be the broadest reasonable interpretation.

Respondent III's interpretation, according to which the claim was directed to monotherapy in the usual meaning of the term, and the negative feature only imposed a limitation on the therapy before and after said monotherapy, was not based on the plain wording of the claim and contradicted the description of the patent as granted (see paragraphs [0015] and [0040]).

Respondent IV's interpretation was likewise not in line with the patent and moreover was not technically sensible. The patent made it clear that no anti-CTLA-4 antibody was to be administered while the patient was receiving the monotherapy (see paragraph [0055]). This interpretation would go against the overall teaching of the invention.

Admittance of arguments into the appeal proceedings

Claim interpretations and related arguments put forward by the respondents for the first time in the appeal proceedings should not be admitted into the proceedings.

Amendments (Article 123(2) EPC) - Claim 1

According to the board's interpretation, the negative feature in claim 1 did not define the term "monotherapy". Therefore, objections relating to the wording of the negative feature were irrelevant.

According to the case law, a change in wording that could not change the subject-matter was irrelevant. Decision G 2/10 did not change this; it concerned the subject-matter that remained after excluding what was defined by the disclaimer; however, in the case of present claim 1 and adopting the board's claim construction, the disclaimer was redundant.

Monotherapy in the usual meaning of the term was disclosed as one of the three options in paragraph [0043] of the application as filed (see last sentence). The respondents submitted that the wording used in that paragraph was not "anti-melanoma agent" but rather "anti-cancer agent". However, in context, there was no difference in meaning between these two terms.

The examples also referred to monotherapy with administration of nivolumab without co-administration of any other agent.

Finally, the description could not be relied upon simultaneously to support a particular claim construction adopted by the board and, at the same time, to argue that the claim related to subject-matter not present in that very description.

The combination of the dosage regimen, nivolumab, and monotherapy in its usual meaning, did not result from

selections from several lists. The dosage regimen was directly and unambiguously disclosed in paragraph [0117], last sentence, of the application as filed. It thus constituted a single selection from a list. The feature "nivolumab" did not require any selection, as it was the preferred antibody on which the invention was based (see examples and paragraph [0058]). Moreover, according to the case law, pointers could be derived from lists of converging alternatives or from the examples (see Case Law of the Boards of Appeal of the EPO, 10th edn., II.E.1.6.2), as was the situation in the present case. Contrary to the respondents' arguments, the examples rather than the claims reflected the core of the invention.

Auxiliary request 1 (filed with the statement of grounds of appeal as auxiliary request 2)

Admittance

This request should be admitted into the appeal proceedings as it addressed an objection by the opposition division that only became apparent from the decision under appeal. Accordingly, it could not have been filed earlier.

Claim construction - Claim 1

In claim 1 of this request, the feature "monotherapy" was completely aligned with the definition in paragraph [0043] of the application as filed. Furthermore, whereas claim 1 of the main request contained a disclaimer, claim 1 of this request defined monotherapy in positive terms.

Amendments (Article 123(2) EPC) - Claim 1

The application as filed provided a clear pointer towards the use of nivolumab as a monotherapy in accordance with the definition in paragraph [0043].

XII. The respondents' arguments of relevance to this decision may be summarised as follows.

Main request
Claim construction - Claim 1

According to respondent III, the term "monotherapy" in claim 1 was to be given its usual meaning in the technical field. However, the subject-matter of the claim was not limited to nivolumab monotherapy, since the claim was directed to the treatment of melanoma (see paragraph [0055] of the patent). Accordingly, the combination therapy to be excluded did not define the monotherapy and concerned an additional administration step. Thus, the claim was directed to a monotherapy in which the administration of the specific combination therapy consisting of nivolumab with an anti-CTLA-4 antibody was excluded both prior to and subsequent to this monotherapy (see paragraphs [0007], [0056], [0057], and [0135] of the patent). This disclaimer or negative feature was not linked to the definitions provided in paragraph [0040] of the patent.

According to respondent IV, the term "monotherapy" in claim 1 should not be given its usual meaning. An understanding of this term to exclude any other active agents or anti-cancer agents would not be the interpretation that was the most technically sensible. Since the negative feature resulted in an inconsistency

within the claim, the description should be used for guidance. However, paragraph [0040] of the patent did not provide a single clear definition of this term. It allowed for combination therapies such as nivolumab with an additional antibody or other therapeutic agent (see lines 16 to 20). It was clear from this paragraph that "monotherapy" did not have its usual meaning. Therefore, it could be concluded that the negative feature in claim 1 merely excluded the simultaneous administration of an anti-CTLA-4 antibody with nivolumab. Therefore, claim 1 should be construed as allowing the administration of an anti-CTLA-4 antibody, provided that it was not co-administered with nivolumab.

The negative feature did not define the monotherapy. Rather it stated that "the patient is not administered a combination of nivolumab and an anti-CTLA-4 antibody". Thus, the patient might be administered combinations other than this specific one.

According to respondent V, in view of the negative feature in claim 1, the term "monotherapy" did not have its usual meaning. Paragraph [0040] of the patent provided several possible meanings for this term and, according to paragraph [0039], the composition could contain more than one antibody to PD-1. In view of the negative feature (or disclaimer) it was ambiguous which subject-matter remained covered by the claim.

Amendments (Article 123(2) EPC) - Claim 1

The term "monotherapy" as usually construed meant treatment with a single drug. If claim 1 was construed to give monotherapy its usual meaning, it lacked direct and unambiguous disclosure in the application as filed.

Claim 1 as filed included a definition of the terms "anti-PD-1 antibody monotherapy" and "combination therapy". The latter was defined as the administration of anti-PD-1 antibody and anti-CTLA-4 antibody. The former was defined to exclude this combination therapy.

The meaning of "anti-PD-1 antibody monotherapy" differed from the usual meaning of "monotherapy". This was emphasised by claim 49 as filed, which referred back to all the higher-ranking claims and defined the treatment as further comprising administering an anti-cancer agent. Accordingly, what is disclosed is the administration of a further agent for the treatment of cancer in the context of the monotherapy of claim 1 as filed. Therefore, the application as filed did not provide a direct and unambiguous disclosure of "nivolumab as monotherapy".

None of the embodiments in paragraph [0043] of the application as filed was in line with the usual meaning of "monotherapy" either.

Respondent V further argued that the disclaimer in claim 1 introduced an ambiguity and for this reason alone the claim contravened the requirements of Article 123(2) EPC.

Respondents III to V objected to the combination of the dosage regimen with nivolumab and "monotherapy" in its usual meaning. The dosage regimen was the result of a selection made after initially selecting a flat dose regimen. Nivolumab was also the result of a selection from at least the alternative pembrolizumab. The example could not be relied upon as a pointer for nivolumab, as it did not concern a flat dosage regimen.

Auxiliary request 1 (filed with the statement of grounds of appeal as auxiliary request 2)

Admittance

This request should not be admitted into the appeal proceedings, as it could and should have been filed in the opposition proceedings. Moreover, it did not overcome the objections raised under Article 123(2) EPC against the main request.

Amendments (Article 123(2) EPC) - Claim 1

The amendments did not overcome the deficiencies identified for the main request. Moreover, the board did not base its claim interpretation on paragraph [0043] of the application as filed - which did not mention nivolumab - but instead gave the term "monotherapy" its usual meaning in the art. Furthermore, the wording in claim 1 differed from that in paragraph [0043]. Finally, in view of claim 49 as filed, the claimed subject-matter represented a non-preferred embodiment and lacked a technical link to the examples.

XIII. The relevant requests of the parties were as follows.

The appellant requested
- that the decision under appeal be set aside and the case be remitted to the opposition division for consideration of the objections under Articles 83, 53, 54 and 56 EPC based on one of the sets of claims of the main request or of auxiliary request 1, filed as

auxiliary request 2 with the statement setting out the grounds of appeal;
- that certain of the respondents' arguments not be admitted into the appeal proceedings, namely the arguments of respondent III in points 9 and 37 to 54 of its reply to the appeal and those of respondent IV in point 103 of its reply to the appeal; and
- that documents D78 and D79 be admitted into the appeal proceedings.

Respondents III, IV and V requested
- that the appeal be dismissed;
- that documents D78 and D79 not be admitted into the appeal proceedings; and
- that none of the auxiliary requests be admitted into the appeal proceedings.

Reasons for the Decision

Main request

Claim construction - Claim 1

1. When assessing whether an amendment complies with the requirements of Article 123(2) EPC, it is first necessary to determine the technical meaning of the amended claim. The question as to whether subject-matter extends beyond the content of the application as filed can only be answered on the basis of a proper construction of the claim from the perspective of the skilled person.

2. The board considers that claim interpretation is a question of law which must be answered by the board.

Technically sensible claim interpretations cannot be discarded merely because they were not brought forward in opposition proceedings as this would prevent the board from properly interpreting the claim. Therefore, the appellant's request not to admit some claim interpretations submitted by the respondents was rejected.

3. Claim 1 is directed to the anti-PD-1 antibody nivolumab, for use in the treatment of melanoma, further defined by

(i) the patient group - "*identified as having a PD-L1 positive melanoma tumor by measuring PD-L1 expression on the melanoma tumor*"

(ii) the dosage regimen - "*a flat dose of 480 mg of nivolumab as monotherapy once every four weeks*"

(iii) a negative feature - "*wherein the patient is not administered a combination of nivolumab and an anti-CTLA-4 antibody or an antigen-binding portion thereof that specifically binds to a human CTLA-4*"

4. The term "monotherapy" has a well-recognised meaning in the technical field of the patent. According to the Merriam-Webster Medical Dictionary Online, it means the use of a single drug to treat a particular disorder or disease; the decision under appeal refers to this same meaning (see point 8.2.1 of the decision); the appellant refers to "alone, without another active agent" (see point 51 of the statement of grounds of appeal). There was therefore no dispute among the parties as regards the usual meaning of this term in the relevant technical field.

5. The dispute as to how to construe the claim rests on whether and how the negative feature modifies the usual meaning of the term "monotherapy". The decisive question is whether the negative feature merely illustrates what is already excluded by the term "monotherapy" in its usual meaning, or whether, on the contrary, it imposes limitations that redefine the term. In answering this question, the claim is to be interpreted with a mind willing to understand, so as to arrive at an interpretation that is technically sensible and takes into account the whole disclosure of the patent.

6. The appellant advanced two arguments for departing from the usual meaning. First, the negative feature itself limited the term "monotherapy", so that the term meant nivolumab therapy excluding an anti-CTLA-4 antibody, but not excluding other drugs. Second, reading the patent as a whole, the skilled person was directed to a special definition of "monotherapy" in paragraph [0040], alternative to its usual meaning.

7. The board is not persuaded by either argument. The negative feature is not drafted as a definition: the wording "wherein the patient is not administered ..." gives no indication that the feature serves to define or redefine the term, and against the well-recognised meaning of "monotherapy" it merely introduces a fundamental ambiguity. Nor does paragraph [0040] of the patent provide a definition; instead it lists various embodiments of the invention, and these relate to "anti-PD-1 antibody monotherapy" in general, whereas claim 1 concerns "nivolumab as a monotherapy" specifically. Construing the claim in light of the description therefore neither yields an unusual definition of "monotherapy" nor resolves the ambiguity

arising from the negative feature. The board concludes that the term "monotherapy" is to be given its usual meaning in the relevant technical field, so that claim 1 relates to nivolumab for use in treating PD-L1 positive melanoma, with nivolumab being used as a single drug.

8. The respondents further argued that all technically sensible interpretations of the claim should be taken into account and that, accordingly, each such interpretation must have a basis in the application as filed for compliance with Article 123(2) EPC. In view of the decision below, there is no need for the board to address this issue in the present case.

Amendments (Article 123(2) EPC) - Claim 1

9. In decision G 2/10, OJ EPO 2012, 376, the Enlarged Board of Appeal held that the gold standard for assessing any amendment for its compliance with Article 123(2) EPC is that any amendment to the parts of a European patent relating to the description, claims and drawings can only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed (see Reasons, 4.3).

10. Therefore, whereas claim 1 of the main request was construed taking into account the description of the patent (see point 7. above), it is the content of the application as filed, including the claims and description as filed, that is relevant for assessing compliance of claim 1 with Article 123(2) EPC.

11. The respondents raised objections to the wording of the negative feature, including the question as to whether the excluded combination therapies should be nivolumab and an anti-CTLA-4 antibody, or generally any anti-PD-1 antibody and an anti-CTLA-4 antibody. In this context, the appellant argued that the wording of the negative feature in claim 1 could not affect the definition of the subject-matter, and it was therefore irrelevant to the question of allowability of the amendments.

12. The board did not base its decision on any assessment of whether the wording of the negative feature had a basis in the application as filed. The board limited its analysis to the question of the basis for the claimed subject-matter as resulting from the claim construction set out in point 7. above. Accordingly, the question to be addressed was whether the application as filed disclosed nivolumab for use in treating PD-L1 positive melanoma as a monotherapy, in the usual meaning of the term, in the dosage regimen set out in the claim. For the reasons provided below, the board concluded that this was not the case.

13. Claim 1 as filed reads

"*1. A method for treating a melanoma comprising:*
(i) identifying a patient having a PD-L1 positive melanoma tumor; and
(ii) administering to the patient an anti-PD-1 antibody or an antigen-binding portion thereof that binds specifically to a human PD-1 ("anti-PDl antibody monotherapy"), wherein the patient is not administered a combination of an anti-PD-1 antibody or an antigen-binding portion thereof and an anti-CTLA-4 antibody or an antigen-binding portion thereof that binds specifically to a human CTLA-4 ("combination therapy").

The use of quotation marks and parenthesis indicates that monotherapy is being assigned a specific definition in claim 1 as filed. That definition is presented in contrast to combination therapy. In this way, the claim defines a treatment of PD-L1 positive melanoma with the administration of an anti-PD-1 antibody and excluding the combined administration of an anti-PD-1 antibody and an anti-CTLA-4 antibody. Such subject-matter is not synonymous with the meaning of the term "monotherapy" in present claim 1.

14. As noted by the respondents, this construction of claim 1 as filed is also consistent with claim 49 as filed. Claim 49 is dependent *inter alia* on claim 1 and specifies that the method further comprises administering an anti-cancer agent. It is thus consistent with the special definition of monotherapy set out in claim 1 as filed, according to which the administration of additional therapeutic agents is not excluded, provided that the patient is not administered the combination of nivolumab and an anti-CTLA-4 antibody.

15. A further matter of dispute was whether the usual meaning of "monotherapy" was directly and unambiguously derived from the remaining parts of the application as filed. The only part offered in this regard was paragraph [0043], last sentence. The respondents contested that this passage disclosed "monotherapy" in its usual meaning. However, for the reasons set out below, this issue can be left open.

16. Even if monotherapy, in the usual meaning of the term, were regarded as one of the embodiments disclosed in this passage, it would still have to be established

whether it was envisaged for therapy with nivolumab in the specified dose (480 mg) and frequency (every four weeks). The board considers this not to be the case. Indeed, the application as filed does not establish any link between this particular dosage regimen and the use of nivolumab as a monotherapy. Such a link cannot be derived from example 1, since this example relates to a clinical trial employing a body-weight-based dosing regimen, whereas claim 1 is directed to a flat-dose regimen. Nor can paragraph [0058] of the application as filed provide such a link, as it contains no disclosure concerning dosage. The board agrees with the appellant that the application discloses the invention as residing in the realisation that patients with PD-L1-positive melanoma do not benefit from additional therapy with an anti-CTLA-4 antibody. Nevertheless, claim 1 does not relate to this general concept. Instead, it specifies one of the many flat doses and administration frequencies. It is not unambiguously derivable from the application as a whole that no additional therapy will be required for this specific dosage regimen.

17. The combination of features in claim 1 of the main request is not directly and unambiguously derivable from the application as filed (Article 123(2) EPC).

Auxiliary request 1

Admittance

18. Admittance of this claim request was contested. However, there is no need to give reasons for its admittance, since, for the reasons given below, the request could not be allowed.

Amendments (Article 123(2) EPC) - Claim 1

19. Compared to claim 1 of the main request, claim 1 refers to monotherapy as administering nivolumab without another anti-cancer agent. In the context of therapy with an anti-PD-1 antibody in general, this same wording is present in paragraph [0043] of the application as filed (see last sentence). This is also the passage of the application cited by the appellant.

20. As regards claim construction, the appellant submitted that the issues arising from the negative feature in claim 1 of the main request were no longer present since "monotherapy" was now defined by a positive feature.

21. However, even on the assumption, in line with the appellant's submission, that claim 1 includes its own definition of monotherapy, the reasoning as set out in point 16. in relation to the main request applies here too.

22. In conclusion, the combination of features in claim 1 of auxiliary request 1 is not directly and unambiguously derivable from the application as filed (Article 123(2) EPC).

Conclusion

23. None of the requests on file comply with the requirements of the EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

C. Rodríguez Rodríguez M. Pregetter

Decision electronically authenticated