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Datasheet for the decision of 18 October 2023

Case Number: T 0737/20 - 3.3.04

Application Number: 11162667.7

Publication Number: 2397155

IPC: A61K39/00, A61P31/12, A61P31/18, A61P31/22, G01N33/53

Language of the proceedings: EN

Title of invention:

Methods and compositions for the treatment of persistent infections by inhibiting the programmed cell death 1 (PD-1)pathway

Patent Proprietor:

Dana-Farber Cancer Institute, Inc.
The Brigham and Women's Hospital, Inc.
Emory University
President and Fellows of Harvard College

Opponents:

Sanofi
Regeneron Pharmaceuticals, Inc.
Janssen Sciences Ireland UC

Headword:

Relevant legal provisions:
EPC Art. 56, 111(1), 113
EPC R. 106
RPBA 2020 Art. 11, 12(2), 23

Keyword:
Remittal - (no)
Right to be heard - violation (no)
Obligation to raise objections - objection dismissed
Inventive step - (no)

Decisions cited:
G 0009/91, G 0010/91, T 2154/15

Catchword:
Right to be heard: see points 16 and 17 of the Reasons

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Beschwerdekammern

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Case Number: T 0737/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 18 October 2023

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 20 January 2020 revoking European patent No. 2397155 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman M. Pregetter
Members: A. Chakravarty
R. Romandini

Summary of Facts and Submissions

I. The patent proprietors filed an appeal against the opposition division's decision to revoke European patent No. 2 397 155, with the title "*Methods and compositions for the treatment of persistent infections by inhibiting the programmed cell death 1 (PD-1) pathway*". The patent proprietors are four separate legal persons, who are all appellants. In this decision "appellant" in the singular is also used to refer to all appellants.

II. The patent had been opposed by three opponents (Opponents 1, 2 and 3, respondents I, II and III, respectively, in the appeal proceedings). In the decision under appeal the opposition division held that the subject-matter of claim 1 as granted lacked novelty. It also held that grounds for opposition under Article 100(c) EPC and under Article 100(b) EPC did not prejudice the maintenance of the patent and that the claimed subject-matter was entitled to priority.

III. With its statement of grounds of appeal, the appellant requested as a main request that the decision under appeal be set aside and that the patent be maintained as granted. It also submitted sets of claims of auxiliary requests 1a to 1o (series 1) and auxiliary requests 2 or 2a to 2o (series 2).

IV. All three respondents replied to the appellant's statement of grounds of appeal.

V. The Board appointed oral proceedings and subsequently issued a communication under Article 15(1) RPBA setting out its preliminary opinion on the appeal case. Since

the appellant had made no substantive submissions on inventive step in the appeal proceedings, it was given a time limit of 2 months from receipt of the communication to do so.

VI. The appellant replied to the Board's communication, and submitted a set of claims which it referred to as main request 1a. This set of claims was to be considered as coming after the main request but before the previously filed auxiliary requests. It also provided a response to the respondents' objections of lack of inventive step.

VII. Claim 1 of the patent as granted (main request) reads:

"A compound that reduces the activity or expression of a Programmed Cell Death-1 (PD-1) polypeptide for use in treating persistent viral infection in a subject, wherein said compound is an anti-PD-1 antibody, an anti-PD-L1 antibody, an anti-PD-L2 antibody, an anti-PD-1 RNAi, an anti-PD-L1 RNAi, an anti-PD-L2 RNAi, an anti-PD-1 antisense RNA, an anti-PD-L1 antisense RNA, or an anti-PD-L2 antisense RNA, wherein said persistent viral infection is an infection with a hepatitis virus, a herpes virus, cytomegalovirus, Epstein-Barr virus, herpes simplex virus 1, herpes simplex virus 2, human herpes virus 6, varicella-zoster virus, hepatitis B virus, hepatitis C virus, papilloma virus, parvovirus B19, polyomavirus BK, polyomavirus JC, human T cell leukemia virus I, and human T cell leukemia virus II".

Claim 1 of main request 1a differs from claim 1 of the main request in that it further defines the persistent viral infection as "characterized by functionally impaired antigen specific CD8+ T-cells".

Claim 1 of series 1 of the auxiliary requests is amended in that either reference to certain compounds (e.g. an anti-PD-L1 or L2 antibody, an anti-PD-L1 or L2 RNAi and an anti-PD-L1 or L2 antisense RNA) is deleted, or reference to certain viruses (e.g. HSV-1 virus and to the Herpes virus and HSV-1, hepatitis C virus and to the Hepatitis C virus) is deleted, or a combination of these amendments.

Claim 1 of series 2 of the auxiliary requests limits the claims to chronic viral infections. Otherwise series 2 mirrors the main request and series 1 of auxiliary requests.

VIII. Oral proceedings before the Board took place as scheduled. At the oral proceedings, the Board heard the parties' submissions on whether to remit the case to the opposition division to allow it to decide on the inventive step of the subject-matter of the main request. The Board informed the parties that it had decided not to remit the case to the opposition division and intended to deal with the issue of inventive step itself. Subsequently, the appellant raised an objection under Rule 106 EPC to the effect that its right to be heard under Article 113 EPC had not been respected. The objection was also submitted to the Board by email. The Board dismissed the objection. At the end of oral proceedings the chair announced the Board's decision.

IX. The following document is referred to in this decision:

D5: Barber D.L. *et al*. (2005), FASEB journal, 19(4) A893, published 4th March 2005.

X. The arguments of the appellant, relevant to the decision, are summarised as follows.

Remittal (Article 111(1) EPC)

The case should be remitted to the opposition division for further prosecution. There were special reasons that warranted remittal of the case back to the opposition division in accordance with Article 11 RPBA

Under Article 12(2) RPBA 2020, the primary object of the appeal proceedings was to review the decision under appeal in a judicial manner. As held by the Enlarged Board of Appeal in decisions G 9/91 and G 10/91 (and supported in e.g. decisions T 2194/14, T 1102/15, T 343/16 and T 632/16), this is a key principle of the appeal procedure. According to these decisions it was not in conformity with the judicial purpose of the appeal proceedings to consider grounds for opposition on which the decision of the opposition division was not based. The appeal procedure was by its very nature less investigative than an administrative procedure. The Enlarged Board's decisions, cited above, stated that although Article 114(1) EPC formally covered the appeal procedure, this provision should be applied in a more restrictive manner in the appeal procedure than in the opposition procedure. This was especially the case with regard to fresh grounds for opposition.

Not remitting the case when considering requests, facts, objections, arguments and evidence on which the decision under appeal was not based went against the RPBA and established case law. The RPBA represented implementing regulations to the EPC. Under Article 23(4) EPC, the RPBA were binding on the Boards. This in turn meant that under Article 12(2) RPBA, the

Board was obliged to remit the case if the decision under appeal had not dealt with an issue, so that each o bjection could be dealt with by two instances. Reference was made to decisions T 1394/21, T 350/17, T 731/17, T 1966/16, T 411/17, T 578/16, T 986/16, T658/17 and T 2017/16 to support this view.

It was further established case law that a case should be remitted if all issues cannot be decided without undue burden (see e.g. T 578/16). In the present case, despite there being no decision on inventive step, each respondent in their reply to the statement of grounds of appeal had provided numerous inventive step attacks using different documents to those referred to in the decision under appeal. There were seven potential closest prior art documents and a further fifteen combinatory documents, only one of which was mentioned in the decision under appeal. The consideration of inventive step studying all these documents for the first time amounted to an undue burden for the appellant and the Board. This was therefore a special reason for remitting the case.

In summary, for the Board not to remit case to the opposition division to decide on inventive step, where the decision under appeal had not dealt with inventive step, constituted a violation of the right to be heard under Article 113(1) EPC, since it deprived the appellant of the opportunity to have its case heard and decided at two instances and went beyond the Board's remit under Article 12(2) RPBA to review the decision under appeal in a judicial manner.

Objection under Rule 106 EPC

After the Board announced its decision not to remit the case to the opposition division but to deal with the issue of inventive step itself, the appellant submitted the following objection under Rule 106 EPC by email:

"*In accordance with Rule 106 EPC and Article 112a(2) EPC we would like it minuted that the Board's refusal to remit this matter back down to the opposition division in accordance with Article 11 RPBA 2020 to discuss inventive step infringes both Articles 112a(2) (c) and (d) EPC.*

Article 112a (2)(c) EPC is infringed because the patentees' right to be heard pursuant to Article 113 EPC is infringed because the patentees' request to have the question of inventive step examined at two different levels of jurisdiction has been refused. This is particularly so when there is no decision on inventive step.

Article 112a(2)(d) EPC is infringed because the refusal of our request to remit this matter to the Opposition Division to discuss inventive step is a fundamental procedural defect taking cognisance of Article 12(2) RPBA 2020, Article 11 RPBA 2020 and Article 23 RPBA 2020".

Main request - claim 1
Inventive step (Article 100 (a) EPC and Article 56 EPC)

The claimed invention was based on the finding that antigen-specific CD8+ (also referred to as CD8 T-cells) T-cells were exhausted in persistent infections due to the induction of PD-1, and that blockade of the PD-1

pathway reactivated the exhausted T-cells and reduced viral titers. This was demonstrated for the first time in the patent by means of an animal model for persistent viral infections. It was only with the detailed data provided in the patent that the skilled person could assess that using a compound that reduced the expression or activity of PD-1 would provide an effective treatment for the persistent viral infections mentioned in the claim. This had not been known from any of the cited prior art documents.

Nor had any of the cited prior art documents provided any evidence of PD-1 expression induced T-cell exhaustion in persistent viral infections or that taught that the claimed compounds would be effective in treating persistent viral infections. Prior to the findings of the present patent, the skilled person had no expectation of success that the claimed compounds could solve the problem of treating the recited persistent viral infections. It was only the data of the patent that gave the skilled person a reasonable expectation that the claimed compounds could treat the recited persistent viral infections.

The opponents had cited a large number of documents in support of their positions that the claims lacked an inventive step. However, there was not a single cited document that provided any data to demonstrate that persistent viral infections could be treated by the claimed compounds despite extensive work carried out in the field. In particular, there was no prior art document demonstrating the mechanism of PD-1 induced T-cell exhaustion or demonstrating that inhibition of PD-1 signaling restored exhausted T-cell function, thereby reducing viral titers.

The closest prior art

Document D5, an abstract, asserted that reversing CD8 T-cell exhaustion might be possible by blocking the PD-1/PD-L1 pathway and that it might provide a useful therapeutic strategy for the treatment of chronic viral infection. However, no data or evidence was presented in the abstract, nor were specific viral infections mentioned. The difference between the disclosure in document D5 and claimed subject matter was therefore actual provision of concrete evidence that put the skilled person in the position to treat specifically identified persistent viral infections.

The technical problem

The objective technical problem was the provision of effective treatments of persistent viral infection. Using the claimed compounds to treat the persistent viral infections as recited in claim 1 was the solution to this problem and was demonstrated in Example 1 of the patent, which for the first time showed that blocking the PD-1/PD-L1 pathway could restore T-cell function and enhance viral control during chronic viral infection in the LCMV model. Specifically, αPD-L1 blocking antibodies resulted in increased CD8+ T-cell proliferation and viral clearance as well as enhancing B-cell responses.

Obviousness

Although the FASEB journal, in which document D5 was published, was a credible journal, abstracts for meetings were not reviewed in the same manner as a scientific paper presented for publication in a scientific journal. Document D5 was an abstract

submitted for the PNAS meeting. When an abstract was presented for a meeting, there was a cursory evaluation as to the relevance of the subject matter to the meeting, but the content of the abstract was not peer reviewed in the same manner as a scientific paper. For this reason, the skilled person would not give document D5 the same credibility as a peer reviewed document.

On a technical level, document D5 did not disclose the technical effect that was the subject matter of the claimed invention. Its assertions were speculative at best. A reasonable expectation of success could only be brought about by a scientific appraisal of the available facts. There was not enough information in document D5 for the skilled person to make a scientific appraisal of the assertions made.

The situation was similar to that dealt with in decision T 296/93 (see Case Law of the Boards of Appeal I.D.7.1), where the competent Board held that, even though something was "obvious to try" or was an interesting area to explore, there was not necessarily a "reasonable expectation of success". A reasonable expectation of success should not have been confused with the understandable "hope to succeed" because the former implied the ability of the skilled person to predict rationally, on the basis of the knowledge existing before a research project was started, the successful conclusion of the said project within acceptable time limits.

In summary, the skilled person would not have concluded based on the content of document D5 and the nature of its publication that there would have been a reasonable expectation of success that the claimed compounds could

have effectively treated the persistent viral infections recited in claim 1.

Admittance
Main request 1a

It was requested that the Board admit this request into the appeal proceedings using its discretion under Article 12(3) RPBA. The request was filed in direct response to paragraph 12 of the Board's communication pursuant to Article 15(1) RPBA, dated 9 May 2023 in which it was noted that it remained to be decided if the expression "persistent viral infection" had clearly defined boundaries.

No further submissions were made on this topic, either in writing or at the hearing.

Auxiliary requests 1a to o (series 1), 2 and 2a to o (series 2).

Admittance

The respondents' position that both series of auxiliary requests were not admissible was not agreed with. The Board had discretion to admit any submission by a party that met the requirements of Article 12(3) RPBA. The grounds of appeal highlighted precisely the amendments made in the requests and the reasons that they had been made. They were filed as part of a complete case and met the requirements of Article 12(2) RPBA.
These parallel sets of claim requests were presented to address the added matter and sufficiency objections raised by the opponents (respondents) during the opposition proceedings and the opposition division's decision based on the Article 54(3) EPC prior art. The

limitation to "chronic" viral infections in series 2 was done for the event that the Board held that claim 1 of the main request was not novel.

XI. The arguments of the respondents, relevant to the decision, are summarised as follows.

Remittal (Article 111(1) EPC)

The case should not be remitted to the opposition division to deal with inventive step. Under Article 111(1) EPC, the Board could exercise any power within the competence of the department which was responsible for the decision appealed. The Board was therefore competent to deal with the objections of lack of inventive step raised by the opponents in their notices of opposition and reiterated in their replies to the statement of grounds of appeal. Indeed, the rules of procedure of the Boards of appeal, in particular Article 11, stated that "*the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so*". Contrary to the appellant's view, the fact that the decision of appeal did not deal with inventive step was not necessarily a special reason. The decisions cited by the appellant in favour of remittal did not support their case because they concerned different circumstances. According to the cases law of the Boards, the decision on remittal was to be decided on a case by case basis depending on the circumstances.

Inventive step (Article 100 (a) EPC and Article 56 EPC)
Main request - claim 1

Closest prior art

In the preliminary opinion issued by the opposition division, document D5 was identified as the closest prior art. Document D5 was a conference abstract published in March 2005, i.e. just before the June 2005 priority date of the opposed patent. It related to blockade of the PD-1 pathway in order to restore function in CD8 T-cells during chronic infection.

Is disclosed that:
- CD8 T-cells in mice chronically infected with lymphocytic choriomeningitis virus (LCMV) expressed high levels of PD-1.
- LCMV infected cells expressed high levels of PD-L1.
- Anti-PD-1 or anti-PD-L1 antibodies induced expansion of T-cells, enhanced cytokine production and increased viral control.

The authors concluded that blocking the PD-1/PD-L1 pathway may provide a "useful strategy" in the treatment of chronic viral infection.

Document D5 mirrored the findings of example 1 of the opposed patent. In fact, a number of authors of document D5 were inventors of the opposed patent, including Rafi Ahmed. The only difference between the disclosure in document D5 and the subject-matter of claim 1 of the main request is that the former did not mention the specific viruses of claim 1.

The technical problem

The problem to be solved was provision of a means for treating the specific viral infections of claim 1. The solution to the problem was the blockade of the PD-1 pathway in patients with the specific infections.

Obviousness

The solution to the problem would have been obvious to the skilled person based on the disclosure in document D5 alone. It disclosed that blockade of the PD-1 pathway in LCMV infected mice, enhanced T cell function and improved viral control. LCMV was the model of persistent infection used in the examples of the opposed patent. LCMV must therefore be an accepted model for all of the viruses of claim 1.

Document D5 not only provided a motivation to try blockade of PD-1 in the viruses of claim 1 but also, given the disclosure of positive results in LCMV mice, a reasonable expectation of success that the problem would be solved in this way. The viral infections listed in claim 1 were simply an arbitrary, obvious selection from all persistent/chronic viral infections, which the skilled person would have made.

The appellant's argument that no conclusions could be drawn from document D5 because it did not provide any data and was not peer reviewed was incorrect. Document D5 was not an example of a document disclosing that a study was conducted, but without providing any indication of the results. On the contrary, it very clearly indicated that positive results were obtained. At the relevant date of the patent, scientists had clearly appreciated the link between PD-1 and persistent viral infections. Against this backdrop, document D5 explicitly disclosed that administration of

anti-PD-1 and anti-PD-L1 antibodies induced the expansion of virus specific CD8 T-cells, enhanced cytokine production and increased viral control in LCMV mice (the same animal model as example 1 of the patent). The results described in D5 are therefore consistent with what the skilled person would have expected based on knowledge in the art at that time.

Auxiliary requests

Admittance

Neither the auxiliary requests filed with the statement of grounds of appeal nor the main request 1a filed with the letter dated 17 July 2023 should be admitted into the appeal proceedings.

Main request 1a

Article 13(2) RPBA applied to main request 1a, according to which late amendments to the case should as a rule not be admitted.

Auxiliary requests - series 1

As noted on page 2, item 7 of the opposition division's decision, series 1 of auxiliary requests were withdrawn by the patentee at the oral proceedings following the decision of lack of novelty for the main request. According to Article 12(6) of the RPBA, the Board should not admit requests which were no longer maintained in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance. There were no such circumstances in the present case.

Auxiliary requests - series 2

These claim requests were presented for the first time with the statement of grounds of appeal. In auxiliary request 2, the references to "persistent viral infection" were replaced with "chronic viral infection". Auxiliary requests 2-2o included "chronic" and then mirrored the main request and the amendments made in auxiliary requests 1a-1o. Auxiliary requests 2-2o are therefore an amendment to the patentee's case and can only be admitted at the discretion of the Board.

According to the appellant, this series of claim requests was filed in case the Board considered that the first series requests lacked novelty over documents D1 and D20. The appellant had not provided any justification for submitting these requests during the appeal proceedings and not at first instance. These requests could have been submitted earlier in the proceedings. In particular, the appellant appeared to have withdrawn auxiliary requests 1a-1o to avoid a finding of lack of novelty on them. This suggested that the appellant knew about the need to to address novelty during the first instance proceedings, but deliberately did not do so.

The parties requests

XII. The appellants requested that the decision under appeal be set aside and that the patent be maintained as granted. Alternatively, the patent should be maintained on the basis of the set of claims of main request 1a (filed with the letter dated 17 July 2023), auxiliary requests 1a to 1o, or on the basis of the set of claims

of auxiliary requests 2 or 2a to 2o (all filed with the statement of grounds of appeal).

The appellant also requested that if the Board decides that the subject-matter of one of the main or auxiliary requests is novel, the case be remitted to the opposition division for further prosecution, in particular to deal with inventive step.

XIII. Respondent I requested that the appeal be dismissed. It further requested that none of the auxiliary requests filed with the statement of grounds of appeal be admitted, that in the event that any auxiliary request is admitted that the case not be remitted to the opposition division for further prosecution, that in the event that the opposition division's decision on novelty is overturned, that the case not be remitted to the opposition division for further prosecution,that document D44 be admitted into the proceedings.

XIV. Respondent II requested that the appeal be dismissed. It further requested that the case not be remitted to the opposition division for further prosecution, that none of the auxiliary requests filed with the statement of grounds of appeal be admitted into the proceedings and that main request 1a, filed with the letter dated 17 July 2023, not be admitted into the proceedings.

XV. Respondent III requested that the appeal be dismissed. It further requested that none of the auxiliary requests filed with the statement of grounds of appeal be admitted into the proceedings.

Reasons for the Decision

Remittal (Article 111(1) EPC)

1. The Board, using its discretion under Article 111(1) EPC, decided not to remit the case to the opposition division for further prosecution.

2. The appellant is correct that the primary object of appeal proceedings is the review of the decision under appeal in a judicial manner. This is clearly reflected in the wording of Article 12(2) RPBA. However, according to established case law, parties have "*no absolute right to have each and every matter examined at two instances*" (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2020, V.A. 9.2.1 and 9.6.1). Article 111(1), second sentence, EPC, leaves it to the Board's discretion to decide on an appeal either by exercising any power conferred on the department of first instance or by remitting the case to that department (*ibid*).

3. The appellant referred to decisions G 9/91 and G 10/91 to support its view that Boards of appeal are barred from dealing with grounds for opposition not dealt with in a decision under appeal, especially in an *inter partes* case. However, decisions G 9/91 and G 10/91 actually relate to different issues. In fact, both are concerned with the question of whether or not an opposition division or a Board of appeal has the power to examine grounds for opposition not raised by the opponent in its notice of opposition. In summary, they ruled that the power of the opposition divisions and of the Boards of appeal to examine and decide on the maintenance of a European patent depended on the extent

to which the patent is opposed in the notice of opposition pursuant to Rule 55(c) EPC 1973 (now Rule 76(c) EPC) and that fresh grounds for opposition may be considered in appeal proceedings only with the approval of the patentee. These rulings do not apply to objections which, as in the present case, were validly raised by the opponents in their notices of opposition, i.e. which are not fresh grounds of opposition.

4. The appellant has cited a number of cases in support of its view that the fact that a decision under appeal does not deal with certain objections constitutes special reason to remit the case under Article 11 RPBA (specifically decisions T 2194/14, T 578/16, T 986/16, T 1966/16, and T 2017/16, T 350/17, T 731/17, T 411/17, T 658/17 and T 1394/21).

5. In all of these decisions, the competent Board decided to exercise its discretion under Article 111(1) EPC to remit the case to the body whose decision was appealed to decide on issues not dealt with in a decision under appeal. However, these decisions establish no general obligation to remit the case under such circumstances. Instead, they highlight the case-by-case nature of the Boards' exercise of discretion, which must take into account the specific legal and factual framework of each case.

6. In deciding not to remit the present case, the Board took into account that the legal and factual framework established by the decision under appeal, in which the opposition division held that the subject-matter of claim 1 as granted lacked novelty over the disclosure in documents D1 and D20 and also held that grounds for opposition under Article 100(c) EPC and under Article 100(b) EPC did not prejudice the maintenance of the

patent, was not significantly altered by dealing with inventive step of claim 1 of the patent as granted. This was *inter alia* because the opposition division had already given a preliminary view on inventive step in its communication of 21 June 2019, issued in preparation for oral proceedings (see points 12 and 12.1 of that communication).

7. Moreover, the respondents' arguments relating to the inventive step of subject-matter of claim 1 of the patent were maintained in their replies to the statement of grounds of appeal (see points 5, 5 and Annex B of respondent I to III's replies to the statement of grounds of appeal, respectively). Furthermore the Board, in its communication under Article 15(1) RPBA, invited the appellant to reply to the above mentioned objections, which it did in its submission of 17 July 2023. There is therefore no question that the appellant was surprised by having to make submissions on inventive step at the oral proceedings.

8. Finally, Article 11 RPBA provides that "*the Board shall not remit the case to the department whose decision was appealed unless special reasons present themselves for doing so. As a rule, fundamental deficiencies which are apparent in the proceedings before that department constitute such special reasons*".

9. Dealing with grounds for opposition admissibly raised in the proceedings before the opposition division and maintained in appeal by the opponents but not dealt with in the decision under appeal does not necessarily constitute special reasons for remittal. In the present case, the appellant had the opportunity to study the respondents' relevant written objections and to reply

to them both in writing and at the oral proceedings. Indeed, the respondents' cases on inventive step of the subject-matter of claim 1, made in writing, have not changed from those made before the opposition division and in the written appeal proceedings and did not change during the oral proceedings before the Board. Such a change of case might have constituted a special reason for remittal to the opposition division for further prosecution. However, this situation did not arise here. As set out in point 2. above and confirmed in decision T 2154/15 (see Reasons 2.3), the RPBA do not deprive the Boards of the discretion conferred on them by Article 111(1) EPC.

10. Further considerations for exercising its discretion under Article 111(1) EPC not to remit the case for further prosecution were reasons of procedural economy and the need to legal certainty considering the age of the patent, which has a filing date of 8 June 2006. Remitting the case would have led to an undue delay in the proceedings, near the end of the patent's term.

11. The appellant submitted that the effort for the Board and the parties, needed to deal with the topic of inventive step, amounted to an undue burden. This criterion may in some cases be a factor in a Board's decision on remittal. However, in the present case the other factors outweighed any extra burden on the Board and the parties. In any event, remittal is not the only way to deal with the possible burden of examining an issue, e.g. inventive step, *ex novo*: other measures could be, *inter alia*, postponing the oral proceedings and/or requesting the parties to make further submissions, or resuming the written proceedings. It may be that one of these measures is preferable, from the perspective of the procedural economy, to a

remittal, because it might ensure a decision on the case in shorter time. The choice of which measure is adopted is at the discretionary assessment of the Board.

Objection under Rule 106 EPC

12. During the hearing before the Board, the appellant raised an objection under Rule 106 EPC. The objection was also submitted by email during the oral proceedings.

13. The objection concerned the fact that the Board did not remit the case to the opposition division for it to decide on inventive step. It consisted of two parts:

- In the appellant's view its right to be heard under Article 113 EPC was violated because of the lack of a first instance decision on inventive step. This meant that the case on inventive step was not decided by two instances.

- Article 12(2) RPBA defined the primary object of the appeal proceedings as being to review the decision under appeal in a judicial manner. The Boards of Appeal were precluded from dealing with issues not dealt with in decisions under appeal. The fact that the present Board had refused the appellant's request to remit the case was a fundamental procedural violation because the RPBA were binding on the Board under Article 23 EPC.

Both contentions are discussed separately below.

Right to be heard under Article 113 EPC

14. There are two reasons why no violation of the right to be heard occurred in the oral proceedings.

15. Firstly, the appellant was heard on the issue of remittal. Indeed, it was given and took advantage of multiple opportunities both in writing and during the oral proceedings to comment on whether the case should be remitted to the opposition division for further prosecution for consideration of inventive step of the patent. The reasons why the Board decided not to remit the case are set out in points 1. to 11. above. Furthermore, it was given and took advantage of multiple opportunities both in writing (see in point X. above) and at the oral proceedings (see the minutes of the oral proceedings before the Board) to comment on the respondents' objections on inventive step.

16. Secondly, where a Board opts not to remit a case and to decide the case on the merits, there is no legal obligation under Article 113 EPC to hear the parties on this matter. The right to be heard is not an end in itself. A party must be heard on matters, whether substantive or procedural, only if these lead to decisions which could adversely affect the legitimate interest of that party. While deciding to remit a case to allow issues to be decided by two instances is one of the two options under Article 111(1) EPC, it must be remembered that the Boards of Appeal have the final say on the allowability of claim requests. Deferring a decision by the Board on the allowability of a claim request through a remittal cannot be regarded as a legitimate interest of a party. No party is adversely affected by a Board's decision to decide the case itself. Any potential adverse effect would be due to

other, later decisions taken by the Board, e.g. on the merits of the case or on the admittance of new requests or objections. It may be noted that in the opposite constellation, where a Board does intend to remit a case to the first instance for further prosecution, an opponent might have a legitimate interest in obtaining legal certainty as to the scope and existence (or otherwise) of a monopoly right. Thus, if a Board were to contemplate remitting a case instead of deciding it itself, there might be a case for hearing the parties on the issue. Legitimate interests of the parties might indeed be affected by the delays associated with a remittal. However, as explained above, this is not the case when a Board does not decide to remit the case. As a consequence, even though the Board considered the extensive submissions of the parties on the issue of remittal, this was not legally necessary.

17. It is settled case law that parties do not have a fundamental right to have their case examined at two levels of jurisdiction. Accordingly, they have no absolute right to have each and every matter examined at two instances (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition, 2020, V.A. 9.2.1). The Board is also aware of the case law that "*any party should, where possible, be given the opportunity to have two readings of the important elements of a case*" (*ibid*). However, the Board is of the view that this latter case law should not be followed in the present procedural constellation. There are three reasons for this. Firstly, Article 111(1) EPC does not establish an obligation to remit a case, rather, this is one of two options, the other being exercising any power within the competence of the department which was responsible for the decision appealed. Secondly, there is no case law according to

which a remittal is mandatory every time a Board, by setting aside a decision, has to consider a new element, not dealt with in the first instance proceedings. Indeed, such a practice would be incompatible with the principle laid down in Article 11 of the current RPBA (see also point 18, below). Thirdly, the practice of remitting the case whenever a new element has to be considered is hardly compatible with the nature the appeal proceedings and the function of the Boards of Appeal, which under Article 111(1) EPC have the power to decide the whole case and not only to set aside the decisions under appeal. What is more, the Boards have to balance the interests of the public and the parties in having examination or opposition proceedings concluded within a reasonable time frame, with the interest of a party that wishes to have its case heard by two instances (*ibid*).

Fundamental procedural violation in view of Article 12(2) RPBA

18. Not remitting the case to the opposition division for further prosecution for consideration of inventive step of claim 1 of the patent is not a fundamental procedural violation in view of Article 12(2) RPBA. As emphasised in Article 11 RPBA and contrary to the appellant's view, Article 12(2) RPBA does not preclude Boards of appeal from dealing with matters not dealt with in the decision under appeal. Instead, the Boards have discretion on this under Article 111(1) EPC. Indeed, as noted in the explanatory remarks on Article 11 RPBA (Supplementary publication 2, OJ 2020), the aim of the new provision is to reduce the likelihood of a "ping-pong" effect between the Boards and the departments of first instance and a consequent undue prolongation of the entire proceedings before the EPO. When exercising their discretion under Article 111(1)

EPC, the Boards should take account of this aim. Whether "special reasons" present themselves is to be decided on a case-by-case basis.

19. For the sake of completeness, the Board notes that the listing of grounds for a petition for review in Article 112a EPC and Rule 104 EPC is exhaustive. The "other" fundamental procedural defects referred to in Article 112a(2)(d) EPC can, according to the current Implementing Rules, only arise from either a failure to arrange oral proceedings requested by a party (see Rule 104(a) EPC) or a failure to decide on a request relevant to the Board's decision (see Rule 104(b) EPC). Therefore, even if the appellant's understanding of Article 12(2) RPBA were correct, the alleged violation of the procedural principle that the appellant had inferred from that provision would not qualify as a ground for petitioning for review.

Inventive step (Article 56 EPC)

Main request - claim 1

Closest prior art

20. It was common ground between the parties that document D5 could serve as closest prior art for assessing inventive step of the claimed invention.

21. Document D5 is an abstract with the title "*PD-L1 Blockade Restores Function to CD8 T cells during Chronic Viral Infection*". It concerns the problem of "*virus-specific CD8 T cells [that] become functionally tolerant to viral antigens during chronic infection, a state referred to as exhaustion*". On this topic it discloses the following information.

"...*we show that during chronic lymphocytic choriomeningitis virus (LCMV) infection of mice, virus-specific CD8 T cells express high levels of the inhibitory receptor programmed death-1 (PD-1) and LCMV infected cells express high levels of the ligand, programmed death ligand-1 (PD-L1). Therapeutic administration of anti-PD-L1 or anti-PD-1 blocking antibodies to chronically infected mice induced the expansion of virus-specific CD8 T cells, enhanced cytokine production, and increased viral control. These data suggest that reversing CD8 T cell exhaustion is possible by blocking the PD-1/PD-L1 pathway and may provide a useful therapeutic strategy for the treatment of chronic viral infection*". This conclusion is similar to that reached in example 1 of the patent.

22. Document D5, in contrast to example 1 of the patent, contains no experimental evidence in support of its conclusions. Moreover, document D5 does not disclose that the persistent infections by the specific viruses named in claim 1 of the patent can be treated. Instead, it refers to chronic viral infection in general. The difference between the disclosure in document D5 and the claimed subject-matter is therefore the provision of an agent for the treatment of the persistent viral infections specifically named in the claim.

The technical problem

23. In view of this difference, the problem to be solved by the claimed invention was the provision of an agent for the treatment of persistent infection with any of the following viruses: hepatitis virus, a herpes virus, cytomegalovirus, Epstein-Barr virus, herpes simplex virus 1, herpes simplex virus 2, human herpes virus 6, varicella-zoster virus, hepatitis B virus, hepatitis C

virus, papilloma virus, parvovirus B19, polyomavirus BK, polyomavirus JC, human T cell leukemia virus I, and human T cell leukemia virus II.

Obviousness

24. The question to be asked in assessing the obviousness of the claimed subject-matter is whether or not the skilled person starting from the disclosure in document D5 and seeking a solution to the above formulated problem would have considered that any of the compounds listed in claim 1 would be suitable to treat any of the persistent viral infections listed in the claim.

25. As noted above, document D5 concludes that "...*that reversing CD8 T cell exhaustion is possible by blocking the PD-1/PD-L1 pathway and may provide a useful therapeutic strategy for the treatment of chronic viral infection*". The skilled person would have understood that chronic viral infection is a form of persistent viral infection. This is confirmed in paragraph [0032] of the patent. They would further have understood that the reference in document D5 is to chronic viral infections in general. From their common general knowledge they would have known that the viral infections recited in the claim were known as being likely to become chronic. As such, the above cited conclusion in document D5 would have led them to known agents capable of blocking the PD-1/PD-L1 pathway, in particular the anti-PD-L1 or anti-PD-1 blocking antibodies reported in document D5 as successful in increasing viral control in mice chronically infected with LCMV. Thus, it must be concluded that the claimed subject-matter was obvious in the light of the disclosure in document D5 alone.

26. Indeed, the appellant's line of argument was not that the skilled person reading document D5 would not have thought of using the claimed compounds to treat the persistent viral mentioned in the claim, but that they would not have had a reasonable expectation that these compounds would represent an effective treatment for these persistent viral infections.

27. It reached this conclusion because in its view, document D5 was only an abstract submitted for a scientific meeting and was not peer reviewed. Moreover, it lacked the experimental evidence of the kind provided in the patent to back up its conclusions. In its view, the skilled person would not have been able to make an informed scientific appraisal and would not have had enough confidence in the information given.

28. The Board does not find these arguments persuasive for the following reasons. Firstly, while document D5 is indeed a meeting abstract, it was published in a reputable journal and its authors were reputable scientists from well known institutions. It is the Board's view that the skilled reader would understand that information published in such a form might be preliminary and/or incomplete but they would not dismiss it or consider it inherently unreliable only for this reason.

29. Secondly, the fact the document D5 does not include experimental results would not automatically be regarded as a lack of reliability of the information provided. The skilled person would not have expected an abstract to contain detailed experimental protocols or results. They would have known that it is the nature of an abstract to provide a brief summary of the findings of work done. In the absence of further reasons to

disregard the information in document D5, the skilled person would have accepted it at face value.

30. In view of the above considerations, the Board concludes that the subject-matter of claim 1 of the patent was obvious to the skilled person and therefore lacks an inventive step.

Auxiliary requests

Admittance

Main request 1a

31. The Board decided not to admit main request 1a (the *de facto* first auxiliary request) or any of the other auxiliary requests on file into the appeal proceedings. The reason for not admitting main request 1a was as follows. It was filed with the submission of 17 July 2023, i.e. after the Board had issued a summons for oral proceedings and after the issue of the communication pursuant to Article 15(1) RPBA. It constitutes an amendment to the appellant's appeal case made after the notification of the summons to oral proceedings. The admittance of this request into the appeal proceedings is therefore subject to Article 13(2) RPBA. Under Article 13(2) RPBA such an amendment shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

32. The appellant did not argue that there were exceptional circumstances in the case that justified the filing of this request at such a late stage in the appeal proceedings and the Board has not identified any such circumstances either. Indeed, the amendments carried

out relate to the meaning of the expression "persistent viral infection", an issue which had already been extensively discussed in the proceedings before the opposition division (see e.g. the minutes of the oral proceedings before the opposition division, points 2 and 8).

Auxiliary requests 1a to 1o (series 1) and 2, 2a to 2o (series 2)

33. Under Article 12(6) RPBA, requests which should have been submitted, or which were no longer maintained, in the proceedings leading to the decision under appeal should not be admitted unless the circumstances of the appeal case justify their admittance.

34. The decision under appeal dealt only with the patent as granted because all previously pending auxiliary requests were withdrawn at the oral proceedings before the opposition division. These sets of auxiliary claim requests (series 1), and additional ones (series 2), were (re-)filed with the statement of grounds of appeal.

35. The Board exercised its discretion not to admit series 1 of auxiliary requests which were not maintained before the opposition division. The appellant did not argue that the circumstances of case justified their admittance.

36. The Board also exercised its discretion not to admit series 2 of auxiliary requests, which were submitted during the appeal proceedings for the same reasons as series 1 and to address objections of lack of novelty, which had been raised by the opponents in their notices

of opposition. Thus, they could and should have been filed earlier.

37. A further consideration in not admitting any auxiliary requests is that none of them is clearly allowable, because the finding of lack of inventive step for the main request would apply equally to them.

38. In the absence of an allowable claim request, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated