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**Datasheet for the decision  
of 10 January 2024**

**Case Number:** T 2716/19 - 3.3.02

**Application Number:** 13164300.9

**Publication Number:** 2682397

**IPC:** C07F9/6561, C07H19/20,  
G01N33/53, A61K31/675,  
A61P31/12, A61P35/00

**Language of the proceedings:** EN

**Title of invention:**

Prodrugs of phosphonate nucleotide analogues and methods for  
selecting and making same

**Patent Proprietor:**

GILEAD SCIENCES, INC.

**Opponents:**

Aechter, Bernd  
Cooke, Richard  
Georg Kalhammer/Stephan Teipel

**Headword:**

GILEAD SCIENCES / PMPA

**Relevant legal provisions:**

EPC Art. 56

RPBA 2020 Art. 25(2)

RPBA Art. 12(1), 12(2), 12(4)

**Keyword:**

Non-admittance decision of opposition division overturned -  
evidence part of appeal proceedings

G 2/21 - post-published evidence taken into account for  
assessing inventive step

Inventive step - (yes)

**Decisions cited:**

G 0007/93, G 0002/21

**Catchword:**



**Beschwerdekammern**

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**Chambres de recours**

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Case Number: T 2716/19 - 3.3.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.02**  
**of 10 January 2024**

**Party to the  
proceedings :**  
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**Decision under appeal:**      **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
26 July 2019 concerning maintenance of the  
European Patent No. 2682397 in amended form.**

**Composition of the Board:**

**Chairman**                    M. O. Müller  
**Members:**                    M. Maremonti  
                                      B. Burm-Herregodts

## Summary of Facts and Submissions

- I. The appeals lodged by opponents 1 to 3 lie from the interlocutory decision of the opposition division, according to which European patent No. 2 682 397 (the patent) as amended in the form of auxiliary request 6, the claims of which had been filed by letter dated 3 June 2019, and the invention to which it relates, meets the requirements of the EPC.
- II. Claim 1 of auxiliary request 6 found allowable by the opposition division reads as follows:
- "1. A method for the manufacture of 9-[2-(phosphonomethoxy)propyl]adenine (PMPA) comprising reacting 9-(2-hydroxypropyl)adenine (HPA), magnesium t-butyl or isopropyl oxide, and protected p-toluenesulfonyloxymethylphosphonate."*
- III. Oppositions by opponents 1 to 3 were filed by invoking the grounds for opposition under Article 100(a) (lack of inventive step under Article 56 EPC) and (c) EPC. By letter dated 3 June 2019, the patent proprietor filed, *inter alia*, sets of claims according to a main request and auxiliary request 6. The following documents were referred to, *inter alia*, during the opposition proceedings:
- D1: US 5 977 089
- D3: Barreira and Leal, "*Standard Molar Enthalpies of Formation of Mg and Ca Alkoxides*", European Journal Of Inorganic Chemistry, 2000, pages 987 to 991
- D4: Mascarenhas *et al.*, "*Simple Metal Alkoxides as Effective Catalysts for the Hetero-Aldol-*

*Tishchenko Reaction*", Organic Letters, 1(9),  
1999, pages 1427 to 1429

D5: WO 98/04569 A1

D8: US 5 739 314

D13: Masada *et al.*, "*Heterogeneous system of ethers using tertiary alkyl substrate New Williamson synthesis method*", Bulletin of the Chemical Society of Japan, 3, 1996, pages 275 to 282

D15: Schultze *et al.*, "*Practical Synthesis of the anti-HIV Drug, PMPA*", Tetrahedron Letters, 39, 1998, pages 1853 to 1856

D18: Ripin *et al.*, "*Process Improvements for the Manufacture of Tenofovir Disoproxil Fumarate at Commercial Scale*", Organic Process Research & Development, 14, 2010, pages 1194 to 1201

D19: Fortunak *et al.*, Green Techniques for Organic Synthesis and Medicinal Chemistry, First Edition, 2012, John Wiley & Sons, Ltd., Chapter 26: "*Green Chemistry for Tropical Diseases*"

D20: Declaration by Prof. Brocchini dated  
17 April 2019

D21: Riley *et al.*, "*An Improved Process for the Preparation of Tenofovir Disoproxil Fumarate*", Organic Process Research & Development, 20, 2016, pages 742 to 750

D22: DE 1 232 946

D23: GB 785 053

D24: Declaration by Richard Wu dated 31 May 2019

IV. The opposition division found, *inter alia*, the following.

- Document D24 was not to be admitted into the proceedings.
  - The subject-matter of claim 1 of the main request did not involve an inventive step in view of D1, D5 or D15 taken as the closest prior art.
  - The subject-matter of claim 1 of auxiliary request 6 involved an inventive step in view of D1, D5 or D15 taken as the closest prior art.
- V. In their statements of grounds of appeal, opponents 1 to 3 argued, *inter alia*, that the subject-matter of the claim request allowed by the opposition division lacked inventive step in view of D1, D5 or D15 taken as the closest prior art.
- VI. In its reply to the statements of grounds of appeal, the patent proprietor (the respondent) rebutted the opponents' arguments and argued that the claimed subject-matter involved an inventive step.
- VII. By letter dated 25 May 2022, the respondent indicated that the patent had lapsed in all designated contracting states.
- VIII. By communication dated 7 June 2022, the board invited opponents 1 to 3 to indicate whether they wanted the continuation of the appeal proceedings (Rule 84(1) EPC).
- IX. By letter dated 8 June 2022, opponent 2 requested that appeal proceedings be continued.
- X. By letters respectively dated 5 and 15 July 2022, opponents 3 and 1 withdrew their appeal.
- XI. As a consequence, opponent 2 remains the sole appellant in the current case and is referred to as such in the following (the appellant). Opponents 1 and 3 remain

parties to these proceedings under Article 107, second sentence EPC.

- XII. The parties were summoned to oral proceedings as per their requests. In preparation for the oral proceedings, the board issued a communication under Article 15(1) RPBA 2020. In this communication, the board expressed, *inter alia*, the preliminary opinion that document D24 should be part of the appeal proceedings and that the subject-matter of the claim request found allowable by the opposition division involved an inventive step in view of D1, D5 or D15 taken as the closest prior art.
- XIII. By letter dated 8 December 2023, the appellant stated that the request for oral proceedings was withdrawn and that the appellant would not be represented at the oral proceedings. No arguments contesting the board's preliminary opinion were submitted.
- XIV. By a subsequent communication, the board cancelled the oral proceedings.
- XV. Final requests relevant to the decision
- The appellant requested that the appealed decision be set aside and that the patent be revoked. The appellant also requested that the opposition division's decision not to admit document D24 into the proceedings be confirmed.
- The respondent requested that the appeal be dismissed, meaning that the patent be maintained in the amended form held allowable by the opposition division (main request). The respondent further requested that the opposition division's decision not to admit document D24 be overturned and that D24 be admitted into the proceedings.



XVI. As regards the parties submissions that are relevant for the decision, reference is made to the reasons for the decision set out below.

### Reasons for the Decision

Main request (auxiliary request 6 underlying the appealed decision) - claim 1 - findings by the opposition division

1. Claim 1 of auxiliary request 6 found allowable by the opposition division reads as follows. The amendment to claim 1 of the then main request, found by the opposition division to lack an inventive step, has been highlighted by the board:

*"1. A method for the manufacture of 9-[2-(phosphonmethoxy)propyl]adenine (PMPA) comprising reacting 9-(2-hydroxypropyl)adenine (HPA), magnesium alkoxide **magnesium t-butyl or isopropyl oxide**, and protected p-toluenesulfonyloxymethylphosphonate."*

1.1 On the then main request, for which inventive step was denied, the opposition division concluded (appealed decision, point 6.2.2, pages 15 and 16) that no technical effect over the closest prior art (D1, D5 or D15) had been substantiated over the whole scope of claim 1 due to the general definition of the base used in the method as *magnesium alkoxide*.

1.2 However, for the then auxiliary request 6, now the main request, the opposition division (appealed decision, point 14.1, page 21) was convinced that a technical effect over the same closest prior art had been credibly shown to derive from the specific use of *magnesium t-butyl oxide* as the base. The opposition division further concluded that, in view of the structural similarity, the same technical effect was expected also from the use of *magnesium isopropyl oxide*

as the base. Therefore, this technical effect could be acknowledged for the subject-matter of claim 1 of the then auxiliary request 6 in view of the restriction of the base used in the method to *magnesium t-butyl* or *isopropyl oxide* (see wording of claim 1 above).

Document D24 - admittance into the proceedings - the decision of the opposition division

2. The respondent filed D24 by letter dated 3 June 2019, i.e. about two weeks in advance of the oral proceedings before the opposition division. It argued that this document represented a reaction to new objections raised by the appellant in the letter dated 18 April 2019, i.e. two months before the oral proceedings, which were based on document D21 filed with the same letter. By reference to D21, which disclosed that no PMPA could be produced when magnesium ethoxide was used as the base, the appellant had argued that no technical effect over the closest prior art could be recognised across the whole scope of claim 1 of the then main request, requiring any magnesium alkoxide as the base. According to the respondent, D24 countered this argument by demonstrating a technical effect deriving from using magnesium isopropyl oxide as the base in the claimed method.
3. The opposition division (appealed decision, point 3.2) concluded that the above objections raised by the appellant in the letter dated 18 April 2019 had already been raised at least by opponent 1 in its notice of opposition. Therefore, the respondent could have filed D24 with its reply to the oppositions. Thus, D24 was late filed. In addition, the opposition division considered D24 not *prima facie* relevant for the inventive step of claim 1 of the then main request since D24 did not contain any data on the use of magnesium ethoxide, which had been addressed by the

appellant with reference to D21. Thus, the opposition division decided not to admit D24 into the proceedings. In its decision, the opposition division did not deal with whether D24 was *prima facie* relevant for any of the auxiliary requests before it, including auxiliary request 6 that it found allowable.

4. In accordance with decision G 7/93 of the Enlarged Board of Appeal (Official Journal of EPO, 1994, page 775, point 2.6 of the reasons), the board can overturn the non-admittance decision by the opposition division only if the latter exercised its discretion according to the wrong principles, without taking into account the right principles or in an unreasonable way. The appellant argued that this was not the case here. According to the appellant, the opposition division correctly concluded that D24 was late filed and assessed its *prima facie* relevance. Therefore, it used the right criterion for deciding on its admittance. The appellant admitted that this assessment had been done by the opposition division only for the subject-matter of claim 1 of the then main request. However, it argued that this was correct. Otherwise, an opposition division would have to repeat this assessment for every auxiliary request on file.
5. The board comes to the conclusion that D24 should have been admitted into the proceedings for the following reasons.

For the sake of argument only and in the appellant's favour, it is assumed that the opposition division correctly concluded that D24 could have been filed with the reply to the oppositions and thus that it was late filed. Under this assumption, the opposition division correctly assessed whether D24 was *prima facie* relevant

for maintaining the then main request when deciding on the admittance of this document.

- 5.1 However, the assessment of the *prima facie* relevance of D24 should not have been limited to the subject-matter of claim 1 of the then main request. It should have extended to the subject-matter of the auxiliary requests on file, especially the subject-matter of claim 1 of then auxiliary request 6 (now the main request), which restricted the base used in the claimed method to either magnesium t-butyl oxide or magnesium isopropyl oxide.
- 5.2 In fact, extending the assessment avoids finding the potentially patentable subject-matter of an auxiliary request unallowable for the sole reason that a document, *prima facie* relevant to the subject-matter of the request, is not considered.
- 5.3 Therefore, the opposition division, when deciding on the admittance of D24, while using the correct criterion of *prima facie* relevance, did use it in an unreasonable way because it limited its assessment to the subject-matter of the then main request.
- 5.4 In view of decision G 7/93 of the Enlarged Board of Appeal (see above), the board thus has the power to overrule this admittance decision by the opposition division.
- 5.5 For the above reasons, the board decides that the decision by the opposition division to not admit D24 has to be set aside.
- 5.6 Since the respondent referred to D24 in its reply to the grounds of appeal, i.e. at the earliest possible stage of the appeal proceedings, and based its inventive-step case on it, the board concludes that D24 should be part of the appeal proceedings pursuant to

Article 12(1), (2) and (4) RPBA 2007 (applicable in view of Article 25(2) RPBA 2020).

- 5.7 A preliminary opinion that D24 should be part of the appeal proceedings had been communicated to the parties in the communication issued by the board under Article 15(1) RPBA 2020. The appellant did not file any reply contesting this board's preliminary opinion.

Main request (auxiliary request 6 underlying the appealed decision) - claim 1 - inventive step under Article 56 EPC

6. Closest prior art

It is common ground that D1, D5 or D15 can be considered the closest prior art. In fact, each of these documents discloses (D1: example 1 in columns 38 to 39, reaction 4b and column 41, line 43 to column 42, line 36; D5: reaction 4b in the scheme on pages 40 to 41, page 41, lines 6 to 17, page 44, line 4 to page 45, line 14; D15: page 1855, scheme 3) a method for the manufacture of PMPA comprising reacting HPA, a lithium alkoxide, especially lithium t-butoxide, and protected p-toluenesulfonyl oxymethyl phosphonate to form diethyl-protected PMPA, which is subsequently de-protected to give PMPA.

7. Distinguishing feature

It is also common ground that the subject-matter of claim 1 of the main request differs from the above disclosures in D1, D5 and D15 only in that magnesium t-butyl oxide or magnesium isopropyl oxide is used in lieu of lithium t-butoxide.

8. Objective technical problem

- 8.1 However, the views of the parties diverge on the technical effect deriving from the above-mentioned distinguishing feature.

8.2 The respondent argued that example 1b of the application as filed demonstrated an improvement in the yield in the reaction of HPA to PMPA when magnesium t-butyl oxide or magnesium isopropyl oxide was used as the base instead of lithium butoxide. This improvement was confirmed by each of the post-published documents D18 to D21 and D24. Further advantages deriving from the use of the claimed base were the possibility to render the de-protection reaction of diethyl-PMPA less laborious than when using lithium butoxide since a "one-pot" process could be used. This led to a more convenient, cheaper and less wasteful method since the product was obtained at a higher purity. Undesired side products were suppressed. Thus, the respondent formulated the objective technical problem as the provision of an improved process, in particular providing an improved yield of PMPA.

8.3 The appellant contested the presence of any technical effect associated with the above-mentioned distinguishing feature on the basis of three lines of argument.

8.3.1 Firstly, it argued that the application as filed did not make the above-mentioned technical effect brought forward by the respondent plausible. The application as filed did not include any evidence that the claimed bases would result in an improved PMPA yield. There was no plausible technical concept. The flaw in the application as filed was that it provided no reason to conclude that the use of the claimed magnesium alkoxides led to any improvement compared with a lithium alkoxide. Therefore, not only was there no absolute proof, there was no evidence whatsoever in the application as filed of any improved yield. Moreover, the respondent had not relied on common general knowledge for justifying the alleged technical effect.

Accordingly, in the absence of plausibility based either on the application as filed or common general knowledge, the opposition division was incorrect to allow the respondent to rely on post-published evidence.

- 8.3.2 This first line of argument is not convincing. Decision G 2/21 of the Enlarged Board of Appeal (order) states that "[e]vidence submitted by a patent applicant or proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date" and that "[a] patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, **would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention**" (emphasis added by the board).

The originally disclosed invention (see e.g. claim 1 as filed) concerns, *inter alia*, a method for the manufacture of PMPA, comprising reacting HPA, a magnesium alkoxide and protected p-toluenesulfonyloxymethylphosphonate. Claim 5 as filed specifies the magnesium alkoxide as either magnesium t-butyl oxide or magnesium isopropyl oxide. No further claim in the application as filed refers to any other specific magnesium alkoxide. The skilled person would thus derive from the application as filed a focus on the two specific alkoxides to which claim 1 of the current main request is restricted. Furthermore, the skilled person would have immediately recognised an improvement in the yield of the desired product, here

PMPA, as a fundamental objective of the disclosed method. In fact, example 1b of the application as filed (pages 26 and 27), disclosing the above manufacture of PMPA from HPA by using either magnesium t-butyl oxide or magnesium isopropyl oxide, explicitly mentions a 50.4% yield of PMPA after isolation, thus confirming the relevance of this parameter in relation to the use of the alkoxides defined in claim 1 of the current main request.

Therefore, the improvement of the PMPA yield in a reaction starting from HPA by using the alkoxides defined in the current main request relied on by the respondent was encompassed by the technical teaching and embodied by the invention originally disclosed in the application as filed. In line with decision G 2/21 (order), this technical effect can thus be relied on by the respondent, and post-published evidence confirming this technical effect cannot be disregarded.

- 8.3.3 In its second line of argument, the appellant submitted that the HPA to PMPA conversion data of example 1b of the application as filed could not be compared with the data reported in D1, D5 or D15 since different operating conditions were used (*inter alia*, different temperatures). Moreover, the post-published evidence D18 invoked by the respondent might not demonstrate any improvement. Even if table 1 of D18 showed higher conversions of HPA to PMPA obtained with magnesium butoxide over lithium butoxide, this higher conversion was irrelevant if PMPA could not be isolated in an equivalent yield. According to D18 itself (page 1196, left-hand column), magnesium salts complicated the isolation and led to a 15% loss of PMPA product. This was because magnesium salts were divalent and thus inherently more complex than monovalent lithium salts. The same problem with magnesium salts was further



disclosed in D21 (page 743, right-hand column). Furthermore, the experimental section of D18 on page 1200 reported a conversion of adenine to HPA of 65% and a conversion of HPA to PMPA of 59%, thus leading to a yield of 38%. This was lower than the yield disclosed in D1 (40-45%). Thus, despite higher HPA to PMPA conversion, still no higher yield of isolated product was obtained over D1. Additionally, the example of D18 involved two base equivalents since Mg was a divalent cation, while the example with lithium butoxide involved only one base equivalent. This difference could have affected the outcome of the reaction since the nature of the cation could be as important as the molar amount of the base.

8.3.4 This line of argument is also not convincing.

The board concurs with the appellant and the opposition division (appealed decision, page 10, point 6.2.1.1) that in view of the different operating conditions used in example 1b of the application as filed (pages 26 and 27) and in D1, D5 and D15 (*loc. cit.*), *inter alia*, a different temperature (75 to 78°C in example 1b vs 30 to 45°C in D1 and D5 and 30 to 35°C in D15), no direct comparison of the obtained PMPA yields can be made.

However, as pointed out by the respondent, D18 (page 1195, right-hand column, table 1 and "stage 2a") discloses the results in terms of HPA conversion to diethyl-PMPA (protected PMPA which is then de-protected to yield PMPA) obtained by using different bases. The conversion obtained with magnesium t-butyl oxide (90%) is much higher than that achieved when lithium-t-butoxide is used (61%). Therefore, a clear improvement deriving from the use of one of the bases required by claim 1 of the main request over the base used in the closest prior art (see above) is reported in D18.

The experimental section on page 1200 of D18 invoked by the appellant confirms a 90% conversion to diethyl-PMPA with magnesium t-butyl oxide as the base (right-hand column, last line). The yield of 59% referred to by the appellant is mentioned on page 1201 of D18, left-hand column, second-last paragraph. However, this data relates to de-protected PMPA and not to diethyl-PMPA, for which the above comparison with lithium-t-butoxide as the base is available in table 1 of D18.

Furthermore, D1 (*loc. cit.*), when reporting the above-mentioned yield of 40-45% with lithium-t-butoxide as the base, also refers to diethyl-PMPA and not to de-protected PMPA. The same is true for D15 (*loc. cit.*), which, while disclosing a yield of diethyl-PMPA from adenine of 55 to 65%, reports a much lower overall yield for de-protected PMPA of 30 to 35%. Therefore, the data reported in D18 for de-protected PMPA are not relevant for the assessment of the technical effect of the above-mentioned distinguishing feature.

As regards the 15% loss of product (diethyl-PMPA) reported in D18 (page 1196, left-hand column, second-last paragraph) and D21 (page 743, right-hand column) deriving from the magnesium salt cake, the board concurs with the respondent that this disclosure is not relevant for establishing the technical effect of the above-mentioned distinguishing feature derivable from the direct comparison of magnesium t-butyl oxide with lithium-t-butoxide reported in table 1 of D18.

Moreover, even with a loss of 15%, a substantial improvement associated with the use of magnesium t-butyl oxide over lithium-t-butoxide would have still been achieved in view of the higher conversion reported in table 1 of D18 (90% for magnesium t-butyl oxide vs 61% for lithium-t-butoxide).

As set out above, the appellant also pointed at the different number of equivalents used in D18 since Mg was a divalent cation while Li was monovalent. However, also in this case the board concurs with the respondent that both D20 and D24 show that even when the molar amount of lithium-t-butoxide was doubled compared with magnesium t-butyl oxide, a clear improvement in the PMPA yield was still achieved by using magnesium t-butyl oxide as the base (D20: figure 4 in combination with the table on page 11 of the reply to the appeal; D24: table on page 2).

8.3.5 Thirdly, the appellant argued that even assuming that an improvement in the PMPA yield achieved by using magnesium t-butyl oxide was derivable from D18, claim 1 of the main request also mentioned magnesium isopropyl oxide. An extrapolation of the technical effect obtained with magnesium t-butyl oxide to magnesium isopropyl oxide was not possible. D18 reported in table 1 that when using Li and Na as cations, the change from butoxide to isopropoxide strongly decreased the conversion. The structure of the alkoxide portion of the base was thus critical to the conversion. This was confirmed by table 2 in D21, showing that magnesium ethoxide did not allow any reaction. The technical effect brought forward was thus not achieved across the whole scope claimed.

8.3.6 This argument is also not convincing. As pointed out by the respondent, D24 (table on page 2) reports an improvement in the PMPA yield achieved by using magnesium isopropyl oxide over lithium-t-butoxide. Moreover, example 1b of the application as filed (pages 26 and 27) discloses that the same results in terms of PMPA yield were obtained independently of whether magnesium t-butyl oxide or magnesium isopropyl oxide was used. Therefore, the same improvement over the use

of lithium-t-butoxide as shown for magnesium t-butyl oxide was obtained by using magnesium isopropyl oxide.

- 8.4 For these reasons, the board holds that, when starting from D1, D5 or D15, the objective technical problem should at least be seen as the provision of a method achieving an improved yield of PMPA.
9. Obviousness of the claimed solution
- 9.1 As the solution to the above-mentioned objective technical problem, claim 1 of the main request provides the use of magnesium t-butyl oxide or magnesium isopropyl oxide as the base in lieu of lithium-t-butoxide.
- 9.2 The appellant argued that magnesium alkoxides were known chemicals as evidenced by each of D3, D4, D8, D13, D22 and D23. The selection of a magnesium alkoxide as an alternative to lithium-t-butoxide was thus an obvious choice for the skilled person aiming to provide a method alternative to the one of the closest prior art.
- 9.3 However, as stated above, the objective technical problem is not the provision of an alternative method but a method achieving an improved PMPA yield. The appellant did not indicate any document disclosing or suggesting that replacing lithium-t-butoxide with either magnesium t-butyl oxide or magnesium isopropyl oxide improved the yield of PMPA. Nor did it rely on common general knowledge.
- 9.4 Therefore, the skilled person facing the above-mentioned objective technical problem would not have been prompted by any available document or common general knowledge to replace the lithium-t-butoxide used in the method of the closest prior art with either

magnesium t-butyl oxide or magnesium isopropyl oxide as required by claim 1 of the main request.

10. For these reasons, the board concludes that the subject-matter of claim 1 of the main request involves an inventive step within the meaning of Article 56 EPC. Therefore, the main request is allowable.
11. A preliminary opinion that the subject-matter of claim 1 of the main request involved an inventive step had been communicated to the parties in the communication issued by the board under Article 15(1) RPBA 2020. The appellant did not file any reply contesting this board's preliminary opinion.

## Order

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

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

M. O. Müller

Decision electronically authenticated