Order
In Application of R.190 RoP - R. 305 RoP - R. 315 RoP
of the Court of First Instance of the Unified Patent Court
Issued on 23 September 2026
Concerning EP 3 689 383

HEADNOTES

1. The RoP do not allow "*aggressive interventions*" or "*principal interventions*" (i.e. interventions whereby the intervener directs claims against one or more of the other parties different to one it supports).
2. A party can be held intervener in the infringement action (and be "*treated as a party*") and defendant in the counterclaim for revocation. The introduction of a counterclaim for revocation will reclassify the status of intervener (patent holder) to defendant, but will not imply the reclassification of the status of this intervener (patent holder) to co-claimant in the infringement proceedings.
3. The managerial powers of the Court in application of R. 305 RoP and R. 315 RoP to reclassify (on its own motion or upon application thereto) the status of party from intervener to co-claimant (or co-defendant) depends on the circumstances of the case.
4. A "*request to invite a party to introduce an application*" is not a proper procedural request. Whether or not an actual application is introduced, should not be based on an invitation by the Court but depends on the applicant's own procedural strategy. Whether such an application would be admissible or not needs to be assessed by the Court once the application has actually been introduced.
5. The term "*for the purpose of the proceedings*" in R. 8.4 RoP applies only for the application of the RoP and more specifically the administrative tasks to be performed by the Court. For this purpose a legal fiction is created. On the other hand, this legal fiction is held not to apply for questions of substantive law and therefore, in an action for which the UPC is competent, a defendant has the right to bring a defence comprising the issue of entitlement. The presumption of entitlement created in R. 8.4 RoP regarding substantive law is rebuttable.
6. When assessing an application to produce evidence, the Court should assess the plausibility of the underlying claims at that stage of the proceedings. The assessment on this plausibility does not affect the assessment of the panel when having to decide the claims on the merits.
7. The condition of "*prior notice*" in Article 47(2) or (3) UPCA should be assessed by the Court when the action is brought, specifically on the date on which the action in application of R. 17.1 RoP is recorded in the register (i.e. after the Registry's formal examination of the Statement of Claim (R. 16 RoP with an explicit reference in R. 16.2 RoP to RoP to R. 13.1(f) RoP). The burden of proof of complying with this condition lies solely on the claimant. However, although the Court should position itself on the moment the action is brought, the

claimant is still allowed to introduce additional evidence in support of the already introduced evidence in application of R. 13.1(f) RoP.

KEYWORDS

- R. 305 RoP (Application Change in Parties)
- R. 315 RoP (Classification of the intervener as Co-Claimant)
- R. 190 RoP (Production of evidence)
- Art. 47 (2) and (3) UPCA (Standing to sue)
- Art. 47 (5) UPCA (Presumption of entitlement)
- R. 8.4 and R.8.5 RoP (Presumption)
- Entitlement as a defence in UPC proceedings

APPLICANTS R. 190 ROP APPLICATIONS
DEFENDANTS REQUEST TO DECLARE THE INTERVENER CO-CLAIMANT
DEFENDANTS INFRINGEMENT ACTION (UPC_CFI_029/2026)
CLAIMANTS COUNTERCLAIM FOR REVOCATION (UPC_CFI_1934/2026 & UPC_CFI_1940/2026)

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(2) JANSSEN BIOTECH, INC. (*)
(3) JANSSEN PHARMACEUTICALS INC. (**)
(4) JANSSEN-CILAG INTERNATIONAL NV (**)
(5) JANSSEN PHARMACEUTICA NV (**)
(6) JANSSEN-CILAG NV (*)
(7) JANSSEN BIOLOGICS B.V. (**)
(8) JANSSEN-CILAG B.V. (**)
(9) JANSSEN-CILAG GMBH (*)
(10) JANSSEN-CILAG SAS (*)
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Hereafter referred to as:	• Cumulatively as "*Defendants*"; • Separate as "*Defendant*" followed by "*1 through 18*" (whichever is applicable); or

- Grouped as "*Defendants 1-14*" or "*Janssen Defendants*" and "*Defendants 15-18*" or "*Legend Defendants*"

RESPONDENT R. 190 ROP APPLICATIONS
APPLICANT REQUEST TO DECLARE THE INTERVENER CO-CLAIMANT

INTERVENER

THE UNITED STATES OF AMERICA, INCLUDING THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF TECHNOLOGY TRANSFER

Represented by:	Mr. Vittorio Cerulli Irelli (vcerulliirelli@trevisancuonzo.com) Mr. Lorenzo Battarino (lbattarino@trevisancuonzo.com) both Trevisan & Cuonzo, Via Brera, 6, 20121 Milan, Italy Mr. Silvia Bertuccio (silvia.bertuccio@tcbm.eu), TCBM, Via Plinio 63, 20129 Milan, Italy.
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Hereafter referred to as:	Intervener or NIH

CLAIMANT INFRINGEMENT ACTION (UPC_CFI_029/2026)
DEFENDANT COUNTERCLAIM FOR REVOCATION (UPC_CFI_1934/2026 & UPC_CFI_1940/2026)

2SEVENTY BIO, INC.

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Additional Representatives:	Mrs. Amy Crouch, Mrs. Camilla Balleny, Mr. Sean Jauss, Mr. Alex Galbraith, Mrs. Anja Koller, Mr. Lauren Woolley and Mr. Liam Batty
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Hereafter referred to as:	Claimant or Applicant or 2SB

PATENT AT ISSUE

Number	Proprietor(s)
EP 3 689 383	The United States of America, as represented by the Secretary, Department of Health and Human Services

LANGUAGE OF THE PROCEEDINGS: English

SUBJECT MATTER: R. 190 RoP (Application to Produce Evidence)
R. 305 RoP (Application to Change Parties)

PANEL - LOCAL DIVISION LD Brussels

Presiding Judge / Judge-Rapporteur:	Samuel Granata
Legally Qualified Judge:	Marije Knijff
Legally Qualified Judge:	Anna-Lena Klein
Technically Qualified Judge:	Renaud Fulconis

DECIDING JUDGES: Order issued by the Panel

I. PROCEDURAL BACKGROUND AND REQUEST

1. On 11 August 2026, the Court received an "*Application for an order to Produce Evidence (Art. 59 UPCA and R. 190 RoP)*" submitted by Janssen Defendants, requesting the production of evidence from the NIH (hereafter referred to as "Application I"), with following requests:

- *Order (the NIH) to produce the documents identified in Section 2.2 above;*
  In Section 2.2. the following categories are provided:
  Category 1: Laboratory notebooks and contemporaneous research records
  Category 2: Employee Invention Report(s) and inventor disclosure forms
  Category 3: Grant applications, annual and progress reports for intramural research grants ZIA BC011417 and ZIA BC011439
  Category 4: Documents evidencing the prior notice given by 2SB to the NIH
- *Order that such documents be produced within two weeks following service of the order;*
- *Order that such documents be produced in electronic form via CMS and by email to counsel for Janssen Defendants;*
- *Order that any documents containing confidential information be disclosed subject to an appropriate confidentiality regime pursuant to Rule 262A RoP;*
- *Order a recurring penalty payment pursuant to Article 82(4) UPCA and Rule 354(3) RoP in the amount of € 10.000 per day for each day of non-compliance or incomplete compliance following the deadline for production; and*
- *Order that any failure to comply with the order, or any incomplete compliance, may be taken into account by the Court when deciding the standing issues in these proceedings.*

2. On 13 August 2026, the Court received a similar application from Legend Defendants 15-18 (hereafter referred to as "Application II") with following requests:

I. Order (the NIH) to produce the documents as identified in Section II. (2) below:

1. <u>Category 1</u>: Laboratory notebooks and contemporaneous research records Laboratory notebooks (whether in paper or digital form), experiment logs and internal research reports and internal presentations regarding the conception, design and execution of the research that led to the filing of US provisional application No. 61/622,600, and/or International application No. PCT/US2013/032029, and/or European application Nos. 13714125.5, 19216091.9 or 25206361.5 and/or was performed under the NIH internal reference HHS Ref. No.: E-040-2012/0-US-01 and/or HHS Ref. No.: E-040- 2012/0-PCT-02, and/or intramural research grants ZIA BC011417 and ZIA BC011439 and/or Application IDs 8553170 and 8553187.

The requested records should cover the period from 1 January 2010 to 31 January 2013, and include records maintained by the National Cancer Institute, Dr. James N.

Kochenderfer, and any collaborating researchers, including Dr. Robert O. Carpenter, Mr. Moses O. Evbuomwan, Dr. Stefania Pittaluga, Dr. Jeremy J. Rose, Dr. Mark Raffeld, Dr. Shicheng Yang, Dr. Ronald E. Gress and Dr. Frances T. Hakim.

2. Category 2: Employee Invention Report(s) and inventor disclosure forms Employee Invention Report(s) (also, Employee Discovery and Invention Report) (EIR) or equivalent NIH inventor disclosure form(s) (such as document ID 201110915 or EIR PHS 6364) and EIR Additional Contributor
forms filed in connection with the alleged invention:
• that led to the filing of US provisional application No. 61/622,600, and/or International application No. PCT/US2013/032029, and/or European application Nos. 13714125.5, 19216091.9 or 25206361.5 and/or
• was performed under the NIH internal reference HHS Ref. No.: E-040- 2012/0-US-01 and/or intramural research grants ZIA BC011417 and ZIABC011439.

If none exists, a statement of a qualified NIH representative detailing the parameters and the query of the search performed in the internal NIH database.

3. Category 3: Grant applications, annual and progress reports for intramural research grants ZIA BC011417 and ZIA BC011439 Grant applications (including the Budget and Budget Justification, as well as the Senior/Key Person Profile Form), annual report(s) (including any Annual Intramural Research Reports), progress report(s) and any review report(s) (including any review report(s) conducted by the Board of Scientific Counselors (BSC)) in connection with intramural research grants ZIA BC011417 and ZIA BC011439 and/or Application ID 8553170 and 8553187.

4. Category 4: Documents evidencing the prior notice given by 2SB to the NIH The September 2025 notification sent by 2SB to the NIH in connection with the commencement of the present proceedings before the UPC in respect of EP 383.

II. *Order that such documents be produced within two weeks following service of the order;*
III. *Order such documents be produced in electronic format by email to Legend's representatives and via the Court's CMS;*
IV. *Order that any documents containing confidential information be disclosed subject to an appropriate confidentiality regime pursuant to Rule 190 RoP and Rule 262A RoP;*
V. *Order a recurring penalty payment pursuant to Article 82(4) UPCA and Rule 354(3) RoP be set in the amount of € 10,000 per day for each day of non-compliance or incomplete compliance following the deadline for production;*
VI. *Order that any failure to comply with the order, or any incomplete compliance, may be taken into account by the Court when deciding the standing issues in these proceedings.*

3. On 28 August 2026, the NIH submitted its comments together with following requests:

a) declare the (NIH) to be a Co-Claimant in these proceedings by exercising its powers under the principles outlined by the LD The Hague in Dolby v. CPYou (8 July 2026, UPC_CFI_1536/2025, UPC_CFI_982/2026, UPC_CFI_1168/2026); in the alternative, to

invite an application from the (NIH) and/or Claimant seeking a declaration of status for the present (NIH) as a Co-Claimant;

b) *dismiss the applications for an order to produce evidence filed by the Defendants on 11 and 13 August 2026;*

c) *in the alternative, should the Court nevertheless consider it appropriate and necessary to issue an order to produce evidence, order that*

(i) *any documents ordered to be produced be limited to what is strictly necessary and proportionate, defining the scope of any such order by reference to specifically identified documents and relevant time periods;*

(ii) *appropriate confidentiality measures be adopted to protect the confidential information of the (NIH) contained in at least some of the documents to be disclosed, limiting access to the natural persons listed by the parties and restricting use of the documents strictly to the purposes of the present proceedings;*

(iii) *the deadline for compliance be set at no less than eight weeks from the date of the order, with the possibility of adjustments in the event objective difficulties arise in the retrieval of the documents and such difficulties are timely communicated by the (NIH);*

(iv) *the penalty payment requested by the Defendants be rejected; and*

(iv) *all costs associated with the identification, retrieval, review and production of the documents be borne in their entirety by the Defendants.*

4. The NIH's reply introduced, besides a direct reply to the Applications, new requests (cf. §3 under a)). Subsequently, the Court invited the Defendants to reply on the NIH's requests, which the Court received on 3 September 2026.

5. In assessing the Applications, the Court noted that parties did not touch upon two legal issues which might be of importance for its further assessment, which it communicated on 4 September 2026 to the parties and requested them for comments (dependent on their position in the proceedings) on 8 and 10 September 2026. Regarding Issue 1 the NIH was first invited followed by the Defendants, regarding Issue 2 the Defendants were first invited followed by the NIH. The following issues were brought to the attention of the Parties:

Issue 1. The procedural status/position of the NIH in the proceedings (request introduced by the NIH).

Art. 47(5) UPCA states that "*The party in an action for infringement wanting to contest the validity of a patent shall have to bring actions against the patent proprietor*". Without prejudging, it seems that this article indicates that the NIH should be considered a party to the proceedings related to the counterclaim for revocation introduced by the Defendants (introduced after the R. 314 RoP order) (UPC_CFI_1934/2026 and UPC_CFI_1940/2026). The Court wished to receive comments regarding the consequences (if any) the above article could have on the proceedings as a whole and in particular the procedural status/position of the NIH in the infringement action.

Issue 2. Regarding Limb (a) (see § 7) and more specifically the plausibility of the claims made:

2.a. The Court noted that, in its Statement of Claim, 2SB indicated that "*the patent proprietor (i.e. the (NIH)) is filing a request for the unitary effect of EP 3 689 383 at the EPO*". The NIH filed such a request on 5 January 2026. This request for unitary effect was granted by the EPO on 13 January 2026.

The relevance of this unitary effect to the proceedings could be linked to entitlement issues, particularly the presumption which results from such effect. While R.8.5(c) RoP states that "*(...), there shall be a rebuttable presumption that the person shown in […] the European Patent Register kept by the European Patent Office is the person entitled to be registered as proprietor or applicant, as the case may be*" (Court's underlining), R.8.4 RoP states that "*for the purposes of proceedings under these Rules in relation to the proprietor of a European patent with unitary effect, the person shown in the Register for Unitary Patent Protection as the proprietor shall be treated as such*" (Court's underlining), which seems to imply a non-rebuttable presumption (see also LD Munich, 25 November 2024, UPC_CFI_443/2024 (*Häfele v. Kunststoff*), and LD The Hague, 29 August 2025, UPC_CFI_374/2025 (*Cilag v. RiVOLUTION*)). The Court wished to receive comments from the parties regarding the consequences (if any) the above could have on the assessment of the plausibility of the claims made under Limb (a) (see § 19 of the Court of Appeal order dated 29 June 2026, UPC_COA_057/2026, *Polytechnic v. Dall*).

2.b. The Defendants did not (at least explicitly) object to the application for intervention based on proprietorship of the patent in question. Subsequently, the R. 314 RoP Order was issued. The Court wished to receive comments from the parties regarding the legal consequences (if any) such non-objection regarding proprietorship of the patent in the comments on the application to intervene could have on the assessment of the plausibility of the claims under Limb (a) (see § 19 of the Court of Appeal order dated 29 June 2026, UPC_COA_057/2026, *Polytechnic v. Dall*).

6. After receiving these additional comments the Applications could be assessed.

II. ARGUMENTS OF THE PARTIES AND ISSUES TO BE ASSESSED

II.A JANSSEN DEFENDANTS AND LEGEND DEFENDANTS

II.A.1. THE REQUESTS MADE IN THE APPLICATIONS

7. The Defendants' arguments to grant the applications find their origin in their challenge to the claim made by 2SB that they have standing to sue under Art. 47 (2) UPCA being the alleged exclusive licensee of the patent EP 3 689 383 (hereafter the "*Patent*"). The Defendants have challenged 2SB's standing in their respective Statements of Defence and Counterclaim for Revocation (hereafter referred to as the "*SoD*") on 1 June 2026, on three distinct grounds (hereafter referred to as "*Limbs*"):

a. The NIH was not assigned the shares of all inventors of the alleged invention underlying (the Patent). Consequently, the NIH never possessed the right to sue in the first place, could not transfer any such right to (2SB), and as a result the NIH lacks standing under Article 47 UPCA;

In support of this Limb (a), the Defendants argued that the alleged invention was developed by several inventors, whereas only one of them – Dr. Kochenderfer – assigned his rights to the NIH.

The basis for this contention rests primarily on Exhibit ME006 filed by 2SB (the Carpenter 2013 Paper, published in the journal Clinical Cancer Research (an AACR journal) - Exhibit ME006)(hereafter referred to as "*Carpenter 2013*") which describes the research that led to the alleged invention. Nine individuals are listed as authors of this paper and cited in the "*Authors' Contributions*" section: Robert O. Carpenter, Moses O. Evbuomwan, Stefania Pittaluga, Jeremy J. Rose, Mark Raffeld, Shicheng Yang, Ronald E. Gress, Frances T. Hakim and James N. Kochenderfer. This listing is linked by the Defendants to the AACR's instructions for authors (Exhibit JJ-I 12) which require that persons listed as authors satisfy three cumulative conditions. They must have contributed substantially to 1) the conception and design of the study, acquisition of data or analysis and interpretation of data, 2) drafting of the article or revising it for important content, and 3) final approval of the version to be published. The Defendants hold that all activities listed in the first condition are directly relevant to the direction of the research. Further, the Defendants hold that the NIH's own Guidelines for Conduct of Research (Exhibit JJ-I 13) also require authorship to be based on "*a significant contribution to the conceptualization, design, execution, and/or interpretation of the research study*".

In conclusion, the Defendants hold that to comply with the AACR instructions on authorship and the NIH's Guidelines for Conduct of Research, the co-authors of Carpenter 2013 would have had to make contributions that could meet the threshold for co-inventorship under U.S. law (i.e. contribution to the conception of the invention), if the research underlying the Patent qualified as invention.

The Defendants subsequently hold that the above is not in line with the sole assignment by Dr. Kochenderfer dated 20 April 2012 (Exhibit JJ-I 18). In addition, the Defendants note that the assignment was executed on the intervener's own template entitled "*ASSIGNMENT FOR NIH/FDA INVENTIONS (NIH OR FDA CO-INVENTORS ONLY)*" and drafted in the plural using formulations such as "*I/we*", "*hereinafter The Inventors*" to accommodate multiple signatories, yet was signed by Dr. Kochenderfer alone.

b. (2SB) has not complied with the requirements of Article 47 UPCA, including giving prior notice to the NIH and as a result lacks standing;

To support the second Limb (b) of its argumentation, Janssen Defendant notably recalls that under Article 47 UPCA all licensees – exclusive or non-exclusive – must give prior notice to the patentee before commencing proceedings. The Defendants hold in this regard that 2SB has failed to demonstrate in its Statement of Claim that it complied with that requirement.

c. *In any event, (2SB) has failed to establish that it holds either a valid license or a valid confirmatory license agreement and as a result fails to establish that it has standing.*

8. The Defendants hold in arguing the Applications that 2SB's and the NIH's Reply to the Statements of Defence and Counterclaim on 5 August 2026 are insufficient to specifically contest the Defendants' Limbs (a) and (b) standing argumentation. The Defendants hold that "*on the contrary, the new elements they put forward reinforce the suspicion surrounding (2SB's) standing*".

9. It is in these circumstances and based on the legal framework of the UPC (which will be detailed in the Grounds) that the Defendants introduce their Applications, seeking production of the primary documents that would enable the Court to rule on 2SB's standing to sue.

II.A.2. THE REQUESTS INTRODUCED BY THE NIH (TO BE TREATED AS A CO-CLAIMANT)

10. In its 3 September 2026 comments related to the NIH's request to "*declare the (NIH) to be a Co-Claimant"* or "*in the alternative, to invite an application from the (NIH) and/or Claimant seeking a declaration of status for the present (NIH) as a Co-Claimant"*, the Defendants bring about the following arguments (in essence):
- The request is inadmissible as (i) it is belated and contrary to the front-loaded principles, (ii) it does not meet the requirements of R. 305 RoP.
- In subsidiary order (should the request be held admissible) it should be considered unfounded as (i) *Dolby v. CPYou* does not support the relief sought and is factually and legally distinguishable, (ii) no different result under R. 305 RoP (if considered applicable – quod non) is achieved, (iii) the requested status shift is unnecessary and is aimed only at trying to neutralize the standing challenge against 2SB, and (iv) adding the NIH as co-claimant would not resolve the objections, so that even the dogmatic approach by the NIH does not justify its request.

II.A.3. REGARDING THE ISSUES RAISED BY THE COURT IN ITS 4 SEPTEMBER 2026 COMMUNICATION (§5)

(i) <u>Issue 1</u>

11. Reduced to its essence, the Defendants argue as follows:
- The Defendants do not challenge that the NIH is a party to the revocation proceedings but hold that this does not impact its status in the infringement proceedings (as intervener). Reference is made to the wording of Art. 47(5) UPCA and additionally R. 25.2 RoP.

- As intervener in the infringement proceedings, the NIH should be "*treated as a party*". There is no valid reason to change its status. Such a change would lead to unfair and disproportionate consequences for the Defendants. Reference is made regarding this line of argument to the decisions of LD Paris dated 6 May 2024, UPC_CFI_440/2024 and the Court of Appeal UPC dated 27 November 2026, UPC_CoA_70/2025. Further, the Defendants point out that (i) it was the NIHs' choice not to initiate proceedings as a Claimant and that it must bear the consequences of such choice, (ii) accepting the NIH as a Co-Claimant would go against the principles of fairness and proportionality as well as the front-loading principle of UPC-proceedings.
- In any event, even if the NIH were to be declared a party or co-claimant, it could not be retroactive and would not have any impact on the standing of 2SB, which must be assessed on the date the infringement action was filed. Reference is made regarding this line of argument to the wording of Art. 47 UPCA and R. 13.1(f) RoP referring further to the decision of the LD Munich dated 7 July 2026 (UPC_CFI_846/2024-UPC_CFI_485/2025-UPC_CFI_535/2025). Further reference is made to European Union procedural law and Belgian procedural law to substantiate that standing must be assessed at the time of introducing legal proceedings and cannot be cured during the proceedings.

(ii) Issue 2

12. Reduced to its essence, the Defendants argue as follows:

- R. 8.4 RoP has no bearing on Limb (a) of the standing challenge. Reference is made regarding this line of argument to the structure of R.8 RoP to conclude that R. 8.4 RoP does not create an irrebuttable entitlement presumption. The position is taken that R. 8.5(c) RoP applies to all European patents (including those with unitary effect), which the Defendants substantiate based on a law professor affidavit. The Defendants hold that there is no reason to apply different standards to European Patents with unitary effect and European Patents. Therefore, the Defendants hold that, in the decisions referred to by the Court, R. 8.4 RoP was not correctly interpreted. The Defendants hold that, in any event, R. 8.4 RoP does not impact Limb (a) and the Defendants' case on the standing and this because R. 8.4 RoP is not relevant (because Limb (a) does not challenge the NIH's status as registered proprietor and because Limb (a) does not target the patent proprietor (the NIH) but its licensee (2SB)). As a final argument, the Defendants state that the Court should only hold the NIH to the arguments they put forward (which was not R. 8.4 RoP).
- The Defendants' non-objection to the NIH's intervention has no legal consequence for the assessment of Limb (a).
- The Court should not determine the merits of Limb (a) when ruling on the Applications. For this reason, the Defendants argue that, should the Applications imply that the Court should assess the merits of the standing challenge, it should defer the ruling "*at least until receipt of the Rejoinder*".

III.B. THE NIH

II.B.1. THE REQUESTS MADE IN THE APPLICATIONS AND THE REQUEST TO BE TREATED AS CO-CLAIMANT

13. As a first defence to the Applications, the NIH requests the Court to exercise its powers following the principles outlined by the LD Hague in *Dolby v. CPYou* (8 July 2026, UPC_CFI_1536/2025, UPC_CFI_982/2026, UPC_CFI_1168/2026) and declare the NIH a co-claimant in the proceedings, on the same basis and for the same claims as the intervention already allowed. As a consequence, the NIH holds that formally confirming the NIH to the status of co-claimant would render the Defendants' Limbs (a) and (b) objections of no practical consequence for these proceedings, allowing the Court to dismiss the Applications. Should the Court not be prepared to declare the NIH a co-claimant of its own motion, the NIH states that the NIH and/or 2SB will make a formal application seeking status as a co-claimant for the NIH.

14. In a second line of arguments, the NIH argues that the Applications are superfluous and unsubstantiated, manifestly excessive, untimely and incompatible with the expedient conduct of the proceedings. These arguments will be, if necessary, further detailed in the grounds of this order, but generally the NIHs holds that (i) the documents sought are immaterial to the determination of the case, (ii) the scope of the disclosure requested is manifestly excessive and (iii) the Applications are untimely and incompatible with the expedient conduct of these proceedings

15. In a third line of arguments, the NIH examines the specific categories for which disclosure is sought and argues as follows:
    - Category 1: The request is unspecified and overbroad. In line with this argument, the NIH argues that the burden imposed on the NIH would be wholly disproportionate to any conceivable relevance of the materials sought.
    - Category 2. The NIH has already provided evidence that the only EIR (i.e. Employee Invention Report) in existence in connection with the claimed invention is that filed by Dr. Kochenderfer (substantiated by the Rodrigues Declaration (Exhibit TC07) and the Supplementary Rodrigues Declaration (Exhibit TC13)). In this respect, the NIH rebuts the allegations made by the Defendants regarding the mentioned declarations. Furthermore, the NIH argues that the request for all EIRs related to project codes BC011417 and BC011439 is unreasonable and disproportionate. These two funding codes have supported a large part of Dr. Kochenderfer's NCI research over the past fifteen years and are associated with numerous inventions that have no relevance whatsoever to the dispute at issue in these proceedings.
    - Category 3. It suffers from the same defects as the preceding ones. Additionally, the NIH considers the specific requested documents which it holds not to add anything to the information which is currently accessible on the NIHReporter database. Further, the NIH argues that the cited publicly available abstracts are counterproductive to their own case (referring to the abstract for project ZIABC011439) and that the grant applications and

progress reports sought by the Defendants are internal institutional records that focus on the administrative and budgetary aspects of the research programs and are not intended to describe the intellectual contributions of individual researchers to the conception of a specific invention.

- Category 4. This request is devoid of merit. NIH argues that Art. 47 (2) or (3) UPCA does not prescribe any particular form for "*prior notice*" and further argues why the already submitted evidence is deemed sufficient to assess this condition.

16. Finally, and in the alternative (should the Court grant the Applications), the NIH puts forward conditions regarding confidentiality and costs.

II.A.2. THE ISSUES RAISED BY THE COURT IN ITS 4 SEPTEMBER 2026 COMMUNICATION (§5)

(i) Issue 1

17. Reduced to its essence, the NIH argues as follows:

- The new procedural position of the NIH following the Counterclaim for Revocation (becoming a Defendant in this action) must extend to the proceedings as a whole as there is no basis in the RoP to formalistically consider the Counterclaim for Revocation brought by the Defendants as the object of separate proceedings.
- The Court has the power to affect the reclassification of the NIH's procedural position in exercise of its case management powers (cf. LD The Hague of 8 July 2026 (*Dolby v. CPYou*).
- The patent proprietor does not have other procedural vehicles to achieve this effect, considering that the RoP do not allow the NIH to bring a counterclaim for infringement in a situation like the one arisen in the present proceedings.
- The reclassification is in line with §5 of the Preamble of the RoP.

(ii) Issue 2

18. Reduced to its essence, the NIH argues as follows:

- R. 8.4 RoP creates an irrebuttable presumption that the registered proprietor is entitled to the patent and shall be treated as such for all relevant purposes. To substantiate this line of argument, the NIH argues the clear wording of R. 8 RoP and its implications for the proceedings.
- The alleged asymmetry between European patents with Unitary effect and traditional European patents is neither absurd nor accidental. Such asymmetry was a clear choice.
- The jurisprudence of the Court confirms the plain interpretation of R. 8.4 RoP. Here, a more detailed reference is made to the decisions the Court had put to the attention of the parties.
- The distinction between "*proprietor*" and "*sole proprietor*" is artificial and defeats the Rule's procedural purpose.
- R. 8.4 RoP forecloses the Defendants' attack on 2SB.
- There is no preclusion to the application of R. 8.4 RoP.

- There are other reasons why Limb (a) of the Defendants' standing objection is not plausible.
- There is no reason for the Court to defer its assessment on the Applications as the standard is not to decide on the merits but to assess the plausibility of the claims.

III. GROUNDS FOR THE DECISION

III.A. THE STATUS OF THE NIH AS CO-CLAIMANT

III.A.1. REQUEST BASED ON THE COURT EXERCISING ITS DISCRETIONARY POWERS UNDER R. 315.4 RoP AND R. 305 RoP

19. The RoP seem only to allow an application to intervene (in the sense of admissible) "*if it is made in support, in whole or in part, of a claim, order or remedy sought by one of the parties (…)*" (R. 313.2 RoP). The reason of such intervention is explicitly stated in R. 313.1 RoP indicating that an application to intervene may be lodged by "*any person establishing a legal interest in the result of an action submitted to the Court*". The legal interest is limited to the "*result*" of an already introduced action. That the application to intervene can only be introduced in "*support*" can further be deducted from the wording of R. 313.4 (c) RoP which indicates that the application to intervene should indicate "*the claim, order or remedy in support of which intervention is sought by the intervener*".

20. Therefore, the RoP do not allow "*aggressive interventions*" or "*principal interventions*" (i.e. interventions whereby the intervener directs claims against one or more of the other parties different to the claims it supports. The RoP only allow "*interventions in support*" or "*incidental interventions*"). Such approach was confirmed by the Court of Appeal UPC in its decision of 27 November 2025 (UPC_COA_70/2025) as follows (in its original procedural language):

> (§17) *(…) dass Prozesshandlungen des Streithelfers nur zulässig sind, soweit sie der Unterstützung der von einer der Parteien gestellten Anträge dienen. Der Streithelfer hat damit keine von der von ihm unterstützten Partei unabhängige Position. Ein Ausscheiden der unterstützten Partei aus dem Rechtsstreit, hat zur Folge, dass die Streithilfe unzulässig wird.*
> (§18) *Entgegen der Auffassung Chainzones ergibt sich Gegenteiliges nicht aus dem Gleichbehandlungsgrundsatz nach R. 315.4 VerfO. Der Gleichbehandlungsgrundsatz steht unter dem Vorbehalt, dass die Handlungen des Streithelfers nicht in Widerspruch zu Handlungen und Erklärungen der von ihm unterstützten Partei stehen und dass die Streithilfe auf den Zweck einer Unterstützung der Partei gerichtet sein muss. (...)*

21. Where the above cited decision refers to the position of an intervener as a co-defendant in an infringement action, the Court should now assess whether the circumstances of the case (where the NIH holds to be reclassified as co-claimant being the defendant in the action related to the counterclaim for revocation) would necessitate the Court to deviate from the referred to decision of the Court of Appeal UPC.

22. In the case at hand, the NIH intervened stating that it is "*the proprietor of the patent in suit EP 3 689 383 ("EP '383" or the "Patent")*" for which it further stated that 2SB has a worldwide exclusive license.

23. Based on Art 47(4) UPCA the NIH noted that it is indeed, as patent proprietor, entitled to "*join the action*". Further, the NIH indicated that it had a "*direct economic interest in the outcome of the action, in particular in relation to Requests III. and V. of the Statement of claim, which are the only claims of the Plaintiff in support of which Intervention is sought under R. 313.2 RoP"*.

24. After allowing the Defendants the possibility to reply, the Court in its 28 April 2026 R. 314 RoP Order held the intervention to be admissible and that "*the (NIH) is to be treated as a party*" (in UPC_CFI_29/2026).

25. After the mentioned order was issued, the Defendants submitted together with their respective Statement of Defence a Counterclaim for Revocation (UPC_CFI_1934/2026 and UPC_CFI_1940/2026) on 1 June 2026. In this Counterclaim, the Defendants request the following:

> *"Revocation European Patent EP 3 689 383 with unitary effect is revoked in its entirety for the territory of the UPC member states Austria, Belgium, Bulgaria, Germany, Denmark, Estonia, Finland, France, Italy, Lithuania, Luxembourg, Latvia, Malta, The Netherlands, Portugal, Romania, Sweden, and Slovenia".*

26. Art. 47 (5) UPCA states the following:

> *(...)*
>
> *5. The validity of a patent cannot be contested in an action for infringement brought by the holder of a licence where the patent proprietor does not take part in the proceedings. The party in an action for infringement wanting to contest the validity of a patent shall have to bring actions against the patent proprietor.*

27. The Defendants indeed could only introduce their respective Counterclaims for Revocation if an "*action was brought against the patent proprietor*". By introducing the mentioned counterclaims, the Defendants as such recognized the NIH not only to be "*treated as a party*" but "*as a party*", at least in actions UPC_CFI_1934/2026 and UPC_CFI_1940/2026. Approaching this differently would mean that the mentioned counterclaims would have to be held inadmissible. It should be noted that the Defendants did not make their mentioned counterclaims conditional based on the assessment whether 2SB has standing to sue. Further, no procedural objection was raised by 2SB or the NIH in this regard.

28. Where the NIH should, therefore, be considered as a party (defendant) in the Counterclaim for Revocation (UPC_CFI_1934/2026 and UPC_CFI_1940/2026), the issue arises whether the NIH should or could be considered co-claimant in UPC_CFI_029/2026. More concrete, the issue to be decided is whether the RoP allow a party to be on the one hand the intervener in an infringement action and on the other hand a party (defendant) in the counterclaim

action, and, if so, whether the decision to hear both actions together would have an impact on this assessment.

29. The Court holds that neither the UPCA nor the RoP oppose such an asymmetric position for the NIH in both actions, and, even more, the RoP do not articulate an automatic reclassification of status of parties in such a situation.

30. The NIH opted not to introduce an infringement action against the Defendants alongside 2SB. It opted to join the proceedings as an intervener which indeed limited the claims it could make against the Defendants (i.e. in support of the claims made by 2SB). Examining the written submissions in the infringement action substantiates this approach, as for the moment no claims are made by the NIH other than to support the position of 2SB.

31. The fact that the Counterclaims for Revocation were introduced "*unconditionally*" implies that such action should be considered separately from the infringement action and therefore it is procedurally logical that the NIH is considered the defendant in this validity action and a mere intervener in the infringement action.

32. The fact that the Court issued its R. 37 RoP order on 15 June 2026, stating that the respective actions UPC_CFI_029/2026 and UPC_CFI_1940/2026 on the one side, and UPC_CFI_1934/2026 and UPC_CFI_1940/2026 on the other side, would be heard together, which the parties did not object to, does not interfere with the above reasoning.

33. Finally, the reference made to the decision of the LD The Hague of 8 July 2026 (*Dolby v. CPYou*) should be addressed. The Court (LD The Hague) exercised their case management powers (in application of R. 315 RoP and R. 305 RoP) in view of the circumstances of the case and added the intervener "*a proper party*" on the side of the original claimant. The circumstances of the case were indeed different. One of the elements (circumstances) which the LD The Hague took into account to exercise its discretionary powers was that the intervener had been treated by the opposing party as a "*proper party*" to the proceedings (and this in view of the fact that the reclassification was requested in response to a challenge on the admissibility of the counterclaim, related to the determination of a FRAND license rate, with the intervener being the entity to grant licenses by the patentee). This element (circumstance) does not apply with regard to the proceedings at hand where, at least for the infringement action, the Defendants never treated the NIH as a "*proper party*". Finally, the Court points out that this reclassification was accepted by the LD The Hague only as an alternative if the Court of Appeal UPC would be of the opinion that the counterclaim was not admissible against the intervener. This situation (circumstance) is not present in the proceedings at hand either. Therefore, the Court holds that the decision of the LD The Hague of 8 July 2026 (*Dolby v. CPYou*) does in no way impact the grounds of the Court earlier mentioned.

III.A.2. Request to Invite an Application from the NIH and/or 2SB seeking a declaration of status for the present intervener (the NIH) as a Co-Claimant

34. The Court holds that a "*request to invite*" is not a proper request and as such is not considered an actual R. 305.1 RoP request. Whether or not the NIH and/or 2SB actually will introduce an application for a declaration of status for the NIH as Co-Claimant (based on R. 305.1 RoP or any other rule deemed applicable) should not be based on an invitation by the Court but depends on its (NIH's and/or 2SB's) own procedural strategy.

35. As such an application is not actually introduced, the Court is not in a position to assess whether the conditions of such an application (whichever rule it would be based on) are met and, as such, whether the application is admissible or not. As such, the arguments related to the admissibility or inadmissibility of such a request are premature.

III.A.3. Conclusion

36. The requests made are rejected as unfounded.

III.B. Assessment of the Applications

III.B.1. Conditions to be applied

37. The Court of Appeal of the UPC in its Order issued on 29 June 2026 (UPC_COA_057/2026, *Polytechnic v. Dall*) tackled the main underlying principles of granting an order to produce evidence.

38. Before giving guidance to the actual conditions to be met to grant a R. 190 RoP order, the Court of Appeal of the UPC, in the mentioned order, stated a general principle (§ 19) holding that "*R. 190 RoP, read in conjunction with Art. 59 UPCA and the broader framework of the Rules of Procedure, empowers the Court to order the production of specified evidence which lies in the control of the opposing party or of a third party, provided that the requesting party has presented reasonably available evidence supporting the plausibility of its claims*."

39. Subsequently, in §27-30, the Court of Appeal of the UPC detailed the cumulative constraints to the Court's power to order the production of evidence as follows:

- *First, such measures may be granted only on the basis of specific and substantiated allegations and cannot serve exploratory or speculative purposes. R. 190 RoP does not permit fishing expeditions but requires a concrete link between the requested measure and the facts relied upon by the requesting party. (…)*
- *Secondly, the requested evidence must be strictly necessary (id est, relevant) to the issues in dispute. The taking of evidence serves the adjudication of the case and must not give rise to unnecessary procedural dispersion or delay; accordingly, only those evidentiary measures that are genuinely necessary for the resolution of the dispute should be ordered. In this context, the Court exercises an active role in the management of the proceedings,*

ensuring that evidentiary measures are limited to what is necessary for the proper resolution of the dispute.

- *Thirdly, the requested measure must be proportionate, in the double sense that the evidence cannot reasonably be obtained by the requesting party through less burdensome means and that the burden imposed on the responding party be justified in the light of the interests at stake.*
- *Finally, the Court must ensure a fair balance between competing rights, including the protection of confidential information, trade secrets and personal data. In that regard, the CJEU has held that the instruments provided for by Directive 2004/48/EC must not be used abusively and must remain subject to safeguards ensuring that they are justified, proportionate and non-abusive (see CJEU 17 June 2021, C-597/19, Mircom).*

40. Designed around the specifics of the case at hand, the Court applies the following cumulative conditions to grant a request for the production of evidence:

Condition 1: The claims made on which the R. 190 RoP procedure are based should be "*plausible*".

Condition 2. The Defendants must have presented evidence "*reasonably available*" in support of the plausibility of its claims (Limbs (a) and (b)). This main condition should be assessed together with the following sub-conditions:

Condition 2(a): The claims made under Limbs (a) and (b) should be specified and substantiated and as such are not speculative.

Condition 2(b): The Court should assess the strict necessity (in the sense of "relevance") of the production of requested evidence for the further assessment of Limbs (a) and (b).

Condition 3: The requested evidence must (a) be "*specified*" and (b) lie in the control of the other party;

Condition 4. The Court must ensure a fair balance between competing rights, including the protection of the other party's confidential information, trade secrets and personal data;

Condition 5. An order to produce evidence must satisfy the requirements of proportionality, equity, and fairness, assessing the following sub-conditions:

Condition 5(a): The timing of the application (as a whole) should meet the condition of "*proportionality, equity, and fairness*" (taking into consideration the stage of the proceedings). Part of this assessment demands the assessment whether the applications (and subsequent grant) may not give rise to unnecessary procedural dispersion or delay and whether the requested evidence cannot be reasonably obtained by the Defendants through less burdensome means.

Condition 5(b): Each individual request which met the above conditions should meet the condition of "*proportionality, equity, and fairness*"

III.B.2. ASSESSMENT OF THE APPLICATIONS

III.B.2.1. LIMB (A)

III.B.2.1.i. R. 8.4 RoP

41. In its Statement of Claim, 2SB indicated that "*(t)he patent proprietor* (i.e. the NIH) *is filing a request for unitary effect of EP 3 689 383 at the EPO* (…)." On 5 January 2026, the NIH filed such request. This request for unitary effect was granted on 13 January 2026 by the EPO.

42. Whether the European patent has unitary effect or not seems to be of relevance regarding the question of entitlement to the patent when reading R.8.5 (c) RoP and R. 8.4 RoP, as R.8.5 (c) RoP indicates that "*(f)or the purposes of paragraph 5, there shall be a rebuttable presumption that the person shown in (…) the European Patent Register kept by the European Patent Office is the person entitled to be registered as proprietor or applicant as the case may be*" and R. 8.4 RoP states that "*(f)or the purposes of proceedings under these Rules in relation to the proprietor of a European patent with unitary effect, the person shown in the Register for unitary patent protection [Regulation (EU) No 1257/2012, Article 2(e)] as the proprietor shall be treated as such*."

43. The Court considers the wording of the above mentioned rules to be clear in the sense that "*for the purpose of the proceedings*" the person shown in the European Patent Register kept by the European Patent Office is entitled to be registered as proprietor for European Patents without unitary effect and that the person shown in the Register for unitary patent protection as the proprietor for European patents with unitary effect shall be treated as such (i.e. a non-rebuttable presumption).

44. The issue which actually should be addressed is what is to be understood by the term "*for the purpose of the proceedings*".

45. The Court understands this term as applying only for the application of the RoP and more specifically the administrative tasks to be performed by the Court and/or the parties. For this administrative purpose, a legal fiction is created. On the other hand, this legal fiction is held not to apply for questions of substantive law and, therefore, in an action for which the UPC is competent, the defendants have indeed the right to bring a defence comprising the issue of entitlement (cf. Tilmann in: Tilmann/Plassmann, Einheitspatent, Unified Patent Court, 1st ed. 2024, Rule 8, §11).

46. Deciding otherwise would not be in line with the principles of the right of defence where a Defendant would be barred from bringing a defence which it holds primordial. It should be noted that the entitlement issue is indeed brought as a defence regarding the standing of a party (see cascade of claims) and not as a stand-alone request (for which the UPC would not

seem competent based on Art. 32 UPCA), but this is an issue which does not need to be assessed.

47. The Court indeed notes a different approach by different divisions regarding the mentioned presumption. Some divisions (i.e. LD Munich 25 November 2024 – UPC_CFI_443/2024 (*Häfele v. Kunststoff KG Nehl & Co*) and LD The Hague 29 August 2025 – UPC_CFI_374/2025 (*Cilag v. RiVOLUTION*)) on the one hand did understand this presumption as not rebuttable when applying questions of substantive law and the CD (CD Munich 2 September 2026, UPC_CFI_523/2025 (*Wittenstein v. Vestas*)) on the other hand allowed that the issue of entitlement could be addressed notwithstanding the wording of R.8.5 RoP. As the Court of Appeal of the UPC has not yet rendered a decision with regard to the interpretation of R. 8.5. RoP regarding its application to substantive law, the Court, with all due respect, deviates from the position taken by the mentioned LDs for the above-mentioned grounds.

48. As such, the presumption of entitlement of the Patent in the sole name of NIH (arguing to own the shares of all inventors) is considered rebuttable under the RoP and the Defendants are as such permitted to introduce a defence questioning such entitlement notwithstanding the wording of R.8.4 RoP.

III.B.2.1.ii. Implications of the absence of opposition to the NIH's intervention with regard to being the patent proprietor

49. The Court notes that, although the NIH was invited to provide its comments (on 10 September 2026) related to possible implications regarding mentioned absence of opposition, it did neither put forward any argument to this respect nor oppose the position taken by the Defendants in their earlier comments filed on 8 September 2026. As such, it should be held that the NIH does not oppose (accepts) the position taken by the Defendants. It would go beyond the competence of the Court to address such possible (procedural) implications on its own motion.

III.B.2.1.iii. Claim cascade and implications for the assessment of plausibility

50. Under Limb (a) the following cascade of claims needs to be assessed regarding their "*plausibility*" (condition 1):

The shares of all inventors were not assigned to the NIH
(No legitimate ownership/entitlement in the invention



No legitimate transfer of rights from the NIH to 2SB



No standing to sue for 2SB (claimant in the infringement action)

51. The Defendants argue that 2SB lacks standing to sue if any of the claims in the cascade is correct. Limb (a) relates to the first step (linked to the second step), whereas limb (b) relates solely to the third step (alleged lack of prior notice). Therefore, in order to assess the plausibility of limb (a) (condition 1 concerning document categories 1-3), the Court should assess whether the Defendants make it plausible that the NIH lacks entitlement. And in order to assess the plausibility of limb (b) (condition 1 concerning document category 4), the Court should assess whether the Defendants make it plausible that 2SB has no standing to sue due to lack of prior notice.

52. The Court has to assess which law should be applied to assess the plausibility of each step in the cascade of claims and this by applying the applicable conflict-of-law rules.

53. The UPCA does not foresee detailed conflict-of-law rules, except for the general Art. 24 UPCA stating that, when hearing a case brought before it under the UPCA, the Court shall base its decisions on: (a) Union law (…), (b) the UPCA, (c) the EPC (d) other international agreements applicable to patents and binding on all the Contracting Member States; and (e) national law. As such, the conflict-of-law principles of the mentioned legislation should be applied.

54. In application of Art. 24 UPCA (as a matter of law), the Court holds as follows:

Legal Issue to be Assessed	Applicable Law
Entitlement to the invention	Parties seem to agree in their approach regarding entitlement follows ownership in the US priority application (US 201261622600 P) (hereafter referred to as "US Application"). The US Application should be assessed using U.S. Law. Parties do not dispute the application of U.S. law regarding the entitlement issue with reference to the US Application. As an underlying issue, the conflict-of-law rules regarding the rights and obligations of employees of the NIH might need to be assessed as the NIH holds that the co-authors of Carpenter 2013 were employed by the NIH (or at least their alleged contributions date from the time of employment). The transfer of rights and the rights/obligations of parties are of a contractual nature. Although no agreements in this regard are given into evidence, it seems reasonable to assume that as the NIH is part of the U.S. administrative structure, U.S. labor law applies.
Transfer of rights from the NIH to 2SB	The transfer of rights (from the NIH to 2SB) is a contractual issue. The assessment of whether rights were legitimately transferred (and to which extent) depends on the law applicable to the contract. As neither the UPCA nor the RoP state any specific rules regarding the legitimacy of transferring patent rights, the Court should revert to Union Law. Union law applicable to the case is Regulation (EC) No.

	593/2008 of the European Parliament and the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I). This Regulation is universal in its scope (cf. Art. 2). Art. 3 of mentioned Regulation states that contract is governed by the law chosen by the parties and in Art. 12(1)(a) that the law applicable to contract also governs its interpretation. In the license agreement (Exhibit TC02) under 14.5. the following is provided: "*The construction, validity, performance, and effect of this Agreement shall be governed by Federal law as applied by the Federal courts in the District of Columbia*". A similar provision can be found in the confirmatory license agreement (Exhibit ME010) under (2) Governing Law.
Standing to sue Based on the Patent	Art. 1 of Regulation (EC) No. 864/2007 of the European Parliament and the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II) (such as the non-contractual obligation arising from an infringement of an intellectual property right (cf. Art. 8)), excludes the application to evidence and procedure. Procedural matters (including the standing to sue) are therefore governed by the rules of private international law of the EU Member States. The issue of standing to sue is therefore not governed by the law applicable to the license agreement, but the procedural law applicable to the forum (i.e. UPC). The rule related to the procedural matter at issue is Art. 47 UPCA.

III.B.2.1.iv. Plausibility of the claims made under Limb (a)

55. The Court does not need to assess the claims under Limb (a) *on the merits* in assessing the Applications, but should limit its assessment to whether these claims are *plausible* (at this stage of the proceedings). Therefore, the Court sees no reason to defer such assessment until the Defendants have submitted their Rejoinder and additional accompanying evidence as an assessment on plausibility does not imply a final assessment of the claims as such (which could differ from a plausibility assessment). The request in this regard introduced by the Defendants is dismissed.

56. The Court holds that the Defendants do not sufficiently prove the plausibility of their claims (at this stage of the proceedings) and as such holds that the Applications with regard to Limb (a) should be dismissed as unfounded. The Court grounds its decision on the following cumulative considerations which specifically pertain to the step of entitlement:

- The Defendants fail to mention the judgement issued by the *Tribunal Judiciaire* of Paris of 6 May 2026 (proceedings involving Claimant's 1 subsidiaries as licensees in the same NIH licence framework and claimant in the French proceedings) rejecting the entitlement issues raised.

Reference was made to this French decision in the NIH's *Reply to the Statement of Defence and Defence to Counterclaims for Revocation* submitted on 5 August 2026, while the Applications date from respectively 11 and 14 August 2026.

- In the parallel proceedings before the High Court of Justice (Business and Property Courts of England and Wales – Intellectual Property List) (Claim No. HP-2026-000007), the issue of entitlement is not brought up by the Defendants (cf. Reply and Defence to Counterclaim as submitted on 27 July 2026 – with a partial overlap of defendants). The defence raised seems only to pertain to the irregular transfer of rights to 2SB**.** Such strategy undermines the plausibility of a position taken in the UK proceedings (not contesting entitlement of the US Application) which was not expressed in the UPC proceedings (contesting the entitlement of the US Application).
- The Patent refers to a priority date (11 April 2012) corresponding to the US Application. The Defendants question the entitlement of the NIH regarding the US Application for the reasons mentioned in §7. The Court is not convinced of the plausibility of the claim (Limb (a) for the following reasons:
  - The criteria for identifying a researcher as co-author of an academic article do not correspond to the legal test for determining co-inventorship. Different standards are used, serving different purposes.
  - Named inventors are under U.S. law presumed to be the true and only inventors (*Ethicon, Inc. v. United States Surgical Corp.,* 133 F.3d 1456, 1460 (Fed. Cir. 1998). Under U.S. law a similar presumption exists as in the RoP (*Ethicon, Inc. v. United States Surgical Corp.,* 133 F.3d 1456, 1460 (Fed. Cir. 1998) and places the burden of proof for challenging the inventorship stated in the patent to the challenger. Therefore, the Defendants need to come forward with clear and convincing evidence that other co-inventors need to be named. Such presumption would not be overcome by mere speculation that some other co-inventors might exist based on named authors in an academic contribution.
  - It seems that all the authors of Carpenter 2013 were employed by the NIH (see Exhibit TC09) at the time the invention was made. With regard to Mr. Yang the Court notes that his involvement in the research leading the invention predates his departure from the NHI in May 2011. This is confirmed not only by Mr. Kochenderfer's declaration but also by a declaration submitted by Mr. Rashad Gibson (titled as HR Specialist at the NIH).
  - In application of the "*United States Public Health Service Technology Transfer Policy Manual - Chapter 201 ("PHS Policy for Reporting Employee Inventions* ")" (applicable to the NIH and its employees), the mentioned authors were at a duty (under C – Policy) to report any invention to which they believed they had contributed to the course of their employment. Further, if the argument of the Defendants would be followed (in the sense that the named persons would be considered co-inventors under U.S. law), a maximum term applies to challenge any contrary determination by the government. According to 28 U.S.C. § 2401(a), the statute of limitations for bringing an Administrative Procedure Act (APA) action is six years (cf. reference in Exhibit TC05 to Corner Post, 144 S. Ct. at 2444).
  - That the authors were indeed aware of the Dr. Kochenderfer's filing of the US Application can be deducted from an earlier publication having the same object as Carpenter 2013 Exhibit TC08 – Annex E):



- This earlier publication includes the following statement in the "*Disclosure Section*":

  > *"[A]s a Principal Investigator [Dr. Kochenderfer] had full responsibility for the design, execution and funding of [his] research at the NCI. This includes the research that led to the Patent, specifically: the identification of BCMA as an ideal target for CAR T-cell therapy for MM, the design of BCMA-directed CAR constructs and devising the analytical framework for the in vitro experiments which demonstrated efficacy of anti-BCMA CAR T-cell therapy for MM*"
  > (Exhibit TC08 – Annex E, p. 3).

- The deadline for these alleged co-inventors to claim co-inventorship by first reporting to NIH that they were co-inventors and then filing an Administrative Procedure Act (APA) action to contest any contrary decision by the NIH would have expired by about 2018. As such, the co-authors of Carpenter 13 would no longer be entitled to challenge the inventorship.
- Even if the co-authors were to be regarded as co-inventors, at the time of the work reported in Carpenter 2013, all of the named authors, as employees of the NIH, had an obligation to assign title to any inventions to NIH. As such they had the same obligation to assign title to the government that Dr. Kochenderfer had.

- In its "*Reply to the Statement of Defence and Defence to Counterclaims for Revocation*" submitted on 5 August 2026, the NIH stated (in §20), making reference to the Defendants' own exhibits (under JJ-I09 and BB21 – the Masur Declaration), that the alleged existence of additional co-inventors would not affect the validity of the license under U.S. law. Therefore, the NIH states that even if the allegations regarding entitlement would be held to be true, the license would remain valid and effective. Although this was a main argument, the Defendants in their respective Applications did not counterargue such statement.

III.B.2.2. LIMB (B)

57. The Applications with regard to Limb (b) are limited to the production of evidence requested under Category 4.

58. 2SB has stated the following in its Statement of Claim regarding its alleged "*entitlement to sue*" (p. 7):

r13.1(f)	Entitlement to commence proceedings: The Claimant is exclusive licensee under EP 3 689 383 [**Exhibit ME002**] and therefore has standing and entitlement to commence proceedings under Article 47.2 UPCA. See Confirmatory Licence [**Exhibit ME010**] and Section 2.4 below. The patent proprietor has been informed of the Claimant's intention to commence these proceedings.

59. The condition of "*prior notice*" in Article 47(2) or (3) UPCA (to be interpreted "*autonomously*"- cf. UPC_CoA_365/2025_UPC_CoA_413/2025, order of 17 June 2025, *Knaus Tabbert/Yellow Sphere and Härtwich*) should be assessed by the Court when the action is brought, specifically on the date on which the action in application of R. 17.1 RoP is recorded in the register (i.e. after the Registry's formal examination of the Statement of Claim (R. 16 RoP with an explicit reference in R. 16.2 RoP to R. 13.1(f) RoP).

60. The burden of proof of complying with this condition lies solely on the claimant (2SB). However, although the Court should position itself on the moment the action is brought, the claimant is still allowed to introduce additional evidence in support of the already introduced evidence in application of R. 13.1(f) RoP.

61. 2SB argues that it has submitted sufficient evidence to prove such "*prior notice*" in application of Art. 47(2) UPCA. The Court does not see a reason why the Defendants should themselves try to obtain more evidence if 2SB is of the opinion that it has submitted enough evidence to this regard. Whether this evidence will indeed be held sufficient, taking into consideration the burden of proof placed on 2SB, will be assessed by the Court when assessing the actions at or after the oral hearing.

IV. ORDER

The Court,

- Dismisses the request made by the NIH to be regarded as the Co-Claimant in the infringement action (UPC_CFI_029/2026) but considers the NIH the Defendant in the (unconditional) counterclaims for revocation (UPC_CFI_1934/2026 and UPC_CFI_1940/2026).
- Dismisses the requests made by the Defendants in their respective applications to produce evidence on 11 and 13 August 2026.
- Refers the assessment on the costs to the final proceedings.

Issued on 23 September 2026 by the Panel

Samuel **GRANATA** Presiding Judge/ Judge-Rapporteur Legally Qualified Judge	Samuel Rocco M Granata Digitally signed by Samuel Rocco M Granata Date: 2026.09.23 12:19:27 +02'00'
Marije **KNIJFF** Legally Qualified Judge	Marije Knijff Digitally signed by Marije Knijff Date: 2026.09.23 10:59:06 +02'00'
Anna-Lena **KLEIN** Legally Qualified Judge	ANNA-LENA KLEIN Firmato digitalmente da ANNA-LENA KLEIN Data: 2026.09.23 12:05:53 +02'00'
Renaud **FULCONIS** Technically Qualified Judge	Renaud, Patrick, Raymond Fulconis 2026.09.22 17:25:50 +02'00'

Notice on Appeal

This Order may be appealed in application of Art. 73(2)(a) UPCA (juncto Art. 59 UPCA) and R. 220.1. RoP (juncto Art. 59 UPCA).