

**IN THE CENTRAL DIVISION (MUNICH SECTION) OF THE UNIFIED PATENT COURT**

**CASE NUMBER ACT\_464985/2023 (UPC\_CFI\_75/2023)**

**EUROPEAN PATENT NUMBER EP 3 056 563**

**APPLICANT:**

**MATHYS & SQUIRE LLP**

The Shard, 32 London Bridge Street, London, SE1 9SG, UK

(Applicant)

**RELEVANT PROCEEDING PARTIES:**

**1) ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE**

9 Technology Drive, MA 01581, Westborough, USA

(Claimant)

**2) HEALIOS K.K**

Hamamatsu-cho 2-chome Minato-ku, 105-6115, Tokyo, Japan

(Defendant)

**3) RIKEN**

2-1, Hirosawa Wako-shi, 351-0198, Saitama, Japan

(Defendant)

**4) OSAKA UNIVERSITY**

1-1 Yamadaoka Suita-shi, 565-0871, Osaka, Japan

(Defendant)

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**APPLICATION FOR A PROCEDURAL ORDER UNDER RULE 9**

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## A. BACKGROUND

1. On 21 November 2023, Mathys & Squire LLP (the “Applicant”) lodged a request under Rule 262.1(b) of the Rules of Procedure (‘RoP) requesting that the Court make available all written pleadings and evidence filed in relation to case no. ACT\_464985/2023 (the “Main Proceedings”).
2. That request was granted, with the Court issuing an order dated 22 August 2024<sup>1</sup> ordering that:

*“The Applicant shall be granted access to the written pleadings and evidence lodged and recorded in the register concerning case ACT\_464985/2023, after redaction of personal data within the meaning of Regulation (EU) 2016/679 subject to keeping confidential of certain information [which the Claimants to the Main Proceedings had requested should be kept confidential.]”*

3. Copies of pleadings and evidence including certain redactions were provided to the Applicant by the Registry on 12 September.
4. Inspection of the pleadings and evidence has revealed that, contrary to the Court’s order of 22 August 2024:
  - a) Not all of the written pleadings and evidence from the Main Proceedings have been provided to the Applicant; and
  - b) Some of the redactions in the documents provided to the Applicant go beyond the redactions provided for by the RoP and Article 45 UPCA.

## B. MISSING DOCUMENTS

5. Copies of the following documents were not provided to the Applicant:
  - Claimant’s letter of 11 August 2023 proposing revised valuation of EUR 4,000,000; and Annex A thereto containing correspondence between the representatives of Claimant and Defendants – referred to in paragraph 7 of the Defendants’ Statement of Defence;
  - Claimant’s letter of 29 January 2024 - referred to in the Defendants’ letter of 9 April 2024; and
  - D18 (second declaration of Dr ██████████)<sup>2</sup> – referred to in Defendants’ letter of 9 April 2024
6. It is possible that the erroneous omission of these documents may have arisen due

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<sup>1</sup> [Order of 22 August 2024, ORD 591107/2023 in case no. App 588681/2023 \(UPC CFI 75/2023\), Mathys & Squire LLP v Astellas Institute for Regenerative Medicine](#)

<sup>2</sup> Identifiable from context as the Second declaration of Dr Monte Radeke.

to errors in the manner in which documents have been recorded in the Court's CMS as although, as they are referenced in the written evidence and pleadings provided to the Applicant, and hence appear to constitute: "*written pleadings and evidence lodged and recorded in the register*", they are not listed as documents in the CMS directory for case no. ACT\_464985/2023 which is accessible by UPC representatives.

7. The Applicant requests that the Court instructs the Registrar to provide the Applicant with access to the documents listed above in fulfilment of the Court order of 22 August 2024.

### **C. ERRONEOUS AND EXCESSIVE REDACTION OF INFORMATION**

8. Personal data is defined by Article 4(1) of Regulation (EU) 2016/679 as:

*"any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person"*

9. The power of the Court to redact personal data within the meaning of Regulation (EU) 2016/679 from documents provided to members of the public under Rule 262.1(b) RoP is subject<sup>3</sup> to Article 45 UPCA which provides that "*proceedings [which the Court of Appeal has ruled include the written procedure]*<sup>4</sup> shall be open to the public unless the Court decides to make them confidential, to the extent necessary, in the interest of one of the parties or other affected persons, or in the general interest of justice or public order."

10. Hence, any redactions of personal data from written pleadings provided under Rule 262.2(b) RoP must be limited to those which are "*necessary, in the interest of one of the parties or other affected persons, or in the general interest of justice or public order.*"

11. Inspection of the copies of the written pleadings and evidence provided to Applicant has revealed that:

- a) Information has been redacted which does not constitute personal data within the meaning of Regulation (EU) 2016/679; and

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<sup>3</sup> Paragraph 1 of the Preamble to the RoP: "*In the event of a conflict between the provisions of the Agreement and/or the Statute on the one hand and of the Rules on the other hand, the provisions of the Agreement and/or the Statute shall prevail.*"

<sup>4</sup> [Ocado Innovation Limited v Christopher Stothers, Decision of 10 April 2024, ORD\\_19369/2024 in action no. APL\\_584498/2023 \(UPC\\_CoA\\_404/2023\)](#) at paragraph [40]

- b) Redactions of personal data have been made beyond those necessary in the interests of the parties or other affected persons or in the general interests of justice or public order contrary to Article 45 UPCA.
12. Dates (e.g. dates of signature of documents or start/end dates of clinical trials), names of commercially-available laboratory equipment and reagents, standard experimental protocols, arbitrary portions of headers, figure labels, tables of contents, etc. do not constitute “personal data” and hence redaction of such information from documents provided in accordance with RoP 262.1(b) is not permissible.
13. Redaction of titles of published academic papers identified by the names of their authors (e.g. in the titles in the form “Fox, Robinson, Wietzke *et al.*”), although strictly falling within the ambit of the definition of “personal data” under Regulation (EU) 2016/679, is not necessary in the interests of any parties or other persons or necessary in the general interest of justice or public order.
14. Further, although the names of expert witnesses,<sup>5</sup> inventors,<sup>6</sup> and public officials,<sup>7</sup> as well as the identities of parties’ representatives and the names and addresses of their law firms<sup>8</sup> may constitute personal data under the definition of personal data under Regulation (EU) 2016/67, the disclosure of such personal data in the context of proceedings before the Unified Patent Court does not impact upon the legitimate interests of any of the parties to such proceedings or the individuals associated with that personal data or the general interest of justice or public order.
15. In view of the above, we request that the Court orders the Registrar provides to the Applicant copies of the written pleadings with the following redactions identified in the annex to this document removed.

**Nicholas Fox, Alexander Robinson & Andreas Wietzke  
For and on behalf of Mathys & Squire LLP**

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<sup>5</sup> e.g. those behind D16, D17 and D18, and any discussion thereof such as in the Reply to the Defence, the Rejoinder to the Reply to the Defence, and the Defendants’ letter of 9 April 2024.

<sup>6</sup> As in the English-language certification of the priority document JP2013212345.

<sup>7</sup> Such as the Commissioner of the Japan Patent Office.

<sup>8</sup> As in the Defendants’ Statement of Defence (“Dr ██████ of ██████ LLP”) and its digital signature.

## REDACTIONS REQUESTED TO BE REMOVED

### Priority document JP 2013212345 and English translation

Redaction	Reason for removal of redaction
Certificate of translation: Name of translator/translation project manager	No relevant interests adversely affected by disclosure.
Japan Patent Office certification of priority document: name of the Commissioner of the Japan Patent Office	Public official. No relevant interests adversely affected by disclosure. Further, this information is visible in the Japanese version of the text.
Japan Patent Office certification of priority document: names of inventors	Public information. No relevant interests adversely affected by disclosure. Further, this information is visible in the Japanese version of the text as well as in the application as filed (PCT/JP2014/077111, published as WO 2015/053375 A1) and in the patent as granted (EP 3056563 B1)

### Statement of Defence (Healios)<sup>9</sup>

Redaction	Reason for removal of redaction
Paragraph 2(b): The name and law firm of "Dr XXXX of XXX LLP"	Public information available via the UPC register of cases and via other documents on file. No relevant interests adversely affected by disclosure.
Paragraph 2(b): The postal address of "Dr XXXX of XXX LLP"	Already accessible via other documents on file, as well as being publicly accessible via J A Kemp website. No relevant interests adversely affected by disclosure.
Paragraph 2(b): "Dr XXX is the defendants' representative pursuant to Rule 8.1 RoP UPC"	Public information available via UPC register of cases. No relevant interests adversely affected by disclosure.
Paragraph 18: "June XXX and August 2015", referring to D13	This is not personal information within the meaning of GDPR. Further, it is not redacted in the second copy of this statement or in Riken's copy of the same statement (see below).
Paragraph 92: titles of documents D2, D3, D4, D5, D3a, D6, D7, D8, D9	Names of documents. No relevant interests adversely affected by disclosure.
Digital signature of representative: "James Ronald XXX"	The name of the representative is a matter of public record, as well as being visible in the otherwise identical statement of defence as filed by Riken and in other documents which have been disclosed. No relevant interests adversely affected by disclosure.

<sup>9</sup> The filenames indicate that this was provided in duplicate; we assume that one of those copies was in fact filed by Osaka University.

## Statement of Defence (Healios) – second copy<sup>10</sup>

Redaction	Reason for removal of redaction
Paragraph 2(b): The name and law firm of “Dr XXXX of XXX LLP”	Public information available via the UPC register of cases and via other documents on file. No relevant interests adversely affected by disclosure.
Paragraph 2(b): The postal address of “Dr XXXX of XXX LLP”	Already accessible via other documents on file, as well as being publicly accessible via J A Kemp website. No relevant interests adversely affected by disclosure.
Paragraph 2(b): “Dr XXX is the defendants’ representative pursuant to Rule 8.1 RoP UPC”	Public information available via UPC register of cases. No relevant interests adversely affected by disclosure.
Paragraph 92: titles of documents D2, D3, D4, D5, D3a, D6, D7, D8, D9	Names of documents. No relevant interests adversely affected by disclosure.
Digital signature of representative: “James Ronald XXX”	The name of the representative is a matter of public record, as well as being visible in the otherwise identical statement of defence as filed by Riken and in other documents which have been disclosed. No relevant interests adversely affected by disclosure.

## Statement of Defence (Riken)

Redaction	Reason for removal of redaction
Paragraph 2(b): The name and law firm of “Dr XXXX of XXX LLP”	Public information available via UPC register of cases and via other documents on file. No relevant interests adversely affected by disclosure.
Paragraph 2(b): The postal address of “Dr XXXX of XXX LLP”	Already accessible via other documents on file, as well as being publicly accessible via J A Kemp website. No relevant interests adversely affected by disclosure.
Paragraph 2(b): “Dr XXX is the defendants’ representative pursuant to Rule 8.1 RoP UPC”	Public information available via UPC register of cases. No relevant interests adversely affected by disclosure.
Paragraph 92: titles of documents D2, D3, D4, D5, D3a, D6, D7, D8, D9	Names of documents. No relevant interests adversely affected by disclosure.
Paragraph 93: URL for document D11	Not personal information within the meaning of GDPR. Further, this is not redacted in either of the other two copies of the same document (see above).

<sup>10</sup> The filenames indicate that this was provided in duplicate; we assume that one of those copies was in fact filed by Osaka University.

**D3a (Miyazaki et al – supplementary information) (as filed by Healios, Riken, Osaka University)**

<b>Redaction</b>	<b>Reason for removal of redaction</b>
Page 1: names of authors	No relevant interests adversely affected by disclosure.

**Reply to defence to revocation (Astellas)**

<b>Redaction</b>	<b>Reason for removal of redaction</b>
Paragraphs 24, 31: “Declaration of XXXX Ph.D.” (D16)	Identifiable as a declaration of Monte Radeke <i>via</i> file name displayed in the CMS. No relevant interests adversely affected by disclosure.

**D16 (Declaration of Dr XXXX)**

<b>Redaction</b>	<b>Reason for removal of redaction</b>
Title and first sentence (“I, XXXX, declare as follows”)	Identifiable as a declaration of Monte Radeke <i>via</i> file name displayed in the CMS. No relevant interests adversely affected by disclosure.
Date below signature block	Not personal information within the meaning of GDPR.
Name on CV	Identifiable as Monte Radeke from context. No relevant interests adversely affected by disclosure.
Details of education in CV (locations and advisors)	No relevant interests adversely affected by disclosure.
Details of education in CV (dates)	Not personal data within the meaning of GDPR.
Details of research experience in CV (locations and name of PI)	No relevant interests adversely affected by disclosure.
Details of research experience in CV (dates)	Not personal data within the meaning of GDPR.

## Rejoinder to reply to defence to revocation (Healios, Riken, Osaka University)<sup>11</sup>

Redaction	Reason for removal of redaction
Paragraph 2.3: "D16 Declaration of XXXX Ph.D."	Identifiable as a declaration of Dr Monte Radeke <i>via</i> file name displayed in the CMS. No relevant interests adversely affected by disclosure.
Paragraph 2.4: "D17 Declaration of XXXX Ph.D."	Identifiable as a declaration of Dr Sawada <i>via</i> file name displayed in the CMS. No relevant interests adversely affected by disclosure.
Paragraph 3.1.2: "expert declaration of XXXX to support its position (D16)"	Identifiable as a declaration of Dr Radeke, as above. No relevant interests adversely affected by disclosure.
Paragraph 3.2.7: "declaration (D17) of Dr XXXX one of the inventors of the patent" & Paragraph 3.2.8: "Dr XXXX confirms, in paragraph 11 of his declaration (D17)"	Identifiable as a declaration of Dr Sawada, as above. No relevant interests adversely affected by disclosure.
Paragraph 3.3.9: "Considering paragraph 19 of D16 in more detail, XXXX first..." & Paragraph 3.3.10: "XXXX has then interpreted the disclosure..."	Identifiable as a declaration of Dr Radeke, as above. No relevant interests adversely affected by disclosure.

## D17 (Declaration of Dr XXXX) (Healios, Riken, Osaka University)

Redaction	Reason for removal of redaction
Title, "Declaration of Dr XXXX" and first sentence, "I, Dr XXXX declare and state as follows"	Identifiable as a declaration of Dr Sawada <i>via</i> file name displayed in the CMS. No relevant interests adversely affected by disclosure.
"Dr XXXX" printed below signature block	Identifiable as a declaration of Dr Sawada, as above. No relevant interests adversely affected by disclosure.
Date printed below signature block	This is not personal information within the meaning of GDPR.

<sup>11</sup> Only a single copy of this document has been provided. We understand that it was filed in triplicate, *i.e.* once on behalf of each Defendant, and that each copy was identical.



**D17B (Supplementary material protocol to D17A (Mandai et al)) (Healios, Riken, Osaka University)**

<b>Redaction</b>	<b>Reason for removal of redaction</b>
Front page: "Protocol for: XXXX M, XXXX A, XXX Y, et al"	No relevant interests adversely affected by disclosure.
Numbered Page 7 (pages 15 and 69 of PDF): "Recently, XXXX and his colleagues at Kyoto University..."	Redacted in Healios and Osaka University copies but not in Riken copy. No relevant interests adversely affected by disclosure.
Numbered Page 16 (pages 24 and 78 of PDF: "placed on a Lumox dish 35 and cut to the appropriate size using PALM MicroBeam XXXX"	This appears to be the name of a commercially available product. Not personal information within the meaning of GDPR.
Numbered Page 20 (pages 28 and 82 of PDF): "A 1 mL syringe XXXX Tokyo, Japan) will be installed in a custom-made holder XXXX XXXX Japan)"	This appears to be information concerning manufacturers of products. Not personal information within the meaning of GDPR.
Numbered Pages 47-8 (pages 55-56 and 109-110 of PDF): authors' names for references 4-14 and 16	Redacted in Healios and Osaka University copies but not in Riken copy. No relevant interests adversely affected by disclosure.
Numbered page 1 (page 113 of PDF): Japanese document version number in lower right hand corner of page	Not personal information within the meaning of GDPR.
Numbered page 3 (page 115 of PDF): Item 6.1 in Japanese table of contents	Not personal information within the meaning of GDPR.

**D17B (Supplementary material protocol to D17A (Mandai et al)) (Healios, Riken, Osaka University) - second copy**

<b>Redaction</b>	<b>Reason for removal of redaction</b>
Numbered page 6 (page 118 of PDF): Identification of Annex 2 in Japanese	Not personal information within the meaning of GDPR.
Numbered page 2 (page 120 of PDF): labels in flowchart	Not personal information within the meaning of GDPR.
Numbered pages 5-6 (pages 123-124 of PDF): miscellaneous aspects of Japanese text	Not personal information within the meaning of GDPR.
Numbered page 10 (page 128 of PDF): portions of page header in Japanese	Not personal information within the meaning of GDPR.
Numbered page 14 (page 132 of PDF): paragraph 5.3.2, "Cell Processing XXXX"	Not personal information within the meaning of GDPR.
Numbered page 15 (page 133 of PDF): paragraphs 5 and 6, "XXXX CKI-7" and "hFGF XXXX"	Not personal information within the meaning of GDPR.
Numbered page 19 (page 137 of PDF): portions of page header in Japanese	Not personal information within the meaning of GDPR.

**D17B (Supplementary material protocol to D17A (Mandai et al)) (Healios, Riken, Osaka University) - third copy**

<b>Redaction</b>	<b>Reason for removal of redaction</b>
Numbered page 21 (page 139 of PDF): “RPE XXXX” and “2013 XX 10”	Not personal information within the meaning of GDPR.
Numbered page 24 (page 142 of PDF): “NEI VFQ-25 (the 25-item XXXXXXXXXXXX Visual Function Questionnaire)”	Not personal information within the meaning of GDPR.
Numbered page 25 (page 143 of PDF): miscellaneous column headers in table at top of page	Not personal information within the meaning of GDPR.
Numbered page 28 (page 146 of PDF): miscellaneous aspects of Japanese text at section 11.3.3	Not personal information within the meaning of GDPR.
Numbered page 30 (page 148 of PDF): authors’ names in English-language citation in footnote	Redacted in Healios copy but not in Riken or Osaka University copies. No relevant interests adversely affected by disclosure.
Numbered page 47 (page 165 of PDF): authors’ names in citations 4-14	Redacted in Healios copy but not in Riken or Osaka University copies. No relevant interests adversely affected by disclosure.

**Letter of 9 April 2024 (Healios, Riken, Osaka University) – all three copies**

<b>Redaction</b>	<b>Reason for removal of redaction</b>
Page 1: “On 29 January 2024, the Claimant filed D18 which is a second declaration of Dr XXXX”	Identifiable from context as a second declaration of Dr Radeke (the declarant behind D16). No relevant interests adversely affected by disclosure.
Page 1: “D18 largely reiterates points already made in the first declaration of Dr XXXX (D16)”	Identifiable as a declaration of Dr Radeke <i>via</i> file name displayed in the CMS. No relevant interests adversely affected by disclosure.
Page 1: “Dr XXXX has misunderstood the arguments”	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 2: “Nothing Dr XXXX says detracts from this argument”	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 2: “Dr XXXX is effectively arguing that RPE cell differentiation...”	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 2: “However, XXXX et al (D6) shows...”	Identification of a document. No relevant interests adversely affected by disclosure.
Page 2: “Dr XXXX reiterates the argument made in his first declaration (D16)...”	Identifiable as a declaration of Dr Radeke <i>via</i> file name displayed in the CMS. No relevant interests adversely affected by disclosure.

Page 2: "Dr XXXX has not addressed them in D18. Rather, D18 provides an explanation as to how Dr XXXX has interpreted D3"	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 2: "Dr XXXX does not deny that laminin-511 E8 is a superior substrate for this purpose"	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 3: "Instead, Dr XXXX criticises Comparative Example 3"	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 3: "D1 does not undermine Dr XXXX opinion"	Identifiable from context as Dr Sawada. No relevant interests adversely affected by disclosure.
Page 3: "Dr XXXX provides in his declaration (D17) a brief history of the invention claimed in the patent. The accuracy of Dr XXXX history is not challenged by Dr XXXX. Dr XXXX however, challenges the opinion given by Dr XXXX"	Author of D17 identified in CMS as Dr Sawada. From context it is clear that this passage relates to a disagreement between Dr Sawada and Dr Radeke. No relevant interests adversely affected by disclosure.
Page 3: "The basis of this challenge is that, according to Dr XXXX, D1..."	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 3: "Dr XXXX has not explained why he considers this observation..."	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 3: "Accordingly, Dr XXXX opinion cannot be discounted..."	Identifiable from context as Dr Sawada. No relevant interests adversely affected by disclosure.
Page 4: "Dr XXXX considers that D1..."	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.
Page 4: "Therefore, Dr XXXX conclusion that collagen..."	Identifiable from context as Dr Radeke. No relevant interests adversely affected by disclosure.