

ORDER (R. 197.3 RoP)
of the Court of First Instance of the Unified Patent Court
Local Division Brussels
Issued on 12 November 2025
Concerning EP 3 401 335 B1

Headnotes

1. A double assessment determines the scope of review proceedings in application of R. 197.3 RoP:
 - a) First, the Court should assess whether it has “*rightly*” (cf. LD Munich 28 May 2025, UPC_CFI_63/2025 and LD Düsseldorf 16 April 2025, UPC_CFI_539/2024) decided to issue an “*ex parte*” order to preserve evidence/for inspection (R.194.1(d) RoP juncto R. 194.2 RoP). In this assessment, the Court should take into consideration the facts and evidence (i) brought forward in the application for an order to preserve evidence/inspection, and (ii) which, if not disclosed to the Court, are either public or not public, but are considered to be reasonably known to the applicant. Before assessing all the facts, the Court should consider whether failing to bring these facts and evidence to its attention could be considered a breach of the applicant's duty to disclose any material fact that might have influenced the Court's decision (R. 192.3 (second sentence) RoP).
 - b) The Court should then assess whether the order to preserve evidence/for inspection is to be confirmed, modified or revoked. In making this assessment, facts and evidence to be taken into consideration are not limited to those that are either public or not public but reasonably known to the applicant, but should include all facts and evidence (Rule 194.3(b) RoP) presented to the Court by the parties. This assessment relates to the substantive assessment of the conditions for granting (Art. 60(1) and (3) of the UPCA), the scope and conditions set out in the order issued to preserve evidence or for inspection.
2. For both assessments (under 1.), the Court should place itself on the date of issuance of the (to be reviewed) order to preserve evidence/for inspection. It is at that date that the Court made its:
 - a) “*ex parte*” assessment based on the application for an order to preserve evidence/for inspection and any additional facts and evidence brought forward by the applicant for such order (and if applicable after having heard the applicant) (first assessment), or
 - b) could have made its assessment if the proceedings had been dealt with “*inter partes*” from the outset (second assessment).
3. As such, the scope of the review assessment does not pertain to the execution of the order to preserve evidence/for inspection, the outcome of such execution, or any information (evidence) gathered during execution. Any requests made by the applicant relating to the

execution of the order to preserve evidence/for inspection, the alleged fact that no evidence proving the infringement was found, or the alleged fact that more was seized than was authorised, are to be dismissed in review proceedings. Such requests must be assessed in separate proceedings and/or as part of the defence after the introduction of PI proceedings and/or proceedings on the merits, which may affect the admissibility and value of such evidence.

4. The general purpose of an order to preserve evidence/for inspection is to
 - a) Enable an applicant who has "*presented reasonably available evidence to support the claim*" to access additional information (evidence) that is not publicly available (and, if necessary, protected by a confidentiality order) in order to prove the infringement and/or the acts constituting infringement, and
 - b) If granted, and based on the preserved/gathered information (evidence), enable the applicant to evaluate the reliable prospects of success in initiating subsequent infringement proceedings. More specifically, the applicant is brought in the position to evaluate whether:
 - (i) to initiate provisional measure proceedings in accordance with the "*no unreasonable delay*" condition set out in Rule 211.4 RoP;
 - (ii) to initiate a procedure on the merits, in accordance with R. 13.1(l)(i) RoP, which refers to an indication of the facts relied upon, particularly the "*alleged or threatened infringement*",
 - (iii) not to initiate proceedings where there would be insufficient evidence of infringement or threatened infringement.
5. Given the general purpose of an order to preserve evidence or for inspection, the term "*about to be infringed*" in Art. 60(1) UPCA and Art. 60(3) UPCA does not have the same meaning as "*urgency*" (in the sense of R. 194(2) RoP) nor "*unreasonable delay*" (in the sense of R. 211.4 RoP (cf. CoA order 15 July 2025, UPC_CoA_327/2025)), nor "*threatened infringement*" (in the sense of R. 13.1(l)(i) RoP). The applicable threshold is that of "*about to be infringed*", which must be proven by the applicant with a certain degree of plausibility. Therefore, there must be a risk of infringement and it must be apparent that it will occur in the future. The specific facts of the case will determine the duration of this period.
6. The in an order to preserve evidence/for inspection appointed experts' task is to filter (evaluate) the gathered/preserved information (evidence) and use only such information (evidence) which he/she deems necessary as possible evidence to prove or disprove the actual infringement of the patent-in-suit.

Keywords

- Order to preserve evidence (R. 192 RoP)
- Order for inspection (R. 199 RoP)
- Review proceedings of an order to preserve evidence (R. 197.3 RoP)
- Review proceedings of an order to preserve evidence (R. 197.3 RoP)
- About to be infringed (Art. 60(1) UPCA and Art. 60(3) UPCA)
- Task of an expert appointed in an order to preserve evidence/for inspection.

APPLICANTS (REVIEW PROCEEDINGS):

ORGANON HEIST B.V.
NV ORGANON

Represented by: **Judith Krens**, Pinsent Masons Netherlands LLP (The Netherlands), Gelrestraat 42-44 - 1079MZ - Amsterdam (The Netherlands)
Co-Represented by: **Vural Ergisi** (Pinsent Masons Netherlands LLP)
Alasdhair McDonald (Pinsent Masons Netherlands LLP)
Emily Flood (Pinsent Masons Netherlands LLP)

DEFENDANTS/RESPONDENTS (REVIEW PROCEEDINGS):

GENENTECH INC.
F. HOFFMANN – LA ROCHE AG

Represented by: **Rutger Kleemans**, Freshfields LLP, Strawinskylaan 10 – 1077 XZ Amsterdam (The Netherlands),
Co-Represented by: **Allard van Duijn** (Freshfields LLP)
Nerissa Teeuwen (Freshfields LLP)

PATENT AT ISSUE

<i>Patent no.</i>	<i>Proprietor</i>
EP 3 401 335 B1	GENENTECH INC

LANGUAGE OF THE PROCEEDINGS: ENGLISH

SUBJECT MATTER OF THE PROCEEDINGS

Application for review of the following identical orders:

- ORD_23125/2025 (ACT_21478/2025 – UPC_CFI_407/2025) (Order to Preserve Evidence)
- ORD_23121/2025 (ACT_21486/2025 – UPC_CFI_408/2025) (Order for Inspection)

PANEL/LOCAL DIVISION

The Panel (LD Brussel) consists of the following judges:

Presiding Judge – Judge-Rapporteur / Legally Qualified Judge:	Samuel Granata
Legally Qualified Judge:	Petri Rinkinen
Legally Qualified Judge:	Rute Lopes

DECIDING JUDGES:

This order is issued by the panel of the Local Division Brussels.

ABBREVIATIONS

To improve the readability of this order, the following abbreviations and references will be used (in alphabetical order):

Applications	The Applications made in workflows ACT_21478/2025 (UPC_CFI_407/2025)(order to preserve evidence) and ACT_21486/2025 (UPC_CFI_408/2025) (order for inspection)
Applications for Review	The Applications in workflows App_33781/2025 (UPC_CFI_407/2025) (order to preserve evidence) and App_33759/2025 (UPC_CFI_408/2025) (order for inspection)
CHMP	Committee for Medicinal Products for Human Use (EMA committee responsible for human medicines)
CN 057	Chinese Patent CN111375057 A filed by Shanghai Henlius Biotech, Inc
CMS (old)	Court Management System used by the Unified Patent Court up to 26 September 2025
CMS (new)	Court Management System used by the Unified Patent Court starting from 26 September 2025
Court	Unified Patent Court
EMA	European Medicines Agency
Enforcement Directive	Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights
EP 335 (or Patent)	EP 3 401 335 B1
EPO	European Patent Office
GENENTECH	Genentech, Inc.
GENENTECH & ROCHE	Genentech, Inc. and F. Hoffmann-La Roche AG (Defendants in the Review Proceedings)
HENLIUS	Shanghai Henlius Biotech, Inc
HLX11	Refers to the bio-similar of Perjeta® that ORGANON has informed that they are going to launch and is the name used presently by ORGANON.
LD	Local Division of the Unified Patent Court
MAA	Market authorization application
Orders	The orders Ord_23121/2025 and Ord_23125/2025 issued on 30 May 2025
ORGANON	Organon Heist BV and NV Organon NV (Applicants in the Review Proceedings)
ORGANON BE	Organon Heist BV
ORGANON NL	Organon NV
ORGANON US	Organon & Co. (incorporated under the laws of the State of Delaware (US))
Perjeta®	Refers to a cancer medicine of ROCHE for treating adults with “HER2-positive” breast cancer. According to GENENTECH & ROCHE the claim 1 of EP 3 401 335 B1 covers Perjeta®
Regulation 726/2004	Regulation (EC) No 726/2004 of the European Parliament and the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Review Proceedings	The proceedings subject of workflows ACT_21478/2025 (UPC_CFI_407/2025)(order to preserve evidence) and ACT_21486/2025 (UPC_CFI_408/2025) (order for inspection)
ROCHE	F. Hoffmann-La Roche AG
RoP	Rules of Procedure of the UPC
§(followed by a number)	Paragraph referred to in this order
UPCA	Agreement on a Unified Patent Court

I. PROCEDURAL BACKGROUND

- GENENTECH & ROCHE filed their Applications on 6 May 2025 against the following defendants:
 - Defendant 1: ORGANON US
 - Defendant 2: ORGANON BE
 - Defendant 3: ORGANON NL
 - Defendant 4: HENLIUS
- On 15 May 2025, the Judge-Rapporteur issued procedural orders summoning GENENTECH & ROCHE to an oral hearing by video conference on 23 May 2025 (see §4).
- In a letter dated 18 May 2025, GENENTECH & ROCHE informed the Court that ORGANON US had initiated invalidity proceedings on 7 May 2025 against GENENTECH regarding BE 335 in

the Netherlands (before the District Court in The Hague). GENENTECH & ROCHE introduced the writ of summons as an additional exhibit (FS28). This was followed by a letter dated 22 May 2025, in which GENENTECH & ROCHE introduced an additional request to allow them to use the outcome of the Orders in the aforementioned parallel proceedings in the Netherlands (see §26).

4. During the oral hearing of 23 May 2025, the Judge-Rapporteur discussed (i.a.) the following issues:

- Additional information related to R. 194.2(c) RoP.
- Actual plan of execution of the order to preserve evidence/for inspection on two locations.

Further, the Judge-Rapporteur requested an additional exhibit (a copy of CN 057). Applicants uploaded this additional exhibit in the CMS.

5. On 30 May 2025, the Court issued the Orders.
6. The Orders were executed on 27 June 2025 in Heist-op-den-Berg (Belgium) (for ORGANON BE) and Oss (The Netherlands) (for ORGANON NL).
7. On 25 July 2025, ORGANON introduced their Applications for Review.
8. On 28 July 2025, the Court issued provisional procedural orders, including one that scheduled the round of written submissions. Although the Court proposed a semi-virtual hearing on 4 September 2025, to be held in the physical presence of the president of the LD Brussels and the representatives of the parties, indicating that a physical hearing in the presence of the full panel could only be organised for October or November 2025, the parties requested a physical hearing. The subsequent procedural order set the oral hearing for 21 October 2025.
9. Following the execution of the Orders and/or Applications for Review, a number of applications and proceedings were introduced. The pending workflows on 25 August 2025 are summarised below:

UPC_CFI	Application/Action Cms (Old)	Subject Matter
UPC_CFI_407/2025	Act_21478/2025	Order to preserve evidence introduced by GENENTECH & ROCHE on 6 May 2025 Order (Ord_23125/2025) issued on 30 May 2024 and executed 27 June 2025
	App_33545/2025	Application for Penalty Payment and Remedy Request introduced by GENENTECH & ROCHE on 23 July 2025
	App_(no number)	Application for confidentiality introduced by GENENTECH & ROCHE on 24 July 2025
	App_33781/2025	Application for review (order to preserve evidence) introduced by ORGANON on 28 July 2025
	App_33913/2025	Application for protection of Confidential Information introduced by ORGANON on 29 July 2025
	App_34515/2025	R. 262A RoP confidentiality introduced by ORGANON on 8 August 2025

	App_34496/2025	Generic Application ((linked with App_34515) (Confidentiality Request)) introduced by ORGANON on 8 August 2025
	App_35260/2025	Confidentiality request linked to App_33781 introduced by ORGANON on 21 August 2025
UPC_CFI_408/2025	Act_21486/2025	Order of Inspection introduced by GENENTECH & ROCHE on 6 May 2025 Order (Ord_23121/2025) issued on 30 May 2024 and executed on 27 June 2025
	App_33550/2025	Application for Penalty Payment and Remedy Request introduced by GENENTECH & ROCHE on 23 July 2025
	App_(no number)	Application for confidentiality introduced by GENENTECH & ROCHE on 24 July 2025
	App_33676/2025	Request for Review (order for inspection) introduced by ORGANON on 28 July 2025
	App_33918/2025	Application for protection of Confidential Information introduced by ORGANON on 29 July 2025
	App_34505/2025	R. 262A RoP confidentiality introduced by ORGANON on 8 August 2025
	App_34498/2025	Generic Application (linked with App_34505 (Confidentiality Request)) introduced by ORGANON on 8 August 2025
	App_35271/2025	Confidentiality request linked to App_33676 introduced by ORGANON on 21 August 2025

10. By procedural orders (Ord_35442/2025 and Ord_35443/2025), dated 25 August 2025, the Court decided to stay the proceedings in the above-mentioned applications (workflows), except for the Review Proceedings, until a final decision has been issued in the Review Proceedings.
11. On 17 September 2025, ORGANON introduced additional R. 9 RoP applications (App_36857/2025 and App_36859/2025) with the following main request:

A. Order that counsel for Roche is to destroy all physical copies and (permanently) delete all digital copies of the Seized Documents and Bailiff Reports in their possession and to maintain strict confidentiality of such documents up to the moment of such deletion and destruction

Based on the parties' comments, the Court ordered, in its preliminary procedural orders dated 30 September 2025, that the proceedings in App_36857/2025 and App_36859/2025 be stayed, in line with the orders in Ord_35442/2025 and Ord_35443/2024, dated 25 August 2025, and this, specifically, until a final decision has been issued in the Review Proceedings.
12. On 20 October 2025, the Court received a R. 9 RoP application requesting the replacement of an exhibit that had been filed incorrectly (see §37-38).
13. On 21 October 2025, the Review procedure was pleaded before the LD Brussels. During the pleadings, and based on a Dutch tradition, the representatives made use of pleading notes. A copy was provided to the Court in accordance with its preliminary procedural order of 2 September 2025. The parties were informed that these notes would not be considered part of the procedural documents submitted in accordance with the scheduled round of submissions.

II. SUMMARY OF THE FACTS

(The court refers to the summary of facts set out in the Orders and reiterates these facts below for the sake of readability, summarising, supplementing and/or paraphrasing them where necessary.)

II.A. Parties

II.A.1. The Applicants of the Order to Preserve Evidence/for Inspection

14. GENENTECH is *“a biotechnology company dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life- threatening diseases. Genentech’s transformational discoveries include the first targeted antibody for cancer and the first medicine for primary progressive multiple sclerosis”*. GENENTECH became a member of the Roche Group in March of 2009. GENENTECH is the proprietor of the Patent.
15. ROCHE is *“a large pharmaceutical company located in Basel, Switzerland”* and *“one of the world’s largest biotech companies, as well as a leading provider of in-vitro diagnostics and a global supplier of transformative innovative solutions across major disease areas”*.

II.A.2. The Defendants of the Order to Preserve Evidence/for Inspection

16. GENENTECH & ROCHE stated in their Application(s) that:
 - HENLIUS is a Chinese biopharmaceutical company with a focus on manufacturing biosimilars, founded in 2010.
 - ORGANON US is a US pharmaceutical company. Its main sites are located in Heist-Op-Den-Berg (Belgium) and Oss (the Netherlands). ORGANON became an independent company in 2021 when it was divested from Merck Sharpe & Dohme.
 - ORGANON BE is a subsidiary of ORGANON US, located in Heist-Op-Den-Berg, Belgium. In Heist-Op-Den-Berg, Belgium, it operates a manufacturing facility where it produces medicines for the Benelux, Europe and the rest of the world.
 - ORGANON NL is a subsidiary of ORGANON US located in Oss, Netherlands. In Oss, ORGANON NL operates a manufacturing facility where it produces medicines for the Benelux, Europe, and the rest of the world.

II.B. The Patent

II.B.1. Grant of EP 335

17. EP 335 was filed with the EPO on 28 January 2009 and expires in January 2029. It was the subject of opposition proceedings in which it was decided that the patent *“shall be maintained in amended form”* (by decision of 24 March 2025, notified to GENENTECH on 7 April 2025).

II.B.2. *The (relevant) claims of EP335*

18. EP 335 is titled *“Composition comprising antibody that binds to domain II of HER2 and acidic variations thereof”* and is a divisional application of EP 09709065.8 (EP 2 2238 172).
19. After the EPO's Opposition Division proceedings, the following independent claim 1 is relevant:

“1. A pharmaceutical formulation comprising a composition comprising a main species HER2 antibody that comprises light chain and heavy chain amino acid sequences in SEQ ID NOs. 15 and 16 respectively and binds to domain II of HER2, and acidic variants of that main species antibody, in a pharmaceutically acceptable carrier, wherein the main species HER2 antibody is the antibody amino acid sequence structure in the composition which is the quantitatively predominant antibody molecule in the composition, wherein the acidic variants include a disulfide reduced variant.”
20. Claim 1 is broken down into the following features by GENENTECH & ROCHE:

(i) a pharmaceutical formulation that comprises
(ii) a pharmaceutically acceptable carrier,
(iii) a main species HER2 antibody, that binds to domain II of HER2, with light chain and heavy chain amino acid sequences according to SEQ ID NOs 15 and 16, respectively,
(iv) which antibody is the quantitatively predominant antibody molecule in the composition,
(v) acidic variants of said main species antibody,
(vi) wherein the acidic variants include a disulfide reduced variant.
21. GENENTECH & ROCHE state that the product commercialized by ROCHE in Europe, Perjeta[®], is covered by EP 335.

II.C. *The alleged (imminent) (threat of) infringement of EP 335*

22. GENENTECH & ROCHE referred in their Applications to the upcoming launch by ORGANON of a *“pertuzumab biosimilar”* (HLX11, which they hold to be infringing claim 1 of EP 335). Regarding the alleged (threat of) infringement, GENENTECH & ROCHE referred (i.a.) to CN 057 *“(showing) that HENLIUS’s HLX11 protein is indeed an HER2 antibody with light chain and heavy chain amino acid sequences according to SEQ ID NOs 15 and 16”*.
23. The (imminent) (threat of) infringement of EP 335 in the relevant market was evidenced by GENENTECH & ROCHE in its Applications referring to the upcoming launch in the territory of the UPC, based on the following facts:
 - Press Release dated 13 June 2022 in which HENLIUS announces that it entered into a license and supply agreement with ORGANON US for the exclusive commercialization of HENLIUS HLX11:

“Shanghai, China, June 13, 2022 - Shanghai Henlius Biotech, Inc. (2696.HK) today announced it has entered into a license and supply agreement with Organon LLC (“Organon”) for the exclusive commercialization of Henlius’ independently developed HLX11 (a pertuzumab biosimilar candidate) and HLX14 (a denosumab biosimilar candidate) in ex-China countries, covering mature markets such as the United States, the European Union and Japan, as well as a number of emerging markets.

Under the agreement terms, Henlius may receive up to a total of \$541 million, including a \$73 million upfront payment. Organon also has an option to negotiate an exclusive license for global commercialization rights for HLX13, an ipilimumab biosimilar candidate developed by Henlius."

- Earnings call on 31 October 2023 regarding Q3 2024 in which the CEO of ORGANON US stated the following:

"Let's move now to our Biosimilars franchise, which grew 17% at constant currency in the third quarter. We expect Biosimilars to deliver low-teens growth for the full year 2024, with Renflexis and Ontruzant at the mature point in their unusually long and impressive growth period. Biosimilars growth next year will be driven by continued uptake of Hadlima in the US, which has performed well and continues to grow sequentially."

The strategy in Biosimilars is to launch a new asset every couple of years. In late 2025 and beyond, additional growth contributors to the Biosimilars franchise will be the denosumab asset then later the pertuzumab asset. Both will be launched in collaboration with Shanghai Henlius, pending FDA review and approval."

- Joint Press Release on 28 March 2025 by HENLIUS and ORGANON US confirming that the EMA has validated the MAA for HLX11.
- Letter by ORGANON US lawyer dated 28 April 2025 to GENENTECH & ROCHE stating that ORGANON US *"(...) intends to launch the Organon Product across Europe in due course following approval of the marketing authorization application, and wishes to obtain legal and commercial certainty in respect of certain patent families which are relevant to pertuzumab and are held by the Roche group of entities."*
- Earnings call on 1 May 2025: in which the CEO of ORGANON US: *"And finally, we anticipate launching the portfolio of Henlius products beginning in late 2025 with the denosumab biosimilar in the US, followed by pertuzumab in Europe."*
- Additionally, GENENTECH & ROCHE refer in their letter to the Court dated 18 May 2025 to the introduction of the national proceedings in the Netherlands (see §3) labelled by ORGANON US as a *"preliminary defence against infringement of (EP 335)"*.

24. Although GENENTECH & ROCHE appeared to state that they had sufficient evidence of infringement of features (i) to (v) of claim 1 of EP 335, they argued in their Applications that they lacked evidence regarding the alleged infringement of feature (vi), as no public information was available on this feature. GENENTECH & ROCHE argued that it was *"highly likely"* that the acidic variants contained in HLX11 also included a disulfide-reduced variant. However, they considered that definitive proof of this could only be obtained by granting the requests as stated in their Applications.

III. THE APPLICATIONS AND THE APPLICATIONS FOR REVIEW

III.A. The Applications

25. In their Applications, GENENTECH & ROCHE requested against the four defendants (see §1) the following, by immediate enforceable order:

As primary requests

- (i) *to authorize the Applicants to proceed through the territorially competent bailiff to make a description of the product manufactured or to be manufactured at any of Organon's premises in Belgium and the Netherlands, by allowing:*

- (a) *taking of photographs and videos (including audio) of the exterior and interior of any appliance and surrounding area that may be used to manufacture the product of claim 1;*
- (b) *taking of samples from any compartment inside such appliance under(a);*
- (c) *taking of 10 (ten) samples of HLX11 biosimilar formulation; and*
- (d) *taking of any other action necessary to describe the manufacturing and composition of the product.*
- (ii) *to authorize the Applicants to proceed through the territorially competent bailiff to acquire physical and/or digital copies of:*
 - (a) *batch records relating to the bio-reactor and/or the product in claim 1 of the Patent, both executed and non-executed form;*
 - (b) *manuals relating to the bio-reactor and/or the product in claim 1 of the Patent;*
 - (c) *any and all other documents, in any format, relating to the bio-reactor and/or the product in claim 1 of the Patent;*
 - (d) *more specifically and in any event, EMA or FDA regulatory documentation for HLX11, more specifically documentation that relates to the characterization of antibody variants in HLX11, more specifically a completed EMA "COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE QUALITY OVERALL SUMMARY OF MODULE 2 AND MODULE 3:QUALITY" https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m-4-q-common-technical-document-registration-pharmaceuticals-human-use-quality-step-5_en.pdf , more specifically a filled in section 2.3, 3.2.S thereof, even more specifically a filled-in section 3.2.S.3.1 and 3.2.P.5 thereof;*
 - (e) *internal Organon/Henlius documentation that relates to HLX11 antibody variants; and*
 - (f) *batch records for the drug substance and/or drug product.*
- (iii) *to appoint the following independent technical experts, who may accompany the bailiff during the execution of measures (i) and (ii):*
 - *Dr. Frank Hanakam of Granzer Regulatory Consulting & Services GmbH in Munich, Germany; and*
 - *Dr. Julia Buschmann of Granzer Regulatory Consulting & Services GmbH in Munich, Germany, which technical experts shall be authorized to engage any necessary auxiliary persons to assist them during and after the execution of the measures (i) and (ii).*
- (iv) *to authorize the Applicants to obtain the samples under (i)(b)-(c) from the bailiff;*
- (v) *to order the Defendants to fully cooperate with the bailiff and independent experts by providing full and unrestricted access to*
 - (a) *any building, room, cabinet or safe at the premises of Organon in Belgium and the Netherlands;*
 - (b) *any device, digital file or document stored at or accessible from the premises of Organon in Belgium and the Netherlands;*
and in particular, to the extent that any device or digital file may be encrypted, password-protected or otherwise be inaccessible, by providing all cooperation to the bailiff and independent experts to gain entry and to decrypt and/or make any such device or digital file accessible in a format which is sufficient for the purposes of aiming to prove infringement of claim 1.
- (vi) *to determine that the Defendants forfeit an immediately payable penalty of € 200,000.00 for each hour that they fail to cooperate with the order under (v).*
- (vii) *to order that the collected information is directly accessible, until further order by the judge, to the lawyers of the Applicants (as defined in the heading of this application) and the technical experts listed above, with the prohibition to disclose the acquired information to third parties.*

As a subsidiary request (and this "should the Court consider that the Defendants' interests in maintaining confidentiality over (parts of) the information seized outweigh immediate disclosure to Applicants")

- (i) to appoint an independent expert to inspect and draft a comprehensive expert report detailing the data and information only pertaining to the infringement of EP335.
- (ii) to order the appointed expert to submit their written report and any collected evidence immediately, and no later than the following day after inspection.

(Note by the Court: This subsidiary request was not formulated in the substantive parts of the applications but is argued in the motivational part of the applications.)

26. In their letter to the Court dated 22 May 2025, GENENTECH & ROCHE additionally requested:
“that the Court’s order to preserve evidence expressly provide that the outcome of the measures to preserve evidence may be used not only in the pending proceedings on the merits before the Unified Patent Court, but also in the parallel nullity action commenced against Genentech Inc. on 7 May 2025 before the Dutch district court concerning European patent EP 3 401 335 (EP 335).”

III.B. The Orders

27. The Applications introduced by GENENTECH & ROCHE where they pertained to Defendant 1 (ORGANON US) and Defendant 4 (HENLIUS) were dismissed for the reasons mentioned in the Orders. No appeal has been introduced regarding this dismissal.

28. Subsequently, the Court held as follows in its Orders:

2. Grant of Requests

- (i) authorizes (GENENTECH & ROCHE) to proceed through the territorially competent bailiff to make a description of the product manufactured or to be manufactured at (ORGANON BE) (...) and (ORGANON NL) (..), by allowing:
 - (a) taking of photographs and videos (including audio) of the exterior and interior of any appliance that may be used to manufacture the product of claim 1;
 - (b) taking of samples from any compartment inside such appliance under(a);
 - (c) taking of 10 (ten) samples of HLX11 biosimilar formulation; and
- (ii) authorizes (GENENTECH & ROCHE) to proceed through the territorially competent bailiff to acquire physical and/or digital copies of:
 - (a) batch records relating to the bio-reactor and/or the product in claim 1 of the Patent, both executed and non-executed form;
 - (b) manuals which relating to the bio-reactor and/or the product in claim 1 of the Patent;
 - (c) any and all other documents, in any format, relating to the bio-reactor and/or the product in claim 1 of the Patent;
 - (d) more specifically and in any event, EMA regulatory documentation for HLX11, more specifically documentation that relates to the characterization of antibody variants in HLX11, more specifically a completed EMA “COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE QUALITY OVERALL SUMMARY OF MODULE 2 AND MODULE 3:QUALITY” https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m-4-q-common-technical-document-registration-pharmaceuticals-human-use-quality-step-5_en.pdf, more specifically a filled in section 2.3, 3.2.S thereof, even more specifically a filled-in section 3.2.S.3.1 and 3.2.P.5 thereof;
 - (e) internal Organon/Henlius documentation that relates to HLX11 antibody variants; and
 - (f) batch records for the drug substance and/or drug product.

(iii) appoints the following independent technical experts, who may accompany the bailiff(s) during the execution of measures (i) and (ii):

- Dr. Frank Hanakam of Granzer Regulatory Consulting & Services GmbH in Munich, Germany; and
- Dr. Julia Buschmann of Granzer Regulatory Consulting & Services GmbH in Munich, Germany,

which technical experts shall be authorized to engage any necessary auxiliary persons to assist them during and after the execution of the measures (i) and (ii).

The experts should send their written report together with its annexes to the Sub-Registry of the LD Brussels within 14 days upon the execution of this order. On the same day the experts should send a copy of this report and its annexes to the representatives of the parties (if known regarding (ORGANON BE) and (ORGANON NL) and this taking into consideration the confidentiality measures ordered under 4 of this order.

(iv) authorizes (GENENTECH & ROCHE) to obtain the samples under (i)(b)-(c) from the bailiff;

(v) orders (ORGANON BE) and (ORGANON NL) to fully cooperate with the bailiff and independent experts by providing full and unrestricted access to

- (a) any building, room, cabinet or safe at their premises in Belgium and the Netherlands which relate to the object of the Applications (i.e. to prove infringement of claim 1);
- (b) any device, digital file or document stored at or accessible from their premises in Belgium and the Netherlands which relate to the object of the Applications (i.e. to prove infringement of claim 1);

and in particular, to the extent that any device or digital file may be encrypted, password-protected or otherwise be inaccessible, by providing all cooperation to the bailiff and independent experts to gain entry and to decrypt and/or make any such device or digital file accessible in a format which is sufficient for the purposes of aiming to prove infringement of claim 1.

(vi) Determines that (ORGANON BE) and (ORGANON NL) forfeit an immediately payable penalty of € 200.000,00 for each hour that they fail to cooperate with the order under (v) and this to a cumulative maximum of € 5.000.000 whereby the start of any hour will be considered as an hour for the calculation of the penalties.

3. Notice

- Orders that this order, together with a copy of the application(s) and its annexes, shall be served by the Bailiff(s) on (ORGANON BE) and (ORGANON NL) at their premises together with the execution of this order, in accordance with the applicable national law on the service of judicial documents.

4. Confidentiality

- Orders that access to all information gathered by the appointed experts during the execution of the order(s), as well as to the expert report itself, shall be limited to the representatives of the parties. Subsequently, a "confidentiality circle" will/could be established in order to identify the relevant information for the purposes of this order, as well as the information that should be considered "confidential" (in accordance with UPCA, RoP and Trade Secret Directive) and should be kept confidential in the sense that access is limited to identified persons.

5. Time-Limits procedure on the merits

- Orders proceedings on the merits to be initiated taking into the consideration the term stipulated under R. 198.1 RoP and this from the date of execution of the order to preserve evidence (ACT_21478/2025) (UPC_CFI_407/2025) and/or the order for inspection (ACT_21486/2025) (UPC_CFI_408/2025).

6. Security

- Orders (GENENTECH & ROCHE), before the execution of this order, to make a make a recorded payment of security by depositing € 25.000,00 on the dedicated UPC account.
 - Requests (GENENTECH & ROCHE) to provide proof to the UPC LD Brussels of such deposit prior to enforcement of the Order(s).
7. Use of the outcome of the executed orders
Allows the use of the outcome of the measures in other proceedings than the proceedings on the merits of the case (limited to the Dutch proceedings initiated before the District Court The Hague on 7 May 2025).
8. Additional Conditions
- Orders (GENENTECH & ROCHE) to execute the order(s) within one month of its issuance.
 - States that the independent technical experts are not considered as experts of the Court and they should limit their contact with (GENENTECH & ROCHE) to the extent necessary to carry out their task. These experts should receive the same information submitted to the Court (i.e., the application(s) and its exhibits) along with this Order and this to ensure their independence.
 - Limits the tasks of the appointed experts to "preserve evidence" and "inspect premises".
 - Orders the appointed experts to perform their tasks without any contact with the parties (except to the extent necessary to perform their duties in accordance with the execution of this Order).
 - Prohibits (ORGANON BE) and (ORGANON NL), should Applicants organize the execution of the respective orders at the premises of (ORGANON BE) and (ORGANON NL) simultaneously, to directly or indirectly contact each other during the execution of the order(s) and this under a pecuniary restraint of € 250.000 for every contact made (by any means).
 - Orders the execution of the granted order during normal business hours, taking into account national holidays in Belgium and the Netherlands.
 - Permits (ORGANON BE) and (ORGANON NL) to contact their legal representative and/or technical representative who may participate in the actual execution of the order, but the actual execution of these orders may not be delayed in any way.
 - Invites the appointed experts, should any problems/issues arise during the execution of the order(s), to contact the LD Brussels by e-mail, whereupon a R. 9 RoP may be issued, if necessary. Any such communication should be sent by the expert(s) also to the parties.

III.C. The Applications for Review

III.C.1. The requests formulated by ORGANON in their Applications for Review

29. ORGANON formulate their requests by way of a conclusion in their Applications for Review as follows:
1. For the reasons set out above and in the Exhibits to this review, (ORGANON) requests that the Order is set aside in its entirety, any and all documents are returned to Organon and copies destroyed, and that the documents and their details shall not be passed to (GENENTECH & ROCHE) or used or referred to in any litigation.
 2. Alternatively, (ORGANON) requests that the Order is modified and that the bailiff is ordered to immediately return and/or destroy all copies of any documents which the Court deems to have been obtained illegitimately or which are considered to be irrelevant in establishing the (GENENTECH & ROCHE)'s allegation of there being an imminent threat of (ORGANON) infringing the Patent.
 3. (ORGANON) also requests that (ORGANON)'s costs associated with responding to the (GENENTECH & ROCHE)'s application are to be borne by (GENENTECH & ROCHE) to the amount of the security set in the Court's orders 23125/2025 and 23121/2025, or to any amount deemed reasonable and appropriate by the Court, and shall be paid to (ORGANON) within 1 month after setting aside or modifying the Order, unless the (GENENTECH & ROCHE)

initiate a main action, in which case these costs are to be further addressed together with the costs in the main action.

30. At the oral hearing of 21 October 2025, ORGANON was requested by the panel to further elaborate on their second (in the *alternative*) request (2), where they mention the Orders to be “*modified*”. ORGANON informed the Court that the following parts of the grant should be deleted:

2. Grant of Requests

(i) authorizes (...)

~~(a) taking of photographs and videos (including audio) of the exterior and interior of any appliance that may be used to manufacture the product of claim 1;~~

~~(b) taking of samples from any compartment inside such appliance under(a);~~

Further, in the subsequent grants, ORGANON informed the Court that any and all reference to the “*bioreactor*” should be deleted.

The Court notes that these requests can be explicitly deducted from the Applications for Review and specifically §22 where ORGANON argue on the non-justification of the grant allowing measures where they pertained to the “*bio-reactor*” or “*appliance*”. As such, the rights of defence have been sufficiently guaranteed. ROCHE & GENENTECH indeed developed a defence related to this line of argumentation (see §31 of their “*written comments in response to the application for review of orders*”).

III.C.2. ORGANON’s arguments

31. The “(International) Jurisdiction and (territorial) Competence” and “Validity of EP 335” are not in dispute in these Review Proceedings.
32. In their Applications for Review and at the oral hearing, ORGANON argue (in essence) as follows:
- The Orders should never have been issued without hearing the defendant. There existed/exists no *imminent* threat to infringe the patent or need for an *ex parte* order. More specifically, ORGANON argues that there is no MA for HLX11 and state that the time-line which GENENTECH & ROCHE referred to their application is “*unrealistic and inconsistent*”. Further, ORGANON argues that the Applications state two serious allegations which ORGANON rejects. These allegations made by GENENTECH & ROCHE relate to the communication by ORGANON’s CEO regarding bringing to the market in Europe of a *Perjeta*® biosimilar and the alleged destruction or removal of documents for the purpose of regulatory authorization and compliance.

- As a second line of arguments, ORGANON argues that a significant portion of the Order should never have been granted in light of the scope of EP 355, resulting in an unjustified scope of the Orders.
 - As a third line of arguments, ORGANON argues that the Orders should never have been granted in *inter partes* procedure.
 - As a fourth line of arguments, ORGANON argues that none of the evidence obtained by execution of the Orders is relevant to the question of infringement, and one piece of evidence was obtained improperly.
 - Finally, ORGANON argues “*Procedural Impropriety*” and this regarding the possibility to contact their legal representative during the execution of the Orders and the actual documents obtained in executing the Orders.
33. In their second written comments (upon receipt of the written comments by GENENTECH & ROCHE on the Applications for Review) ORGANON further argue that the basis of the Applications (essentially) was the alleged presence of acidic variants of Pertuzumab claimed in EP 355 and argues that the Orders are actually not limited hereto. These “*further written comments*” then elaborate on the time-line issues and the implications of the statements by their CEO. In a further line of arguments ORGANON argue that there is no evidence that HLX11 will be manufactured in Belgium or the Netherlands. Then the “*further written comments*” touch upon the issues (and alleged facts) related to the actual execution of the Orders. In a final line of arguments all the arguments seem to be bundled under a general allegation that the incorrect legal standard was applied by the Court when granting the Orders. Again, this general allegation relates in essence to the argument that there existed no “*imminent threat of infringement*” which ORGANON indicates as the main question in these proceedings.

III.C.3. GENENTECH & ROCHE’s arguments

34. GENENTECH & ROCHE indicate that (as a principle) the review considerations/assessment can only pertain to the justification of the Orders at the “*time it was made*”. Review proceedings may not touch upon the assessment of the actual evidence obtained in light of the execution of the Orders and the circumstances of the actual execution of the Orders.
35. Subsequently, GENENTECH & ROCHE argue that the Orders were granted in line with Art. 60 UPCA and the applicable rules articulated in the RoP: the patent is valid and there exists an actual threat of patent infringement. GENENTECH & ROCHE elaborate on the threat of patent infringement where they refer to the public releases, the investor presentations, the statement made by ORGANON’s CEO, ORGANON’s letter of notice of 28 April 2025 and ORGANON’s initiation of nullity proceedings against the Patent before the national competent court in The Netherlands.
36. When arguing the above GENENTECH & ROCHE indicate that they presented the Court with all available evidence at the time of the Applications (indicating the correct timelines) and

further arguing that the correct legal standard was applied by the Court when issuing the Orders.

IV. PROCEDURAL ISSUE (R. 9 RoP APPLICATION DATED 20 OCTOBER 2025)

37. The day before the oral hearing (20 October 2025) GENENTECH & ROCHE requested the Court by a R. 9 RoP application that a correction of exhibit FS04 (i.e. *FS04 (corrected): Press release from Organon of 28 March 2025, announcing the European Medicines Agency (EMA) validation of Henlius and Organon filing for Perjeta® (pertuzumab) biosimilar candidate HLX11*) would be allowed. GENENTECH & ROCHE argued as follows

"(...)

Upon review of our case file, we discovered that the previously submitted version of FS04 inadvertently contained a screenshot of an older and unrelated press release. Roche notes that all references and citations in its application of 6 May 2025 and subsequent submissions correctly refer to the 28 March 2025 press release and the EMA validation.

The corrected exhibit reflects information that is not in dispute between the parties and is known to both sides. Accordingly, its submission at this stage of the proceedings does not harm the defendants in their defence.

(...)".

38. The Court requested ORGANON to comment on this request at the hearing of 21 October 2025. ORGANON agreed to the correction/replacement but also requested that the incorrectly filed exhibit FS04 would be kept in the records. As GENENTECH & ROCHE did not oppose to this request and the two exhibits FS04 will be kept in the records, the request of correction/replacement is allowed.

V. GROUNDS FOR THE ORDER

V.A. Scope of the Review Proceedings (R. 197.3 RoP)

39. Review proceedings are explicitly linked to granted orders to preserve evidence/for inspection *"without hearing the defendant"* (R. 197.1 RoP).
40. A double assessment determines the scope of review proceedings in application of R. 197.3 RoP:
- a) First, the Court should assess whether it has *"rightly"* (cf. LD Munich 28 May 2025, UPC_CFI_63/2025 and LD Düsseldorf 16 April 2025, UPC_CFI_539/2024) decided to issue the *"ex parte"* Orders (R.194.1(d) RoP juncto R. 194.2 RoP). In this assessment (see Review Assessment First Step §54-67), the Court should take into consideration the facts and evidence (i) brought forward in the Applications, and (ii) which, if not disclosed to the Court, are either public or not public, but are considered to be reasonably known to GENENTECH & ROCHE. Before assessing all the facts, the Court should consider whether failing to bring these facts and evidence to its attention could

be considered a breach of the GENENTECH & ROCHE 's duty to disclose any material fact that might have influenced the Court's decision (R. 192.3 (second sentence) RoP).

- b) The Court should then assess whether the Orders are to be confirmed, modified or revoked. In making this assessment, facts and evidence to be taken into consideration are not limited to those that are either public or not public but reasonably known to GENENTECH & ROCHE, but should include all facts and evidence (Rule 194.3(b) RoP) presented to the Court by the parties. This assessment relates to the substantive assessment of the conditions for granting (Art. 60(1) and (3) of the UPCA) (see Review Assessment Second Step §68-72), the scope (see Review Assessment Second Step §73-78) and conditions set out in the Orders (see Review Assessment Second Step §79-82).
41. For both assessments (see §40), the Court should place itself on the date of issuance of the Orders. It is at that date that the Court made its:
- a) “*ex parte*” assessment (after an “*ex parte*” oral hearing) based on the Applications and any additional facts and evidence brought forward by GENENTECH & ROCHE based on the procedural order dated 15 May 2025 (see §4) and GENENTECH & ROCHE’s letters of 18 May 2025 and 22 May 2025 (see §3) (first assessment), or
 - b) could have made its assessment if the proceedings had been dealt with “*inter partes*” from the outset (second assessment).
42. As such, the scope of the review assessment does not pertain to the actual execution of the Orders and/or the outcome of such execution or any information (evidence) gathered during such execution. Any requests made by ORGANON related to the actual execution of the Orders, the alleged fact that no evidence was found proving the infringement, the alleged fact that more was seized than was granted are to be dismissed in these Review Proceedings. Such requests must be assessed in separate proceedings (see §83-86) and/or as part of the defence after the introduction of PI proceedings and/or proceedings on the merits, which may affect the admissibility and value of such evidence.

V.B. General guidelines of the assessment of an application to preserve evidence/for inspection and actual arguments related hereto made by ORGANON in their applications for review

(The court refers to the guidelines set out in the Orders, which - for the sake of readability - are partly summarised, supplemented, and/or paraphrased in view of the arguments developed by the parties in the Review Proceedings)

43. The general purpose of an order to preserve evidence/for inspection is to:
- a) Enable an applicant who has “*presented reasonably available evidence to support the claim*” to access additional information (evidence) that is not publicly available (and, if necessary, protected by a confidentiality order) in order to prove the infringement and the acts constituting infringement, and

- b) If granted, and based on the preserved/gathered information (evidence), enable the applicant to evaluate the reliable prospects of success in initiating subsequent infringement proceedings. More specifically, the applicant is brought in the position to evaluate whether (see also UPC CoA 23 July 2024, UPC_CoA_177/2024 (§10):
- (i) to initiate provisional measure proceedings in accordance with the "*no unreasonable delay*" condition set out in Rule 211.4 RoP;
 - (ii) to initiate a procedure on the merits, in accordance with R. 13.1(l)(i) RoP, which refers to an indication of the facts relied upon, particularly the "*alleged or threatened infringement*",
 - (iii) not to initiate proceedings in cases where there is insufficient evidence of infringement or threatened infringement.
44. In the Orders, the Court further detailed the four steps to be taken in its assessment of the application to preserve evidence/for inspection:
45. As a first step (see §40 – 47 of the Orders), the Court should consider whether to hear or not hear the defendants. If the Court would consider not to hear the defendants, Art. 60(5) UPCA stipulates as follows (with parallel wording in R. 197.1 RoP):
- Measures shall be ordered, if necessary, without the other party having been heard, in particular where any delay is likely to cause irreparable harm to the proprietor of the patent, or where there is a demonstrable risk of evidence being destroyed.*
- The options available to the Court are set out in detail in R. 194.1 RoP, which states that the Court shall have the discretion to:
- (a) inform the defendant of the application and invite them to submit an objection;
 - (b) summon the parties to an oral hearing;
 - (c) summon the applicant to an oral hearing in the absence of the defendant; or
 - (d) decide on the application without hearing the defendant.
46. When exercising its discretion, the Court shall consider the following elements of R. 194.2 RoP:
- (a) the urgency of the action;
 - (b) whether the reasons for not hearing the defendant are well-founded;
 - (c) the probability that evidence may be destroyed or otherwise become unavailable.
- Applying this rule requires the Court to perform a balancing assessment, weighing these elements separately, in the sense that none of them should be considered absolute (cf. the use of the word "*or*" in Art. 60(5) UPCA).
47. When the applicant requests measures to be ordered without hearing the defendant (i.e. requesting the option articulated in R. 194.1(d) RoP), the Court should not be misled by the applicant. This is articulated in R. 192.3 (second sentence) RoP as follows:
- "(...) The applicant shall be under a duty to disclose any material fact known to it which might influence the Court in deciding whether to make an order without hearing the defendant. (...)*

ORGANON argue that GENENTECH & ROCHE failed to fulfil their duty to disclose all material facts known to them, not only in the first-step assessment, but also in the subsequent second-step assessment.

48. In the Court's substantive assessment of whether or not to grant the requests (see §48 – 59 Orders) (second step), the requirements regarding an order to preserve evidence are not directly articulated in the RoP, but rather in Art. 60(1) and (3) UPCA (cf. Art. 7 Enforcement Directive):

“At the request of the applicant which has presented reasonably available evidence to support the claim that the patent has been infringed or is about to be infringed the Court may, even before the commencement of proceedings on the merits of the case, order prompt and effective provisional measures to preserve relevant evidence in respect of the alleged infringement, subject to the protection of confidential information.”

Similar requirements regarding the order for inspection are stipulated in Art. 60(3) UPCA:

“The Court may, even before the commencement of proceedings on the merits of the case, at the request of the applicant who has presented evidence to support the claim that the patent has been infringed or is about to be infringed, order the inspection of premises. (...)”

More specifically, the Court has to assess whether the patent *“has been infringed or is about to be infringed”*.

Regarding the *standard of proof* for these assessments, the Court rightfully referred in its Orders to the LD Mannheim 3 March 2025, UPC_CFI_142/2025 and cited that *“a certain degree of plausibility of the infringement or the threat thereof”* should be taken into consideration. The Court, upon review, rephrases this standard to *“a certain degree of plausibility of the patent being infringed or about to be infringed”* with reference to above wording of Art. 60(1) and (3) UPCA. The Court further rightfully stated in its Orders (§37 Orders) that the standard of proof for applicants is lower compared to infringement actions (on the merits) and preliminary measures actions. The Court finally stated rightfully that the burden of presenting and proving facts rests on GENENTECH & ROCHE (referring again to R. 192.3 (second sentence) RoP).

49. The parties disagree on the interpretation of the term *“about to be”* (Art. 60(1) and (3) UPCA). ORGANON argues that this term should be read as *“imminent”* (as it is according to ORGANON closely related to the *“urgency”* assessment in R. 194.2 RoP) and, as such, argues that the Orders were *“premature”*.
50. Given the general purpose of an order to preserve evidence or for inspection (see §43), the term *“about to be infringed”* in Art. 60(1) UPCA and Art. 60(3) UPCA does not have the same meaning as *“urgency”* (in the sense of R. 194(2) RoP) nor *“unreasonable delay”* (in the sense of R. 211.4 RoP (cf. CoA order 15 July 2025, UPC_CoA_327/2025)), nor *“threatened infringement”* (in the sense of R. 13.1(l)(i) RoP). The applicable threshold is that of *“about to be infringed”*, which must be proven by the applicant of an order to preserve evidence/for

inspection with a certain degree of plausibility. Therefore, there must be a risk of infringement and it must be apparent that it will occur in the future. The specific facts of the case will determine the duration of this period.

51. In a third step (see §60 – 71 Orders), if an order to preserve evidence/ for inspection is granted, the Court should assess whether the actual requests cover the purpose for which the Application was introduced, again balancing the fundamental rights of the parties. ORGANON indeed argues that the earlier assessment by the Court is flawed and requests a review.
52. In a fourth step (see §72 – 76 Orders), additional conditions regarding the execution of the order to preserve evidence/for inspection may be ordered by the Court based on the circumstances of the case.
53. Further conditions may be set depending on the specifics of the place of execution (see §77– 78 Orders). Except for the argument based on “*procedural impropriety*”, ORGANON does not question any of the additional conditions set by the Court. Where they question whether these additional conditions were adhered to during execution, the Court has already ruled that such arguments do not fall within the scope of these review proceedings (see §42).

V.C. Review Assessment

V.C.1. First Step: Not hearing the defendant (*R. 192.3 (second sentence) RoP*)

V.C.1.1. *R.192.3 (second sentence) RoP*

54. ORGANON argues that the Court, in exercising its discretion when applying R. 194.1 RoP and deciding whether or not hear the defendant, was misled (misinformed) by GENENTECH & ROCHE regarding the element of urgency (R. 194.2(a) RoP) and the probability that the evidence may be destroyed or otherwise cease to be available (R. 194.2(c) RoP).
55. Upon review, the Court holds that GENENTECH & ROCHE did abide by the above-mentioned duty, more specifically, GENENTECH & ROCHE did disclose all material facts, known to them, when applying for the Orders. Where ORGANON holds that these facts allegedly cannot be interpreted the way GENENTECH & ROCHE held in their Applications, such an argument does not pertain to *the lack of disclosure* but is to be considered part of a legal or factual assessment.

V.C.1.2. *Urgency (R. 194.2(a) RoP)*

56. When arguing “*urgency*” in the sense of R. 194.2(a) RoP GENENTECH & ROCHE reasons the “*imminent launch*” of ORGANON’s Perjeta® biosimilar referring to a possible launch date and

the fact that waiting until the product is on the market will lead to irreparable harm (see §115 and 116 Applications).

57. According to Art. 60(5) UPCA measures shall be ordered, if necessary without the other party having been heard, in particular where any delay is likely to cause irreparable harm to the proprietor of the patent, or where there is a demonstrable risk of evidence being destroyed. “Urgency” is not defined in the UPCA as precondition for ordering such “*ex parte*” measures.

Further, according to R. 194.2(a) RoP, “urgency” is only one of the elements that the Court should consider when exercising its discretionary powers and, therefore, cannot be considered a compulsory precondition for granting the requested measures “*ex parte*”. It should also be noted that the wording of R. 194.2 RoP does not include the words “and” or “or”, leaving the relationship between the required conditions open to the Court's interpretation. There are situations in which urgency could be of paramount importance, such as when certain products are presented at a trade fair. Conversely, there are situations in which the risk of destroying evidence or otherwise ceased to be available is the leading reason for not hearing the defendant. In the latter situations, ordering “*ex parte*” measures may be acceptable, even in the absence of an element of urgency.

58. When assessing the “urgency” element and upon review, the Court also takes into consideration the general processing time of granted orders to preserve evidence/for inspection with the possibility of review (leading to possible reformulation) and the actual access which will be given to the applicant to the gathered information in order to access its enablement to evaluate its further procedural steps (see §43).
59. Upon review, the Court holds that opting for R. 194.1(d) RoP after hearing GENENTECH & ROCHE as a preliminary procedural measure was justified, as the timeline put forward by GENENTECH & ROCHE could be considered likely to be accurate and hence create urgency in the sense of R. 194.2(a) RoP.
60. The allegation of ORGANON that it is likely that the MA grant would take more time than GENENTECH & ROCHE argued (referring to the (i) 210-day assessment period which does not reflect real world approval times and (ii) the miscalculation of the “sunset” period), does not as such make it impossible or even *unlikely* that the MA would be granted on an earlier date. GENENTECH & ROCHE convincingly refer to the “fastest timetable in practice” which makes it feasible from a regulatory perspective that an MA would be granted within one year of the validation, which places a plausible grant in early 2026 taking into consideration the date of application (based on the list of applications under review by the EMA on 16 April 2025 and the agenda of the CHMP meeting of 21 – 24 July 2025 listing the HLX11 application at the stage of adoption of the Day 120 list of questions). This is indeed demonstrated by the timeline which ORGANON itself presents as examples in their written submissions:

Biosimilar products	Date of MA Application	Decision of EC to grant MA	Total period (approximate)
Pavblu (an aflibercept biosimilar)	8 February 2024	4 April 2025	14 months
Stoboclo (a denosumab biosimilar)	8 March 2024	14 February 2025	11 months
Yesintek (an ustekinumab biosimilar)	10 February 2024	14 February 2025	12 months
Osenvelt (a denosumab biosimilar)	8 March 2024	14 February 2025	11 months
Avtozma (a biosimilar of Roche's Tocilizumab)	9 February 2024	14 February 2025	12 months

Finally, GENENTECH & ROCHE convincingly argue that, between the MA grant and further national administrative steps to be taken, some proactive steps will reasonably have to be taken by the producer or distributor in order to meet the launch date. Upon review, the Court holds this to be sufficient indication to justify the “urgency” in view of the earliest possible date when the MA would be granted.

61. Upon review, the Court holds that the element of “urgency” is further sufficiently substantiated by the following elements/considerations which could be reasonably attributed to ORGANON BE and/or ORGANON NL:
- The 31 October 2024 ORGANON US’s CEO (see §23) declared that “*in date 2025 and beyond*” additional growth contributors to the Biosimilar franchise will be the pertuzumab asset.
 - The 28 April 2025 letter of notice (see §23) in which ORGANON expressly stated that it had concluded that the validity of EP 335 is “*not evident*” implying an intention to proceed with the launch after the grant of the MA.
 - The 1 May 2025 statement by ORGANON US’s CEO (see §23), stating that after launching “*the portfolio of HENLIUS products*” beginning in the late 2025 with the denosumab biosimilar in the US, which will be “*followed by pertuzumab in Europe*”.
 - The nullity proceedings initiated in the Netherlands (see §26), which ORGANON during the oral hearing of 21 October 2025 described as part of setting the stage to launch HLX11.

V.C.1.3. *Probability that evidence may be destroyed or otherwise cease to be available (R. 194.1(c) RoP)*

62. In their Applications, GENENTECH & ROCHE stated that if ORGANON were to be alerted that they were seeking to seize evidence or inspect the premises, ORGANON would likely remove the information or evidence from the locations where the Orders would be executed (see §123 and subsequent in the Applications). GENENTECH & ROCHE referenced in these review proceedings also to digital files being made inaccessible or physical files being relocated. These actions could be taken “*easily and quickly*”.
63. It is important to note that uncertainty regarding the actual MA applicant (raised by ORGANON) only arose after the Orders were granted. During the oral hearing, ORGANON

stated that it was wrong to assume that ORGANON NL would be the MA applicant when, in reality, it is HENLIUS. Not only is this statement not evidenced (ORGANON being the most suitable party, if not the only party, to provide such evidence), but GENENTECH & ROCHE convincingly indicate that the actual MA applicant was not made public at the time of the Applications, or when the Orders were issued (the relevant date for the Court's review assessment). Furthermore, the Court holds that this fact could not be deduced from the public ORGANON communication provided as evidence by GENENTECH & ROCHE in their Applications (e.g. in the communication dated 31 October 2023, the "*Biosimilars franchise*" is mentioned, and such franchise does not exclude ORGANON NL or BE from applying for the MA).

Therefore and upon review, the Court holds on the relevant review assessment date (see §41), that GENENTECH & ROCHE provided "*reasonably available evidence*" to suggest that ORGANON NL would act as the EU MA holder. Specifically, GENENTECH & ROCHE reasonably assumed, and the Court rightly followed this assumption, that ORGANON NL, being the only ORGANON entity holding centralised MAs for the ORGANON group in the EU, would be the MA applicant. In these Review Proceedings, GENENTECH & ROCHE supported this assumption by providing an overview of the European Commission Register, which indeed lists ORGANON NL as the sole MA holder of the ORGANON group in the EU.

Furthermore, the joint press release by ORGANON US and HENLIUS mentioned a licence and supply agreement for HLX11. This led to the reasonable assumption that one or other ORGANON facility in the EU would be active as a manufacturer and/or stockpiler (or preparing to do so) and/or responsible for batch certification. As previously mentioned, ORGANON only has two facilities in the EU: ORGANON BE and NL. Therefore, it is plausible that relevant information/evidence could be found at the premises of either ORGANON NL (as the MA applicant) and/or ORGANON BE (as the manufacturer, stockpiler, preparative agent, etc.).

64. ORGANON further counterargues the element of "*the probability that evidence may be destroyed or otherwise cease to be available*" by arguing that they would never "*(destruct) or (remove) documents that it is required to keep and maintain for the purpose of regulatory authorization and compliance*". ORGANON bases its arguments on the highly regulated European industry, which requires those engaged in these activities to maintain scrupulous and accurate records of all aspects of medicinal products within the European supply chain.
65. However, the threshold for assessing this element is not the *intention* of ORGANON, but rather the *probability* of a demonstrable risk of evidence being destroyed (Article 60(5) UPCA and R. 197.1 RoP) or otherwise ceasing to be available (R. 197.1 RoP). The Court accepts that it would not be probable that ORGANON would destroy such documentation or material but at the same time there exists *probable* risk that such material is moved from these two locations to elsewhere for a shorter or a longer period of time and as such ceasing to be available.

66. Upon review, the Court holds that GENENTECH & ROCHE have sufficiently proven this demonstrable risk.

V.C.1.4. Conclusion

67. Taking all of the above elements into account and upon review, the Court holds that it initially rightfully decided when weighing the elements to be taken into consideration to issue the Orders “*ex parte*”.

V.C.2. Second Step: (Review of the) Substantive assessment (Art. 60 UPCA)

68. As mentioned, the validity of the Patent is not at dispute in these Review Proceedings.
69. Further, upon review, the Court notes that no arguments are brought forward to argue that HLX11 would not infringe EP 553.
70. The only substantive assessment in these Review Proceedings is limited to the wording of “*about to be infringed*”. As already mentioned in §50 the term “*about to be infringed*” in Art. 60(1) UPCA and Art. 60(3) UPCA does not encompass “*urgency*” (in the sense of R. 194.2 RoP) or “*unreasonably delay*” (in the sense of R. 211.4 RoP) nor “*threatened infringement*” (in the sense of R. 13.1 (I)(i) RoP). The standard/threshold to apply is that of “*about to be infringed*” as a stand-alone threshold, which is to be proven with “*a certain degree of plausibility*”.
71. Upon review, the Court holds that GENENTECH & ROCHE has sufficiently proven in the review proceedings (in the sense of “*a certain degree of plausibility*”) that EP 335 is “*about to be infringed*”. The Court specifically refers to the application for an MA and the additional elements referred to under §61. The Court further adds that the fact that an MA application, as such, would (possibly) not constitute a “*threat of infringement*” when GENENTECH & ROCHE would have applied for provisional measures (cf. UPC CoA 13 August 2025, UPC_CoA_446/2025 which actually also refers to additional circumstances of the case to be taken into consideration) but indeed could be sufficient to prove with a certain degree of plausibility that the patent is “*about to be infringed*” (as is further substantiated with the elements under §61).
72. Upon review of all the above elements, the Court holds that the substantive conditions of Art. 60(1) and (3) UPCA are met and, therefore, that the Orders holding that EP 335 was about to be infringed on the relevant date (§41) should be confirmed.

V.C.3. Third Step: (Review of the) Assessment of the scope of the Orders

73. As a third assessment in these Review Proceedings and upon review, the Court should address whether the Orders were justified in view of the Applications and, subsequently, whether the means for preserving evidence/for inspection (scope of the Orders) were justified.
74. Firstly, ORGANON argues that the scope of the Orders was overly broad, referring to GENENTECH & ROCHE's statement that they had sufficient evidence of infringement of features (i) to (v) of claim 1 of EP 335 (see §24). ORGANON states that the Orders should therefore have been limited to the seizure of evidence regarding feature (vi) of claim 1 of EP 335.
75. Upon review, the Court holds that even though GENENTECH & ROCHE, in their view, indeed would have had ample evidence of infringement of features (i) to (v) of claim 1 of EP 335, the grant itself should therefore not be limited to the seizure of evidence regarding feature (vi). The elements brought forward by GENENTECH & ROCHE indeed were an indication of EP 335 about to be infringed and rightfully allowing GENENTECH & ROCHE to gather *any* evidence necessary to successfully enforce the prohibitive rights arising from Art. 25 UPCA (cf. LD Düsseldorf 16 April 2025, UPC_CFI_539/2024 (§28-29)). This preserving/gathering of information (evidence) should not be limited to the missing technical information related to feature (vi) of the claim 1 of EP 335, but also encompasses a request to have access to information (evidence), including but not limited to the MA materials, which could prove the acts constituting the infringement under Art. 25 UPCA.
76. Secondly, another issue to address in the review is whether the scope of the Orders should be modified, as argued by ORGANON in §30, specifically by deleting any reference to the *"appliance"* or *"bioreactor"* from the granted measures. To support this request, ORGANON refers to the expert report of Dr. Uwe Gottschalk (ORGANON Exhibit 1), holding in general that the granted measures, where they allow the gathering of evidence related to
- the *"appliance that may be used to manufacture the product"* ((2)(i)(a) – (b) of the substantive part of the Orders);
 - the *"bioreactor"* (mentioned in (2)(ii)(a) – (b) of the substantive part of the Orders);
 - the *"batch records"* ((2)(ii)(f) of the substantive part of the Orders)
- are extremely broad and as such would not allow to give an indication of the infringement of EP 335.
77. However, upon review, the Court holds that the initial grants are justified and were not wrongfully granted based on the following reasoning:
- ORGANON's party expert limited the scope of his report to evidence that could prove whether or not HLX11 falls within the claims of the Patent. As indicated above, the purpose of an order to preserve evidence/for inspection is broader, allowing the collection of evidence concerning the alleged infringing acts listed in Art. 25 UPCA.
 - R. 196.1(c) RoP allows the physical *seizure* of *"implements used in the production"* (a measure which was not ordered), so it is reasonable to conclude that the *"detailed description"* permitted under R. 196.1(a) RoP (which the Court permitted to be

provided in any form) also encompasses the “implements” (i.e. the “appliance” and “bio-reactor”).

- R. 199 RoP (regarding the order for inspection) explicitly allows inspection of “products, devices, methods, premises or local situations in situ”.
- Both R. 196.1 and R. 199.1 RoP are in line with Art. 7 Enforcement Directive, which allows “the detailed description, with or without taking samples, or the physical seizure of the infringing goods, and, in appropriate cases, the materials and implements used in the production and/or distribution of these goods and the documents related thereto”.
- Both R. 196.1 RoP and R. 199.1 RoP strike a balance between the scope of the measures permitted by the Court and the protection of confidential information. This protection was secured in the substantive part (4) “Confidentiality” of the Orders and will be reinforced in subsequent orders issued in accordance with R. 262(A) RoP.
- ORGANON disregards the role of the appointed experts. These appointed experts' task is to filter (evaluate) all the gathered/preserved information/evidence and use only that which they deem necessary as potential evidence to prove or disprove the actual infringement of EP 335.

78. In conclusion and upon review, the Court holds that the Orders are and were rightly balanced in that sufficient evidence was presented by GENENTECH & ROCHE to prevent the misuse of the legal tool of an order to preserve/for inspection as a fishing expedition, while also allowing the Court to grant measures that covered the general aim of an order to preserve evidence/for inspection to be executed on the two Organon sites within the UPC territory. Consequently, the requests introduced by ORGANON to limit the scope of the orders are dismissed.

V.C.4. Fourth step: (Review of the) Other Conditions

79. Under the heading “Additional Conditions” of the Orders, the Court stated (i.a.) the following:
“Permits (ORGANON NL and ORGANONG BV) to contact their legal representative and/or technical representative who may participate in the actual execution of the order, but the actual execution of these orders may not be delayed in any way.”
80. ORGANON hold that this provision is “extremely onerous” because it would mean, in effect, that all or part of the *saisie* is likely to be conducted in the absence of proper legal presentation.
81. Upon review, the Court notes that the presence of a legal or technical representative is not a prerequisite for executing the Orders. The Court allowed such presence in its Orders, on the condition that it would not delay their execution, as an additional element to balance the rights of ORGANON against those of GENENTECH & ROCHE. The condition was set to balance the interests of the parties, and was rightly in favour of GENENTECH & ROCHE, taking into consideration the probability of evidence being destroyed or made unavailable, especially as

the Orders were to be executed at two different premises, increasing the risk of contact between the entities, especially in case of delay at one of these premises.

82. Upon review, the Court holds that the requests introduced by ORGANON related to alter these “*other conditions*” should be dismissed.

VI. STREAMLINING THE PENDING APPLICATIONS/PROCEDURES

83. When outlining the procedural background, the Court provided an overview of the pending applications. As a new CMS (new) was introduced on 26 September 2025 that does not follow the workflow-setup of the CMS (old), it seems opportune, from a procedural efficiency point of view, to streamline these pending applications/procedures.
84. Issues and requests relating to the execution of orders will be grouped together (even if they form part of applications regarding confidentiality, which have no direct bearing on a confidentiality assessment). In practice, this means that requests in the following workflows (old CMS) will be dealt with in a single subsequent order:

UPC_CFI	Application	Subject Matter
UPC_CFI_407/2025 UPC_CFI_408/2025	App_33545/2025 App_33550/2025	Application for Penalty Payment and Remedy Request introduced by GENENTECH & ROCHE on 23 July 2025 <u>Request:</u> <i>impose the periodic penalty payments provided for in term (vi) of the Order, i.e. the cumulative maximum of € 5,000,000 for every hour of non-compliance; and</i> <i>to order (ORGANON BE and ORGANON NL) to provide access to, or produce, the evidence covered by the Order and reiterated under 5.1 of this application that [...], and to impose new periodic penalty payments of €400,000 per hour of continued noncompliance, up to a cumulative maximum of €10,000,000, or such other amount as the Court deems appropriate to ensure effective enforcement of its Order.</i>
UPC_CFI_407/2025 UPC_CFI_408/2025	App_33781/2025 App_33676/2025	Application for review (order to preserve evidence) introduced by ORGANON on 28 July 2025 <u>Request:</u> <i>For the reasons set out above and in the Exhibits to this review, (ORGANON) requests that the Order is set aside in its entirety, any and all documents are returned to (ORGANON) and copies destroyed, and that the documents and their details shall not be passed to (GENENTECH & ROCHE) or used or referred to in any litigation.</i> <i>Alternatively, (ORGANON) requests that the Order is modified and that the bailiff is ordered to immediately return and/or destroy all copies of any documents which the Court deems to have been obtained illegitimately or which are considered to be irrelevant in establishing the (GENENTECH & ROCHE)'s allegation of there being an imminent threat of (ORGANON) infringing the Patent.</i>
UPC_CFI_407/2025 UPC_CFI_408/2025	App_33913/2025 App_33918/2025	Application for protection of Confidential Information introduced by ORGANON on 29 July 2025 <u>Request:</u> Primarily: Order that <u>none</u> of <i>The NL Bailiff and BE Bailiff report; and</i> <i>The Seized Documents</i> <i>The expert report(s) (to the extent that they were drafted)</i> <i>can be made accessible to Claimants or used in legal proceedings, such in accordance with Art. 58 UPCA and R. 262A.1 RoP; and order that within 2 business days, any and all of a., b. and/or c. above, as far as already obtained by outside legal counsel for the Claimants, is to be permanently destroyed and, in case of digital copies, permanently deleted;</i>
UPC_CFI_407/2025 UPC_CFI_408/2025	App_36857/2025 App_36859/2025	Generic Application (for the destruction and deletion of confidential information) introduced on 17 September 2025 <u>Request:</u>

		<i>A. Order that counsel for Roche is to destroy all physical copies and (permanently) delete all digital copies of the Seized Documents and Bailiff Reports in their possession and to maintain strict confidentiality of such documents up to the moment of such deletion and destruction;</i>
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In order to assess the requests made in the aforementioned workflows, the Court sets the following dates for additional and/or concluding written comments:

Party	Term (deadline)
For ORGANON	19 November 2025
For GENENTECH & ROCHE	26 November 2025
For ORGANON	1 December 2025
For GENENTECH & ROCHE (with the exception of arguments related to their requests made in App_33545/2025 and App_33550/2025 where ORGANON (as Defendant should have the last opportunity to comment)	4 December 2025

Parties are informed that, only if held necessary which will be decided in a separate procedural order, a virtual hearing will be organized on 8 December 2025.

85. Issues and requests relating to the assessment of the applications based on R. 262A RoP, and specifically to the confidential nature of the seized documents and the level of confidence (including the establishment of a confidentiality circle), will be grouped together but will be put on hold (stayed) until the orders mentioned in §84 are issued and parties are given the opportunity to comment as to be determined in a separate procedural order.
86. Parties are informed that up till then (issuance of definite order as referred to in §85), access to the preserved/gathered information/evidence is limited to the representatives of the parties and the appointed experts.

VII. PRACTICAL APPROACH REGARDING THE FOLLOW-UP OF THE ORDERS

87. Although upon review the Court confirms the Orders, it deems it opportune, due to procedural efficiency, to further indicate the steps to be taken in follow-up of the Orders:
 - As mentioned in §86, the preserved/gathered information (evidence) will continue to be kept confidential (only allowing access to the representatives of the parties and the appointed experts until a “Confidentiality Circle” is established as indicated in the Orders under “Confidentiality”)(see §85).
 - Although the appointed experts were instructed to present their report within 14 days upon the execution of the Orders, the experts are ordered to stay their activities until the Court has decided which preserved/gathered information (evidence) falls within the rightful execution of the Orders and/or which information should additionally be supplied by ORGANON BE and/or ORGANON NL (§84).

- Orders the appointed experts to deliver their report to the Court (by uploading in the CMS under the confidentiality regime “M”):
 - Either 14 days after the issuance of the order referred to under §84,
 - Either 21 days after the issuance of the order referred to under §84 only if the aforementioned term or part of the 14 days comprises the period between 24 December 2025 and 1 January 2026.

VIII. R. 198.1 RoP (TERM FOR INITIATING INFRINGEMENT PROCEEDINGS)

88. Taking into consideration the pending proceedings between the parties, which will affect the date on which GENENTECH & ROCHE will have access to the preserved and gathered information upon execution of the orders, enabling them to make the evaluation referred to in §43, the court sets the term for initiating infringement proceedings at 31 calendar days or 20 working days (whichever is longer) from the date of presentation of the experts' report. This date depends on the subsequent order to be issued regarding the requests made by the parties in the proceedings referred to in §84. Any previous order regarding this matter is therefore replaced by this term.

IX. COSTS

89. The decision on the costs relating to the different applications including the Applications for Review will be made as part of a (possible) infringement procedure, if one is introduced by GENENTECH & ROCHE, or in separate proceedings based on a separate application should not infringement procedure be initiated.

X. ORDER

The Court, upon review of the Orders:

1. Allows the request for correction/replacement of exhibit FS04 (i.e. *FS04 (corrected): Press release from Organon of 28 March 2025, announcing the European Medicines Agency (EMA) validation of Henlius and Organon filing for Perjeta® (pertuzumab) biosimilar candidate HLX11*) introduced by GENENTECH & ROCHE on 20 October 2025 and orders that the original replaced FS04 should be kept in the file.
2. Dismisses the requests introduced by ORGANON BE and ORGANON NL which are related to the actual execution of the Orders and the outcome of such execution as being outside the scope of these review proceedings and are considered as such as inadmissible.
3. Dismisses the other requests introduced by ORGANON BE and ORGANON NL.
4. Orders parties to abide by the schedule as provided in §84 of this order.
5. Stays the procedures related to the requests made by the parties related to R. 262(A) RoP and this until an order has been issued related to the requests made listed in §84 of this order.
6. Stays the activities of the appointed experts as provided in §87 of this order.

7. Orders the appointed experts to deliver their report to the Court (by uploading in the CMS as under the confidentiality regime “M”):
 - Either 14 days after the issuance of the order referred to under §84,
 - Either 21 days after the issuance of the order referred to under §84 only if the aforementioned term of 14 days comprises the period between 24 December 2025 and 1 January 2026.
8. Sets the term for introducing infringement proceedings to 31 calendar days or 20 working days (which ever is the longer) starting from the date of presentation of the experts’ report (R. 198.1 RoP)(see also under item 6 of this order).
9. Confirms that the preserved/gathered information (evidence) will continue to be kept confidential (only allowing access to the representatives of the parties and the appointed experts) and this until an order has been issued as referred to under §85 of this order.
10. Stays a decision on the costs (regarding the different applications and the review application) which will be assessed either part of a (possible) infringement procedure, if one is introduced by GENENTECH & ROCHE, or in separate proceedings based on a separate application.

This order is issued on 12 November 2025 by the panel of the LD Brussels:

Samuel GRANATA Judge-Rapporteur Presiding judge LD Brussels Legally Qualified Judge	
Petri RINKINEN Legally Qualified Judge	
Rute LOPES Legally Qualified Judge	
Clerk LD Brussels	

APPEAL

As this order is an order to review an Art. 60 UPCA order, it should also be considered as an Art. 60 UPCA order. This review order may be appealed in application of R. 220 .1(c) RoP and this within the term as mentioned in Art. 73(2)(a) UPCA.

SPECIFIC ORDER FOR THE REGISTRY

Orders the Sub-Registry of the LD Brussels to send this review order by electronic mail to the appointed experts should they not automatically receive this order through the CMS (new).



UPC_CFI_407/2025 - UPC_CFI_408/2025

ORDER DETAILS (OLD CMS)

ORD_33808/2025

Action Number:

APP_33781/2025 (regarding UPC-CFI_407/2025)

ORD_33759/2025

Action Number:

APP_33759/2025 (regarding UPC-CFI_408/2025)