Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Brussels - Local Division

UPC_CFI_1357/2025
UPC_CFI_629/2025

Procedural Order (R.190 RoP)
of the Court of First Instance of the Unified Patent Court
Issued on 14 April 2026
Concerning EP 3 107 487 B1

HEADNOTES

When assessing an application to produce evidence (R. 190 RoP application), the Court must consider the following cumulative conditions (cf. LD The Hague Order of 14 October 2024 in the case of Winnow v Orbisk, § 8, as further developed):

1. The requesting party must have presented evidence "*reasonably available*" in support of its claims. The assessment of this condition is *prima facie* and twofold:
   (a) Did the requesting party present "*reasonable available"* evidence to support its underlying assertions?
   (b) As an implied condition, could the requested evidence enable the requesting party to conclusively prove its assertions?
2. The evidence to which access is requested must (i) be "*specified*" and (ii) lie in control of the other party.
3. The other party's confidential information must be protected.
4. The requirements of proportionality, equity, and fairness must be satisfied. This assessment is twofold:
   (a) The "*timing*" of the application as such taking into consideration the stage of the proceedings.
   (b) Each individual request as a final assessment.

KEYWORDS

Application to produce evidence (R. 190 RoP)

APPLICANTS R. 190 ROP APPLICATION
DEFENDANTS INFRINGEMENT ACTION (UPC_CFI_1357/2025)
CLAIMANTS COUNTERCLAIM FOR REVOCATION (UPC_CFI_629/2026)

(1) GC AESTHETICS PARENTCO LIMITED
(2) NAGOR LIMITED
(3) GC AESTHETICS MANAGEMENT LIMITED
(4) GC AESTHETICS (DISTRIBUTION) LIMITED
(5) GC AESTHETICS (France) SAS
(6) EUROSILICONE SAS
(7) GC AESTHETICS ITALY S.R.L.
(8) GC AESTHETICS GmbH
(9) GC AESTHETICS SPAIN, S.L.U.
(10) GLOBAL CONSOLIDATED AESTHETICS (UK) LIMITED

(11) GC AESTHETICS HOLDINGS LIMITED
(12) GC AESTHETICS FINANCE LIMITED
(13) ROMED N.V.

Represented by:	Bristows (Ireland) LLP Brian Cordery Dr Gregory Bacon Andrew Bowler James Boon
Electronic address for servicing:	gregory.bacon@bristows.com
Hereafter referred to as:	Collectively as "*Defendants*"

RESPONDENTS R. 190 ROP APPLICATION
CLAIMANTS INFRINGEMENT ACTION (UPC_CFI_1357/2025)
DEFENDANTS COUNTERCLAIM FOR REVOCATION (UPC_CFI_629/2026)

ESTABLISHMENT LABS S.A.

Represented by:	Haseltine Lake Kempner LLP Haseltine Lake Kempber PartG mbB Joanna Deas Alex Rogers Harriet Crawford Joseph Lenthall
Electronic Address for servicing:	jdeas@hlk-ip.com
Hereafter referred to as:	*"Claimant"* or "*LABS*"

PATENT AT ISSUE

Number	Proprietor(s)
EP 3 107 487 B1	ESTABLISHMENT LABS S.A.

LANGUAGE OF THE PROCEEDINGS: English

SUBJECT MATTER: Application R. 190 RoP

PANEL - LOCAL DIVISION

Presiding Judge (Judge-Rapporteur):	Samuel Granata
Legally Qualified Judge:	Carine Gillet
Legally Qualified Judge:	Marije Knijff
Technically Qualified Judge:	Paolo Gerli

DECIDING JUDGES: Order issued by the panel

I. PROCEDURAL BACKGROUND AND REQUEST

1. On 30 October 2025, LABS submitted its Statement of Claim (serviced to all Defendants on 14 November 2025) (hereafter referred to as "*SoC*").

2. On 16 February 2026, the Defendants submitted their Statement of Defence including a Counterclaim for Revocation (hereafter referred to as "*SoD-CC*").

3. On 20 March 2026 the Defendants submitted an "*Evidence Production Request*" (hereafter "*R. 190 RoP Application*"). LABS was given the opportunity to comment this application by Court communication dated 22 March 2026 and this the latest by 27 March 2026.

LABS submitted "*preliminary comments*" on 23 March 2026. In these "*preliminary comments*", LABS requested that if the Court could not "*resolve*" the R. 190 RoP application "*solely*" on the grounds put forward in these comments, LABS should be allowed the right to provide further "*detailed comments on each specific request*".

By communication dated 24 March 2026, the Court informed LABS that it will assess the R. 190 RoP Application, and this by taking into consideration all counterarguments submitted by LABS. The court will therefore not consider the application in stages, first considering the "*preliminary comments*" and then the more detailed comments. The court allowed LABS to elaborate further on their comments, with the deadline extended to 30 March 2026 (which they met).

II. REQUEST

4. In their R. 190 RoP application the Defendants request as follows:

I. ***PRIMARY ORDER***
Pursuant to Art. 59 UPCA and R.190 RoP, (LABS) shall produce to the Defendants, within 14 days of the Order, the following evidence including documents (where possible, in electronic format), to the extent they exist and are within (LABS)'s possession, custody or control, in relation to the Motiva SilkSurface (references to the term SilkSurface in the operative provisions of the Order also include SmoothSilk, on the understanding that these terms are used interchangeably by (LABS)):

a. ***Motiva SilkSurface sales figures****: total sales volumes for all countries where any generation of Motiva implant including the Motiva SilkSurface has been sold, from first launch until the priority date of the Patent. To the extent that all of these sales are said by (LABS) to be subject to confidentiality arrangements, (LABS) is to provide the documentation underlying the claim to confidentiality in each instance;*

b. ***Physical samples manufactured before the priority date:*** *three physical samples (or two, if three are not available; or one, if two are not available) of each generation of Motiva implant including the Motiva SilkSurface which was manufactured before the priority date of the Patent, together with documentation confirming the manufacturing date of each sample provided;*

c. ***Physical samples manufactured after the priority date:*** *three physical samples (or two, if three are not available; or one, if two are not available) of each generation of Motiva implant including the Motiva SilkSurface which was manufactured after the*

priority date of the Patent, together with documentation confirming the manufacturing date of each sample provided. Where a range of manufacturing dates are available for a given generation of Motiva implant including the Motiva SilkSurface, (LABS) is to provide sample(s) from the earliest manufacturing date for which the implant remains within its recommended shelf life, or, if that is not possible, sample(s) from the latest manufacturing date available;

d. ***Promotional and marketing materials:***
   i. *all versions (in all languages) of the Motiva Implant Matrix Digital Product Brochure subsequent to **Exhibit GCA-20** that were made available to the public before the priority date of the Patent;*
   ii. *all versions (in all languages) of the Motiva Implant Matrix Product Performance Qualification Summary, other than **Exhibit GCA-32**, that were made available to the public before the priority date of the Patent (including the version dated August 2012 referred to in paragraph 253 of the Statement of Defence and Counterclaim for Revocation and the version dated January 2014 referred to in **Exhibit GCA-69**);*
   iii. *all versions (in all languages) of the Motiva Matrix Implants Clinical Data Summary, other than **Exhibit GCA-21**, that were made available to the public before the priority date of the Patent;*
   iv. *all versions of any Motiva implant product brochure, directed to patients and/or surgeons, that refers to the Motiva SilkSurface, that were made available to the public before the priority date of the Patent;*

e. ***Third-party test reports:*** *the following documents which are referred to by (LABS) in its own materials (see: i. and ii.); and / or referred to by (LABS) in its own correspondence with the United States Patent Office (concerning US patents US10595979 and US11890179) between 2016 and 2021 (see: iii. and iv.):*
   i. *Laboratoire National de Métrologie et d'Essais: Mechanical characterization of Motiva Implant Matrix Silicone Breast Implants Test-file L050836-28/MAY/2010 (see pages 4 and 6 of **Exhibit GCA-32**);*
   ii. *characterisation and testing report carried out by the group at Manchester University referred to on page 2 of **Exhibit GCA-39** and pages 4 and 5 of **Exhibit GCA-35;***
   iii. *the Manchester University test report entitled "Implant Surfaces Analyzed" produced in 2012 in relation to Motiva implants manufactured between October 2011 and May 2012 (see **Exhibit GCA-27** and **Exhibit GCA-70)**;*
   iv. *the LNE Test Report Documents (i.e., File L050836 – Documents DE/2, DE/3, and DE/4, each dated 8 December 2010) reporting testing conducted between 20 August 2010 and 22 October 2010 on Motiva implants (see **Exhibit GCA-27** and **Exhibit GCA-70)**;*

f. ***Technical specification documents:*** *all technical specification documents and/or product specification sheets (in all languages) for each generation of Motiva implant including the Motiva SilkSurface, manufactured both before and after the priority date of the Patent to the extent that they specify any of the following surface topography parameters:*
   i. *profile roughness (Ra);*
   ii. *mean surface roughness (Sa);*
   iii. *mean surface skewness (Ssk); or*
   iv. *maximum peak height to trough depth (Sz);*

g. ***Claimant's performance qualification report and performance specifications:*** *all versions (in all languages) of the following internal performance specifications and internal product performance qualification report:*
   i. *VAL-001.R Motiva Product Performance Qualification Report (based on LNE-Laboratoire National de Métrologie et d'Eessais, Trappes, France: Mechanical characterization of Motiva Implant Matrix® Silicone Breast Implants Test Report – file L050836- 28/MAY/2010) (see pages 4 and 5 of **Exhibit GCA-32**);*
   ii. *VMP-001: Establishment Labs S.A. Validation Master Plan (see page 6 of **Exhibit GCA-32**);*
   iii. *QP-001: Motiva Round Implants Quality Plan (see page 6 of **Exhibit GCA- 32**)*
   iv. *VAL-003: Motiva Round Implant Product Performance Qualification Protocol (see page 6 of **Exhibit GCA-32**).*

h. ***European regulatory documentation:*** *all documentation submitted by (LABS) to support its applications for certification for its Motiva implants submitted under the Medical Device Regulation and / or Medical Device Directive, including its first application for certification in 2011 and any subsequent material submitted in respect of this certification or any re-certification, to the extent that those documents refer to any surface topography parameters of the Motiva SilkSurface. For the avoidance of doubt, this request includes any material submitted in accordance with the regulatory regime under the Medical Device Regulation and / or Medical Device Directive relating to a change in the surface topography parameters of the Motiva SilkSurface in any generation of Motiva implant before or after the priority date of the Patent; and*

i. ***Design History File (surface topography records):*** *all sections of (LABS)'s Design History File (or equivalently named file or record keeping system) for each generation of Motiva implant including the Motiva SilkSurface both before and after the priority date of the Patent, to the extent that these refer to any surface topography parameters of the Motiva SilkSurface, including those that refer to any changes in the design or development of the Motiva SilkSurface.*

II. ***AUXILIARY ORDER (in the event the Court does not grant the Primary Order in full)***
In the alternative, if the Court considers any of the categories in (the primary order) to be too broadly defined, the Defendants request that the Court grant such lesser order as the Court considers appropriate and proportionate in the circumstances, including by limiting any category to a subset of the evidence and / or documents described therein.

III. ***In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER****, (LABS) is to provide a witness statement from a duly authorised officer of (LABS) or a person fully acquainted with the relevant facts (including in relation to the identification / production of relevant samples), verified by a statement of truth, within 14 days of the Order, to confirm that:*
   a. *the provisions of the Order have been complied with in full; and*
   b. *any redaction that has been applied to a document concerns only information that is irrelevant to the terms of the Order and is confidential.*

IV. ***In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER****, the process of applying redactions is to take place under the supervision of (LABS)'s Authorised Representatives.*

V. ***In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER****, the Defendants seek a recurring penalty payment to be made by (LABS) to the Court of up to € 2.000 for each day of delay beyond the deadline as stipulated and ordered by the Court for (LABS) to produce the evidence as categorised above.*

VI. ***In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER,*** *access to the evidence including documents is limited to:*

a. the legal team representing the Defendants in these proceedings; and
b. independent experts assisting the Defendants; and
c. one natural person employed by the GCA group,

subject to appropriate terms of non-disclosure, in accordance with the guiding principles regarding the interpretation and application of Rule 262A RoP.

VII. ***In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER****, an appeal to the order to produce evidence may be brought by (LABS) in accordance with Article 73 UPCA and Rule 220.1 RoP.*

VIII. ***In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER****, the costs of the Application are to be awarded to the Defendants, such costs to be determined following a decision on the merits in this Action and Counterclaim.*

5. In its more elaborated comments (submitted on 30 March 2026) LABS concludes and requests as follows:

74. For the reasons set out above, (LABS) respectfully submits that the Defendants have failed to satisfy the requirements of Article 59 UPCA and Rule 190 RoP. The Application is premature, unsupported by specific and necessary grounds, and disproportionate in scope.

75. Accordingly, (LABS) respectfully requests that the Court:

(a) dismiss the Defendants' Application for an order to produce evidence in its entirety; or
(b) in the alternative, limit any production strictly to documents or evidence demonstrably necessary to prove clearly identified and contested facts, such limitation to be determined following the filing of (LABS)'s Reply to the Defence and Counterclaim and subject to appropriate confidentiality protections and redactions; or
(c) in the further alternative, defer any decision on the Application or any request for production of evidence until a later stage of the proceedings, once the issues in dispute have been properly defined following the completion of the written procedure;
(d) deny any request for recurring penalties or other coercive measures in connection with the proposed Primary or Auxiliary Orders; and
(e) order that the costs of the Application be borne by the Defendants.

76. For the avoidance of doubt, (LABS) has addressed both the procedural objections and the individual categories of evidence requested in accordance with the Court's directions and reserves the right to rely on further evidence and submissions in its Reply to the Defence and Counterclaim.

III. (REDUCED) FACTUAL BACKGROUND OF THE R. 190 ROP APPLICATION AND DEFENDANTS' ARGUMENTS

6. The Patent covers soft tissue (breast) implants. LABS asserts that the Defendants have infringed claims 1, 4, 7, 10, 11 and 13, specifically with regard to its "*Perle*" breast implant.

7. The alleged infringed claims of the Patent state as follows:

Claim 1	*A soft tissue body implant comprising a synthetic implant material comprising an irregular textured surface having superimposed macro-roughness and micro-roughness features, the surface having a mean surface roughness Sa value of a) from 1 µm to 20 µm at an area scale of 1 mm x 1 mm, and a mean surface roughness Sa value of:* *b) from 0.1 µm to 5 µm at an area scale of 90 µm x 90 µm; and/or* *c) from 10 nm to 1 µm at an area scale of 10 µm x 10 µm; and/or* *d) from 2 nm to 15 nm at an area scale of 1 µm x 1 µm* *wherein the surface comprises a biocompatible polymer; and wherein the implant material forms at least part of the surface layer of the implant.*
Claim 4	*An implant according to any one of the previous claims wherein the surface at the respective area scales has a mean surface skewness Ssk value of:* *a) from -1.0 to +1.0, preferably about zero, at an area scale of 1 mm x 1 mm; and/or* *b) from -1.0 to +1.0, preferably about zero, at an area scale of 90 µm x 90 µm; and/or* *c) from -0.7 to +0.7, preferably about zero, at an area scale of 10 µm x 10 µm.*
Claim 7	*An implant according to any one of the previous claims wherein the surface has a maximum peak height to trough depth Sz value of from 10 µm to 80 µm at an area scale of 1 mm x 1 mm.*
Claim 10	*An implant according to any one of the previous claims wherein the surface comprises organosilicon polymer, optionally a silicone, optionally polydimethylsiloxane, and/or wherein the implant material forms at least part of the surface layer of a prosthetic implant, optionally a breast implant.*
Claim 11	*An implant according to any one of the previous claims, wherein the surface is free from open cell textures.*
Claim 13	*An implant according to any one of the previous claims, the implant being a prosthetic implant, optionally a breast implant.*

8. The Defendants' approach regarding the lack of novelty and/or inventive step makes reference to "*unusual parameters*", which relate to:
(i) roughness surface (Sa) value, mentioned in independent claim 1;
(ii) mean surface skewness (SsK), mentioned in dependent claim 4; and
(iii) peak height to trough depth (Sz), mentioned in dependent claim 7.

9. The Defendants hold that the parameters are "*unusual*" in the sense that the standard surface area on which these parameters should be calculated is 4mm² (i.e. 2mm x 2mm) (based on the norm ISO 14607:2009 Annex A (numbered page 10 of EXHIBIT GCA-28), in force at the priority date).

However, the Patent, and specifically claims 1, 4 and 7, makes use of different (*"unusual"*) areas (1 mm x 1 mm). The Defendant's main argument regarding the alleged lack of novelty

and/or inventive step is that LABS uses these "*unusual parameters*" *"in order to disguise a finding of lack of novelty/inventive step"*.

10. The aforementioned claims are challenged on the grounds of novelty and/or inventive step, as they are deemed to be anticipated by two products sold prior to the priority date ("*Motiva SilkSurface" and "Cereform*") and by one patent publication (US 2013/0211310, "*Bommarito*").

The request to produce evidence concerns the product *Motiva SilkSurface* and more specifically the following generations:

- First generation: *Motiva SilkSurface* (The Round) allegedly available from 2010 (or from 2011 in Europe)
- Second generation: *Motiva SilkSurface* (The Round Plus) allegedly launched in 2012
- Third generation: *Motiva SilkSurface* (The Round Ergonomix) allegedly launched in 2014

11. The Defendants' thesis is that the breast implant materials "*Motiva SilkSurface*", allegedly produced, marketed and sold by LABS since 2010 (thus before the Patent's priority date of 17 February 2014), already met the parameters indicated in the claims. The Defendants argue that, to conclusively prove a lack of novelty and/or inventive step, the *Motiva SilkSurface* breast implants must be tested (and/or results need to be deduced from other evidence/information), particularly using the "*unusual parameters*" mentioned in the Patent.

12. The Defendants argue that LABS possesses all the evidence and information requested (which is not publicly available), and that this evidence and information would assist them and the Court to determine the counterclaims of lack of novelty and/or inventive step. This specifically regards the "*Motiva SilkSurface*" samples sold before priority (i.e. 10 years earlier).

13. The assertions on which the Defendants base their R. 190 RoP application are:

(a) the *Motiva SilkSurface* was made available to the public without any restriction of confidence before the priority date of the Patent, i.e. 17 February 2014 (see section D paragraphs 60-64 and section H paragraphs 243-259 and 361 SoD-CC); and

(b) claims 1, 4, 7, 10, 11 and 13 of the Patent are invalid in light of the *Motiva SilkSurface* for lack of novelty (see section H paragraphs 241-387 SoD-CC) and/or inventive step (see section I paragraphs 507-527 SoD-CC).

(*Hereafter these assertions will be referred to as assertion (a) and assertion (b)*).

IV. LABS'S ARGUMENTS

14. LABS argues and structures its arguments as follows:

- The R. 190 RoP Application as such is "*premature*", "*circumvents the procedural framework*" and is "*disproportional*".
- The Defendant's assertion (a) and (b) are opposed.

- The specific requests as listed in primary order (I) do not meet the threshold to be granted.
- The auxiliary order (II) are opposed for the same reasons concluding that the R. 190 RoP Application also in its specific or reduced requests should be dismissed.
- Finally (and subsidiary to the above) the penalties and the temporary requirement of 14 days are objected to.

V. GROUNDS FOR THE DECISION

Preliminary remark regarding the extent of arguments put forward by LABS

15. Although the Court had requested LABS to bring forward *all* its arguments relating to the R. 190 RoP Application, it noted, in LABS's comments submitted on 30 March 2026, that LABS frequently mentions that it "*will supply its full reasoning, evidence and demonstration*", and/or "*further substantiate*" its position in its Reply to the Defence and Counterclaim, which is due on 24 April 2026 (hereafter referred to as "*Reply*").

16. As indicated in the Court's communication dated 24 March 2026, it will only take into consideration comments received and will not await LABS's position in its Reply.

V.A. Regulatory framework and application of this framework

17. In addition to the general principles set out in Art. 41(3) and 42 UPCA, the following legal framework is relevant in assessing the R. 190 RoP Application:

- Article 6 of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 (hereafter referred to as the "Enforcement Directive")

  "6. Member States shall ensure that, on application by a party which has presented reasonably available evidence sufficient to support its claims, and has, in substantiating those claims, specified evidence which lies in the control of the opposing party, the competent judicial authorities may order that such evidence be presented by the opposing party, subject to the protection of confidential information."
- Article 59 UPCA:

  "1. At the request of a party which has presented reasonably available evidence sufficient to support its claims and has, in substantiating those claims, specified evidence which lies in the control of the opposing party or a third party, the Court may order the opposing party or a third party to present such evidence, subject to the protection of confidential information. Such order shall not result in an obligation of self-incrimination.

  2. At the request of a party the Court may order, under the same conditions as specified in paragraph 1, the communication of banking, financial or commercial documents under the control of the opposing party, subject to the protection of confidential information."
- *Rule 172 RoP*

1. *Evidence available to a party regarding a statement of fact that is contested or likely to be contested by the other party must be produced by the party making that statement of fact.*
2. *The Court may at any time during the proceedings order a party making a statement of fact to produce evidence that lies in the control of that party. If the party fails to produce the evidence, the Court shall take such failure into account when deciding on the issue in question.*

- Rule 190 RoP:

"1. Where a party has presented reasonably available and plausible evidence in support of its claims and has, in substantiating those claims, specified evidence which lies in the control of the other party or a third party, the Court may on a reasoned request by the party specifying such evidence, order that other party or third party to produce such evidence. For the protection of confidential information the Court may order that the evidence be disclosed to certain named persons only and be subject to appropriate terms of non-disclosure."

V.B. Conditions to be met to grant a request for the production of evidence:

18. When assessing the R. 190 RoP Application, the Court must consider the following cumulative conditions (cf. LD The Hague Order of 14 October 2024 (*Winnow v Orbisk)*, §8 and further developed by case-law (if necessary cited later in this order):
    1. The requesting party must have presented evidence "*reasonably available*" in support of its claims;
    2. The evidence to which access is requested must be "*specified*" and lie in control of the other party;
    3. The other party's confidential information must be protected;
    4. (…) Any order to produce evidence must satisfy the requirements of proportionality, equity, and fairness.

    (Hereafter these conditions will be referred using the above numbering)

V.C. Assessment

19. The last condition (Condition 4: "*proportionality, equity, and fairness*") needs to be assessed on a double level in line with LABS's arguments:
    - Regarding the "*timing*" of the R. 190 RoP application *as such* and taking into consideration the stage of the proceedings as a general assessment (Condition 4(a)). One of the elements to be taken into consideration is the stage of the proceedings when the request to produce evidence was introduced (cf. CoA 24 September 2024, UPC_CoA_298,299,300/2024 (*Guangdong v Panasonic)* (headnote 3).
    - Regarding each individual request as a final assessment (Condition 4(b)).

V.C.1. Condition 4(a): The (alleged) premature nature of the R. 190 RoP Application

20. As its main defence, LABS argues that the R. 190 RoP Application is "*premature*", "*circumvents the procedural framework*", and is "*disproportionate at this stage of the proceedings*".

21. Neither the Enforcement Directive nor the UPCA nor the RoP set out a timeframe for submitting a R. 190 RoP Application that would render it (in)admissible. There is also no procedural framework indicating that such an application can only be introduced once all parties' arguments have been finalised.

As a general principle, once a R. 190 RoP applicant deems that the conditions are met, it can submit such application at any stage of the proceedings. The procedural path will then allow the respondent to comment, after which the Court will assess and decide on the application.

22. Although no timeframe has been set, it is clear that a R. 190 RoP Application could be dismissed if the Court deems it to be too early in the proceedings, based on the circumstances of the case.

Such a dismissal would be based on general principles of "*proportionality, equity and fairness*" and/or case management considerations, rather than on a specific time-related condition. This can be inferred from the case law to which LABS refers (LD Munich, 3 April 2025, UPC_CFI_846/2024, *Promosome v BioNTech*; and LD Mannheim, 20 October 2024, UPC_CFI_471/2023, *Dish v Aylo II*), in which the application was refused on the basis that it was unclear which facts needed to be proven, and whether the respondents would dispute the allegations in the reply.

23. None of these circumstances are present in the R. 190 RoP Application at hand:
- It is clear from the R. 190 RoP Application (juncto the SoD-CC) which facts need to be proven (cf. assertion (a) and (b)).
- LABS clearly states in its comments that the '"*allegations*" on which the Defendants base their application are "*not accepted*", indicating that they dispute the allegations and the assertions made. As previously mentioned, LABS intends to elaborate on this position in their Reply. However, the Court cannot consider this position as it needs to assess the R. 190 RoP application based on the comments that LABS was permitted to submit by 30 March 2026 at the latest (see §2, 15-16). Additionally, the Court notes that the Defendants base their application on LABS's position as set out in their comments, which states that "*(LABS) can address the application either by admitting the assertions above or by engaging with the substance of the application*". Clearly, LABS disputes the assertions put forward by the Defendants.

24. Taking into consideration the procedural efficiency of the UPC's proceedings (which aim to hold an oral hearing within one year, as set out in §7 of the Preamble to the Rules of Procedure (RoP)) and the time it is expected to take to test the requested samples, the Court does not consider it premature to assess the R. 190 RoP Application.

25. Concluding, the Court holds that condition 4(a) has been met.

V.C.2. Condition 1: Presentation of "*reasonable available evidence sufficient to support its claims*"

26. Where LABS (generally) holds that a party should "*first exhaust reasonably available avenues to substantiate their allegations*", the Court notes that this is neither explicitly provided in Article 59 UPCA nor in R. 190 RoP (see also LD Hamburg order of 1 November 2024, UPC_CFI_22/2023 (LD Hamburg), *10x Genomics v Vizgen (*section II.3). Further, the Court notes that LABS gives no indication which available avenues could and should be exhausted (as the evidence allegedly is not publicly available).

27. This assessment is based on a *prima facie* approach as it would be circular to demand conclusive proof of these assertions before ordering production of evidence that is relevant for establishing it. The evidence on which the Defendants base their assertions should therefore be based on "*reasonably accessible evidence*" (cf. LD Paris Order of 4 February 2026, UPC_CFI_583/2025, *Bostik v Henkel.* (at page 4).

28. The *prima facie* assessment of this condition is twofold (cf. LD Munich, order dated 3 April 2025, UPC_CFI_846/2024 (*Promosone v. BioNTech*) with reference to LD The Hague, order dated 14 October 2024, UPC_CFI_327/2024 (*Winnow v. Orbisk*)):
    (a) Did the Defendants present "*reasonable available"* evidence to support its underlying assertions (a) and (b)?
    (b) As an implied condition, could the requested evidence enable the Defendants to conclusively prove their assertions (a) and (b).

(i) *Sufficient proof of the underlying assertions (a) and (b)*

29. In relation to assertion (a) (specifically, the alleged fact that *Motiva's SilkSurface* (the two first generations) was made available to the public without restriction before the priority date of the Patent), the Defendants submit the following evidence:
- the timeline on numbered page 4 of the Motiva Catalogue dated 2019 (EXHIBIT GCA-19);
- the prospectus summary provided in LABS's S-1 registration statement filed with the US Securities and Exchange Commission on 21 June 2018, which states that: "*To date, most of our revenues have been generated from sales of our Motiva implants. We began selling Motiva implants outside the United States in October 2010* …" (page 1 of EXHIBIT GCA-2915); and
- a similar statement in LABS's 10-K for the fiscal year ended 31 December 2024: "*Since launching Motiva implants in October 2010, the majority of our revenue has been generated from sales of Motiva implants*." (see numbered page 4 of EXHIBIT GCA-3016) and
- another timeline from a Motiva Catalogue from 2024 (EXHIBIT GCA-31).

30. Further, the Defendants submit the following "*Pre-priority marketing of Motiva implants including the Motiva SilkSurface*":
- Motiva Implant Matrix Digital Product Brochure from June 2011 (EXHIBIT GCA-20);

- Motiva Matrix Implants Clinical Data Summary dated 15 January 2012 (EXHIBIT GCA-21 in Spanish with English machine translation at EXHIBIT GCA-22);
- Motiva Implant Matrix Product Performance Qualification Summary dated August 2012 (EXHIBIT GCA-32); and
- Motiva Implant Matrix Brochure dated 13 February 2014 (EXHIBIT GCA-33 in German with English machine translation at EXHIBIT GCA-34).

31. As LABS does not specifically or in detail contest the above, and as the Court holds that the Defendants have presented sufficient "*reasonable available*" evidence to prove assertion (a), the Court rules in favour of the Defendants.

32. With regard to assertion (b) and specifically the "*unusual parameters*" in the Patent that led to assertions of the lack of novelty and/or inventive step, the Defendants submit the following evidence:
- Motiva Matrix Implants Clinical Data Summary dated September 2015 (EXHIBIT GCA-39);
- "*A guide to the safety innovations of Motiva Implant Matrix*" brochure dated 23 September 2015 (EXHIBIT GCA-35);
- Preliminary 3-Year Evaluation of Experience with SilkSurface and VelvetSurface Motiva Silicone Breast Implants: A Single-Center Experience With 5813 Consecutive Breast Augmentation Cases, Sforza *et al*, Aesthetic Surgery Journal, online published 14 September 2017 (hereafter referred to as "*Sforza*") (EXHIBIT GCA-40);
- Six-Year Prospective Outcomes of Primary Breast Augmentation With Nano Surface Implants, Quirós et al, Aesthetic Surgery Journal, online published 13 November 2018 (hereafter referred to as "Quirós") (EXHIBIT GCA-41);
- "*The Science of Breast Tissue Management*" presentation (EXHIBIT GCA-13);
- Motiva catalogue from 2024 (EXHIBIT GCA-31);
- The norm ISO 14607:2009 Annex A (page 10 of EXHIBIT GCA-28)

33. In assessing "*prima facie"* condition (b) and specifically the "*unusual*" character of the parameter (not as such contested by LABS in its comments), the Court refers to mentioned Quirós and Sforza (post-published documents). Regarding the *Motiva SilkSurface*, which is allegedly produced, marketed and sold prior to the relevant priority date, the following data is published (presumably based on the aforementioned ISO 14607:2009 Annex A standard):

Surface parameters	
Area scale	**2 mm by 2 mm**
Sa (µm)	3.84
Ssk	0.4-0.6
Sz (µm)	53.24

Table 4: Motiva SilkSurface surface parameters

The mentioned tabled data is difficult to compare with Claim 1 of the Patent, where the reference area surface is different (or as the Defendants state "*unusual*"):

a) 1mm X 1mm
b) 90 µm x 90 µm
c) 10 µm x 10 µm
d) 1 µm x 1 µm

34. Although the Defendants rely on the surface data of their own product, "*Perle*" (i.e. the product accused of infringement), for comparison, as presented in the SoC (pages 61–62), the relevant table contains surface data measured on both the 2 mm × 2 mm scale and the area scales a), b), c) and d), which are relevant to claim 1. The Defendants have *prima facie* provided sufficient proof and calculations to demonstrate:

- the Sa values on the area scale a) 1mm X 1mm, deviate by ± 4% from the ISO-conform, 2mm x 2mm-based value; applying this range of deviation to the 2mm x 2mm-based value known for *Motiva SilkSurface* (3.84 µm), the predictable 1mm x 1mm-based value would range between 3.69-3.99, i.e. well within the claimed 1-20 µm range.
- Similarly, the Sa values on the area scale b) 90 µm x 90 µm deviate by ± 7% from the ISO-conform, 2mm x 2mm-based value; applying this range of deviation to the 2mm x 2mm-based value known for *Motiva SilkSurface* (3.84 µm), the predictable 90 µm x 90 µm-based value would range between 3.57-4.11, i.e. well within the claimed 0.1-5 µm range.

The Court notes that a similar approach and prediction is presented for the SsK (claim 4) and Sz (claim 7) parameters. This is considered sufficient *prima facie* proof that, in those cases, the predicted data for the (allegedly pre-priority) *Motiva SilkSurface*, calculated on the corresponding claimed area scales, fell within the terms of claims 4 and 7.

35. As LABS does not specifically or in detail contest the above, and as the Court holds that the Defendants have presented sufficient "*reasonable available*" evidence to prove assertion (b) , the Court rules in favour of the Defendants.

36. In conclusion, the Court is sufficiently *prima facie* convinced, that the Defendants have presented evidence that is reasonably available and plausible in support of both assertions.

(ii) *Could the requested evidence assist the Defendants to conclusively prove their assertions?*

37. The threshold is considered to be low. The LD Hamburg (cf. *10x Genomics v. Vizgen*) stated that the requests should be addressed collectively, in the sense that not every piece of requested evidence should be assessed based on whether it allows a "*direct conclusion*", and that "*a review of the documents as a whole may reveal arguments for or against*". Furthermore, as the requested information is not yet available, it is premature to definitely assess its effectiveness in conclusively proving an assertion. Therefore, in their assessment, the Court should use again a *prima facie approach*".

38. When applying the above to the actual request for the production of specific evidence, the Court holds as follows:

Request I.a *"Motiva SilkSurface sales figures: (…)*
Related to assertion (a)

39. In their comments, LABS argues that these figures would not support the Defendants' assertion (b), as they claim that such figures "*do not constitute public disclosure of the technical features as claimed in the patent*". However, this is not the argument made by the Defendants. The Defendants sufficiently, *prima facie*, convince the Court that this evidence could conclusively prove assertion (a).

Request I.b *"Physical samples manufactured before the priority date (…)*
Related to assertion (a) and (b)

40. The Court holds that this information could indeed enable the Defendants in conclusively proving assertions (a) and (b), as every sample should be accompanied by a production date. Making available for analysis the requested physical samples of the products released to the public before priority (and more specifically the former generations manufactured before the priority date (insofar as the claimed parameters were not commonly measured at the priority date) is *prima facie* considered by the Court an important source of information required.

Request I.c *Physical samples manufactured after the priority date: (…)*
Related to assertion (b)

41. Although the Defendants were able to retain three samples of the first- and second-generation *Motiva SilkSurface* (The Round and The Round Plus respectively – see §10), all of these samples have a production date after the priority date (see table SoD-CC §330). The Defendants state that additional samples would be necessary in case LABS *might* argue that the samples obtained are not representative of their products, and/or in case LABS *might* argue that samples manufactured before the priority date have degraded and are therefore not representative of LABS's products before the priority date.

42. Although LABS made this last argument before the EPO (Exhibit GCA-68), the Court cannot be certain that it will be used in these proceedings. Therefore, the Court holds that this request will not aid the Defendants any further, given the similar evidence they already have at their disposal and subsequently dismisses this request.

43. Should LABS submit above arguments later in these proceedings (and based on changed conditions), the Defendants could reintroduce this request.

Request I.d *"Promotional and marketing materials: (…)*
Related to assertion (a) and (b)

44. The Defendants sufficiently *prima facie* demonstrate that the requested materials might assist to verify that the *Motiva SilkSurface* was disclosed to the public before the Patent's priority date. These materials will clarify which aspects of the *Motiva SilkSurface* were common general knowledge, based on the fact that the skilled person would have been aware of public information about the latest generation of breast implants on the market at the Patent's priority date, including the *Motiva SilkSurface* (see section D, paragraph 46, SoD-CC).

Request I.e *Third-party test reports: (…)*
Related to assertion (b)

45. The Defendants sufficiently *prima facie* demonstrate that these test reports may contain information relating to the surface topography of the *Motiva SilkSurface*. More specifically, the Defendants sufficiently *prima facie* convince the Court that the testing material is relevant to disclosing the *Motiva SilkSurface* at the priority date in the context of the Patent's claims, and as such it might help the Defendants conclusively prove assertion (b).

46. That such evidence could assist in the assessment to be made by the Court is implicitly confirmed by LABS where it states on p. 7 of its comments that it will in its Reply provide all relevant information and evidence necessary to substantiate its case "*including any references to third-party testing such as the testing report carried out by Manchester University and the LNE Test Report Documents that the Defendants allege are material to the issues in dispute*".

Request I.f *Technical specification documents: (…)*
Related to assertion (b)

47. The Defendants sufficiently *prima facie* convince the Court that LABS' technical documentation on surface topography parameters, relevant to the disclosure of the *Motiva SilkSurface* at the patent's priority date, might aid them prove assertion (b) conclusively.

Request I.g *Claimant's performance qualification report and performance specifications: (…)*
Related to assertion (b)

48. The Defendants sufficiently *prima facie* convince the Court that LABS's internal performance specifications and internal product performance qualification report, relevant to the disclosure of the *Motiva SilkSurface* at the priority date of the Patent, might assist them in conclusively proving assertion (b).

Request I.h *European regulatory documentation: (…)*
Related to assertion (a) and (b)

49. The Defendants state that LABS sought CE mark approval for its *Motive SilkSurface* in 2011 (see p.5, Exhibit GCA-19). At that time, the key regulatory requirement for soft tissue (breast)

implants in Europe appeared to be Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (hereafter referred to as the "*Medical Device Directive*"). To affix a CE mark to a Class III medical device product, a manufacturer had to follow the procedure set out in Annex II ("*full quality assurance*") or, alternatively, the procedure set out in Annex III (coupled with supplementary documentation). Both Annexes II and III set out the technical documentation required to be submitted, as well as documentation retention requirements. Since 26 May 2021, the key regulatory requirement for soft tissue (breast) implants in Europe has been the EU Medical Device Regulation (Regulation 2017/745) (hereafter referred to as the "*Medical Device Regulation*"). As part of the Medical Device Regulation's transitional provisions and the phase-out of the old Medical Device Directive, Class III medical devices (including breast implants as implantable devices) that obtained a CE certificate of conformity under the Medical Device Directive can be placed on the market until 31 December 2027, provided they continue to comply with the previous Medical Device Directive and there have been 'no significant changes in the design and intended purpose' of the device (Article 120(3c) of the Medical Device Regulation). The Medical Device Regulation stipulates new conformity requirements, i.e. the technical documents that must be provided to obtain CE mark certification for a Class III medical device. The Medical Device Regulation also contains document preservation requirements (Article 10(8)), for which the same 15-year preservation period applies to implantable devices as per the Medical Device Directive.

The Defendants hold that, despite the change in governing regulations since Motiva implants were first launched in Europe, a regulatory requirement to retain documents submitted for the conformity assessment that justified the issue of the relevant CE mark certification has been in place at all material times. This certification is required to place the implants on the European market. The Defendants, therefore, *prima facie* convincingly argue that the content requirements of these documents are similar under both regulatory regimes and that the retention period for these documents is the same under each regime (i.e. 15 years).

Therefore, the Defendants *prima facie* convincingly argue that the documents should be retained by LABS for every generation of breast implant, as the first-generation implants that used the *Motiva SilkSurface* were manufactured and made available until at least 2012, when the second-generation products were introduced — less than 15 years ago.

LABS does not seem to dispute the above regulatory framework and the obligations which should be met to apply a CE-mark on breasts implants.

50. Furthermore, the Defendants *prima facie* convincingly argue that, under both the Medical Device Directive and the Medical Device Regulation, a manufacturer must seek re-approval for a product if they make any changes to its design that impact its intended use, safety or performance. This is because the certificate of conformity issued to the manufacturer in relation to a given product must be updated to reflect these changes (see Annex II, section 4.4 and Annex III, section 6 of the Medical Device Directive, and consequently Annex IX, chapter II, section 4.10 and Annex X, section 5 of the Medical Device Regulation) , the Defendants

presume that, if LABS has made any such changes to the *Motiva SilkSurface* since obtaining CE certification in 2011, it would have been required to submit the relevant documentation for a new conformity assessment, explaining the changes made, in order for the Motiva implants to be reassessed. The Motiva implants are high-risk Class III medical devices which are stringently assessed for patient safety and are subject to tightly prescribed conditions in the EU. The Defendants also refer *prima facie* convincingly to the claims made by LABS concerning the importance of its surface properties. See section H, paragraphs 260–266 and 362, and Table 3 of the SoD-CC. It is clear that LABS's position is that any change to the surface properties would have the potential to impact the intended use, safety, or performance of the Motiva implants and would therefore require re-assessment for certification under the relevant regulations. Accordingly, the Defendants *prima facie* convincingly hold that, contrary to their assertion (see section H, paragraphs 325–328 of the SoD-CCS), if the surface topography of the Motiva implants, including *Motiva SilkSurface*, has changed at any time since LABS first obtained CE certificates in 2011, then LABS would possess applications highlighting these changes and seeking certification for the changed Motiva implants to be sold.

The only argument that LABS puts forward in its comments dated 30 March 2026 is that it "*disputes the assumptions*" regarding the alleged "*change to product design or surface characteristics*" (p. 10). However, this seems to contradict its earlier argument on page 6, where it stated that it "*implemented changes after the priority date, which resulted in implants exhibiting different surface characteristics, including features falling within the scope of the asserted claims*".

51. Based on the above regulatory framework, the Defendants sufficiently *prima facie* convince the Court that accessing the regulatory documents (available for all generations of implants using *Motiva SilkSurface* technology) might assist them to conclusively prove assertions (a) and (b).

Request I.i *Design History File (surface topography records): (…)*
Related to assertion (a) and (b)

52. The Defendants have provided *prima facie* sufficient evidence to convince the Court:

- That, in accordance with common industry practice and the requirements set out in the international ISO standards referred to below, LABS is expected to have a Design History File ('DHF') or an equivalent file or record-keeping system for each generation of its Motiva implants, including the *Motiva SilkSurface*.
- That the DHF (or equivalent) will include the documents that LABS must record in relation to the design and development of the Motiva implants under section 7.3 of ISO 13485:2016 (Exhibit GCA-71). ISO Standard 13485 (2016) governs the quality management systems of medical device manufacturers (this standard was also in place prior to the priority date of the patent (see Exhibit GCA-72)). Section 7.3 lists a number of design and development documents that a manufacturer must maintain to ensure compliance with the standard.

Manufacturers are required to retain these documents and records for the time period stipulated in sections 4.2.4 and 4.2.5 of the ISO standard, i.e. the lifetime of the medical device.

- That, referring to the product lifetime of its Motiva implants as 10–20 years, LABS will have retained documents relating to all generations of Motiva implants containing the *Motiva SilkSurface* (also known as *SmoothSilk*) for this period (see the LABS website here: https://surgeonssupport.motiva.health/hc/en-us/articles/4408672422675-How-long-do-Motiva-Implants-last).
- That section 7.3.9 of the 2016 version of the ISO 13485 standard (see also section 7.3.7 of the 2012 version of the standard) states that where a design and/or development change has been made to a medical device, records relating to the change must be produced and subsequently retained in accordance with the time periods stipulated in section 4.2.5. Therefore, the Defendants hold that should LABS have changed the design of the Motiva implants, including the *Motiva SilkSurface*, at any point since they were first marketed, they would be required to produce documents to establish the extent of any such design changes and retain them for the stipulated time periods.

53. Based on the above, the Defendants sufficiently *prima facie* convince the Court, that access to the design history file, which is deemed available for all generations of implants using *Motiva SilkSurface* technology, could aid them to conclusively prove assertions (a) and (b).

V.C.3. Condition 2: the evidence to which access is requested must (a) be "*specified*" and (b) lie in control of the other party

54. These assessments are limited to the "*Physical samples manufactured before the priority date"* (request I.b) and *"Physical samples manufactured after the priority date: (…)"* (request I.c). For all other request (I.a and I.d through I.i), LABS does neither argue that the requested evidence is not sufficiently specified (except for which it argues that it is too broad – see §64) nor that the requested evidence is under its control.

Request I.b "Physical samples manufactured before the priority date: (…)

55. LABS only argues that these samples are not under its control as allegedly destroyed. Specifically, LABS holds that "*in accordance with its standard product retention policies implant samples are not retained indefinitely*". LABS further states that "*(LABS's) policy is to destroy implant samples after a period of five years*" to conclude that no samples relating to products sold exist within LABS's possession, custody or control that pre-date the priority date of the Patent.

56. As R. 284 RoP obliges representatives not to "*misrepresent cases or facts before the Court, either knowingly or with good reason to know*", the Court should in principle accept this representation as true. However, the Court holds that, due to the absence of sanctions for failing to comply with mentioned obligation, as well as a lack of evidence regarding the

referred LABS policy and proof of the actual destruction of the samples, it has no certainty whether these samples are indeed not available anymore.

57. That being said, the Court will accept (in application of Rule 172.2 RoP) two witness statements from duly authorised officers of LABS which is acquainted with the above indicated relevant facts confirming the above, and specifically stating the actual unavailability and as such not having possession, custody or control over any of the requested for samples.

Such statements should be in line with R. 175 RoP, and specifically include that the witnesses "*are aware of their obligation to tell the truth, and of their liability under applicable national law in the event of a breach of this obligation*".

Request I.c Physical samples manufactured after the priority date: (…)

58. As this request was denied above (see §41-43), the Court should no further assess the sufficient specification and/or the fact whether these samples are under the control of LABS.

V.C.4. Condition 3: Protection of Confidential Information

59. In its comments, LABS refers to the fact that some of the requests made (specifically those under I. (f)–(h)) would involve making confidential internal documents available. LABS seems to deduce that they should therefore not be produced. However, the UPC's legal framework (specifically R. 262A RoP) allows parties to share confidential information that may be relevant to infringement and validity proceedings. Simply stating that information is confidential and internal is insufficient to deny a request for evidence to be produced.

60. The Defendants are aware of the confidential nature of some of the evidence which they request to be produced by LABS. For this reason, the Defendants are willing to be subjected to a strict confidentiality regime to limit access. They propose to limit access to the to be produced (confidential) documents and samples to (i) the legal team representing the Defendants in these proceedings and (ii) independent experts assisting the Defendants and (iii) one natural person employed by Defendants, subject to appropriate terms of non-disclosure.

61. As such, confidentiality appears to be secured, although a separate order regarding this will need to be issued, including the personal details of the independent experts (ii) and the natural person (iii). For this reason, requests for the production of evidence will be granted conditional on the submission of these details by the Defendants, and subsequently on the agreement of LABS, or, if disputed, on a confidentiality order. The Defendants are requested to submit mentioned details before 20 April 2026 (6pm CEST).

62. LABS has the option of requesting R. 262 RoP confidentiality, should it wish to do so.

V.C.5. Condition 4(b): "*proportionality, equity, and fairness*" of each individual request

63. In addition to the assessment of this condition in relation to the R. 190 RoP Application *as such* (see §20-25) and the conditions that have already been evaluated above, LABS asserts that several requests are disproportionate. LABS generally argues that allowing the requests to be granted would shift the burden of proof and would therefore be disproportionate. However, the Court cannot agree with such approach based on the principles of procedural loyalty, the fact that LABS disputes the assertions (a) and (b), the obligation stipulated under R. 172 RoP, and the fact the Defendants seek access to evidence which is under the control of LABS and therefore not publicly available.

64. LABS (secondary to its main argument) argues that the specified requests are too broad but fails to put forward detailed arguments which limitation of the requested information would suffice. Reference can be made to:

- request I.d. where LABS holds it "*does not consider it appropriate or proportionate to produce all versions of marketing and promotional materials, in multiple languages which may not be relevant to the dispute in this case*" without indicating what it would consider "*appropriate and proportional*". As such the Court, who can maybe argue *ex officio* whether a request is "*appropriate and proportional*" as a whole, is not in a position to assess which version in which language could be relevant.
- Request I.f. where LABS holds that seeking "*all versions of technical documentation across multiple generations of products, without temporal limitation and regardless whether these documents are relevant to any properly defined issue in dispute*". Where the Court already assessed why such information (across several generations) might aid the Defendants to conclusively prove its assertions (a) and (b), the Court is not given any information which "*versions*" would to allow the Defendants to conclusively prove their assertions. Therefore, the Court cannot access which version would be appropriate and proportional without input from LABS to this regard.
- Request I.g. where LABS, once again, seems to argue the appropriate and proportional nature of the request (referring to "*all versions*") without providing information to the Court which version would be held appropriate and proportional.
- Request I.g. where LABS points at the extreme broadness in scope of the request. The Court has already accessed why these documents may be necessary to allow the Defendants to conclusively prove their assertions (a) and (b), and has no input which specific document overreach the limits of appropriateness and proportionality.
- Request I.h. where LABS states that the Defendants have failed to argue (and prove) why such facts cannot be addressed by the requested intrusive means. However, it is up to LABS to indicate which less intrusive means could be used by the Defendants to prove the assertions.

65. The lack of more concrete (secondary) arguments to assess the requirements of *proportionality equity and fairness* is balanced by the absolute discretionary power of the Court to grant or not the requested measures. However, in case of doubt and due to the lack

of concrete (secondary) arguments by LABS, preference should be given to the actual requested measures.

66. However, as indicated above, several requests cover the respective assertions (a) and (b), meeting conditions 1–3 (with the exception of I.c not meeting condition 1 – see §41-42).

Taking into consideration the general and overriding conditions of "*proportionality equity and fairness*" and, more specifically, in view of the burden that LABS may encounter in having to comply with all granted requests (and this for which conditions 1-3 are met), it is held proportional to allow the granted requests based on the actions of LABS when complying to this order. The grant is therefore based on the position which LABS will take when complying with the order:

(a) Should LABS comply with request I.b (to this end the physical delivery of samples is absolutely necessary) and declare that the *Motiva SilkSurface* of the first and/or second generation represented by the samples as listed in the table of the SoD-CC (§330) were publicly available without confidentiality restrictions before the priority date of the Patent, the remaining requests are considered to be disproportional.

(b) Should LABS comply with request I.b (to this end the physical delivery of samples is absolutely necessary) but not declare that the *Motiva SilkSurface* of the first and/or second generation represented by the samples as listed in the table of the SoD-CC (§330) were publicly available without confidentiality restrictions before the priority date of the Patent, the requests I.a, I.d, I.e, I.f, I.g, I.h and I.i are not considered to be disproportional and should be complied with.

(c) Should LABS not be able to make available physically to the Defendants the requested samples under request I.b and only would comply with this request by submitting witness statements (see §57), the requests I.a, I.d, I.e, I.f, I.g, I.h and I.i are not considered to be disproportional and should be complied with.

67. Finally, LABS argues that the requests made are disproportionate given the timeframe (14 days) for producing all the requested evidence. LABS refer to the breadth of the requests, the need to review and potentially redact confidential information, and the ongoing preparation of the Reply. The Court agrees that the Defendants have created an imbalance, especially given that their SoD-CC dates from 16 February 2026, leaving more than one month between submitting the SoD-CC and this Application. This delay indeed puts LABS in a position where complying with this order could reasonably interfere with the time allocated for preparing and submitting the Reply.

On the other hand, as assessed above, LABS already has under its control all the requested evidence which met the above conditions, so complying with the order within a relatively short timeframe (without endangering the intended pleading date) is not unreasonable. Further, it is considered procedurally efficient to already make the necessary preparations to comply with the order from the date the Application was introduced (i.e. 20 March 2026).

Taking into consideration the above, the deadline for complying with the order is set at 21 days from the date of issuance of this Order.

68. If this term endangers the Defendants' ability to submit subsequent submissions (especially, but not limited to this circumstance, if testing is necessary), they have the right to request an extension of the term (R. 9 RoP), which will follow the usual procedural path before being granted or rejected.

V.D. Penalties

69. An order or decision may provide for periodic penalty payments (cf. Art. UPCA 82(4) and R. 354.3 RoP) if LABS fails to comply with the terms of the order. The penalty amount that may be forfeited shall be set by the Court, considering the importance of the order in question. This amount should be sufficiently deterrent to be coercive, but also within reasonable limits for it to be an appropriate (proportionate) penalty – CoA, 14 October 2025, UPC_CoA_699/2025.

70 The Court considers it necessary and appropriate to impose such a penalty to ensure that LABS complies with the obligation to provide the requested evidence.

71. LABS states that it objects to any recurring penalty for non-compliance with this order, yet it fails to put forward any arguments in this regard.

72. The Court, based on proportionality and equity, hold a recurring penalty in the amount of € 2.000 for each day of delay beyond the deadline as stipulated and ordered by the Court for LABS to produce the evidence.

V.E. Costs of the procedure

73. The costs for this procedure will be assessed together with the costs to be determined following a decision on the merits in both actions.

VI. ORDER

The Court

I. Orders LABS pursuant to Art. 59 UPCA and R.190 RoP, to produce to the Defendants, within 21 days of the issuance of this Order the requests made as "*Primary Order*" (with the exception of I.c and an adjustment to request I.b). As such the following evidence should be produced:

I.a. *Motiva SilkSurface sales figures: total sales volumes for all countries where any generation of Motiva implant including the Motiva SilkSurface has been sold, from first launch until the priority date of the Patent. To the extent that all of these sales are said by (LABS) to be subject to confidentiality arrangements, LABS is to provide the documentation underlying the claim to confidentiality in each instance;*

I.b. *Physical samples manufactured before the priority date: three physical samples (or two, if three are not available; or one, if two are not available) of each generation of Motiva implant including the Motiva SilkSurface which was manufactured before the priority date of the Patent, together with documentation confirming the manufacturing date of each sample provided;*

Should LABS not be able to produce such samples, LABS should submit two witness statements from duly authorised officers of LABS which are acquainted with the relevant facts confirming and stating the actual unavailability and as such LABS not having possession, custody or control over any of the requested for samples.

I.d. *Promotional and marketing materials:*

i. *all versions (in all languages) of the Motiva Implant Matrix Digital Product Brochure subsequent to Exhibit GCA-20 that were made available to the public before the priority date of the Patent;*

ii. *all versions (in all languages) of the Motiva Implant Matrix Product Performance Qualification Summary, other than Exhibit GCA-32, that were made available to the public before the priority date of the Patent (including the version dated August 2012 referred to in paragraph 253 of the Statement of Defence and Counterclaim for Revocation and the version dated January 2014 referred to in Exhibit GCA-69);*

iii. *all versions (in all languages) of the Motiva Matrix Implants Clinical Data Summary, other than Exhibit GCA-21, that were made available to the public before the priority date of the Patent;*

iv. *all versions of any Motiva implant product brochure, directed to patients and/or surgeons, that refers to the Motiva SilkSurface, that were made available to the public before the priority date of the Patent;*

I.e. *Third-party test reports: the following documents which are referred to by LABS in its own materials (see: i. and ii.); and / or referred to by (LABS) in its own correspondence with the United States Patent Office (concerning US patents US10595979 and US11890179) between 2016 and 2021 (see: iii. and iv.):*

i. *Laboratoire National de Métrologie et d'Essais: Mechanical characterization of Motiva Implant Matrix Silicone Breast Implants Test-file L050836-28/MAY/2010 (see pages 4 and 6 of Exhibit GCA-32);*

ii. *characterisation and testing report carried out by the group at Manchester University referred to on page 2 of Exhibit GCA-39 and pages 4 and 5 of Exhibit GCA-35;*

iii. *the Manchester University test report entitled "Implant Surfaces Analyzed" produced in 2012 in relation to Motiva implants manufactured between October 2011 and May 2012 (see Exhibit GCA-27 and Exhibit GCA-70);*

iv. *the LNE Test Report Documents (i.e., File L050836 – Documents DE/2, DE/3, and DE/4, each dated 8 December 2010) reporting testing conducted between 20 August 2010 and 22 October 2010 on Motiva implants (see Exhibit GCA-27 and Exhibit GCA-70);*

I.f. *Technical specification documents: all technical specification documents and/or product specification sheets (in all languages) for each generation of Motiva implant including the Motiva SilkSurface, manufactured both before and after the priority date of the Patent to the extent that they specify any of the following surface topography parameters:*

i. profile roughness (Ra);
ii. mean surface roughness (Sa);
iii. mean surface skewness (Ssk); or
iv. maximum peak height to trough depth (Sz);

I.g. Claimant's performance qualification report and performance specifications: all versions (in all languages) of the following internal performance specifications and internal product performance qualification report:
i. VAL-001.R Motiva Product Performance Qualification Report (based on LNE-Laboratoire National de Métrologie et d'Eessais, Trappes, France: Mechanical characterization of Motiva Implant Matrix® Silicone Breast Implants Test Report – file L050836- 28/MAY/2010) (see pages 4 and 5 of Exhibit GCA-32);
ii. VMP-001: Establishment Labs S.A. Validation Master Plan (see page 6 of Exhibit GCA-32);
iii. QP-001: Motiva Round Implants Quality Plan (see page 6 of Exhibit GCA- 32)
iv. VAL-003: Motiva Round Implant Product Performance Qualification Protocol (see page 6 of Exhibit GCA-32).

I.h. European regulatory documentation: all documentation submitted by (LABS) to support its applications for certification for its Motiva implants submitted under the Medical Device Regulation and / or Medical Device Directive, including its first application for certification in 2011 and any subsequent material submitted in respect of this certification or any re-certification, to the extent that those documents refer to any surface topography parameters of the Motiva SilkSurface. For the avoidance of doubt, this request includes any material submitted in accordance with the regulatory regime under the Medical Device Regulation and / or Medical Device Directive relating to a change in the surface topography parameters of the Motiva SilkSurface in any generation of Motiva implant before or after the priority date of the Patent; and

I.i. Design History File (surface topography records): all sections of (LABS)'s Design History File (or equivalently named file or record keeping system) for each generation of Motiva implant including the Motiva SilkSurface both before and after the priority date of the Patent, to the extent that these refer to any surface topography parameters of the Motiva SilkSurface, including those that refer to any changes in the design or development of the Motiva SilkSurface.

II. Allows LABS to lesser her burden to produce the requested evidence as follows:

(a) Should LABS comply with request I.b (to this end the physical delivery of samples is absolutely necessary) and declare that the *Motiva SilkSurface* of the first and/or second generation represented by the samples represented by the samples as listed in the table of the SoD-CC at §330 were publicly available without confidentiality restrictions before the priority date of the Patent, the remaining requests are considered to be disproportional and can be dismissed.

(b) Should LABS comply with request I.b (to this end the physical delivery of samples is absolutely necessary) but not declare that the *Motiva SilkSurface* of the first and/or second generation represented by the samples represented by the samples as listed in the table of the SoD-CC at §330 were publicly available without confidentiality restrictions before the priority date of the Patent, the requests I.a, I.d, I.e, I.f, I.g, I.h and I.i are not considered to be disproportional and should be complied with.

(c) Should LABS not be able to make available physically to the Defendants the requested samples under request I.b and only would comply with this request by submitting

witness statements mentioned under (1), the requests I.a, I.d, I.e, I.f, I.g, I.h and I.i are not considered to be disproportional and should be complied with.

III. Orders LABS to produce and provide a witness statement from a duly authorised officer of (LABS) or a person fully acquainted with the relevant facts (including in relation to the identification / production of relevant samples), verified by a statement of truth, within 14 days of the Order, to confirm that:
   a. the provisions of the Order have been complied with in full; and
   b. any redaction that has been applied to a document concerns only information that is irrelevant to the terms of the Order and is confidential.

IV. Orders LABS to pay a recurring penalty payment to the Court in the amount of € 2.000 for each day of delay beyond the deadline as stipulated and ordered by the Court for (LABS) to produce the evidence to be submitted in compliance with (I).

V. Conditions the above consecutive grants on the submission of details by the Defendants regarding the personal details of the independent experts and the natural person to be granted access to the unredacted version of the evidence submitted and this before 20 April 2026 (6pm CEST), upon which (after following the set procedure) a R. 262A RoP order will be issued by the Court.

VI. Assessment of the costs for this procedure will be assessed together with the costs to be determined following a decision on the merits.

VII. Stipulates that if LABS fails to comply with this order, the Court shall take such failure into account when deciding on the actions in question (R. 190.7 RoP).

Issued by the panel of the LD Brussels on 14 April 2026

Samuel GRANATA Judge-Rapporteur Presiding Judge LD Brussels Legally Qualified Judge	Samuel Rocco M Granata Digitally signed by Samuel Rocco M Granata Date: 2026.04.14 08:55:20 +02'00'
Carine Gillet Legally Qualified Judge	Carine Gillet 2026.04.13 14:42:39 +02'00'
Marije Knijff Legally Qualified Judge	Marije Knijff Digitaal ondertekend door Marije Knijff Datum: 2026.04.13 15:52:51 +02'00'
Paolo Gerli Technically Qualified Judge	PAOLO GERLI Firmato digitalmente da PAOLO GERLI Data: 2026.04.14 08:49:34 +02'00'

Information on Appeal

An appeal may be lodged in accordance with Art. 73 UPCA and R. 220.2 RoP (R. 158.3 RoP).