Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Brussels - Local Division

UPC_CFI_1357/2025
UPC_CFI_629/2025

Order II (R.190 RoP)
of the Court of First Instance of the Unified Patent Court
Issued on 26 June 2026
Concerning EP 3 107 487 B1

HEADNOTES

In parallel national and UPC proceedings and based on the circumstances of the case, the UPC should endeavour as much as possible to align the means for obtaining evidence and specifically the submitted requests (in the UK, based on common law, in disclosure proceedings and at the UPC based (i.a.) on R. 190 RoP). Such alignment of requests will lead to a common evidence basis when assessing the infringement action and/or counterclaim for revocation and/or separate invalidity action. This approach is dictated by procedural efficiency and proportionality, balancing the respondent's burden of submitting evidence with the applicant's right to obtain it.

KEYWORDS

Application to produce evidence (R. 190 RoP)
Parallel proceedings UPC and third countries

APPLICANTS R. 190 ROP APPLICATION II
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
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Hereafter referred to as: Collectively as "*Defendants*"

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

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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

1. On 30 October 2025, LABS submitted its Statement of Claim (serviced to all Defendants on 14 November 2025).

2. On 16 February 2026, the Defendants submitted their Statement of Defence including a Counterclaim for Revocation.

3. On 20 March 2026 the Defendants submitted their first "*Evidence Production Request*" (hereafter "*Application I*"). Subsequently, on 14 April 2026, the Court issued a R. 190 RoP order (hereafter "*Order I*") with the following operative part:

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).

4. On 24 April 2026, LABS submitted its "*Defence to Counterclaim and Reply to Infringement Defence*" including an "*application to amend patent*".

5. On 5 May 2026, LABS produced the material which it believed to be in line with Order I. More concrete, LABS produced the seven categories of evidence to the Defendants, in the form of an electronic upload of various documentary materials to the CMS and by transporting three physical implant samples to the offices of the Defendants' legal representatives.

6. On 4 June 2026, the Court issued an order in application of R.263.3 RoP and R. 361 RoP in which (i.a.) the Court granted LABS leave to limit its claims and specifically "*by no longer pursuing a claim for infringement by Defendants 1, 2, 4 and 10 (GC Aesthetics ParentCo Limited, Nagor Limited, GC Aesthetics (Distribution) Limited and Global Consolidated Aesthetics (UK) Limited, respectively, for infringing acts in the UK*" and granted the Defendants leave to limit its counterclaims pertaining to the same territory. These grants were based on GC Aesthetics (Brazil) Ltd (a member of the GCA corporate group) initiating UK revocation proceedings on 16 February 2026 against LABS.

7. In the main proceedings (infringement action and counterclaim), for which the oral hearing is set on 2 December 2026, the Defendants will have to submit their "*Rejoinder to Reply and Reply to Defence to Counterclaim*" on 30 June 2026

8. On 16 June 2026, the Defendants introduced a second R. 190 RoP request (hereafter referred to as "*Application II*"). The Court notes that where it requested LABS to comment on Application II by 22 June 2026, the Defendants submitted the same day a response to these comments.

9. A hearing concerning disclosure requests was listed on 23 June 2026 in the parallel UK disclosure proceedings. In LABS's opinion, this hearing substantially overlaps with a number of the categories raised in Application II. Parties were therefore given the opportunity to inform the Court on 24 June 2026 regarding the outcome of the UK disclosure hearing.

10. On 24 June 2026, the Court was informed as follows:
    - The parties in the UK disclosure proceedings reached a compromise on the terms of the order for specific disclosure in the UK.
    - The UK disclosure hearing was used to confirm the position taken by the parties.
    - A copy of the Order and the Confidential Annex 1 was uploaded in the CMS.

11. On 24 June 2026, the Defendants sent two letters to the court.. In the first, they submitted further arguments to the Court regarding Application II and indicated, in the light of the development in the case, that they wished to amend their request in relation to Category B (see hereafter § 14). In a second letter of the same day, the Defendants further amended their request in relation to Category C (by deleting Category C (ii))(see hereafter § 14).

12. In their letter dated 24 June 2026, LABS informed the Court regarding the UK proceedings and additionally as a response to the position held by the Defendants further counter-argued the requests.

II. PARTIES' REQUESTS AND ARGUMENTS

13. In Application II the Defendants request as follows:

PRIMARY ORDER

67. Pursuant to Art. 59 UPCA and R.190 RoP, the Claimant 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 the Claimant'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 the Claimant).

CATEGORY A

i Further sample of the pre-priority Motiva SilkSurface product in its original blister pack that was identified further to the First Order

CATEGORY B

i. Any and all testing data and documents, referring to surface properties, that relate to implants manufactured from the "gen 1" mould referred to and identified in WO 2017/196973 A2

ii. All correspondence and other documents (including but not limited to work products, reports and testing data) passing between Establishment Labs S.A. and The University of Manchester or anyone affiliated with the University of Manchester, and / or such documents which passed internally between personnel at Establishment Labs S.A., relating to the University of Manchester data sheet dated 31 October 2016 which compares Motiva SilkSurface with the Patent (LABS190-4-09)

iii. All correspondence and other documents (including but not limited to work products, reports and testing data) passing between Establishment Labs S.A. and The University of Manchester or anyone affiliated with the University of Manchester, and / or such documents which passed internally between personnel at Establishment Labs S.A., relating to the collaboration project between Establishment Labs S.A. and the University of Manchester

CATEGORY C

i. All available further clinical follow up reports i.e. those following on from the LABS190-3-05 to LABS190-3-07 reports entitled "Motiva Matrix Implants Clinical Data Summary" for years 1, 2 and 3 respective

ii. All documentation describing all versions of the workmanship standard (referred to as WS-008), as referred to in LABS190-5-12 and in LAB190-5-09 dated 11 June 2015, including but not limited to: (i) all versions of the standard itself and (ii) all versions of the "workmanship standard control log"
referred to as LIS-033 including, but not limited to, the version in place at 10 January 2014 (LABS190-5-06.1) and revised on 29 May 2015 from a prior 9 March 2015 version (LABS190-5-03)

CATEGORY D

i. LNE - Test Report L050836 – DE/1

ii. Colour versions of each of LABS190-4-04, LABS190-4-05, LABS190-4-06, LABS190-4-07 and LABS190-4-08

iii. Any and all change-control documentation in relation to the process of manufacture of implants with the Motiva SilkSurface (including but not limited

to references to shell surface molds), including, where applicable, details of any design change (in compliance with §7.3.9 and §4.2.5 of the ISO standard 13845 (2016))
iv. The documents referred to by cross references 55 and 60 on page 18 of LABS190-7-03
v. A complete copy of the table at page 23 of LABS190-7-03, including the column and row headings

AUXILIARY ORDER (in the event the Court does not grant the Primary Order in full)

68. *In the alternative, if the Court is not minded to grant the production of all the categories listed at paragraph 67, 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.*
69. *In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER, the Claimant is to provide a witness statement from a duly authorised officer of the Claimant 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.
70. *In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER, the Defendants seek a recurring penalty payment to be made by the Claimant to the Court of up to EUR 2,000 for each day of delay beyond the deadline as stipulated and ordered by the Court for the Claimant to produce the evidence as categorised above.*
71. *In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER, access to the evidence including documents is limited to the Confidentiality Circle as imposed under the Court's Confidentiality Order dated 23 April 2026:*
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.
72. *In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER, an appeal to the order to produce evidence may be brought by the Claimant in accordance with Article 73 UPCA and Rule 220.1 RoP.*
73. *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.*
74. *In relation to both the PRIMARY ORDER and / or the AUXILIARY ORDER, if the Claimant 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).*
75. *And make any further or other order(s) that the Court deems necessary.*

14. As mentioned above, the Defendants in their letters dated 24 June 2026, amended their requests (limited to their primary order and more specifically Category B and C) as follows:

CATEGORY B

i *Any and all documents that contain reference to, or contain data relating to, measurements of the surface topography of Motiva SilkSurface implants, limited to:*

(i) Roughness, measured as either area surface roughness (Sa) or profile roughness (Ra);

(ii) Skewness, measured as either surface skewness (Ssk) or linear profile skewness (Rsk);

and/or

(iii) Maximum peak height to trough depth, measured as either area maximum peak height to trough depth (Sz) or profile peak height to trough depth or (Rz or Wt)

relating to Motiva SilkSurface Implants which were manufactured before 29 May 2015 (irrespective of the date of testing or when the data and/or documents were generated).

CATEGORY C

i *All available further clinical follow up reports i.e. those following on from the LABS190-3-05 to LABS190-3-07 reports entitled "Motiva Matrix Implants Clinical Data Summary" for years 1, 2 and 3 respectively*

15. The Defendants argued in their Application II and subsequent comments that the request formulated above is necessary "*to assist in the determination of (their) claim of lack of novelty and/or lack of inventive step of the patent in light of the Motiva SilkSurface*". The Defendants hold that having considered and reviewed all of the evidence as provided by LABS under Order I, in combination with the LABS's own case on validity as set out in the Defence to Counterclaim dated 24 April 2026, it has become apparent that there is further evidence in LABS's control that is relevant to aspects of LABS's pleaded case. The Defendants hold that the evidence made available by LABS as a result of Order I is not satisfactory. As such it seems that Defendants do not hold that LABS has provided evidence for each of the categories requested and granted in Order I, but that this evidence is not sufficient to conclusively prove the Defendants' assertions. For this reason the Defendants wish to have access to "*further*" evidence in LABS's control.

16. A further line of arguments relates to the introduction by LABS of an application to amend the claims filed on 24 April 2026. The Defendants hold that the additional sought evidence addresses the amended claims, which they could not have raised prior to the auxiliary requests only advanced on 24 April 2026.

17. More detailed arguments, related to the specific categories will be dealt with in the grounds of this order.

18. LABS originally requested the Court as follows:

(a) Reject all requests for production save for such limited categories of documents as (LABS) has indicated it is prepared to provide voluntarily;

(b) in any event, order that the scope and timetable of any further production (should the Court consider any appropriate) be determined only after the Court has ruled on the Application and after hearing the parties on those issues;

(c) order the Defendants to bear the costs of the Application; and
(d) grant such further or other relief as the Court considers appropriate.

19. In its letter dated 24 June 2026 and based on the developments in the UK (disclosure) proceedings, LABS altered its requests as follows:

(a) Take note of the developments in the parallel UK proceedings before Mr Justice Richards, including the consent order dated 23 June 2026 and the parties' agreed compromise on disclosure, as reflected in the Confidential Annex 1.
(b) Acknowledge and give effect to the fact that the agreed disclosure regime in the UK proceedings addresses, in substance, the scope of the Defendants' request under Category D, and that compliance is ongoing in accordance with the timetable set out in the UK order.
(c) Declare and find that (LABS's) proposed search methodology and limitations in respect of Category B—namely the agreed search terms, product scope, and temporal restriction to pre-29 May 2015 materials—are reasonable, proportionate, and sufficient for the purposes of these proceedings.
(d) Dismiss or reject any further or expanded disclosure requests insofar as they go beyond the parameters agreed between the parties or ordered in the UK proceedings, as being disproportionate, unduly burdensome, or unnecessary.
(e) Confirm that no further disclosure is required in respect of Category A beyond the samples already provided under the First Order pursuant to Rule 190 RoP, and that the retention of one sample by (LABS's) is justified for ongoing and/or parallel proceedings.
(f) Take note of (LABS's) position that WS-008 is a physical workmanship standard rather than a document, is not appropriately subject to disclosure, and in any event has been withdrawn from request in the UK proceedings; and accordingly make no order for its production.
(g) Take note of the parties' agreement and/or withdrawal of requests in relation to LIS-033, and make no further order in that respect.
(h) Order that disclosure obligations under Category C are satisfied by the (LABS's) undertaking to search for and, if located, disclose any additional clinical reports consistent with the parameters already disclosed (LABS190-3-05 to LABS190-3-07).
(i) Order confidentiality protections in respect of any documents produced pursuant to the above disclosure regime, consistent with the existing confidentiality regime and the treatment of Confidential Annex 1.
(j) Acknowledge that the Defendants' proposed 14-day deadline for the further production of evidence is not appropriate in circumstances where disclosure is already governed by a binding consent order dated 23 June 2026 in the parallel UK proceedings.
(k) Acknowledge that, in view of the agreed search methodology and the potentially large volume of documents potentially responsive, any timetable for disclosure should be aligned with the UK order and implemented in a coordinated manner in order to avoid duplication, undue burden, and procedural inefficiency.
(l) Order that the issue of costs be reserved to the final decision or further order of the Court.

20. By second letter dated 24 June 2026 (18:00), LABS further altered its request as follows (and this specifically with regard to Category B):

1. *Reject Category B of the Defendants' Second Application on the basis that the Claimant has already complied with the Court's First Rule 190 Order and that no further disclosure in respect of this category is necessary or proportionate; or, alternatively*
2. *If the Court considers that further disclosure should be ordered under Category B, order that any such disclosure be limited to the same subject matter, search parameters, and timetable as those already agreed between the parties and ordered in the parallel UK proceedings.*

21. LABS, in general, holds that the Defendants do not identify any genuine evidential gap arising from the material already disclosed (in execution of Order I). Further, they argue that Application II is founded largely upon speculation as to what further documents may exist on the assumptions concerning the provenance and meaning or significance of documents already produced. With these general arguments on the background and also in view of the outcome of the UK disclosure proceedings LABS goes into each of the 4 categories.

III. (REDUCED) FACTUAL BACKGROUND OF APPLICATION II

22. Hereafter reference is made to Order I, which for the convenience of the reader is cited:

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)).

23. The same assertions form the basis of Application II, which the Defendants set out in Application II as follows:
    (a) Breast implants incorporating the Motiva SilkSurface were made available to the public without any restriction of confidence before the priority date of the Patent (i.e. were manufactured by the Defendant in Costa Rica and made available to clinics and patients from 2010 in at least Latin America, and from 2011 in at least Europe) and;
    (b) Such implants fall within the scope of at least claims 1, 4, 7, 10, 11 and 13 of the Patent.

V. GROUNDS FOR THE DECISION

V.A. Regulatory framework and application of this framework

24. The Court refers to its Order I (see § 17 Order I).

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

25. The Court refers to Order I (see §18 through §68 Order I) setting and assessing the following cumulative conditions to grant such a request:

Condition 1. The requesting party must have presented evidence "reasonably available" in support of its claims. This condition should be assessed by assessing the following sub-conditions:
- Condition 1(a): Did the Defendants present "*reasonable available"* evidence to support its underlying assertions (a) and (b)?
- Condition 1(b) As an implied condition, could the requested evidence enable the Defendants to conclusively prove their assertions (a) and (b)?

Condition 2: The requested evidence must (a) be "specified" and (b) lie in control of the other party;

Condition 3. The other party's confidential information must be protected;

Condition 4. An order to produce evidence must satisfy the requirements of proportionality, equity, and fairness, assessing the following sub-conditions:
- Condition 4(a): The timing of the application (as a whole) should meet the condition "proportionality, equity, and fairness"(taking into consideration the stage of the proceedings).
- Condition 4(b): Each individual request which met the above conditions should meet the condition "proportionality, equity, and fairness"

V.C. Assessment (Application II)

26. In the assessment of the conditions, the Court focuses on the counter-arguments articulated by LABS. Should these counter-arguments not touch upon the conditions already assessed in

Order I (under V.C.1 through V.C.5 Order I), they are restated, except if differently approached hereafter.

V.C.1. Category A

27. When the Defendants request an additional implant sample, LABS convincingly argue that it had complied with Order I by providing three pre-priority implant samples. The fact that they did not transmit the blister-sealed implant from 2011, which they still have in their possession, does indeed not indicate the withholding of evidence under Order I.

28. Furthermore, it appears that the Defendants have conducted testing and submitted the results in the UK parallel case. The Court is surprised that these results are not mentioned in Application II. While the Defendants allege that they were deprived of the opportunity to "*best present the evidence*" in their case by being prevented from testing a further 2011 sample against the argument of sample degradation, this line of argument could have been proven by presenting the Court with the results of the sample that had already been tested. However, the Defendants chose not to raise or use such results in their Application II. Further, the Court cannot assess whether the existing test would indeed be insufficient, nor can it ascertain why a second 2011 implant would alter the outcome of such testing. Therefore, the Court cannot agree with the Defendants' argument that it would be "*destructive*" for LABS not to provide them with two blister-sealed samples.

29. Applied to the conditions to be met, the Court holds that that the following conditions are not met:

- Condition 1 and specifically Condition 1(b). As the Defendants already are in the possession of three samples (one blister-sealed) and the Defendant already performed testing, no sufficient proof has been submitted which would indicate an additional sample would assist the Defendants more to conclusively prove their assertions. Therefore, the Defendants do not sufficiently identify the evidential gap arising from the (tested) samples and therefore prove insufficiently to have exhausted reasonably available avenues to substantiate their allegations.
- Condition 4(b) is not met as LABS has already submitted the evidence which was requested for in compliance of Order I. Requesting additional evidence but on the other hand not questioning the compliance by LABS of Order I, taking into consideration the burden of proof for the Defendants, is held to be not proportional, equitable and fair.

30. Where the Defendants refer to the auxiliary request as a line of argument to be granted access to the additional information (2011 implant), the Court is not convinced. Auxiliary request 1 seems to make obligatory the determination of Sa at the area scale of 90 x 90 µm, which feature was initially asserted by LABS for infringement. The evidence needed to counterargue this line of argument seemed already the object of Application I and based thereon Order I was issued. The Defendants assert that the other Auxiliary requests go in deeper details, however the Defendants are not prevented to examine these details making use of the

implants already made available by LABS. No sufficient proof has been submitted to the Court that the counter-arguing the position taken by LABS (be it based on the auxiliary requests) would make it necessary to be supplied an additional sample to prove the Defendants' assertions beyond doubt.

31. Further, the Court deems is opportune that the second (2011) blister-sealed sample is not handed over to the Defendants taking into consideration the destructive nature of cutting up the samples already used for testing and as such leaving a possible option for the Court (if it would deem it necessary based i.a. on the test results presented by the Defendants and the counter-arguments from LABS) to order experimental testing by a Court appointed independent expert making use of a Court approved testing protocol.

V.C.2. Category B

32. When assessing Category B, it is opportune to compare the agreed upon requests in the UK disclosure proceedings (as mentioned in Confidential Annex 1 under 1 and 2) with the requests made before the UPC (as mentioned under Category B):

UK Proceedings (Confidential Annex 1)	UPC (Category B)
[redacted]	*Any and all documents that contain reference to, or contain data relating to, measurements of the surface topography of Motiva SilkSurface implants, limited to:* *(i) Roughness, measured as either area surface roughness (Sa) or profile roughness (Ra);* *(ii) Skewness, measured as either surface skewness (Ssk) or linear profile skewness (Rsk);* *and/or* *(iii) Maximum peak height to trough depth, measured as either area maximum peak height to trough depth (Sz) or profile peak height to trough depth or (Rz or Wt)* *relating to Motiva SilkSurface Implants which were manufactured before 29 May 2015 (irrespective of the date of testing or when the data and/or documents were generated).*

33. Although the objective of the two requests seems to be the same, in the UK disclosure proceedings the search seems to be limited insofar as retrievable under one specific search query of LABS's internal document collection database; whereas under the UPC request LABS is obliged to produce the target documents *insofar as they exist*. As such the search scope as well as the burden for LABS is broader.

34. For procedural efficiency (i.a. to avoid possible discussions as to the completeness of the submitted evidence and for the parties to align its arguments before the UK Court and the UPC) and, subsequently, in order to meet Condition 4(b) (proportionality, equity and fairness) the Court amends the requested for Category B to the agreed upon search request before the UK court. As the search is limited to the amended Category B, LABS's argument of the request being too broad and not clearly defined does not need any further assessment.

V.C.3. Category C

35. Regarding Category C (i), the Court notes LABS willingness to search for and/or to provide additional disclosure of any further clinical reports following from those disclosed as LABS190-3-05 and LABS 190-3-07 which is confirmed in the Confidential Annex (under 3) to the Uk Disclosure Order dated 23 June 2026.

V.C.4. Category D

36. This category relates to documents that LABS has already agreed to provide in the parallel UK proceedings as additional disclosure (beyond that evidence produced in compliance with Order I).

37. As LABS has agreed to comply with the UK Disclosure Order dated 23 June 2026 (see in particular Confidential Annex under 4 through 8 which are identical to the request formulated under Category D), this request is granted.

V.D. Timeframe

38. Regarding Category B, LABS wishes to comply with this request within the same timeframe as set in the UK order. In the UK order the timeframe is set on 28 days from the date of the UK order (23 June 2026) if the searches return 500 pages or less. Should the searched return more than 500 pages, the parties should try to reach an agreement on alternatives searches and/or a longer period for the disclosure. Should the parties not reach an agreement, they should address the UK court. As the Court already aligned the requested for Category B to the UK proceedings and to avoid duplication, undue burden and procedural inefficiency, it seems reasonable to also align the timeframe for LABS for submitting the evidence under this UPC order. As a starting point the date of issuance of the UK (disclosure) order is used.

39. Regarding Category C, LABS's request to comply within the same timeframe as set in the UK order, being 28 days of the date of the UK (disclosure) order (23 June 2026), for the reasons mentioned above (see §38) is reasonable and proportional.

40. Regarding Category D, LABS already agreed to comply with these requests within 14 days of the date of the UK order (i.e. 23 June 2026). As such there seems not problem for LABS to comply with the timeframe set by the UK Court.

41. Should mentioned timeframe endanger the Defendants' ability to make further submissions and, as such, their right of defence, they have the right to request some procedural fine-tuning (R. 9 RoP), which will follow the usual procedural process before being granted or rejected. In this regard, the parties are strongly invited to reach an agreement on changes to be made to the procedural agenda, taking into consideration the date of the OH (2 December 2026) which the Court would like to maintain. Parties are in this regard informed that the Court has the option to postpone the interim conference, currently scheduled for 21 September 2026, to a later date.

V.E. Penalties

42. 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.

43. The Court considers it necessary and appropriate to impose such a penalty, which is as such not disputed by LABS, to ensure that it complies with the obligation to provide the requested evidence.

44. 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.F. Costs of the procedure

45. 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

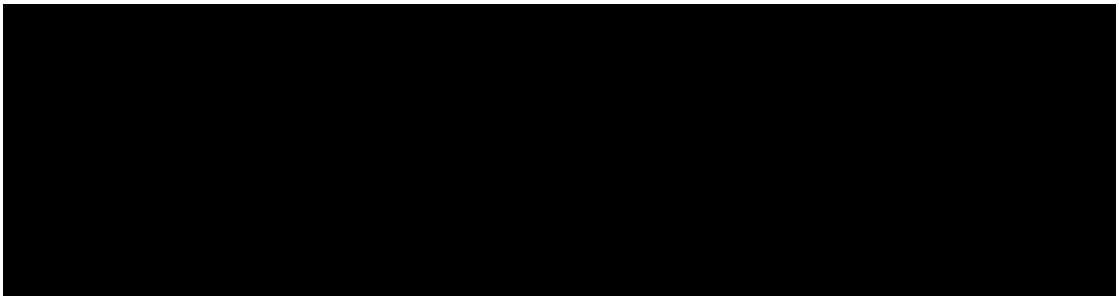
The Court

I. Orders LABS pursuant to Art. 59 UPCA and R.190 RoP, to produce to the Defendants listed in the requests made as "*Primary Order*" under Category B, C and Category D, more specifically:

I.1. Regarding Category B as amended by the Court, within 28 days from the date of the UK (disclosure) order (23 June 2026) by the High Court of Justice – Business and Property Courts – Intellectual Property List (CHS) – Patents Court (claim no. HP-2026-000009) if the searches return 500 pages or less. Should the searched return more than 500 pages, the parties should try to reach an agreement on alternatives searches and/or a longer period for the disclosure. Should the parties not reach an agreement, they should address the Court.

I.2. Regarding Category C, within 28 days of the issued UK (disclosure) order (23 June 2026) by the High Court of Justice – Business and Property Courts – Intellectual Property List (CHS) – Patents Court (claim no. HP-2026-000009),

I.3. Regarding Category D, within 28 days of issued UK (disclosure) order (23 June 2026) by the High Court of Justice – Business and Property Courts – Intellectual Property List (CHS) – Patents Court (claim no. HP-2026-000009)



[redacted]

II. Dismisses all other requests.

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 the same timeframe as mentioned under I for each specific Category, 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. Orders that access to the evidence is limited to the Confidentiality Circle set by the Court on 23 April 2026.

VI. Stipulates that 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 26 June 2026

Samuel GRANATA Judge-Rapporteur Presiding Judge LD Brussels Legally Qualified Judge	Samuel Rocco M Granata Digitally signed by Samuel Rocco M Granata Date: 2026.06.26 13:05:59 +02'00'
Carine Gillet Legally Qualified Judge	Carine Gillet 2026.06.26 12:32:03 +02'00'
Marije Knijff Legally Qualified Judge	Marije Knijff Digitally signed by Marije Knijff Date: 2026.06.26 10:55:26 +02'00'
Paolo Gerli Technically Qualified Judge	PAOLO GERLI Firmato digitalmente da PAOLO GERLI Data: 2026.06.26 10:19:16 +02'00'

Information on Appeal

An appeal may be lodged in accordance with Art. 73 UPCA and R. 220.1 RoP.