Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Paris Local Division

UPC_CFI_808/2025
Final Order
of the Court of First Instance of the Unified Patent Court
delivered on 23/*01/2026*

HEADNOTES:

1) Unreasonable delay under R. 211.4 RoP: In the present case, a three-month period constitutes a reasonable delay to prepare the application for provisional measures by gathering the necessary evidence, given that the case involves several patents and a complex and sophisticated technology.

2) Added matter (divisional patent): It is decisive whether all the elements are directly and unambiguously derivable from the patent as originally filed (in the present case: the PCT application) or whether the latter is used as some kind of reservoir from which scattered fragments can be combined, in which case there is a whole series of different 'inventions' included in the PCT application.

3) Added matter: From the selections that have been made without any clear indication in the earlier application, the Court concludes that the invention as now worded in the granted claim cannot directly and unambiguously be derived from the patent as filed.

4) Demonstration of an infringement with a sufficient degree of certainty (R. 211.2 RoP): The burden of proof for the alleged infringement lies with the party invoking it. Applicant cannot rely solely on the disputed information from a press release to demonstrate how Defendants' software processes data. Additional in-depth investigations into how Defendants' platform operates or more technical documentation on the 'accused software' would have been necessary.

KEYWORDS:

Provisional measures. Unreasonable delay. R. 211.4 RoP. Added matter. Sufficient degree of certainty-Infringement- Burden of proof. R. 211.2 RoP.

APPLICANT:

Guardant Health, Inc.
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represented by

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UPC representatives.

DEFENDANTS:

1) **Sophia Genetics SA**
La Pièce 12,
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2) **Sophia Genetics SAS**
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158 allée Fauste d'Elhuyar
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PATENTS AT ISSUE

Patent no.	*Proprietor*
EP 3470533	Guardant Health, Inc.
EP 3591073	Guardant Health, Inc.
EP 3443066	Guardant Health, Inc.
EP 3766986	Guardant Health, Inc.

PANEL:

Camille Lignières, Presiding judge and Judge Rapporteur
Carine Gillet, Legally qualified judge
Maximilian Haedicke, Legally qualified judge
Cornelis Schüller, Technically qualified judge

LANGUAGE OF PROCEEDINGS: English

ORDER

The parties

1. The Applicant (hereinafter "GUARDANT HEALTH") is a US company founded in 2012, based in Palo Alto (California) and incorporated in Delaware, which is focused on cancer diagnosis through genetic testing and mutation detection. It is specialised in the "liquid biopsy" approach, in which mutant genetic material from tumours is isolated from a simple blood sample rather than requiring an invasive solid biopsy. Its marketed tests include "Guardant360", "Guardant Reveal", and "SHIELD". The Applicant is the owner of several European patents relating to the use of liquid biopsy for diagnostic purposes.

2. The Defendants are part of the SOPHIA GENETICS group (hereinafter "SOPHIA GENETICS"). Defendant 1 (Sophia Genetics SA) is the parent company settled in Switzerland, Defendants 2 (Sophia Genetics SAS), 3 (Sophia Genetics SRL), and 4 (Sophia Genetics GmbH) are subsidiary companies based respectively in France, Italy and Germany. SOPHIA GENETICS is a cloud-native healthcare technology company on a mission to expand access to data-driven medicine by using AI to deliver world-class care to patients with cancer and rare disorders across the globe. It is the creator of SOPHiA DDM™, a platform that analyses complex genomic and multimodal data and generates real-time, actionable insights for a broad global network of hospitals, laboratories, and biopharma institutions.

3. According to GUARDANT HEALTH, the Defendants offer and supply the "MSK-ACCESS® powered with SOPHiA DDM" test (hereinafter "MSK-DDM") in the Unified Patent Court (hereinafter "UPC") territories, Spain, Switzerland, the Czech Republic, Poland and Norway.

Summary of proceedings

4. On 29 August 2025, GUARDANT HEALTH lodged an application (hereinafter "the Application") for provisional measures (pursuant to Art. 62 UPCA and R. 206 RoP) before the Paris Local Division, against SOPHIA GENETICS, for infringement of four of its European Patents: EP-3470533-B2 ("EP'533") EP-3591073-B1 ("EP'073") EP-3443066-B1 ("EP'066"), EP-3766986-B1 ("EP'986"). At the stage of the Reply to Objection, the Applicant withdrew its request with regard to EP'533.

5. The Applicant is the sole proprietor of the three patents in suit (Exhibits GH 29, GH 34, and GH 37).

6. Jurisdiction of the UPC and the internal competence of the Paris Local Division were not contested by the Defendants concerning the UPC territories (Contracting Member States: France, Italy and Germany). This case concerns a dispute related to the marketing of MSK-DDM product, purportedly covered by the above-mentioned European patents, and one of the Defendants is a French company, the other Defendants are part of the same group participating in the commercialisation of the accused products. The Court confirms its jurisdiction to hear the dispute under Art. 32.1(a) and at least Art. 33.1(b) of the UPCA.

7. The scope of the jurisdiction for the non-UPC territories Switzerland, Spain, Poland, the Czech Republic and Norway, is contested by the Defendants.

8. No protective letter has been filed before the filing of the Application by SOPHIA GENETICS.

9. According to a timetable set by procedural order of 1st October 2025, SOPHIA GENETICS filed its Objection on 27 October 2025. GUARDANT HEALTH filed its Reply to the Objection on 10 November 2025, and SOPHIA GENETICS submitted its Rejoinder on 24 November 2025.

10. After the oral hearing of 12 December 2025, SOPHIA GENETICS filed on 16 December 2025 an application under R. 336 RoP, requesting that the preliminary opinion of the Board of Appeal of the European Patent Office issued on 15 December 2025 regarding EP'073 be admitted as evidence in this case. By procedural order of 18 December 2025, the Presiding Judge granted this request.

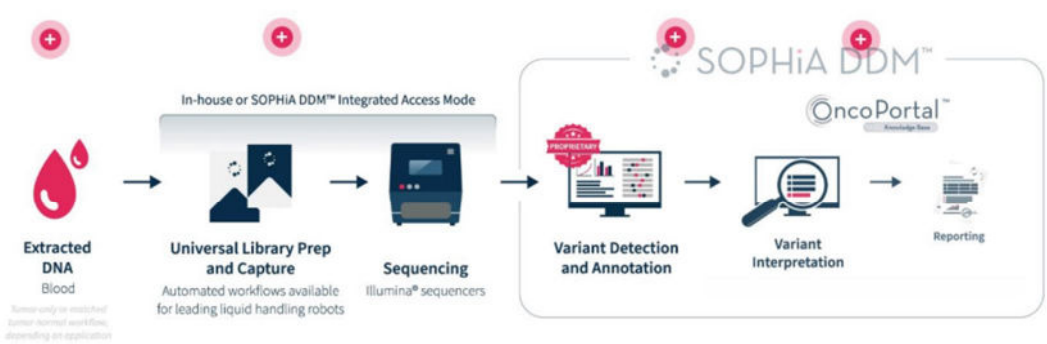
11. A technically qualified judge has been allocated to the panel upon the Judge Rapporteur's request at the earliest stage of the proceedings.

12. The value of the case has been declared as amounting to 6 million euros, and this amount is not contested by the Defendant.

<u>The accused products</u>

13. GUARDANT HEALTH accuses SOPHIA GENETICS of infringing its patents by offering and supplying the products called "MSK-ACCESS® powered with SOPHiA DDM" test (hereinafter "MSK-DDM") in the UPC territories, and Spain, Switzerland, the Czech Republic, Poland and Norway. The accused product is a liquid biopsy test.

14. The basic steps in the MSK-DDM test are shown on the Defendant's website, as follows (Exhibit GH 22, §88 of the Application):



https://www.sophiagenetics.com/sophia-ddm-for-genomics/liquid-biopsy/

15. This test thus has six overall steps:

(i) DNA extraction from blood,
(ii) capture of DNA and preparation of a sequencing library,
(iii) sequencing the library,
(iv) detecting and annotating sequence variants within the DNA,
(v) interpreting the detected sequence variants, and
(vi) reporting information to the user.

16. In general terms, these steps can be classified as "wet" (steps (i) to (iii), which involve dealing with blood and DNA) and "dry" (steps (iv) to (vi) which deal with data). The alleged infringing activities arise both from the combined wet & dry stages (EP'073, and EP'066), or from the dry stage alone (EP'986). The wet stage relies on the Defendants' kit known as "SOPHiA GENETICS™ Universal Library Prep for fragmented DNA" (see page ii of GH 22, product 300232); the dry stage relies on the Defendants' SOPHIA DDM software platform.

Parties' requests

17. In its last submission (Reply dated 10 November 2025), GUARDANT HEALTH requests that the Court grant the following provisional measures:

Under EP'533:

Requests A to C in the Application are withdrawn.

Under EP'073:

D. The Defendants are ordered, in the territories of Austria, Belgium, Germany, France, Italy, the Netherlands, and Sweden, and the Czech Republic, Switzerland, Spain, Poland and Norway, to cease and desist from:

I. using and/or offering for use,

1. a method for processing at least one set of tagged parent polynucleotides, comprising steps of:

a. converting initial starting genetic material into the tagged parent polynucleotides using non-unique barcode oligonucleotides, wherein converting comprises enzymatic ligation;
b. amplifying the tagged parent polynucleotides in the set to produce a corresponding set of amplified progeny polynucleotides;
c. sequencing a subset of the set of amplified progeny polynucleotides, to produce a set of sequencing reads; and
d. collapsing the set of sequencing reads to generate a set of consensus sequences, each consensus sequence corresponding to a unique polynucleotide among the set of tagged parent polynucleotides, wherein *(i)* the initial starting genetic material is cell-free DNA isolated from a body fluid, and comprises no more than 100 ng of polynucleotides, and *(ii)* detection of the non-unique barcodes in combination with sequence data of beginning and end portions of sequencing reads allows assignment of a unique identity to a parent polynucleotide;

(Direct infringement of Claim 1 as upheld)

2. in particular, the method of Claim 1, wherein the barcodes comprise oligonucleotides at least 3, 5, 10, 15, 20 25, 30, 35, 40, 45, or 50 base pairs in length;

(Direct infringement of Claim 2 as upheld)

3. in particular, the method of any one of the preceding claims, wherein the body fluid is blood;

(Direct infringement of Claim 3 as upheld)

4. in particular, the method of any of the preceding claims, comprising enriching the set of amplified progeny polynucleotides for polynucleotides mapping to one or more selected mappable positions in a reference sequence by:

> (i) selective amplification of sequences from initial starting genetic material converted to tagged parent polynucleotides;
> (ii) selective amplification of tagged parent polynucleotides;
> (iii) selective sequence capture of amplified progeny polynucleotides; or
> (iv) selective sequence capture of initial starting genetic material;

(Direct infringement of Claim 4 as upheld)

5. in particular, the method of any one of the preceding claims, further comprising:

> e. analyzing the set of consensus sequences for the sets of tagged parent polynucleotides separately or in combination;

(Direct infringement of Claim 5 as upheld)

6. in particular, the method of Claim 5, wherein analyzing comprises detecting mutations, rare mutations, indels, copy number variations, transversions, translocations, inversion, deletions, aneuploidy, partial aneuploidy, polyploidy, chromosomal instability, chromosomal structure alterations, gene fusions, chromosome fusions, gene truncations, gene amplification, gene duplications, chromosomal lesions, DNA lesions, abnormal changes in nucleic acid chemical modifications, abnormal changes in epigenetic patterns, abnormal changes in nucleic acid methylation infection or cancer;

(Direct infringement of Claim 6 as upheld)

7. in particular, the method of Claim 5 or Claim 6, wherein analyzing comprises normalizing a measure taken from a set of consensus sequences against a measure taken from a set of consensus sequences from a control sample;

(Direct infringement of Claim 7 as upheld)

8. in particular, the method of any one of Claims 5 to 7, wherein analysis further comprises detection and monitoring of an abnormality or disease within an individual, such as infection and/or cancer;

(Direct infringement of Claim 8 as upheld)

9. in particular, the method of any one of Claims 5 to 8, comprising providing a plurality of sets of tagged parent polynucleotides, wherein each set is mappable to a different mappable position in a reference sequence, optionally wherein the mappable position in

the reference sequence is the locus of a tumor marker and analyzing comprises detecting the tumor marker in the set of consensus sequences;

(Direct infringement of Claim 9 as upheld)

10. in particular, the method of any one of the preceding claims, comprising filtering out reads with an accuracy or quality score of less than a threshold;

(Direct infringement of Claim 10 as upheld)

11. in particular, the method of any one of the preceding claims, wherein collapsing comprises detecting and/or correcting errors, nicks or lesions present in the sense or antisense strand of the tagged parent polynucleotides or amplified progeny polynucleotides;

(Direct infringement of Claim 11 as upheld)

12. in particular, the method of any one of the preceding claims, wherein collapsing

comprises:

a. grouping sequences reads sequenced from amplified progeny polynucleotides into families, each family amplified from the same tagged parent polynucleotide; and
b. determining a consensus sequence based on sequence reads in a family;

(Direct infringement of Claim 12 as upheld)

13. in particular, the method of any one of the preceding claims, where the method is used:

a. to construct a genetic profile of the subject, from which the body fluid derives, over the course of a disease; or
b. to generate a profile, fingerprint or set of data that is a summation of genetic information derived from different cells in a heterogeneous disease of the subject from which the bodily fluid derives;

(Direct infringement of Claim 13 as upheld)

14. in particular, the method according to Claim 13, wherein the profile allows the subject or a practitioner to adapt treatment options in accord with the progress of the disease;

(Direct infringement of Claim 14 as upheld)

II. supplying and/or offering to supply for use means, which are suitable and intended for use in,

1. a method for processing at least one set of tagged parent polynucleotides, comprising steps of:

a. converting initial starting genetic material into the tagged parent polynucleotides using non-unique barcode oligonucleotides, wherein converting comprises enzymatic ligation;
b. amplifying the tagged parent polynucleotides in the set to produce a corresponding set of amplified progeny polynucleotides;
c. sequencing a subset of the set of amplified progeny polynucleotides, to produce a set of sequencing reads; and

d. collapsing the set of sequencing reads to generate a set of consensus sequences, each consensus sequence corresponding to a unique polynucleotide among the set of tagged parent polynucleotides, wherein (i) the initial starting genetic material is cell-free DNA isolated from a body fluid, and comprises no more than 100 ng of polynucleotides, and (ii) detection of the non-unique barcodes in combination with sequence data of beginning and end portions of sequencing reads allows assignment of a unique identity to a parent polynucleotide;

specifically

• the software for accessing the 'SOPHiA DDM™ platform and

• the library preparation and hybridization capture kit and components thereof, including but not limited to the 'SOPHiA GENETICS CUMIN™ adapters, 'Probes by SOPHiA GENETICS' and Instructions for Use,

without

- in the case of an offer, expressly and clearly indicating that the means may not be used without the consent of the Applicant as the proprietor of the European patent 3,591,073 for the method of determining copy number variation according to D.II.,

- in the case of supply, imposing on the purchasers, subject to a contractual penalty payment to the Applicant of EUR 10,000 for each case of infringement, a written obligation not to use the means for the method of determining copy number variation according to D.II. without the prior consent of the Applicant as the patent proprietor of the European patent 3,591,073; and

• **alternative to request D.I,** the MSK-ACCESS powered with SOPHiA DDM™ test;

(Indirect infringement of Claim 1 as upheld)

2. in particular, the method of Claim 1, wherein the barcodes comprise oligonucleotides at least 3, 5, 10, 15, 20 25, 30, 35, 40, 45, or 50 base pairs in length;

(Indirect infringement of Claim 2 as upheld)

3. in particular, the method of any one of the preceding claims, wherein the body fluid is blood;

(Indirect infringement of Claim 3 as upheld)

4. in particular, the method of any of the preceding claims, comprising enriching the set of amplified progeny polynucleotides for polynucleotides mapping to one or more selected mappable positions in a reference sequence by:

(i) selective amplification of sequences from initial starting genetic material converted to tagged parent polynucleotides;
(ii) selective amplification of tagged parent polynucleotides;
(iii) selective sequence capture of amplified progeny polynucleotides; or
(iv) selective sequence capture of initial starting genetic material;

(Indirect infringement of Claim 4 as upheld)

5. in particular, the method of any one of the preceding claims, further comprising: e. analyzing the set of consensus sequences for the sets of tagged parent polynucleotides separately or in combination;

(Indirect infringement of Claim 5 as upheld)

6. in particular, the method of Claim 5, wherein analyzing comprises detecting mutations, rare mutations, indels, copy number variations, transversions, translocations, inversion, deletions, aneuploidy, partial aneuploidy, polyploidy, chromosomal instability, chromosomal structure alterations, gene fusions, chromosome fusions, gene truncations, gene amplification, gene duplications, chromosomal lesions, DNA lesions, abnormal changes in nucleic acid chemical modifications, abnormal changes in epigenetic patterns, abnormal changes in nucleic acid methylation infection or cancer;

(Indirect infringement of Claim 6 as upheld)

7. in particular, the method of Claim 5 or Claim 6, wherein analyzing comprises normalizing a measure taken from a set of consensus sequences against a measure taken from a set of consensus sequences from a control sample;

(Indirect infringement of Claim 7 as upheld)

8. in particular, the method of any one of Claims 5 to 7, wherein analysis further comprises detection and monitoring of an abnormality or disease within an individual, such as infection and/or cancer;

(Indirect infringement of Claim 8 as upheld)

9. in particular, the method of any one of Claims 5 to 8, comprising providing a plurality of sets of tagged parent polynucleotides, wherein each set is mappable to a different mappable position in a reference sequence, optionally wherein the mappable position in the reference sequence is the locus of a tumor marker and analyzing comprises detecting the tumor marker in the set of consensus sequences;

(Indirect infringement of Claim 9 as upheld)

10. in particular, the method of any one of the preceding claims, comprising filtering out reads with an accuracy or quality score of less than a threshold;

(Indirect infringement of Claim 10 as upheld)

11. in particular, the method of any one of the preceding claims, wherein collapsing comprises detecting and/or correcting errors, nicks or lesions present in the sense or antisense strand of the tagged parent polynucleotides or amplified progeny polynucleotides;

(Indirect infringement of Claim 11 as upheld)

12. in particular, the method of any one of the preceding claims, wherein collapsing

comprises:

a. grouping sequences reads sequenced from amplified progeny polynucleotides into families, each family amplified from the same tagged parent polynucleotide; and

b. determining a consensus sequence based on sequence reads in a family;

(Indirect infringement of Claim 12 as upheld)

13. in particular, the method of any one of the preceding claims, where the method is used:

a. to construct a genetic profile of the subject, from which the body fluid derives, over the course of a disease; or
b. to generate a profile, fingerprint or set of data that is a summation of genetic information derived from different cells in a heterogeneous disease of the subject from which the bodily fluid derives;

(Indirect infringement of Claim 13 as upheld)

14. in particular, the method according to Claim 13, wherein the profile allows the subject or a practitioner to adapt treatment options in accord with the progress of the disease;

(Indirect infringement of Claim 14 as upheld)

E. The Defendants are ordered to deliver up to a bailiff appointed by the Applicant, at their own expense, any physical means referred to under D. in stock and/or otherwise held, owned, or in the direct or indirect possession of the Defendants in Austria, Belgium, Germany, France, Italy, the Netherlands, and Sweden, and the Czech Republic, Switzerland, Spain, Poland and Norway, within one week after service of this order, and to provide the Applicant's counsel with proper evidence of the full and timely compliance with this order within 10 days after the delivery to the bailiff.

F. For each individual violation of the orders under D. and E., the respective Defendant shall pay to the court a penalty payment of up to EUR 10,000. Each infringing act in relation to MSK-ACCESS powered with SOPHiA DDM™ in respect of request D.I and/or any means in respect of request D.II will be considered as a separate violation. Further, in the case of continuous non-compliance or continuous infringement such as the offering of on the internet or non-compliance with the obligation under E., the respective Defendant shall pay to the court a penalty payment of up to EUR 100,000 per day.

Under EP'066:

G. The Defendants are ordered, in the territories of Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Romania, Slovenia, Sweden, Switzerland, and Spain, to cease and desist from

I. using and/or offering

1. a method for detecting the presence or absence of colorectal cancer, ovarian cancer, lung cancer or pancreatic cancer in a subject comprising:

sequencing circulating cfDNA from the subject at a depth of at least 50,000 reads per base to detect one or more genetic variants associated with cancer, wherein the sequencing is performed on an enriched set of amplified cfDNA molecules which comprises a panel of genomic regions, wherein the genomic regions in the panel comprise one or more loci from each of the genes AKT1, ALK, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, ESR1, FGFR2, GATA3, GNAS, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, PTEN, RB1, SMAD4, STK11 and

TP53, and further comprising amplifying the cfDNA prior to sequencing, and determining a consensus sequence from sequence reads obtained from the sequencing to reduce errors from amplification or sequencing;

(Direct infringement of Claim 1)

2. in particular, the method of Claim 1, wherein the one or more genetic variants associated with cancer are selected from the group consisting of an SNV, CNV, indel, fusion, or nucleosome binding pattern;

(Direct infringement of Claim 2)

3. in particular, the method of Claim 2, wherein the SNV is detected in a gene selected from the group consisting of AKT1, ALK, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, ESR1, FGFR2, GATA3, GNAS, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, PTEN, RB1, SMAD4, STK11, and TP53;

(Direct infringement of Claim 3)

4. in particular, the method of any one of Claims 1 to 5, wherein the enriched set of cfDNA molecules comprises one or more enhancer sequences or promoter sequences;

(Direct infringement of Claim 6)

5. in particular, the method of any one of Claims 1 to 6, further comprising comparing sequence information from the cfDNA to sequence information obtained from a cohort of healthy individuals, a cohort of cancer patients, or germline DNA from the subject;

(Direct infringement of Claim 7)

6. in particular, the method of any one of Claims 1 to 7, wherein the germline DNA from the subject is obtained from leukocytes from the subject;

(Direct infringement of Claim 8)

7. in particular, the method of any one of Claims 1 to 8, wherein determining the consensus sequence is performed on a molecule-by-molecule basis or a base-by-base basis;

(Direct infringement of Claim 9)

8. in particular, the method of any one of Claims 1 to 9, wherein determining the consensus sequence is performed using molecular barcodes that tag individual cfDNA molecules derived from the subject;

(Direct infringement of Claim 10)

9. in particular, the method of any one of Claims 1 to 10, wherein determining the consensus sequence is optimized by comparing the consensus sequence to those obtained from a cohort of healthy individuals, a cohort of cancer patients, or the germline DNA from the subject;

(Direct infringement of Claim 11)

10. in particular, the method of any one of Claims 1 to 11, further comprising tagging the cfDNA molecules with a barcode such that at least 20% of the cfDNA in a sample derived from the subject are tagged optionally wherein:

(a) the tagging is performed by attaching adaptors comprising a barcode, optionally wherein the adaptors comprise any or all of blunt end adaptors, restriction enzyme overhang adaptors, or adaptors with a single nucleotide overhang, optionally wherein the adaptors with a single nucleotide overhang comprise C-tail adaptors, A-tail adaptors, T-tail adaptors, and/or G-tail adaptors;
(b) the tagging is performed by PCR amplification using primers with barcodes;
(c) the barcode is single stranded; or
(d) the barcode is double stranded;

(Direct infringement of Claim 12)

11. in particular, the method of any one of Claims 1 to 13, wherein the cfDNA comprises at least 4000, at least 5000, at least 7,000, at least 10,000, or at least 15,000 unique molecules for every base to be sequenced or analyzed.

(Direct infringement of Claim 14)

II. supplying and/or offering to supply for use means, which are suitable and intended for use in,

1. a method for detecting the presence or absence of colorectal cancer, ovarian cancer, lung cancer or pancreatic cancer in a subject comprising:

sequencing circulating cfDNA from the subject at a depth of at least 50,000 reads per base to detect one or more genetic variants associated with cancer, wherein the sequencing is performed on an enriched set of amplified cfDNA molecules which comprises a panel of genomic regions, wherein the genomic regions in the panel comprise one or more loci from each of the genes AKT1, ALK, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, ESR1, FGFR2, GATA3, GNAS, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, PTEN, RB1, SMAD4, STK11 and TP53, and further comprising amplifying the cfDNA prior to sequencing, and determining a consensus sequence from sequence reads obtained from the sequencing to reduce errors from amplification or sequencing;

specifically

• the software for accessing the 'SOPHiA DDM™ platform and

• the library preparation and hybridization capture kit and components thereof, including but not limited to the 'SOPHiA GENETICS CUMIN™ adapters, 'Probes by SOPHiA GENETICS' and Instruction for Use,

without

- in the case of an offer, expressly and clearly indicating that the means may not be used without the consent of the Applicant as the proprietor of the European patent 3,443,066 for the method of determining copy number variation according to G.II.,

- in the case of supply, imposing on the purchasers, subject to a contractual penalty payment to the Applicant of EUR 10,000 for each case of infringement, a written obligation not to use the means for the method of determining copy number variation according to G.II. without the prior consent of the Applicant as the patent proprietor of the European patent 3,443,066; and

• **alternative to request G.I**, the MSK-ACCESS powered with SOPHiA DDM™ test;

(Indirect infringement of Claim 1)

2. in particular, the method of Claim 1, wherein the one or more genetic variants associated with cancer are selected from the group consisting of an SNV, CNV, indel, fusion, or nucleosome binding pattern;

(Indirect infringement of Claim 2)

3. in particular, the method of Claim 2, wherein the SNV is detected in a gene selected from the group consisting of AKT1, ALK, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, ESR1, FGFR2, GATA3, GNAS, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, PTEN, RB1, SMAD4, STK11, and TP53;

(Indirect infringement of Claim 3)

4. in particular, the method of any one of Claims 1 to 5, wherein the enriched set of cfDNA molecules comprises one or more enhancer sequences or promoter sequences;

(Indirect infringement of Claim 6)

5. in particular, the method of any one of Claims 1 to 6, further comprising comparing sequence information from the cfDNA to sequence information obtained from a cohort of healthy individuals, a cohort of cancer patients, or germline DNA from the subject;

(Indirect infringement of Claim 7)

6. in particular, the method of any one of Claims 1 to 7, wherein the germline DNA from the subject is obtained from leukocytes from the subject;

(Indirect infringement of Claim 8)

7. in particular, the method of any one of Claims 1 to 8, wherein determining the consensus sequence is performed on a molecule-by-molecule basis or a base-by-base basis;

(Indirect infringement of Claim 9)

8. in particular, the method of any one of Claims 1 to 9, wherein determining the consensus sequence is performed using molecular barcodes that tag individual cfDNA molecules derived from the subject;

(Indirect infringement of Claim 10)

9. in particular, the method of any one of Claims 1 to 10, wherein determining the consensus sequence is optimized by comparing the consensus sequence to those obtained from a cohort of healthy individuals, a cohort of cancer patients, or the germline DNA from the subject;

(Indirect infringement of Claim 11)

10. in particular, the method of any one of Claims 1 to 11, further comprising tagging the cfDNA molecules with a barcode such that at least 20% of the cfDNA in a sample derived from the subject are tagged optionally wherein:

(a) the tagging is performed by attaching adaptors comprising a barcode, optionally wherein the adaptors comprise any or all of blunt end adaptors, restriction enzyme overhang adaptors, or adaptors with a single nucleotide overhang, optionally wherein the adaptors with a single nucleotide overhang comprise C-tail adaptors, A-tail adaptors, T-tail adaptors, and/or G-tail adaptors;
(b) the tagging is performed by PCR amplification using primers with barcodes;
(c) the barcode is single stranded; or
(d) the barcode is double stranded;

(Indirect infringement of Claim 12)

11. in particular, the method of any one of Claims 1 to 13, wherein the cfDNA comprises at least 4000, at least 5000, at least 7,000, at least 10,000, or at least 15,000 unique molecules for every base to be sequenced or analyzed;

(Indirect infringement of Claim 14)

H. The Defendants are ordered to deliver up to a bailiff appointed by the Applicant, at their own expense, any physical means referred to under G. in stock and/or otherwise held, owned, or in the direct or indirect possession of the Defendants in Austria, Belgium, Bulgaria, Germany, Denmark, Estonia, Finland, France, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Romania, Slovenia, Sweden, Switzerland, and Spain, within one week after service of this order, and to provide the Applicant's counsel with proper evidence of the full and timely compliance with this order within 10 days after the delivery to the bailiff.

I. For each individual violation of the orders under G. and H., the respective Defendant shall pay to the court a penalty payment of up to EUR 10,000. Each infringing act in relation to MSK-ACCESS powered with SOPHiA DDM™ in respect of request G.I and/or any means in respect of request G.II will be considered as a separate violation. Further, in the case of continuous non-compliance or continuous infringement such as the offering of as the offering on the internet or non-compliance with the obligation under H., the respective Defendant shall pay to the court a penalty payment of up to EUR 100,000 per day.

Under EP 986:

J. The Defendants are ordered, in the territories of Belgium, Germany, France, Italy, the Netherlands, Switzerland and Spain, to cease and desist from

I. using and/or offering for use,

1. a computer implemented method comprising use of a computer database to identify one or more effective therapeutic interventions for a subject having cancer, wherein the computer database includes, for each of a plurality of subjects having cancer:

(i) tumor genomic testing data, including somatic alterations, collected at two or more time intervals per subject via serial biopsy of cell-free DNA;
(ii) one or more therapeutic interventions administered to each of the subjects at one or more times; and
(iii) efficacy of the therapeutic interventions;

(Direct infringement of Claim 1)

2. in particular, the method of any one of Claims 1-4, wherein the plurality of subjects is at least 50, at least 500 or at least 5000 subjects;

(Direct infringement of Claim 5)

3. in particular, the methods of any one of Claims 1-6, wherein weight, adverse treatment effects, histological testing, blood testing, radiographic information, prior treatments, and/or cancer type is used to help classify treatment efficacy;

(Direct infringement of Claim 7)

4. in particular, the method of any one of Claims 1-8, wherein the method comprises classifying effectiveness of treatment using a classification algorithm, such as:

(i) linear regression processes, such as multiple linear regression, partial least squares, regression and principal components regression;
(ii) binary decision trees, such as recursive partitioning processes such as classification and regression trees;
(iii) artificial neural networks such as back propagation networks;
(iv) discriminant analyses such as Bayesian classifier or Fischer analysis;
(v) logistic classifiers; and/or
(vi) support vector classifiers, such as support vector machines;

(Direct infringement of Claim 9)

5. in particular, the method of any one of Claims 1-9, wherein both germline and somatic alterations are used for determining treatment efficacy;

(Direct infringement of Claim 10)

6. in particular, the method of any one of Claims 1-12, wherein the tumor genomic testing data is DNA sequencing data;

(Direct infringement of Claim 13)

7. in particular, the method of Claim 13, wherein the DNA sequencing data includes polynucleotides mapping to specific loci in the genome that are the subject of interest, and have been isolated for sequencing by sequence capture or site-specific amplification;

(Direct infringement of Claim 14)

8. in particular, the method of any one of claims 1-14, wherein the cell free DNA has been tagged or tracked in order to permit subsequent identification and origin of the particular polynucleotide.

(Direct infringement of Claim 15)

II. supplying and/or offering to supply for use means, which are suitable and intended for use in,

1. a computer implemented method comprising use of a computer database to identify one or more effective therapeutic interventions for a subject having cancer, wherein the computer database includes, for each of a plurality of subjects having cancer:

(i) tumor genomic testing data, including somatic alterations, collected at two or more time intervals per subject via serial biopsy of cell-free DNA;

(ii) one or more therapeutic interventions administered to each of the subjects at one or more times; and
(iii) efficacy of the therapeutic interventions;

specifically

• the software for accessing the 'SOPHiA DDM™ platform and

• the library preparation and hybridization capture kit and components thereof, including but not limited to the 'SOPHiA GENETICS CUMIN™ adapters, 'Probes by SOPHiA GENETICS' and Instructions for Use,

without

- in the case of an offer, expressly and clearly indicating that the means may not be used without the consent of the Applicant as the proprietor of the European patent EP 3 766 986 for the method of determining copy number variation according to J.II.,

- in the case of supply, imposing on the purchasers, subject to a contractual penalty payment to the Applicant of EUR 10,000 for each case of infringement, a written obligation not to use the means for the method of determining copy number variation according to J.II. without the prior consent of the Applicant as the patent proprietor of the European patent EP 3 766 986; and

• **alternative to request J.I**, the MSK-ACCESS powered with SOPHiA DDM™ test;

(Indirect infringement of Claim 1)

2. in particular, the method of any one of Claim 1-4, wherein the plurality of subjects is at least 50, at least 500 or at least 5000 subjects;

(Indirect infringement of Claim 5)

3. in particular, the methods of any one of Claims 1-6, wherein weight, adverse treatment effects, histological testing, blood testing, radiographic information, prior treatments, and/or cancer type is used to help classify treatment efficacy;

(Indirect infringement of Claim 7)

4. in particular, the method of any one of Claims 1-8, wherein the method comprises classifying effectiveness of treatment using a classification algorithm, such as:

(i) linear regression processes, such as multiple linear regression, partial least squares, regression and principal components regression;
(ii) binary decision trees, such as recursive partitioning processes such as classification and regression trees;
(iii) artificial neural networks such as back propagation networks;
(iv) discriminant analyses such as Bayesian classifier or Fischer analysis;
(v) logistic classifiers; and/or
(vi) support vector classifiers, such as support vector machines;

(Indirect infringement of Claim 9)

5. in particular, the method of any one of Claims 1-9, wherein both germline and somatic alterations are used for determining treatment efficacy;

(Indirect infringement of Claim 10)

6. in particular, the method of any one of Claims 1-12, wherein the tumor genomic testing data is DNA sequencing data;

(Indirect infringement of Claim 13)

7. in particular, the method of Claim 13, wherein the DNA sequencing data includes polynucleotides mapping to specific loci in the genome that are the subject of interest, and have been isolated for sequencing by sequence capture or site-specific amplification;

(Indirect infringement of Claim 14)

8. in particular, the method of any one of Claims 1-14, wherein the cell free DNA has been tagged or tracked in order to permit subsequent identification and origin of the particular polynucleotide.

(Indirect infringement of Claim 15)

K. The Defendants are ordered to deliver up to a bailiff appointed by the Applicant, at their own expense, any physical means referred to under J. in stock and/or otherwise held, owned, or in the direct or indirect possession of the Defendants in Belgium, Germany, France, Italy, the Netherlands, Switzerland and Spain, within one week after service of this order, and to provide the Applicant's counsel with proper evidence of the full and timely compliance with this order within 10 days after the delivery to the bailiff.

L. For each individual violation of the orders under J. and K., the respective Defendant shall pay to the court a penalty payment of up to EUR 10,000. Each infringing act in relation to MSK-ACCESS powered with SOPHiA DDM™ in respect of request J.I and/or any means in respect of request J.II will be considered as a separate violation. Further, in the case of continuous non-compliance or continuous infringement such as the offering of on the internet or non-compliance with the obligation under K., the respective Defendant shall pay to the court a penalty payment of up to EUR 100,000 per day.

In addition:

The Applicant also requests:

M. Any orders shall be immediately enforceable.

N. The Defendants pay the costs of the proceedings pursuant to Article 69.

O. An interim award of costs under Rule 211.1(d). The Defendants are ordered to provisionally reimburse the applicant for costs in the amount of EUR 600,000.

Finally, the Applicant requests the allocation of a technically qualified judge under Rule 33 due to the complexity of the field of technology. The relevant field of technology is generally DNA sequencing and sequence analysis, particularly in the field of cancer diagnosis.

18. In their Objection and in their last submission (Rejoinder dated 24 November 2025), SOPHIA GENETICS entities request:

I. The Application for provisional measures dated 29 August 2025 is refused;

II. The Applicant is ordered to pay the costs of the proceedings; and

III. An interim award of costs under R.211.1(d) RoP, for costs in the amount of EUR 600,000.

IV. In the alternative to Requests I to III, the alleged infringement is allowed to continue subject to the provision of a security the amount of which is left to the discretion of the Court (but which should not exceed the value in dispute) by the Defendants within two weeks. The security can be provided in the form of a bank guarantee.

V. In the alternative to Requests I to IV, the enforcement of the order for provisional measures is dependent on the provision of security by Applicant in the amount of at least EUR 12 million, whereby the security can be provided in the form of a bank guarantee.

VI. With respect to any order for provisional measures concerning indirect infringement, the accused supply or offer of essential means be modified solely by application of the warning label requested by the Applicant (and not modified by contractual penalty).

VII. With respect to any order for provisional measures, enforcement be stayed for a period of three months, to allow hospitals, labs and research institutions to transition to another liquid biopsy product so that patients' access to critical healthcare is not interrupted.

VIII. With respect to any order for provisional measure concerning EP'073 or EP'533, enforcement is stayed pending the outcome of the EPO Technical Board of Appeal case T0717/24. The provisional measures are only then enforceable in the event the claims of EP'073 survive in their current form.

IX. With respect to all requests, the Applicant is ordered to pay the costs of the proceedings for all patents and claims unsuccessfully asserted. With respect to all alternative requests, any order for injunctive relief is limited to the Contracting Member States where the patents (respectively) are in force, or in the further alternative, is limited to the Contracting Member States and other EU states where the patents (respectively) are in force.

GROUNDS FOR THE ORDER

I. Requirements concerning all the patents in suit

Entitlement regarding all the patents in suit

19. It is undisputed that the Applicant is the sole and registered proprietor of the four patents at hand, so it is entitled to file the present Application.

20. It has already been mentioned that, in the course of the proceedings, GUARDANT HEALTH withdrew all its claims based on EP'533.

21. The three patents in suit, respectively EP'073, EP'066, and EP'986, will be presented further on in the decision when examining the respective requirements under R. 211.2 RoP regarding "*sufficient degree of certainty*" for validity and for infringement.

22. The Court finds it opportune in the present case to address firstly the requirement under R. 211. 4 RoP, which concerns the whole request regarding all the patents in suit.

On the requirement of "*any unreasonable delay in seeking provisional measures*" under R. 211.4 RoP

-legal framework

23. R. 211 RoP (Order on the Application for provisional measures) foresees in its point 4: "*The Court shall have regard to any unreasonable delay in seeking provisional measures*".

24. The Order of 25 September 2024 (CoA, *Mammut Sport v Ortovox*, UPC CoA ORD_44387/2024, Headnotes 5), states that: "*The delay within the meaning of R. 211.4 RoP shall be calculated from the day on which the applicant became aware, or should have become aware, of the infringement that would enable him, in accordance with R. 206.2 RoP, to file an application for provisional measures with a reasonable prospect of success. Thus, the decisive point in time is when the applicant has, or should have had, after exercising due diligence, the necessary facts and evidence within the meaning of R. 206.2(d) RoP.*" (English translation of the Order issued in German).

-parties' arguments

25. The Applicant contends that it was informed of the marketing in the UK of the allegedly infringing test in May 2025, whereupon it promptly conducted the necessary investigations into MSK-DDM tests and realised that these tests infringed several of its patents. GUARDANT HEALTH then sent a letter on 27 May 2025 to SOPHIA GENETICS UK on the basis of its UK patents (in particular the UK national parts of EP'533 and EP'073). GUARDANT HEALTH explains that as SOPHIA GENETICS UK responded late and without a sufficiently clear explanation, it brought an infringement action on the merits before the UK national court on 14 July 2025. GUARDANT HEALTH then investigated the possible marketing of allegedly infringing products throughout Europe and discovered that marketing had already begun in various European hospitals from March 2025 onwards in France (Exhibits GH 11 to 14), Italy, Germany and Belgium (Exhibits GH 11 to 14), and was set to expand to other European countries. GUARDANT HEALTH adds that it also became aware of a webinar held on 27 August 2025 (presented by a senior scientist from SOPHIA GENETICS) relating to tests using "clinical cfDNA material".

26. The Defendant argues that the Applicant cannot provide a specific date on which it became aware of the alleged acts of infringement within the UPC territory, nor the specific circumstances in which it became aware of them. According to SOPHIA GENETICS, the first commercial use of the allegedly infringing products in France was made public on 19 June 2024 (Exhibit SG 20). SOPHIA GENETICS adds that the expansion of the customer base invoked by the claimant cannot constitute a revival of the criterion of urgency. SOPHIA GENETICS argues that the date on which GUARDANT HEALTH became aware of SOPHIA GENETICS's activities must be set prior to May 2025 given that a webinar presented the products in question on 25 February 2025, and it was attended by one of GUARDANT HEALTH's employees (Exhibits SG 42 and GH 33); that a second webinar on the accused products was presented on 25 March 2025 and was attended by four GUARDANT HEALTH employees (Exhibits GH 23 and SG 42); that this webinar was viewed on 20 March 2025 by the 'Vice President of Clinical Laboratory Production at GUARDANT HEALTH' (Exhibit SG 42) and by one of the Applicants in the present action on 18 April 2025 (Exhibit SG 43); and that in August 2024, two GUARDANT HEALTH employees (a "*Staff Field Applications Scientist*" and an "*Associate Director of Bioinformatics*") requested a demo from Sophia

DDM (Exhibit SG 44). Finally, SOPHIA GENETICS argues that on 11 July 2025, a webinar presented the allegedly infringing products and their results, and it was attended by three GUARDANT HEALTH employees (Exhibit SG 45). SOPHIA GENETICS adds that both parties belong to the same networks (notably ELBS memberships) and have access to the same scientific publications, and that GUARDANT HEALTH monitors or should monitor the liquid biopsy market. SOPHIA GENETICS concludes that GUARDANT HEALTH was or should have been aware of the accused products prior to receiving the letter of 20 June 2025, as the only additional evidence they needed concerned the existence of activity in Europe, which had been announced a year earlier, on 19 June 2024 (Exhibits SG 20-21).

-response to the arguments

27. The Applicant's diligence must be assessed on a case-by-case basis. The Court shall take into account, when stating the starting point of the reasonable delay, that the Applicant had sufficient evidence at such time to guarantee a reasonable prospect of success of their case.

28. In the present case, the Court first notes that, contrary to SOPHIA GENETICS's assertion, the Applicant proposes the starting point as being 27 May 2025. This date refers to the letter sent by GUARDANT HEALTH to SOPHIA GENETICS concerning the UK market, invoking several European patents, including EP'533 and EP'073, in force in the UK, as well as two UK patents. It is clear from reading this letter that it was sent by GUARDANT HEALTH to SOPHIA GENETICS at the time of the opening of a tender by NHS England in relation to the supply of liquid biopsy testing services (Expressions of interest from the current seven genomic laboratory hubs - Exhibit SG 049). In this letter, GUARDANT HEALTH drew up an initial comparative table between Claim 1 of EP'533 and what GUARDANT HEALTH knew regarding the allegedly infringing product, which was available on SOPHIA GENETICS's website (*i.e.* "*the factsheet*" and "*the user manual*"). Therefore, the Court is sufficiently informed concerning the circumstances in which the Applicant claims to have first become aware of the existence of an infringement or a risk of infringement in Europe.

29. Furthermore, the Defendants' arguments regarding the fact that one of its competitors had announced the marketing of a test in the field of liquid biopsy as early as June 2024, and the fact that GUARDANT HEALTH employees were attending online SOPHIA GENETICS seminars (without establishing whether the aforementioned employees have the necessary IP knowledge and/or a position in the management of the group to decide on a judicial action) prior to May 2025 cannot be considered as sufficient, taking into account the specificity of such a highly complex technology. Accordingly, the Court finds relevant the Applicant's arguments put forward in §6 of their Reply, as follows:

"*Technical analysis of the Defendants' test between May and July was not straightforward, and this work took several weeks due to the complexity of the patents' technology and the lack of public technical information on how MSK-DDM works. For example, it was not readily apparent whether MSK-DDM used non-unique tagging. Or, by way of another example, the Applicant obtained a copy of GH 22, the user manual for MSK-DDM Capture Solutions, which is crucial for showing infringement, only on 11 July 2025.*"

30. The Court notes that, to establish that the allegedly infringing product reproduces the claims of the patents in question, the Applicant primarily relies on GH 21 and GH 22.

31. Regarding GH 21: even though SOPHIA GENETICS in its Rejoinder §7 and 8 (Exhibits SG 100 and 101 and GH 21) asserts and justifies with a screenshot on Google that the manual in GH 21 was online as early as October 2024, GUARDANT HEALTH cannot be expected to monitor the Internet for all competing products when it had not been alerted by SOPHIA GENETICS's activity concerning said products in Europe (or at least in the States where the European patent in question are in force) before May 2025.

32. Regarding GH 22: the fact that GUARDANT HEALTH only had access to GH 22 in July 2025 is not disputed by the Defendants; the latter replies in its Rejoinder that GUARDANT HEALTH could have established its case based solely on GH 21. However, the demonstration of the infringement of patents EP'073 and EP'066 is based on GH 22 regarding some key features (see GUARDANT HEALTH Application: §187 for EP'073 and §205 for EP'066).

33. Concerning the alleged infringement of EP'986, the Applicant mainly relies on GH 21 as well as on Exhibit GH 39, and it is not contested that this latest document was posted online in the course of April 2025 (see §223 of GUARDANT HEALTH Application).

34. Finally, the Court notes that the other information cited by the Defendants prior to May 2025 is either too general in scope (*i.e.* commercial documents that do not contain technical information) or relates to activities outside Europe (particularly in the USA). It has not been sufficiently demonstrated by SOPHIA GENETICS that, on the one hand, the marketing of the tests in Europe was obvious and known and, on the other hand, that the technical specifications (*i.e.* the characteristics and functionalities of the test accused of infringement) were disclosed in sufficient detail to allow for an analysis of the possible reproduction of the patents in suit.

35. Consequently, the starting point for the reasonable delay in seeking provisional measures required by R. 211.4 RoP, that is to say the date on which GUARDANT HEALTH became (or should have become) aware of an infringement or risk of infringement of its European patents by the SOPHIA GENETICS tests in question, is set by the Court at 27 May 2025 (*i.e.* the date on which a correspondence began between the parties on the subject of the present dispute).

36. The Court considers that a three-month period (until the application dated 29 August 2025) constitutes a reasonable delay to prepare its action by gathering the necessary evidence, given that the case involves several patents and a complex and sophisticated technology.

37. Regarding the Defendant's argument that GUARDANT HEALTH was prepared to initiate provisional measures proceedings before the UPC as early as 27 May 2025, the date on which GUARDANT HEALTH sent a letter relating to proceedings in the UK, the Court considers this irrelevant. In the aforementioned letter, GUARDANT HEALTH refers to financial report GH 49, stating: "*You are targeting UK customers for this technology*" (SOPHIA GENETICS financial report for the second quarter of 2024). Contrary to SOPHIA GENETICS's argument, this document did not mention any customers in Europe outside the UK for the accused tests. In particular, it did not mention the University of Heidelberg in Germany. Furthermore, GUARDANT HEALTH did not consider itself ready to bring an action in the UK on the national patents and EP'533 and EP'073 until 14 July 2025, and it took several more weeks before taking action before the UPC. This was to establish the facts of infringement in European countries outside the UK (*i.e.* the Member States of the UPC) and

to gather sufficient evidence concerning the four patents it considered to have been infringed, using the public information available at that time regarding the accused tests. This evidence had to be sufficient from the outset of the provisional measures proceedings before the UPC, which are characterised by a "*summary procedure*" and a "*front-loaded*" system.

38. Consequently, SOPHIA GENETICS fails to demonstrate that GUARDANT HEALTH sought provisional measures within a delay that was unreasonable under R. 211.4 RoP.

II. Requests under EP'073

Presentation of the patent in suit

39. EP'073 is titled "*Methods to detect rare mutations and copy number variation*".

40. The application was filed on 4 September 2013.

41. The patent in suit claims priority of four US applications: 4 September 2012 US 201261696734 P, 21 September 2012 US 201261704400 P, 15 March 2013 US 201361793997 P and 13 July 2013 US 201361845987 P.

42. EP'073 is a divisional application of EP'533 (the patent for which the requests have been withdrawn by the applicant during the present proceedings) which in turn is a divisional application of EP 2893040 which has been revoked by the EPO in appeal proceedings.

43. The notice of patent grant was published on 1 December 2021. Opposition has been filed at the EPO, and the opposition division upheld the patent in slightly amended form (*i.e.* by combining granted claims 1 and 3). An appeal against this decision is pending, and oral proceedings are scheduled for 24 April 2026.

44. In its preliminary opinion issued on 15 December 2025 regarding EP'073, admitted as new evidence in the present case by procedural order of 18 December 2025, the EPO Board of Appeal (BoA) holds that Claim 1 "*does not comply with requirements of Art. 76(1) EPC*" and is "*currently of the opinion that Claim 1 of each of the auxiliary requests filed with the respondent's reply to the appeals fails to comply with the requirements of Articles 76(1) and 123(2) EPC*" relating to added subject-matter. In its concluding remarks, the BoA notes that "*it is likely that the appeal will be allowed and the patent be revoked*".

45. The patent is currently in force in Austria, Belgium, Germany, France, Italy, the Netherlands and Sweden. Outside the UPC territories, it is also in force in the Czech Republic, Switzerland, Norway, Spain, Poland and the UK.

46. EP'073 had been opted out of the UPC's jurisdiction, but the opt-out was withdrawn on 28 August 2025.

47. The patent in suit comprises 14 claims.

48. Claim 1 reads as follows:

    1. *A method for processing at least one set of tagged parent polynucleotides, comprising steps of:*

       a. converting initial starting genetic material into the tagged parent polynucleotides using non-unique barcode oligonucleotides, wherein converting comprises enzymatic ligation;

b. amplifying the tagged parent polynucleotides in the set to produce a corresponding set of amplified progeny polynucleotides;

c. sequencing a subset of the set of amplified progeny polynucleotides, to produce a set of sequencing reads; and

d. collapsing the set of sequencing reads to generate a set of consensus sequences, each consensus sequence corresponding to a unique polynucleotide among the set of tagged parent polynucleotides,

wherein (i) the initial starting genetic material is cell-free DNA isolated from a body fluid, and comprises no more than 100 ng of polynucleotides,

and (ii) detection of the non-unique barcodes in combination with sequence data of beginning and end portions of sequencing reads allows assignment of a unique identity to a parent polynucleotide.

-the subject-matter of the invention in EP'073

49. [001] and [002] of the concerned patent provide the background of the invention:

[0001] *The detection and quantification of polynucleotides is important for molecular biology and medical applications such as diagnostics. Genetic testing is particularly useful for a number of diagnostic methods. For example, disorders that are caused by rare genetic alterations (e.g., sequence variants) or changes in epigenetic markers, such as cancer (..), may be detected or more accurately characterized with DNA sequence information.*

[0002] *Early detection and monitoring of genetic diseases, such as cancer is often useful and needed in the successful treatment or management of the disease. One approach may include the monitoring of a sample derived from cell free nucleic acids, a population of polynucleotides that can be found in different types of bodily fluids. In some cases, disease may be characterized or detected based on detection of genetic aberrations, such as a change in copy number variation and/or sequence variation of one or more nucleic acid sequences, or the development of other certain rare genetic alterations. Cell free DNA ("cfDNA") has been known in the art for decades, and may contain genetic aberrations associated with a particular disease. With improvements in sequencing and techniques to manipulate nucleic acids, there is a need in the art for improved methods and systems for using cell free DNA to detect and monitor disease.*

50. EP'073 relates to methods which treat small quantities of cell-free DNA (hereinafter "cfDNA") (100 ng or less) in a way which allows the sequence of individual cfDNA molecules to be identified even after the noisy steps of amplification and sequencing. The claimed method tags cfDNA in a sample with barcodes, and the tagged cfDNA is then amplified and sequenced to produce sequence reads. (see §83 of the Application).

51. The sequence reads are then arranged into groups which correspond to an original cfDNA molecule, and the members of this group are analysed to provide a consensus sequence (see §71 of the Application) for the original cfDNA molecule:

"Where a DNA molecule has been sequenced multiple times, the various sequence reads can be compared to generate 'calls' that represent the best prediction (or consensus) for the true identity of the nucleotide at each position in that molecule. Differences between sequence reads for the same molecule (e.g. due to experimental noise) are thus removed."

52. An important aspect of Claim 1 is that it uses non-unique tagging, meaning that the same tag (barcode) is used for multiple cfDNA molecules.

53. Claim 1 of the patent, as maintained by the EPO opposition division, reads as follows (the "*feature breakdown*" presentation by the Applicant is not contested by the Respondent and adopted by the Court):

1.1	A method for processing at least one set of tagged parent polynucleotides, comprising steps of:
1.2	a. converting initial starting genetic material into the tagged parent polynucleotides using non-unique barcode oligonucleotides, wherein converting comprises enzymatic ligation;
1.3	b. amplifying the tagged parent polynucleotides in the set to produce a corresponding set of amplified progeny polynucleotides;
1.4	c. sequencing a subset of the set of amplified progeny polynucleotides, to produce a set of sequencing reads; and
1.5	d. collapsing the set of sequencing reads to generate a set of consensus sequences, each consensus sequence corresponding to a unique polynucleotide among the set of tagged parent polynucleotides,

1.6	wherein (i) the initial starting genetic material is cell-free DNA isolated from a body fluid, and comprises no more than 100 ng of polynucleotides,
1.7	and (ii) detection of the non-unique barcodes in combination with sequence data of beginning and end portions of sequencing reads allows assignment of a unique identity to a parent polynucleotide.

Claim interpretation regarding EP'073

-the skilled person

54. Only the Defendants propose a definition of the person skilled in the art in the present case: "*Like 533, 073 is addressed to a skilled person working in the genomic analysis of cfDNA*" (§194 of the Objection). This definition was not contested by the Applicant in its Reply.

55. Provided that the concerned method is a variation/improvement of an existing sequencing technology as can be found in the cited prior art, the Court asserts that the relevant skilled person in the present case (under EP'073) is a molecular biologist, familiar with Next-generation sequencing technology ("NGS")[1] and genetic testing.

-principles for claim interpretation

56. In accordance with Art. 69 of the European Patent Convention (EPC) and the Protocol on its Interpretation, the present panel adopts the standard for the interpretation of patent

[1] *The NGS is used to determine the order of nucleotides in entire genomes or targeted regions of DNA or RNA wherein a big number of fragments are sequenced at the same time.*

claims set by the UPC Court of Appeal in two recent orders (UPC_CoA_335/2023 and UPC _CoA_1/2024), as follows:

1) The patent claim is not only the starting point, but the decisive basis for determining the protective scope of the European patent.

2) The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim.

57. However, this does not mean that the patent claim serves only as a guideline and that its subject-matter may extend to what, from a consideration of the description and drawings, the patent proprietor has contemplated.

58. The patent claim is to be interpreted from the point of view of a person skilled in the art.

59. In applying these principles, the aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties.

60. These principles for the interpretation of a patent claim apply equally to the assessment of the infringement and validity of a European patent. This follows from the function of patent claims, which under the EPC serve to define the scope of protection of the patent under Art. 69 EPC and thus the rights of the patent proprietor in the designated Contracting States under Art. 64 EPC, while considering the conditions for patentability under Art. 52 to 57 EPC.

61. In the present case, the Applicant presents Claim 1 of EP'073 with the following interpretation:

Feature 1.1: a method for dealing with tagged polynucleotides in which:

Feature 1.2: In step (a), enzymatic ligation is used to convert *"initial starting genetic material"* into tagged material.

- The "initial starting genetic material" is defined in part (i) of the final portion of the claim (Feature 1.6) as being *"cell-free DNA isolated from a body fluid"* and includes *"no more than 100 ng"* of polynucleotides.
- The tagging uses *"non-unique barcode oligonucleotides*".

The reference to *"non-uniquely tagging"* in Claim 1 thus means that a low number of different tags is used in step (a), such that *"individual target polynucleotides will receive the same tag oligonucleotide"*

Feature 1.3: In step (b), the tagged cfDNA is amplified (*e.g.* using PCR) to produce the *"progeny polynucleotides".* Tumor-derived cfDNA is present at very low levels, and so the original molecules are amplified to assist in sequencing. However, amplification techniques are inherently noisy and there is therefore a requirement to remove this noise.

Feature 1.4: In step (c) a subset of the progeny polynucleotides is sequenced, which provides a set of sequencing reads.

Feature 1.5: Step (d) involves "collapsing" the set of sequencing reads *"to generate a set of consensus sequences*". The tagging in step (a) *(Feature 1.2)* means that sequence reads can be linked back to individual starting cfDNA molecules, and any noise added during steps (b) & (c) *(Features 1.3 & 1.4)* can be corrected. The various sequencing reads which originate

from the same original cfDNA molecule are 'collapsed' to generate a 'consensus sequence' *i.e.* they are grouped together and tracked back to original cfDNA molecules (see [0084] of EP'073) and then the most likely (*i.e.* consensus) true nucleotide at each sequenced position in the original cfDNA molecules is identified, thereby removing noise.

Feature 1.7: Part (ii) in the final portion of the claim provides more details on how the 'collapsing' step *(feature 1.5)* operates. Because non-unique tagging was used in step (a) *(Feature 1.2)* it is not possible to identify individual starting cfDNA molecules by using the tags alone. Rather, the claim states that the link back to starting molecules is made by detecting *"the non-unique barcodes in combination with sequence data of beginning and end portions of sequencing reads"*, and this combination of information provides *"a unique identity to a parent polynucleotide*.

62. Regarding the claims of EP'073, the Defendants accept the Applicant's characterisation of features 1.2, 1.3 and 1.4 as set out in §173 of the Application. The Defendants agree with the Applicant that the only concept in Claim 1 of EP'073 not present in Claim 1 of the parent patent EP'533 is that the sequences are collapsed into a consensus sequence (see feature 1.5 of EP'073).

63. The parties disagree on the interpretation of the terms "*collapsing into a consensus sequence*" in features 1.5 and 1.7.

64. The Defendant argues (§88, 196 to 198 and 200 of the Objection) that collapsing sequences into consensus sequences is a well-known process. The patent describes that there are two ways to do this:

    1) a straightforward way where sequences are aligned, and the most frequent nucleotide at a certain position is the consensus nucleotide, as shown in the following scheme (§22 of the Rejoinder)

    2) probabilistic methods.

65. According to SOPHIA GENETICS, in EP'073, claims only relate to the first method since it mentions only consensus sequences. Therefore, probabilistic methods would be excluded from the scope of protection covered by the patent as mentioned in the description, but not being claimed.

66. The Applicant states in its Reply (§33 to 40) that Claim 1 is not limited to any particular way of analysing the consensus sequences or detecting variants. According to GUARDANT HEALTH, the Defendants read limitations into the claim that are not present. The claim encompasses the approach described in [0124] as well as approaches that take into account "*all of the sequence reads in all of the CUMIN families*" when determining if a variant is present at a particular frequency at a particular position (see §213 of the SoD). The specification of the patent in [0078] mentions the use of 'probabilities' not as an alternative to feature 1.5; rather, this subject matter falls within the scope of Claim 1. The last sentence of [0078] states that "*Furthermore, determining frequencies of base calls based on probabilities derived from family information also reduces noise in the received*

message from an ensemble of molecules." The word 'furthermore' provides a continuation of the preceding sentence concerning 'collapsing'.

-Response to the parties' arguments

67. The Court notes that EP'073 mentions in its description (§78, and §123 to 175) two alternative methods for analysing grouped amplified sequence reads in order to reduce the noise (effect of errors) caused by amplification and sequencing.

68. As indicated by Defendants, and this point has not been contested by GUARDANT HEALTH, the probabilistic method was well-known at the time of the grant of the patent at hand, so the skilled person will understand that the invention concerns the other way, *i.e.,* "*the base to base method*" as expressly mentioned in Claim 1.

69. Therefore, the Court is of the opinion that in the present case, EP'073 clearly teaches the person skilled in the art that the method based on probabilities is mentioned in the patent's specification as an illustration of other methods but is not mentioned in the claim, thus it does not fall within the scope of the protection of EP'073 (see CoA, 25 November 2025, *Meril v Edwards*, UPC_CoA_464/2024, Headnotes).

On the requirement that the patent in question is valid with a sufficient degree of certainty (R. 211.2 RoP)

70. SOPHIA GENETICS contends that provisional measures requested by GUARDANT HEALTH on the basis of EP'073 cannot be granted since this patent is not valid on several grounds: added-matter and lack of inventive step.

-added-matter

Legal framework

71. Art. 76 and 123(2) EPC

72. UPC caselaw: The UPC Court of Appeal has set out the following principles regarding added-matter for divisional applications (CoA, 2 October 2025, *expert e-Commerce GmbH and expert Klein GmbH v. Seoul Viosys*, UPC_CoA_764/2024):

« *Headnote*

- There is added-matter if the claim as granted contains subject-matter that extends beyond the content of the application as filed. In order to ascertain whether there is added-matter, the Court must thus first ascertain what the skilled person would derive directly and unambiguously using his common general knowledge and seen objectively and relative to the date of filing, from the whole of the application as filed, whereby implicitly disclosed subject-matter, i.e. matter that is a clear and unambiguous consequence of what is explicitly mentioned, shall also be considered as part of its content.

- Where, as here, the patent results from a divisional application, this requirement applies to each earlier application. The subject-matter of the granted claim 1 thus may not extend beyond (1) the disclosure of the application as filed for the patent in suit and (2) the disclosure of the original PCT application that entered the regional phase and is the parent application for the divisional application."

Parties' arguments

73. SOPHIA GENETICS argues (§271 of the Objection) that Claim 1 comprises a combination of features that is not directly and unambiguously disclosed in the application as filed. The Applicant has pointed to embodiment 78 in the original PCT application (Exhibit SG 91: application of WO 2014/034556) as the starting point for the combination of features in Claim 1. However, embodiment 78 does not contain *(i)* the initial starting material being cell free DNA isolated from body fluid; *(ii)* comprising no more than 100 ng of polynucleotides; *(iii)* using non-unique barcode oligonucleotides in combination with the start and end portions of the parent polynucleotides to convert the parent polynucleotides into uniquely identifiable molecules; and (iv) that the conversion comprises enzymatic ligation. Regarding features *(i)*, *(iii)* and *(iv)* above, the EPO opposition division itself held at paragraph 45 of its decision that the "embodiments" on pages 85-113 of the Application (including, therefore, embodiment 78 on page 93) do not, on their own, provide a basis for all of these features in combination. Accordingly, the opposition division should have held that Claim 1 adds matter. Whilst each of these additional features may be disclosed elsewhere in the PCT application, this is not in relation to original embodiment 78 and there is no teaching to suggest to the skilled person that all of these features should be combined. SOPHIA GENETICS adds (§271 of the Objection) that each of dependent Claims 2-14 are invalid for added-matter. Again, whilst the additional features in these claims may be disclosed somewhere in the application as filed, they are not disclosed in combination with all of the other features in Claim 1.

74. GUARDANT HEALTH replies (§44 of the Reply*)* that the opposition division considered at length the notion of basis in more than 15 pages of its decision (§16-111 of GH 31) and concluded that the upheld claims find basis. In particular, the opposition division correctly found that Claim 1 finds basis at embodiment 83 (which is dependent on embodiments 78 and 82), and [00202], [00237], [00238], and [00243]; and that the dependent claims also find basis. The opposition division also correctly explained in §46-50 of GH 31 where the combination of features of Claim 1 find basis.

Response to the parties' arguments

75. The Applicant refers to the EPO opposition division decision to defend against attacks on the validity of its patent, however the Court notes that in this decision under appeal, the BoA, in its recent preliminary opinion of 15 December 2025, considers revoking the patent in suit on the grounds of added-matter.

76. The Court also notes that there are indeed scattered fragments in the original PCT application (Exhibit SG 91) which serve as the basis for the application, in particular in the embodiment 78, as suggested by SOPHIA GENETICS. However, there are several elements missing from this embodiment:

    i) the initial starting material being cell free DNA isolated from body fluid;
    ii) comprising no more than 100 ng of polynucleotides;
    iii) using non-unique barcode oligonucleotides in combination with the start and end portions of the parent polynucleotides to convert the parent polynucleotides into uniquely identifiable molecules; and
    iv) that the conversion comprises enzymatic ligation

77. It is also clear that all these missing elements can be found in the patent application as filed (Exhibit SG 91). The question is whether they are directly and unambiguously derivable from the PCT application or whether the latter is used as some kind of reservoir from which scattered fragments can be combined, in which case there is a whole series of different 'inventions' included in the PCT application.

78. Embodiment 78 in the original PCT application reads as follows:

    A method comprising:
    a. providing at least one set of tagged parent polynucleotides, and for each set of tagged parent polynucleotides,
    b. amplifying the tagged parent polynucleotides in the set to produce a corresponding set of amplified progeny polynucleotides;
    c. sequencing a subset (including a proper subset) of the set of amplified progeny polynucleotides, to produce a set of sequencing reads; and
    d. collapsing the set of sequencing reads to generate a set of consensus sequences, each consensus sequence corresponding to a unique polynucleotide among the set of tagged parent polynucleotides.

79. The tagged parent polynucleotides come from embodiment 82 which refers back to embodiment 78:
    82. The method of embodiment 78 further comprising converting initial starting genetic material into the tagged parent polynucleotides.

80. The 100 ng starting material is in embodiment 83, which refers back to Claim 82.
    83. The method of embodiment 82 wherein the initial starting genetic material comprises no more than 100 ng of polynucleotides.

81. The other elements come from different parts of the description *i.e.* cell-free DNA, enzymatic ligation, bodily fluid such as blood, as follows:

    [*00237]* *The systems and methods disclosed herein may be used in applications that involve the assignment of unique or non-unique identifiers, or molecular barcodes, to cell free polynucleotides. Often, the identifier is a bar-code oligonucleotide that is used to tag the polynucleotide*

    [00238] *Often, the method comprises attaching oligonucleotide barcodes to nucleic acid analytes through an enzymatic reaction including but not limited to a ligation reaction.*

    [00202] *The systems and methods may be particularly useful in the analysis of cell free DNAs. In some cases, cell free DNA are extracted and isolated from a readily accessible bodily fluid such as blood.*

82. It follows from these multiple elements from the PCT application that the detection of non-unique barcodes in combination with sequence data of beginning (start) and end (stop) portions of sequence reads may allow for the assignment of a unique identity to a particular molecule. The claims form a clear basis to start with, [237] shows unique and non-unique identifiers or molecular barcodes and they can often be oligonucleotides. This means there are already several alternatives. [238] adds that oligonucleotides can be added by enzymatic reactions which can be litigation but also other reactions, which constitute a choice of alternatives. Finally, non-unique barcodes can be used combined with start and stop portions of sequences.

83. When examining the alleged invalidity of the patent due to an inadmissible extension of its subject-matter, the Court must ascertain what the skilled person would derive directly and unambiguously using their common general knowledge, as seen objectively with respect to the date of filing, from the whole PCT application as filed. On the basis of this, implicitly disclosed subject-matter, *i.e.* elements that are a clear and unambiguous consequence of what is explicitly mentioned, shall also be considered as part of its content. However, the content of an application must not be considered to be a reservoir from which features pertaining to separate embodiments of the application could be combined in order to artificially create a particular embodiment. This concept applies when considering features originally disclosed in separate lists of alternatives, except when there is a pointer to combine these numerous specific features, which encourages the skilled person to combine all these different elements in a particular combination.

84. In the present case, GUARDANT HEALTH merely replied to the attack based on added-matter that the EPO opposition division has taken all the various scattered elements found in the PCT application to conclude that the invention derives directly and unambiguously from that document. It does not provide any arguments to convince the Court that, among all the elements mentioned in the PCT application, the person skilled in the art would have been prompted to choose from among the alternatives proposed, those leading to the invention disclosed in EP'073.

85. Consequently, Applicant fails to demonstrate that the invention disclosed in the patent in suit is a clear and unambiguous consequence of what is explicitly mentioned in the earlier PCT application.

Conclusion on the inadmissible extension

86. Against this background, the Court considers in the context of a preliminary injunction that it has not been demonstrated with a sufficient degree of certainty that EP'073 meets the criterion of Article 123 EPC. This patent is more likely than not to be invalid because of added-matter.

87. In view of the above, dependent Claims 2 to 14 of the patent as maintained after opposition are also more likely than not to be invalid for the same reasons.

88. Moreover, the Court notes that the criterion according to which the existence of infringement must be demonstrated with sufficient certainty (R. 211.2 RoP) has not been met either concerning the infringement of EP'073 (Claim 1) by the alleged infringing product, since feature 1.5, as explained in the claim interpretation, excludes the method based on probabilities, and that it is not disputed between the parties that the SOPHIA GENETICS test accused of infringement uses only the method based on probabilities in the accused test and not the method claimed in feature 1.5 which is the way where sequences are aligned and the most frequent nucleotide at a certain position is the consensus nucleotide.

III. REQUESTS UNDER EP'066

Presentation of the patent in suit

89. EP'066 is titled "*Methods for early detection of cancer*".

90. The application was filed on 14 April 2017.

91. The patent in suit claims priority of 6 US applications: 14 April 2016: 2016 US201662322783 P, US201662322773 P, US201662322786 P, US201662322784 P, US201662322775 P, and 18 April 2016: US201662324287 P.

92. The notice of patent grant was published on 2 October 2024. No opposition has been filed at the EPO.

93. The patent is currently in force in the UPC territories in Belgium, Germany, France, Italy, and the Netherlands. Outside the UPC territories, it is also in force in Switzerland, Spain, and the UK. The patent in suit comprises 14 claims.

94. Claim 1 reads as follows:

    1. *A method for detecting the presence or absence of colorectal cancer, ovarian cancer, lung cancer or pancreatic cancer in a subject comprising:*

       sequencing circulating cfDNA from the subject at a depth of at least 50,000 reads per base to detect one or more genetic variants associated with cancer,

       wherein the sequencing is performed on an enriched set of amplified cfDNA molecules which comprises a panel of genomic regions, wherein the genomic regions in the panel comprise one or more loci from each of the genes AKT1, ALK, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, ESR1, FGFR2, GATA3, GNAS, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, PTEN, RB1, SMAD4, STK11 and TP53, and

       further comprising amplifying the cfDNA prior to sequencing, and determining a consensus sequence from sequence reads obtained from the sequencing to reduce errors from amplification or sequencing.

-the subject-matter of the invention in EP 066

95. The background of the invention is provided as follows in the description of the patent in suit:

    [0001] *Cancer is a major cause of disease worldwide. Each year, tens of millions of people are diagnosed with cancer around the world, and more than half of the patients eventually die from it. In many countries, cancer ranks the second most common cause of death following cardiovascular diseases. Early detection is associated with improved outcomes for many cancers.*

    [0002] *To detect cancer, several screening tests are available. A physical exam and history survey general signs of health, including checking for signs of disease, such as lumps or other unusual physical symptoms. A history of a patient's health habits and past illnesses and treatments will also be taken. Laboratory tests are another type of screening test and may include medical procedures to procure samples of tissue, blood, urine, or other substances in the body before conducting laboratory testing. Imaging procedures screen for cancer by generating visual representations of areas inside the body. Genetic tests detect*

certain gene deleterious mutations linked to some types of cancer. Genetic testing is particularly useful for a number of diagnostic methods.

96. EP 066 relates to methods for identifying four major types of cancer (colorectal, ovarian, lung, pancreatic) by using "deep sequencing" of cfDNA. The concept of sequencing depth was explained in §70 of the Application[2], and the claim uses a depth of at least 50,000x for a panel of 25 specific genes to improve the detection of rare variants. Although this panel is relatively small (the human genome contains around 25,000 genes in total), the examples in the patent show that focusing on these 25 genes permits high sensitivity for detecting the four listed cancers. Like for EP'073, the method includes a step in which errors from the noisy processes of amplification and sequencing are reduced.

Claim interpretation of Claim 1 EP'066

97. Reference shall be made to the principles of interpretation set out by the aforementioned UPC CoA, and the same definition of the skilled person mentioned for patent EP'073 shall be used since it concerns the same technological field.

98. Granted Claim 1 of EP'066 reads as follows (see §195 Application and Exhibit GH 35 for claim feature breakdown):

1.1	A method for detecting the presence or absence of colorectal cancer, ovarian cancer, lung cancer or pancreatic cancer in a subject comprising:
1.2	sequencing circulating cfDNA from the subject
1.3	at a depth of at least 50,000 reads per base to detect one or more genetic variants associated with cancer,
1.4	wherein the sequencing is performed on an enriched set of amplified cfDNA molecules
1.5	which comprises a panel of genomic regions, wherein the genomic regions in the panel comprise one or more loci from each of the genes AKT1, ALK, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, ESR1, FGFR2, GATA3, GNAS, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, PTEN, RB1, SMAD4, STK11 and TP53, and
1.6	further comprising amplifying the cfDNA prior to sequencing, and
1.7	determining a consensus sequence from sequence reads obtained from the sequencing to reduce errors from amplification or sequencing.

[2] §70 of GH Application: "*A sample will usually contain multiple copies of DNA from a particular region in the genome (e.g. many millions of copies of a particular gene even in 1 mL of blood). In a single experiment, any particular nucleotide in a genome can thus be seen in multiple different sequence reads. The number of times that a particular nucleotide is seen is referred to as its 'sequencing depth'. It is denoted as a multiple e.g. a depth of 1,000x means that a particular nucleotide was sequenced 1,000 times, and was seen in 1,000 different sequence reads.*"

99. The Applicant presents Claim 1 of EP'066 with the following elements (§196 of the Application):

Feature 1.1: A method which is used for detecting colorectal, ovarian, lung, or pancreatic cancer.

Feature 1.2: The method includes a step where cfDNA taken from a subject is subjected to a DNA sequencing reaction in order to find variants which are associated with cancer.

Feature 1.3: This sequencing is performed *"at a depth of at least 50,000 reads per base"*. This means that any particular nucleotide position of interest has been seen in the sequence reads at least 50,000 times (see above)

Feature 1.4: Sequencing is *"performed on an enriched set of amplified cfDNA molecules"*. Thus, the cfDNA is subjected to both enrichment and amplification prior to sequencing. The pre-sequencing amplification step is also mentioned in the final clause of the claim.

a) Enrichment focuses sequencing reactions on regions of interest. The human genome contains around 25,000 genes, but Claim 1 specifies a panel of 25 different genes (0.1% of the total), and enrichment is used to ensure that these 25 genes can be deeply sequenced. See [0187]-[0188] in the description for more details.
b) Amplification (also *Feature 1.6*) is used to ensure that there is enough DNA to be detected. Tumor-derived cfDNA is present at very low levels and so the original molecules are amplified to assist in sequencing. Various amplification techniques can be used (*e.g.* see [0181]-[186]), but PCR is most typical. However, as explained already, these amplification techniques are inherently noisy (see also [0207]) and so there is a downstream requirement to remove this noise.

Feature 1.5: The enrichment and sequencing are performed for *"one or more loci"* (*i.e.* at least one position) in each of 25 named genes. These genes are identified by their standard recognised names (*"AKT1, ALK, ..."*), which typically represent an abbreviation of the protein which the gene encodes.

Feature 1.7: Amplification and sequencing both have an inherent noise level which can obscure the detection of variants (see also [0207] of EP'066). To remove this noise the claim collates the various reads from the sequencing step "to reduce errors from amplification or sequencing" in order to determine a consensus sequence. Overall, a starting cfDNA molecule is amplified (a noisy process) and sequenced (another noisy process), but techniques are used to remove the noise and thereby identify the true nucleotide at each position in the original cfDNA molecule.

100. The Defendants do not dispute GUARDANT HEALTH's presentation of each of the features, but they do dispute the purpose of the invention with regard to the detection of the presence or absence of cancer. Thus, SOPHIA GENETICS claims (§278 of its Objection) that the purpose is to determine whether a patient has a specific type of cancer (*e.g.* colorectal cancer). In support of this argument, SOPHIA GENETICS points out that in several paragraphs of the patent description [111], [112] and [114], explicit reference is made to gene panels for each of the four cancers listed in Claim 1, and that [183] notes that within regions of the genome that are targeted for sequencing, there are factors which infer the presence or absence of a certain classification of cancer cells or type of cancer.

101. According to GUARDANT HEALTH, the purpose of the invention is that the selection of these 25 genes is particularly effective in detecting the presence or absence of several types of cancer, including the four types mentioned in Claim 1 (feature 1.1).

102. For the reasons put forward by GUARDANT HEALTH, the Court considers that the purpose of the invention is to detect the presence or absence of the four types of cancers mentioned in 1.1 using a particularly effective selection of these 25 genes.

On the requirement that the patent in question is valid with a sufficient degree of certainty (R. 211.2 RoP)

103. SOPHIA GENETICS contends that provisional measures requested by GUARDANT HEALTH on the basis of EP'066 cannot be granted since this patent is not valid on several grounds: added-matter and lack of inventive step.

-added-matter

104. The Court refers to the same legal framework as that indicated above for the examination of EP'073, as EP'066 also relates to the same technological field.

Parties' arguments

105. In support of the added-matter's attack (§314 to 315 of the Objection), SOPHIA GENETICS starts from Claim 1 in the original PCT application (Exhibit SG 94) and contends that on several points a selection from different lists of genes as can be found in the description has to be made in order to arrive at Claim 1 of the patent in suit. SOPHIA GENETICS concludes that Claim 1 cannot be directly and unambiguously derived from the application as filed.

106. In its Reply, GUARDANT HEALTH (§70 of the Reply) argues that the start from Claim 1 of the original PCT application is not correct; rather, the basis for the current claim should be found in original PCT Claims 37/44/52/56 in combination with [0145], [0155], and [0159] (Exhibit SG 94).

107. The elements invoked by GUARDANT HEALTH in the parent application to demonstrate the absence of extension of the subject-matter by the divisional patent EP'066 are as follows:

108. Claims of the earlier application:

> 37. A method for detecting cancer in a subject comprising: sequencing circulating cell-free DNA (cfDNA) from the subject at a depth of at least 50,000 reads per base to detect one or more genetic variants associated with cancer.
>
> 44. The method of claim 37, wherein the sequencing is performing on an enriched set of cfDNA molecules.
>
> 52. The method of claim 44, wherein the cancer is colorectal cancer, ovarian cancer, lung cancer, pancreatic cancer, or liver cancer.

109. In the original PCT application's description, it is mentioned:

[0145] *Methods herein can be used to detect cancer in a subject. Cell free DNA can be sequenced in subjects not known to have cancer or suspected of having cancer to diagnose the presence of absence of a cancer. Sequencing cell free DNA provides a non-invasive method for early detection of cancer or for 'biopsy' of a known cancer. Cell free DNA can be sequenced in subjects diagnosed with cancer to provide information about the cancer. Cell free DNA can be sequenced in subjects before and after treatment for cancer to determine the efficacy of the treatment.*

[0155] *To improve the likelihood of detecting tumor indicating mutations, the region of DNA sequenced may comprise a panel of genes or genomic regions. Selection of a limited region for sequencing (e.g., a limited panel) can reduce the total sequencing needed (e.g., a total amount of nucleotides sequenced. A sequencing panel can target a plurality of different genes or regions to detect a single cancer, a set of cancers, or all cancers.*

[0159] *In some cases, the one or more regions in the panel can comprise one or more loci from one or a plurality of genes, including one or more of AKT1, ALK, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, ESR1, FGFR2, GATA3, GNAS, IDH1, IDH2, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, PTEN, RB1, SMAD4, STK11, and TP53.*

110. In its Rejoinder, SOPHIA GENETICS demonstrates that what is taught in EP'066 is not an unambiguous consequence of what is explicitly mentioned in the whole original PCT application (Exhibit SG 94) to which GUARDANT HEALTH refers (see §59 of the Rejoinder).

The Court's opinion

111. It was noted above in the section on "claim interpretation" that the invention taught by EP'066 discloses a specific method of sequencing cfDNA that aims to detect the presence or absence of four types of cancer by analysing 25 specifically selected genes. The method taught makes it possible to determine whether the patient is a carrier of one of the four cancers mentioned in feature 1.1. The selection of this list of 25 genes and the four types of cancer targeted are essential features of the invention in EP'066. However, claims 37, 44 and 52 of the concerned earlier parent application do not disclose these features. Even in the description of this application, five and not four types of cancer are mentioned, and there is nothing to prompt a person skilled in the art to select four out of the five. Furthermore, with regard to the 25 genes mentioned in the description in §159, there is no teaching in this paragraph regarding a panel comprising one or more loci from each and every one of the 25 genes listed in the claim. On the contrary, the granted claims mention one or more loci from each of the genes.

112. Thus, the Applicant fails to demonstrate that a skilled person would arrive at the subject-matter of EP'066, as a clear and unambiguous consequence of what is explicitly mentioned in the whole application of the original PCT application.

113. From the selections that have been made without any clear indication in the earlier application, the Court concludes that the invention as now worded in the granted Claim 1 cannot directly and unambiguously be derived from the patent as filed.

114. Consequently, EP'066 is more likely than not to be invalid on the grounds of added-matter. The limitations in dependent claims 2-14 do not solve these issues; they are also more likely than not to be invalid for added-matter.

IV. Request under EP'986

Presentation of the patent in suit

115. EP'986 is titled "*Detection and treatment of disease exhibiting disease cell heterogeneity and systems and methods for communicating test results*" (Exhibit GH 37).

116. The application was filed on 28 December 2015 as a divisional application of EP 3 240 911.

117. The patent in suit claims priority of US201462098426 P of 31 December 2014 and US201562155763 P of 1 May 2015.

118. The notice of patent grant was published on 1 June 2022. No opposition has been filed at the EPO.

119. The patent is in force in Belgium, Germany, France, Italy, and the Netherlands. Outside the UPC territories it is also in force in Switzerland, Spain, and the UK.

120. The patent in suit comprises 15 claims.

121. Claim 1 reads as follows:

1. *A computer implemented method comprising use of a computer database to identify one or more effective therapeutic interventions for a subject having cancer, wherein the computer database includes, for each of a plurality of subjects having cancer:*

   (i) tumor genomic testing data, including somatic alterations, collected at two or more time intervals per subject via serial biopsy of cell-free DNA;

   (ii) one or more therapeutic interventions administered to each of the subjects at one or more times; and

   (iii) efficacy of the therapeutic interventions.

-the subject-matter of the invention in EP'986

122. The background of the invention is provided in [002] to [005] of the concerned patent:

[0002] *One of the reasons cancer is difficult to treat is that current testing methods may not help doctors match specific cancers with effective drug treatments. And it is a moving target - cancer cells are constantly changing and mutating. Cancers can accumulate genetic variants* (...)

[0003] *Cancers can evolve over time, becoming resistant to a therapeutic intervention. Certain variants are known to correlate with responsiveness or resistance to specific therapeutic interventions. More effective treatments for cancers exhibiting tumor heterogeneity would be beneficial. Such cancers may be treated with a second, different, therapeutic intervention to which the cancer responds.*

[0004] *DNA sequencing methods allow detection of genetic variants in DNA from tumor cells. Cancer tumors continually shed their unique genomic material into the bloodstream. Unfortunately, these telltale genomic "signals" are so weak that current genomic analysis technologies, including next-generation sequencing, may only detect such signals sporadically or in patients with terminally high tumor burden. The main reason for this is that such technologies are plagued by error rates and bias that can be orders of magnitude higher than what is required to reliably detect de novo genomic alterations associated with cancer.*

[0005] *In a parallel trend, to understand the clinical significance of a genetic test, treating professionals must have a working knowledge of basic principles of genetic inheritance and reasonable facility with the interpretation of probabilistic data. Some studies suggest that many treating professionals are not adequately prepared to interpret genetic tests for disease susceptibility. Some physicians have difficulty interpreting probabilistic data related to the clinical utility of diagnostic tests, such as the positive or negative predictive value of a laboratory test.*

123. To remedy these problems encountered by treating professionals in detecting cancer and interpreting tests, the patent in question proposes the following invention:

[008] *The invention provides a method comprising use of a computer database to identify one or more effective therapeutic interventions for a subject having cancer, wherein the computer database includes, for each of a plurality of subjects having cancer: (i) tumor genomic testing data, including somatic alterations, collected at two or more time intervals per subject via serial biopsy of cell-free DNA; (ii) one or more therapeutic interventions administered to each of the subjects at one or more times; and (iii) efficacy of the therapeutic interventions.*

124. EP'986 relates to (see §213 and 214 of the GUARDANT HEALTH Application) the use of a database to make a link between *(i)* cfDNA genomic testing data measured over time, which is used to track a tumor, and *(ii)* the efficacy of therapeutic interventions. The description explains how the database *"is useful to infer efficacy of the therapeutic interventions in subjects with a tumor"* (see [0014]) and *"can be consulted in determining a therapeutic intervention for a disease with a particular profile"* ([0022]). The database is particularly useful when the tumor is heterogeneous. [0019] notes that cfDNA is an ideal way of detecting such heterogeneity, and [0020] reports that this information *"can be used by a health care provider, e.g., a physician, to develop therapeutic interventions."* Moreover, [0021] states that "M*onitoring changes in the profile of disease cell heterogeneity over time allows therapeutic intervention to be calibrated to an evolving tumor."*

Claim interpretation of Claim 1 EP'986

125. Reference shall be made to the same principles of interpretation set out by the UPC CoA as aforementioned.

126. Regarding the relevant definition of the skilled person, SOPHIA GENETICS proposes, given the features of EP'986's claims which overlap multiple fields, "a team of experts with an interest in multiple domains, including processing, analysing and storing genomic sequencing data, therapy selection for cancer patients, and the design of related decision

support tools." (§368 of the Objection). GUARDANT HEALTH does not raise any objection regarding this definition.

127. The Court adopts this definition, which is relevant for EP'986.

128. Claim 1 of the patent reads as follows (the "*feature breakdown*" presentation by the Applicants is not contested by the Respondent and adopted by the Court) (§215 of the Application and Exhibit GH 38):

1.1	A computer implemented method comprising use of a computer database to identify one or more effective therapeutic interventions for a subject having cancer, wherein
1.2	the computer database includes, for each of a plurality of subjects having cancer:
1.3	(i) tumor genomic testing data, including somatic alterations, collected at two or more time intervals per subject via serial biopsy of cell-free DNA;
1.4	(ii) one or more therapeutic interventions administered to each of the subjects at one or more times; and
1.5	(iii) efficacy of the therapeutic interventions.

129. The Applicant presents Claim 1 of EP'986 with the following interpretation (see §215 of the GUARDANT HEALTH Application).

Features 1.1 & 1.2: The computer database includes at least three pieces of information from a number of cancer patients ("*subjects*"):

Feature 1.3: Genomic testing data from their tumor (*e.g.* DNA sequencing data, as specified in claim 13), which includes data on somatic alterations. This information can include single nucleotide variations, indels, gene fusions, copy number variations, *etc.* (see [0049]). This data is based on analysis of cfDNA. The information was collected from the patient in a series of two or more time points.

Feature 1.4: At least one therapeutic intervention was administered to the patient. Examples of such interventions are given in [0142] to [0152] of the patent.

Feature 1.5: Details of whether the therapeutic intervention(s) was/were efficacious. The database is used (*feature 1.1*) to identify effective therapeutic interventions for a subject who has cancer.

130. SOPHIA GENETICS does not dispute the presentation of the characteristics as described by GUARDANT HEALTH in its Application, but provides more detailed explanations on all the features of EP'986 (§370 to 389 of the Objection). In view of these explanations, Defendants conclude (§390 of the objection) that the efficacy of therapeutic interventions contained in the database must be based upon analysis of the data outlined in features 1.3 and 1.4 (serial genomic testing data of a specific patient in combination with a known therapeutic intervention administered) and must result in a conclusion of efficacy of the therapeutic intervention based on this. All three of these pieces of information (1.3 to 1.5) must therefore be matched for each patient.

131. The Court agrees with SOPHIA GENETICS's interpretation of features 1.3 and 1.4, which is in-line with what is disclosed in Claim 1 of EP'986 and the specification of the patent in suit.

On the requirement that the patent in question is infringed with a sufficient degree of certainty (R. 211.2 RoP)

132. GUARDANT HEALTH accuses SOPHIA GENETICS of direct (and indirect) infringement of Claim 1 and dependent Claims 1, 5, 7, 9, 10 and 13-15 of EP'986.

133. SOPHIA GENETICS contends that provisional measures requested by GUARDANT HEALTH on the basis of EP'986 cannot be granted since this patent is not infringed by the accused SOPHIA GENETICS's test, and since this patent is more likely than not to be invalid (lack of inventive step over prior art documents "Elton" and "Forshew").

-GUARDANT HEALTH's arguments

134. GUARDANT HEALTH provides a comparison between the features of Claim 1 of the patent in suit and the accused product based on Exhibit GH 39, as follows (§233 of the Application):

Claim 1	**'MSK-ACCESS® powered with SOPHiA DDM™'**
1.1 A computer implemented method comprising use of a computer database to identify one or more effective therapeutic interventions for a subject having cancer, wherein	GH39 refers to the generation of a collection of data (*i.e.* a computer database) which will be used to *"gain deeper insights into the efficacy of therapies"*. It also refers to the MSK-DDM liquid biopsy test, which is used only for cancer patients.
1.2 the computer database includes, for each of a plurality of subjects having cancer:	GH39 confirms that the database is built using data of *"how patients responded to previous treatments"*. Indeed, it would be meaningless to create a database with data from only one patient.
1.3 (i) tumor genomic testing data, including somatic alterations, collected at two or more time intervals per subject via serial biopsy of cell-free DNA;	GH39 refers to the MSK-DDM test, and factsheet GH20 confirms that this test provides tumor genomic testing data derived from cfDNA. To determine *"how patients responded to previous treatments"* (as mentioned in GH39) based on the output of the test, cfDNA from a patient must be analysed at more than one time point. In this regard: • Flyer GH19 highlights the use of the test for *"longitudinal monitoring"* *i.e.* to follow their cfDNA genomic testing data over time. • GH23 similarly states that the MSK-DDM test will be used for *"longitudinal tracking"* of a patient. In particular, it can *"use that information to track disease over time. And this is a feature we've implemented in both MSK ACCESS but also ..."* • Page 2 of GH21 states that the test considers if variants were *"previously identified as somatic variants in MSK-ACCESS® powered with SOPHiA DDM™ for the same subject"*
1.4 (ii) one or more therapeutic interventions administered to each of the subjects at one or more times;	GH39 states that the database is built using data of *"how patients responded to previous treatments"*, and also refers to *"retrospective clinical trial data analysis"*.

135. GUARDANT HEALTH bases their infringement primarily on Exhibit GH 39. The Applicant explains that, when investigating the defendants' activities, they found a joint press release (Exhibit GH 39) that was issued in collaboration with 'Precision for Medicine' and which explains, according to GUARDANT HEALTH, that they are using the MSK-DDM test to develop a database and computer-implemented method precisely as defined in Claim 1 of EP'986:

1.1 A computer-implemented method comprising the use of a computer database to identify one or more effective therapeutic interventions for a subject having cancer, wherein

GH 39 refers to the generation of a collection of data (i.e. a computer database) which will be used to "gain deeper insights into the efficacy of therapies". It also refers to the MSK-DDM liquid biopsy test, which is used only for cancer patients.

1.2 The computer database includes, for each of a plurality of subjects having cancer:

GH 39 confirms that the database is built using data of "how patients responded to previous treatments". Indeed, it would be meaningless to create a database with data from only one patient.

1.3 (i) tumor genomic testing data, including somatic alterations, collected at two or more-time intervals per subject via serial biopsy of cell-free DNA;

GH 39 refers to the MSK-DDM test, and factsheet GH20 confirms that this test provides tumor genomic testing data derived from cfDNA.

To determine "how patients responded to previous treatments" (as mentioned in GH39) based on the output of the test, cfDNA from a patient must be analysed at more than one time point. In this regard:

- *Flyer GH19 highlights the use of the test for "longitudinal monitoring" i.e. to follow their cfDNA genomic testing data over time.*
- *GH23 similarly states that the MSK-DDM test will be used for "longitudinal tracking" of a patient. In particular, it can "use that information to track disease over time. And this is a feature we've implemented in both MSK ACCESS but also ..."*
- *Page 2 of GH21 states that the test considers if variants were "previously identified as somatic variants in MSK-ACCESS® powered with SOPHiA DDM ™ for the same subject"*

1.4 (ii) one or more therapeutic interventions administered to each of the subjects at one or more times;

GH39 states that the database is built using data of "how patients responded to previous treatments", and also refers to "retrospective clinical trial data analysis".

1.5 (iii) efficacy of the therapeutic interventions.

GH 39 refers to the inclusion of "retrospective clinical trial data", to "understanding how patients responded to previous treatments", and to using information to "gain deeper insights into the efficacy of therapies".

136. The Applicant affirms that (§122-126 of the Application), the Defendants are already offering and distributing MSK-DDM in the UPC territory. This software is already equipped to track a user's mutations over time. User manual (GH 21, page 20) explains that variants detected in MSK-DDM *"are stored for future use as prior knowledge"* and that the software stores a "*prior knowledge variants list"*. The bottom of page 20 is unambiguous that data on somatic variations are stored and then subsequently used as "*prior knowledge*".

137. According to GUARDANT HEALTH, at a webinar on 27 August 2025, a scientist working for the Defendants was asked about the MSK-DDM test and his answer included the following statement (Exhibit GH 15):
What is available right now for the users at MSK-ACCESS as of today is the ability to identify previous variants in the same patient and revisit this over longitudinal timepoints.

138. GUARDANT HEALTH concludes that this already gives the ability to track or link variants to therapeutic interventions.

139. The Applicant adds that MSK-DDM has already been distributed in the UPC territory and is already storing detected variants, the defendants have created or are creating the database according to Claim 1, and they have started or will start imminently using and/or offering the method according to Claim 1 (§226 of the Application).

140. In support of its objection, SOPHIA GENETICS first notes that the alleged infringing product (the DDM test itself) plays no role in the exploitation of the analyses and that what GUARDANT HEALTH alleges to be infringement of this patent is "*the software for the SOPHIA DDM platform as a whole*" (§364 of the Objection). Defendants explain that the only feature that could be reproduced by their platform would be indirectly feature 1.3 concerning two-stage information collection, which they deny, and they allege that in any event, the sole production of GH 39 (a press release), which is the document on which GUARDANT HEALTH essentially based its comparison table seeking to demonstrate the reproduction of each of the features taught in Claim 1, cannot be sufficient to prove the alleged infringement.

141. Furthermore, SOPHIA GENETICS argues that the Exhibit GH 39, which is a joint press release with Precision for Medicine announcing a partnership, is vague as to what the work of the Precision for Medicine will entail in the future, and many of the statements made by Precision for Medicine are aspirational in nature, and not reflective of any work being done at present. Regardless, all of the quotes the Applicant points to in this document are from a single paragraph focused on the Product being provided to Precision for Medicine's customers rather than the partnership more generally. This is no surprise given that the Applicant seeks an injunction against only the Defendants in relation to the Product, rather than any other project associated with this partnership (§400 of the Objection).

142. SOPHIA GENETICS criticises GUARDANT HEALTH for constructing an argument by extrapolating from evidence that is insufficient to prove the alleged reproduction (§405 of the Objection). Thus, the Defendants note that the Applicant lifts a single quote from the passage above in GH 39 to support this argument ("*gain deeper insights into the efficacies of therapies*"). SOPHIA GENETICS argue that this quote is in relation to what users can do with the data generated using the Product, and it is in the context of retrospective clinical trial data analysis. According to SOPHIA GENETICS, this is not relevant to infringement for three reasons: *(i)* the Product plays no part in such retrospective analysis; *(ii)* the Product does not collect any data on therapies and thus the Defendants cannot generate a corresponding database; and *(iii)* such analysis is performed after a therapy has already been given to patients on a clinical trial.

143. In its Reply, Defendants emphasise that GH 39 proves that SOPHIA GENETICS's software uses the two stages of information (prior knowledge stored, which is then used for a second knowledge) as taught by the method disclosed in EP'986 (Claim 1.3 to 1.5). GUARDANT HEALTH subsequently responds to the Defendants' argument that it is not SOPHIA GENETICS that implements the method taught by EP'886 through its test but rather its partner or customers, by asserting that even if the conditions for direct infringement were not met, there would still be indirect infringement since SOPHIA GENETICS when offering the accused test would provide their partner or their customers with the means to reproduce the method taught by EP'986 by offering the accused test.

Response to the parties' arguments

144. Firstly, it should be reminded that the alleged infringement under EP'986 concerns only the dry stage performed by "*SOPHIA DDM software platform*" *(see §16 in the decision above on the presentation of the ACCUSED PRODUCT).*

145. The Court notes, in line with SOPHIA GENETICS's argument on this point (§183 and 185 of the Objection), that the manner in which information is processed in SOPHIA GENETICS's software has not been sufficiently proven. Indeed, the Applicant primarily makes use of the press release GH 39. From this press release, it becomes that the accused test is deployed globally with the support of AstraZeneca. This press release gives no further details as to what is done and what information is stored in a database.

146. The accused test is meant to retrospectively analyse cancer treatment in clinical trials and to use this information to refine and optimise clinical trial design and improve patient recruitment for trials. The refining and supporting of clinical trial design is not the same as the identification of one or more effective therapeutic interventions.

147. From a Q&A of a webinar (Exhibit GH 15), it appears that at the development level "*What is available right now for the users at MSK-ACCESS as of today is the ability to identify previous variants in the same patient and revisit this over longitudinal timepoints. So this already gives the ability to track or link variants to therapeutic interventions."* This means that for individual patients it becomes possible to follow the 'fate' of the variants over time.

148. Against this background, it follows that the Applicant has not demonstrated that there is any actual database provided by SOPHIA GENETICS which uses the method of Claim 1 to identify one or more effective therapeutic interventions, nor that such a database is being developed. The burden of proof for the alleged infringement lies with the party invoking it. It cannot rely solely on the disputed information from GH 39 to demonstrate how SOPHIA GENETICS's software processes data. Additional in-depth investigations into how the SOPHIA platform operates or more technical documentation on the 'accused software' would have been necessary. It is not sufficient to rely mainly on a press release such as Exhibit GH 39. This is true both for proving allegations of direct infringement (Art. 25 UPCA) and those of indirect infringement (Art. 26 UPCA). The Court concludes that the allegations of infringement of GUARDANT HEALTH clearly suffer from a "*lack of evidence*".

149. Therefore, the Applicant has failed to demonstrate the existence of an infringement of EP'986's Claim 1, and subsequently of its dependent claims, by "DDM access" with a sufficient degree of certainty as required by R. 211.2 RoP.

V. General conclusion

150. Consequently, GUARDANT HEALTH's requests for provisional measures against SOPHIA GENETICS under the three patents in suit shall be rejected, as well as all of its subsequent requests.

151. As GUARDANT HEALTH's claims have been rejected, it is not necessary to examine SOPHIA GENETICS's subsidiary requests, notably the guarantee.

VI. Costs

152. The application for provisional measures is rejected. The consequence of this as regards the costs, is that GUARDANT HEALTH shall be ordered to pay the legal costs of the proceedings incurred by SOPHIA GENETICS.

153. R. 211.1(d) RoP provides the opportunity to give an interim award of costs in these proceedings.

154. In this case, both parties requested reimbursement of the costs amounting to 600.000 euros to be awarded to the winning party. This amount corresponds to the ceiling set by the decision of the Administrative Committee of 24 April 2023 for a case with a value estimated at 6 million euros.

155. However, the Court takes into account that the present proceedings are a request for a provisional measure that only provides for a limited set of submissions in the context of a summary procedure. It further takes into account the fact that this dispute involves four different patents. Even though the applicant withdrew one of its four patents during the proceedings, the defendant had to examine its defence for the four patents that were opposed in its Objection of 27 October 2025, while the withdrawal occurred later in GUARDANT HEALTH's reply to the Objection, on 10 November 2025.

156. The Court considers the amount of 400.000 euros as reasonable and proportionate in the present case. GUARDANT HEALTH will be ordered to pay SOPHIA GENETICS this amount as an "interim" award of costs.

ORDER

1. The Court notes the withdrawal of the requests under EP 3 470 533.

2. The Application for provisional measures under EP 3 591 073, EP 3 443 066 and EP 3 766 986 is rejected.

3. The Court orders the Applicant to pay to the Defendants interim costs of the proceedings amounting to 400.000 euros.

An appeal against this order may be brought in accordance with Art. 73 (2) (a) UPCA and R. 220.1 (c) and 224.1(b) RoP within 15 calendar days of the notification of the order to the Applicants.

Issued in Paris, on 23 January 2026.

Camille Lignières, Presiding judge and Judge Rapporteur

Camille Lignières Date : 2026.01.23 10:34:36 +01'00'

On behalf of Carine Gillet, Legally qualified judge

Signed by Camille Lignières (due to technical issues)

Camille Lignières Date : 2026.01.23 10:35:09 +01'00'

On behalf of Maximilian Haedicke**,** Legally qualified judge

Signed by Camille Lignières (due to technical issues)

Camille Lignières Date : 2026.01.23 10:35:37 +01'00'

On behalf of Cornelis Schüller, Technically qualified judge

Signed by Camille Lignières (due to technical issues)

Camille Lignières Date : 2026.01.23 10:36:00 +01'00'

Charlotte Ferhat, Clerk

CHARLOTTE CAMILLE CLAIRE FERHAT Signature numérique de CHARLOTTE CAMILLE CLAIRE FERHAT Date : 2026.01.23 11:56:30 +01'00'

ORDER DETAILS

UPC number: UPC_CFI_808/2025
Date of issue: 23/01/2026
Application Type: Application for provisional measures (R. 205 *et seq.* RoP)