

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GUARDANT HEALTH, INC.,)	
)	
Plaintiff,)	C.A. No. 17-1623-LPS
)	
v.)	
)	JURY TRIAL DEMANDED
PERSONAL GENOME DIAGNOSTICS, INC.,)	
)	REDACTED - PUBLIC VERSION
)	
Defendant.)	

**DEFENDANT PERSONAL GENOME DIAGNOSTICS, INC.’S
AMENDED ANSWER TO SECOND AMENDED COMPLAINT,
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendant Personal Genome Diagnostics, Inc. (“PGDx”) hereby submits its amended answer to the Second Amended Complaint of Plaintiff Guardant Health, Inc. (“Plaintiff” or “Guardant”) and counterclaims as follows:

NATURE OF THE ACTION

1. Paragraph 1 of the Second Amended Complaint (the “SAC”) alleges legal conclusions, such that no response is required. To the extent that any response is required, PGDx admits that actions for patent infringement arise under the patent laws of the United States and specifically under Title 35 of the United States Code, Section 271 et seq., but expressly denies that Plaintiff’s claims against PGDx have any merit.

2. PGDx denies the allegations of paragraph 2 of the SAC and expressly denies that PGDx is now infringing or has ever infringed U.S. Patent No. 9,598,731 (the “’731 Patent”), U.S. Patent No. 9,834,822 (the “’822 Patent”), U.S. Patent No. 9,840,743 (the “’743 Patent”), or U.S. Patent No. 9,902,992 (the “’992 Patent”).

PARTIES

3. PGDx lacks knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the SAC and therefore denies them.

4. PGDx lacks knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the SAC and therefore denies them.

5. PGDx lacks knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the SAC and therefore denies them.

6. PGDx admits that it is a corporation organized and existing under the laws of the state of Delaware and that it maintains a principal place of business at 2908 Boston Street, Suite # 503, Baltimore, Maryland 21224. PGDx further admits that it markets and sells a liquid biopsy known as PlasmaSELECT 64®. PGDx further admits that it performs the PlasmaSELECT 64® at a facility in Baltimore, Maryland.

JURISDICTION AND VENUE

7. Paragraph 7 of the SAC alleges legal conclusions, such that no response is required. To the extent that any response is required, PGDx admits that 28 U.S.C. §§ 1331 and 1338(a) generally confer subject matter jurisdiction upon this Court to hear claims brought under the Patent Act, 35 U.S.C. § 100 et seq., and that 28 U.S.C. §§ 2201 and 2202 generally permits this Court to issue declaratory judgments in cases of actual controversy within its jurisdiction.

8. Paragraph 8 of the SAC alleges legal conclusions, such that no response is required. To the extent that any response is required, PGDx admits that 28 U.S.C. §§ 1391 and 1400(b) address venue, that venue is proper within the District of Delaware, but denies that this Court is the most convenient forum for Plaintiff's action. PGDx further denies that it is now

infringing or has ever infringed the '731 Patent, the '822 Patent, the '743 Patent, or the '992 Patent in this district or anywhere else.

9. Paragraph 9 of the SAC alleges legal conclusions, such that no response is required. To the extent that any response is required, PGDx admits that it is a Delaware corporation.

10. Paragraph 10 of the SAC alleges legal conclusions, such that no response is required. To the extent that any response is required, PGDx admits that it offers for sale and sells the PlasmaSELECT 64® test within Delaware and is subject to the Court's personal jurisdiction, but expressly denies that PGDx is now infringing or has ever infringed the '731 Patent, the '822 Patent, the '743 Patent, or the '992 Patent in this district or anywhere else, and denies the remaining allegations of paragraph 10 of the SAC.

11. Paragraph 11 of the SAC alleges legal conclusions, such that no response is required. To the extent that any response is required, PGDx admits that it has transacted business within Delaware and is subject to the Court's personal jurisdiction, but expressly denies that PGDx is now infringing or has ever infringed the '731 Patent, the '822 Patent, the '743 Patent, or the '992 Patent in this district or anywhere else, and denies the remaining allegations of paragraph 11 of the SAC.

12. Paragraph 12 of the SAC alleges legal conclusions, such that no response is required.

BACKGROUND

13. PGDx restates and incorporates its responses to the foregoing paragraphs.

14. PGDx admits that it began commercializing PlasmaSELECT 64® in or around late-2016. PGDx further admits that Exhibit 5 to the SAC appears to be a copy of a press release

published on October 4, 2016 published by Cision PR Newswire with news provided by PGDx. PGDx further admits that Exhibit appears to contain, inter alia, the language quoted in paragraph 14, and denies the remaining allegations of paragraph 14 of the SAC.

15. PGDx admits that Exhibit 6 to the SAC appears to be a copy of an article published by Jillian Phallen, among others, in the journal Science Translational Medicine, entitled “Direct detection of early-stage cancers using circulating tumor DNA,” bearing a publication date of August 16, 2017. PGDx further admits that Exhibit 6 contains, inter alia, the figure included in paragraph 15 of the SAC. PGDx denies the remaining allegations of paragraph 15 and Plaintiff’s characterization of Exhibit 6, which is a document that speaks for itself.

16. PGDx admits that Exhibit 7 to the SAC appears to be a copy of an article published in April 2017 by trade publication, GenomeWeb, that contains, inter alia, the language quoted in the second sentence of paragraph 16. PGDx further admits that Exhibit 8 to the SAC appears to be a copy of an article published in trade publication, GenomeWeb, that contains, inter alia, the language quoted in the third sentence of paragraph 16. PGDx denies the remaining allegations of paragraph 16.

17. PGDx admits that paragraph 17 of the SAC appears to quote claim 1 of the ’731 Patent. PGDx denies the remaining allegations of paragraph 17 and expressly denies that it is now infringing or has ever infringed the ’731 Patent.

18. PGDx denies the allegations of paragraph 18 of the SAC and expressly denies that its PlasmaSELECT 64® test now leads to or has ever led to infringement of the ’731 Patent.

19. PGDx admits that Exhibit 9 to the SAC purports to be a claim chart. PGDx denies the remaining allegations of paragraph 19 of the SAC and denies the allegations in the

accompanying claim chart attached to the SAC as Exhibit 9. PGDx further expressly denies that the PlasmaSELECT 64® test is now infringing or has ever infringed the '731 Patent.

20. PGDx admits that paragraph 20 of the SAC appears to quote claim 1 of the '822 Patent. PGDx denies the remaining allegations of paragraph 20 and expressly denies that it is now infringing or has ever infringed the '822 Patent.

21. PGDx denies the allegations of paragraph 21 of the SAC and expressly denies that its PlasmaSELECT 64® test now leads to or has ever led to infringement of the '822 Patent.

22. PGDx admits that Exhibit 10 to the SAC purports to be a claim chart. PGDx denies the remaining allegations of paragraph 22 of the SAC and denies the allegations in the accompanying claim chart attached to the SAC as Exhibit 10. PGDx further expressly denies that the PlasmaSELECT 64® test is now infringing or has ever infringed the '822 Patent.

23. PGDx admits that paragraph 23 of the SAC appears to quote claim 10 of the '743 Patent. PGDx denies the remaining allegations of paragraph 23 and expressly denies that it is now infringing or has ever infringed the '743 Patent.

24. PGDx denies the allegations of paragraph 24 of the SAC and expressly denies that its PlasmaSELECT 64® test now leads to or has ever led to infringement of the '743 Patent.

25. PGDx admits that Exhibit 11 to the SAC purports to be a claim chart. PGDx denies the remaining allegations of paragraph 25 of the SAC and denies the allegations in the accompanying claim chart attached to the SAC as Exhibit 10. PGDx further expressly denies that the PlasmaSELECT 64® test is now infringing or has ever infringed the '743 Patent.

26. PGDx admits that paragraph 26 of the SAC appears to quote claim 1 of the '992 Patent. PGDx denies the remaining allegations of paragraph 26 and expressly denies that it is now infringing or has ever infringed the '992 Patent.

27. PGDx denies the allegations of paragraph 27 of the SAC and expressly denies that its PlasmaSELECT 64® test now leads to or has ever led to infringement of the '992 Patent.

28. PGDx admits that Exhibit 12 to the SAC purports to be a claim chart. PGDx denies the remaining allegations of paragraph 28 of the SAC and denies the allegations in the accompanying claim chart attached to the SAC as Exhibit 12. PGDx further expressly denies that the PlasmaSELECT 64® test is now infringing or has ever infringed the '992 Patent.

COUNT I

29. PGDx restates and incorporates its responses to the foregoing paragraphs.

30. PGDx admits that the '731 Patent appears to bear an issue date of March 21, 2017 and to be entitled "Systems and Methods to Detect Rare Mutations and Copy Number Variation." PGDx lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 30 and therefore denies them.

31. PGDx denies that Exhibit 8 to the SAC is a claim chart. PGDx further denies the remaining allegations of paragraph 31 of the SAC and expressly denies that it infringes any claims of the '731 Patent.

32. PGDx denies the allegations of paragraph 32 of the SAC and denies the allegations in the accompanying claim chart attached to the SAC as Exhibit 9.

COUNT II

33. PGDx restates and incorporates its responses to the foregoing paragraphs.

34. PGDx admits that the '822 Patent appears to bear an issue date of December 5, 2017 and to be entitled "Systems and Methods to Detect Rare Mutations and Copy Number Variation." PGDx lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 34 of the SAC and therefore denies them

35. PGDx denies that Exhibit 9 to the SAC is a claim chart detailing alleged infringement of the claims of the '822 Patent. PGDx further denies the remaining allegations of paragraph 35 of the SAC and expressly denies that it infringes any claims of the '822 Patent.

36. PGDx denies the allegations of paragraph 36 of the SAC and denies the allegations in the accompanying claim chart attached to the SAC as Exhibit 10.

COUNT III

37. PGDx restates and incorporates its responses to the foregoing paragraphs.

38. PGDx admits that the '743 Patent appears to bear an issue date of December 12, 2017 and to be entitled "Systems and Methods to Detect Rare Mutations and Copy Number Variation." PGDx lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 38 of the SAC and therefore denies them.

39. PGDx denies that Exhibit 10 to the SAC is a claim chart detailing alleged infringement of the claims of the '743 Patent. PGDx further denies the remaining allegations of paragraph 39 of the SAC and expressly denies that it infringes any claims of the '743 Patent.

40. PGDx denies the allegations of paragraph 40 of the SAC and denies the allegations in the accompanying claim chart attached to the SAC as Exhibit 11.

COUNT IV

41. PGDx restates and incorporates its responses to the foregoing paragraphs.

42. PGDx admits that the '992 Patent appears to bear an issue date of February 27, 2018 and to be entitled "Systems and Methods to Detect Rare Mutations and Copy Number Variation." PGDx lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 42 of the SAC and therefore denies them.

43. PGDx admits that Exhibit 12 to the SAC purports to be a claim chart. PGDx denies the remaining allegations of paragraph 43 of the SAC and expressly denies that it infringes any claims of the '992 Patent.

44. PGDx denies the allegations of paragraph 44 of the SAC and denies the allegations in the accompanying claim chart attached to the SAC as Exhibit 12.

JURY DEMAND

45. Paragraph 45 is a demand for a jury trial to which no response is required.

PRAYER FOR RELIEF

PGDx denies that Plaintiff is entitled to any of the relief enumerated in the SAC.

DEFENSES

First Defense – Non-Infringement

Plaintiff is not entitled to any relief against PGDx because PGDx is not now infringing nor has it ever infringed, literally or by the doctrine of equivalents, any valid and enforceable claim of the '731 Patent, the '822 Patent, the '743 Patent, or the '992 Patent.

Second Defense – Invalidity

Upon information and belief, the '731 Patent, the '822 Patent, the '743 Patent, and the '992 Patent are invalid for failing to meet one or more of the requisite Conditions of Patentability specified in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, 112, 115, 116, and/or the doctrine of double patenting.

Third Defense – Unclean Hands, Equitable Estoppel, and/or Waiver

Any purported claim by Plaintiff for equitable relief is barred by the doctrine of unclean hands, waiver, and/or estoppel.

Fourth Defense – Failure to State a Claim

The SAC fails to state a claim upon which relief can be granted because Guardant has failed to demonstrate direct infringement of the '731 Patent, the '822 Patent, the '743 Patent, or the '992 Patent.

Fifth Defense – Prosecution History Estoppel

If and to the extent Plaintiff relies on the doctrine of equivalents to establish infringement, Plaintiff may be estopped from construing the asserted claims of the '731 Patent, the '822 Patent, the '743 Patent, or the '992 Patent to read on PGDx's products, including the PlasmaSELECT 64®, by reasons of statements, concessions, or representations made to the U.S. Patent and Trademark Office during the prosecution of the applications that led to the issuance of those patents.

Sixth Defense – Adequate Remedy at Law

Plaintiff is not entitled to any injunctive relief because any alleged injury to Plaintiff is not immediate or irreparable, Plaintiff has an adequate remedy at law for any alleged injury, Plaintiff is not being, and is not in danger of being, irreparably injured, the balance of hardships is not in its favor, and there is a compelling public interest in allowing PGDx to continue to use, sell, and offer to sell PGDx's offerings.

Seventh Defense – Lack of Specificity of Pleading

Plaintiff's Complaint should be dismissed, with costs, pursuant to Fed. R. Civ. P. 8, for failure to state its claims with specificity.

Eighth Defense – No Recovery of Costs

Plaintiff is barred from recovering costs pursuant to 35 U.S.C. § 288.

Ninth Defense – Good Faith by PGDx

PGDx acted in good faith in all activities relevant to this action, thereby precluding Plaintiff from recovering its reasonable attorneys' fees and/or costs under 35 U.S.C. § 285, even if Plaintiff prevails.

Tenth Defense – Inequitable Conduct

PGDx incorporates herein by reference the facts set forth with particularity in paragraphs 8 to 50 of its Counterclaims, *infra*. As alleged in the incorporated paragraphs, the '731 Patent, the '822 Patent, the '743 Patent, and the '992 Patent are unenforceable for inequitable conduct.

ADDITIONAL DEFENSES AND RESERVATIONS OF RIGHTS

PGDx generally denies all allegations of the SAC not expressly admitted herein.

PGDx expressly reserves the rights to allege additional defenses of which it becomes aware during the course of this action.

**PERSONAL GENOME DIAGNOSTICS, INC.'S COUNTERCLAIMS AGAINST
GUARDANT HEALTH, INC.**

Subject to and without waiving its defenses as set forth above, PGDx hereby asserts the following counterclaims against Plaintiff Guardant Health, Inc.

PARTIES

1. Personal Genome Diagnostics, Inc. ("PGDx" or "Counterclaim Plaintiff") is a Delaware corporation with its principal place of business at 2908 Boston Street, Suite # 503, Baltimore, Maryland 21224.

2. In the SAC, Guardant Health, Inc. ("Guardant" or "Counterclaim Defendant") asserts that it is a Delaware corporation with its principal place of business at 505 Penobscott Dr., Redwood City, CA 94063.

JURISDICTION AND VENUE

3. PGDx asserts violations of federal antitrust law, specifically Section 2 of the Sherman Act, 15 U.S.C. § 2. PGDx also asserts counterclaims against Guardant pursuant to Title 35 of the United States Code and seeks declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202 and Federal Rule of Civil Procedure 13.

4. This Court has subject matter jurisdiction over these counterclaims pursuant to 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331, 1337, 1338(a), 2201(a), and 2202.

5. This Court has personal jurisdiction over Guardant because Guardant is a Delaware corporation. Guardant admits that it “is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 505 Penobscot Dr., Redwood City, CA 94063.” (Dkt. 20 ¶ 3.)

6. Venue is proper for these counterclaims in this District pursuant to 15 U.S.C. § 22, and 28 U.S.C. §§ 1391 and 1400. Guardant admits “[v]enue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).” (Dkt. 20 ¶ 8.)

7. Guardant’s misconduct occurs in and affects interstate commerce. Guardant’s conduct threatens to harm competition throughout the United States and affect the price and volume of goods shipped or services provided in interstate commerce.

ALLEGATIONS COMMON TO ANTITRUST COUNTERCLAIMS

A. Nature of Suit

8. PGDx bring these counterclaims to seek damages and permanently enjoin Guardant’s ongoing efforts to block, or significantly limit and hinder, competition in the relevant antitrust liquid biopsy market.

9. Liquid biopsy is the sampling and analysis of non-solid biological material (*e.g.*, blood) as a diagnostic and monitoring tool for cancer. Unlike a tissue biopsy, which involves the removal of solid cells or tissue, liquid biopsy typically involves drawing blood. Thus, liquid biopsy is largely non-invasive. As a result, it can be performed more frequently and can track tumors and mutations over time. The use of liquid biopsies may also be used to validate the efficacy of a treatment drug by taking multiple samples over time.

10. [REDACTED]

11. Using anticompetitive practices, Guardant has attempted to maintain and enlarge its monopoly power in the liquid biopsy market. As detailed below, Guardant and its founders, Helmy Eltoukhy and AmirAli Talasaz, engaged in an orchestrated campaign of fraud to obtain and secure exclusive rights to the Patents-in-Suit. [REDACTED]

[REDACTED]

[REDACTED] By so doing, Guardant unlawfully consolidated patent rights in a single entity in an attempt to ensure that no other entity could claim ownership and practice the patents or license others to do the same. Guardant's conduct was intended to have the anticompetitive effect of eliminating, or substantially hindering, competition in the liquid biopsy market.

12. Guardant then asserted the fraudulently obtained Patents-in-Suit in an attempt to exclude, or substantially hinder, competition. In particular, Guardant is attempting to enforce the patents against PGDx and Foundation Medicine, Inc. (“FMI”), which Guardant asserts are its most significant competitors. Guardant did so to maintain and strengthen its monopoly power and tighten its stranglehold on the liquid biopsy market.

13. On information and belief, Guardant knows its patents are unenforceable, as evidenced by statements and testimony by its founders and executives, its representations to this Court, and other evidence. Guardant nonetheless continues to assert patents that it knows are invalid and unenforceable in an attempt to exclude competition and maintain its monopoly power in the liquid biopsy market. Accordingly, PGDx now brings claims of monopolization and attempted monopolization under Section 2 of the Sherman Act, 15 U.S.C. § 2.

B. Relevant Technology and The Patents-in-Suit

14. The technology at issue relates to diagnosing, characterizing, monitoring, and treating cancer. Typically, a clinician needs to extract a sample of potentially cancerous cells and conduct a tissue biopsy to diagnose and characterize cancerous cells. The technology at issue here allows clinicians to draw a patient’s blood and conduct a liquid biopsy that does not require a sample from the potentially cancerous tissue. As a result, liquid biopsy techniques are less invasive than tissue biopsy and can be repeated more easily.

15. The Patents-in-Suit explain that liquid biopsy techniques typically involve extracting cell-free DNA from blood, sequencing cell-free DNA to acquire data, and then applying bioinformatics techniques to detect mutations. Because the amount of cell-free DNA to be analyzed is small, it is often “amplified” by making numerous copies before sequencing. However, errors may be introduced during the process of amplification and sequencing. Such

errors may make it difficult to discern true mutations from errors that were introduced during amplification and sequencing.

16. Guardant's presentation to the Court in connection with the claim construction hearing (the "Technical Tutorial") alleges that the inventors of the Patents-in-Suit solved this problem using a solution found in "communication theory." According to Guardant's Technical Tutorial, "the sequence of a polynucleotide can be thought of as an original message. This message must be both amplified, sent through a communications channel, then read and decoded. During each of these steps, noise can be introduced into the signal, distorting it."

17. Similar to how codes are added to communications before transmission, the Patents-in-Suit "tag[] the signal (cfDNA molecules) prior to amplification," which allows one "to treat all similarly tagged signals as members of the same family, containing the same information. In this way any noise that may be introduced to one particular signal will not affect the total output of the whole family." If a base is present in all of the sequence reads, it can be assumed to be the base in the original sequence before amplification. If a base is present in one or few of the sequence reads, it can be assumed to be an error that arose from the amplification process. The resulting sequence is called a consensus sequence and represents the sequence of the original cfDNA molecule.

18. The Patents-in-Suit implement this alleged communication-coding solution by (i) tagging sequence reads, (ii) grouping sequence reads with the same tags into families, and then (iii) collapsing the sequence reads to create consensus sequences. The asserted claims contain specific claim limitations directed to this approach. *See, e.g.*, '731 Patent, Claim 1 (b)-(f); '822 Patent, Claim 1 (b)-(f); '992 Patent, Claim 1 (b)-(f); '743 Patent, Claims 12, 15, 19.

C. Guardant’s Inequitable Conduct

19. As detailed below, evidence has come to light in this case that reveals Eltoukhy invented, or at least substantially contributed to, the “communication theory” solution claimed in the Patents-in-Suit. [REDACTED]

[REDACTED]

1. Eltoukhy Substantially Contributed To the Claimed Inventions

a. [REDACTED]

20. Eltoukhy explained in writing: “Guardant Health was practically fated to be. Co-founders Helmy Eltoukhy and AmirAli Talasaz both received PhDs in electrical engineering from Stanford and worked in the same lab in the Stanford Genome Technology Center....[A] few years later, [REDACTED]

[REDACTED]

21. Eltoukhy and Talasaz incorporated Guardant and secured the domain name

[REDACTED]

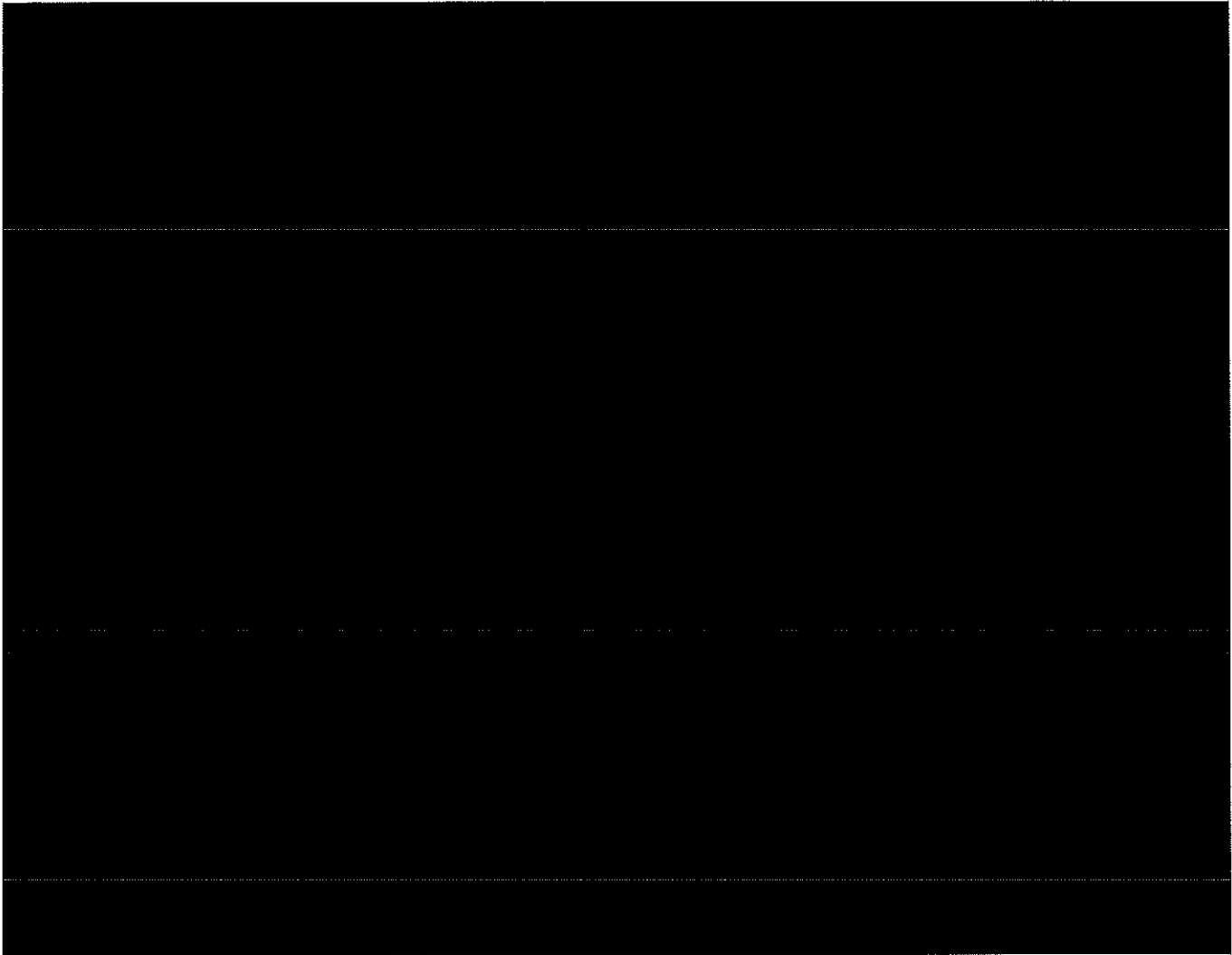
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹ All emphasis is added unless noted otherwise.



25. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

26. On information and belief, and consistent with other evidence and testimony below, [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

b. Eltoukhy Substantially Contributed to the Conception Of The Claimed Inventions of the Patents-In-Suit

27. As shown above, Eltoukhy knew of the alleged fundamental solutions of the Patents-in-Suit before Talasaz allegedly did so. In particular, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

28. Eltoukhy thus substantially contributed to the conception of the Patents-in-Suit. For example, limitations b through f of Claim 1 of the '731 Patent are directed to attaching barcodes to DNA, amplifying and sequencing the tagged polynucleotides, grouping the sequence reads into families based at least in part on the tags, and comparing the sequence reads grouped within each family to determine consensus sequences. [REDACTED]

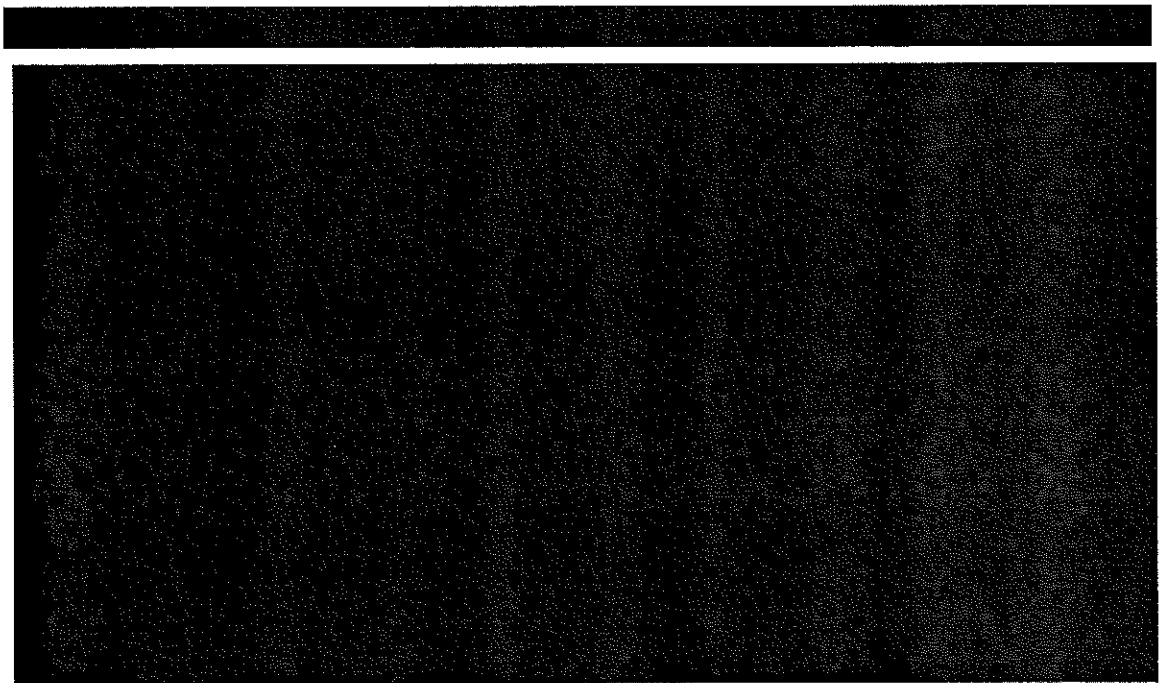
[REDACTED] Claim 1 of the '731 Patent is also directed to the analysis of cell-free DNA. As discussed below, Guardant's corporate representative testified that the fundamental ideas discussed above were jointly conceived by Eltoukhy and Talasaz and were "specifically designed to be used with cell-free DNA." 5/31/17 Tr. at 108. Claim 1 is also directed to the use of non-unique tags. As discussed below, Guardant's Chief Medical Officer testified that the founders jointly conceived of using nonunique tags. 3/13/19 Tr. at 175.

29. Eltoukhy also substantially contributed to the conception of at least Claim 1 of the '822 Patent. For example, Claim 1 limitations b through f are directed to [REDACTED]

[REDACTED]

[REDACTED] Eltoukhy contributed to those concepts for the same reasons discussed above.

30. Eltoukhy also substantially contributed to the conception of one or more claims of the '743 Patent. For example, Claims 12, 15, 16, and 19 are directed to concepts discussed above. Eltoukhy contributed to those concepts for the same reasons. Claim 10 is directed to the determination of "unique sequence reads." [REDACTED]



31. Eltoukhy also substantially contributed to the conception of at least Claim 1 of the '992 Patent, on which Eltoukhy is named as an inventor. Limitations b through f in Claim 1 of the '992 Patent are directed to the same concepts discussed above. Eltoukhy contributed to those concepts for the same reasons. At his deposition, Eltoukhy claimed he made only a minor contribution to the '992 patent that is reflected in a single dependent claim, Claim 17.² In reality,

² Claim 17 states: "The method of claim 1, wherein the base call for each family possesses an error rate below 0.0001%."

as discussed throughout, Eltoukhy contributed to the fundamental ideas that Guardant has identified as the alleged inventions of the '992 Patent.

c. **Eltoukhy's Conception Is Strongly Corroborated By the Testimony and Evidence In This Case**

32. Eltoukhy has repeatedly taken credit for developing the fundamental "communication theory" ideas that Guardant identified as the invention of the Patents-in-Suit.

For example, [REDACTED]

[REDACTED]

[REDACTED] Eltoukhy continued, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

33. Guardant's corporate testimony also credits Eltoukhy for the same fundamental ideas. In *Foundation Medicine, Inc. v. Guardant Health, Inc.*, Case No. 2:16-cv-00523-JRG-RSP (E.D. Tex.), Guardant designated Stefanie Mortimer to testify regarding the conception of the Guardant360 products, which Guardant claims practice all of the Patents-in-Suit. Mortimer testified that Eltoukhy and Talasaz together had the "idea in 2012" that "you can filter out random" noise by "barcoding molecules" so "you can determine its origination." 5/31/17 Tr. at 107-09. Mortimer testified that the idea in 2012 was "specifically designed to be used with cell-free DNA." 5/31/17 Tr. at 108. Mortimer explained that Eltoukhy and Talasaz "conceived of this idea" in "Palo Alto, California, at Helmy Eltoukhy's residence," in Eltoukhy's "pool house."

5/31/17 Tr. at 106. Mortimer characterized this as “the idea that was the basis of the intellectual property that forms the basis of Guardant360.” 5/31/17 Tr. at 108.

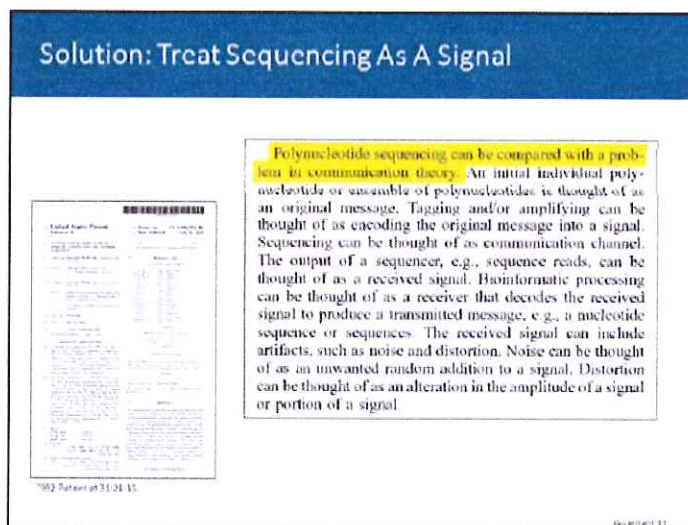
34. Mortimer confirmed the above testimony in this case and explained that her testimony on Guardant’s behalf was based on her review of [REDACTED] [REDACTED] 2/26/19 Tr. at 15-30. She also specifically connected the ideas conceived by Eltoukhy and Talasaz with claim limitations of the Patents-in-Suit implementing those ideas. For example, Mortimer testified that the “grouping” in claim 1(f) of the ’992 Patent was “part of the concept” conceived by Eltoukhy and Talasaz at Eltoukhy’s pool house. 2/27/19 Tr. at 106. The ’731 and ’822 Patents claim the same “grouping” concept. Mortimer’s testimony confirms Eltoukhy at least contributed to the conception of those claims.

35. Richard Lanman, Guardant’s Chief Medical Officer, testified that Eltoukhy and Talasaz developed “the notion that you could code with nonunique molecular tags the DNA fragments in blood.” 3/13/19 Tr. at 57. Lanman testified, “I believe the idea of nonunique molecular bar-coding ... then the sequencing followed by the bioinformatics is -- *is their original ideas.*” 3/13/19 Tr. at 175. Lanman’s testimony was based on his job interview with Eltoukhy and Talasaz, where they told him “*We* developed this. *We* had these ideas, then *we* made them work.” 3/13/19 Tr. at 58. [REDACTED] [REDACTED] [REDACTED]

36. Justin Odegaard, Guardant’s Vice President of Clinical Development, likewise testified that Eltoukhy and Talasaz jointly came up with the idea of using molecular barcoding to identify unique molecules to address the problem of noise. 3/7/19 Tr. at 227-28. He testified

that his “understanding is that it was primarily the founders, Helmy Eltoukhy and AmirAli Talasaz” and that “[t]he *two of them together* came up with it.” 3/7/19 Tr. at 227-28.

37. Eltoukhy’s contributions are further corroborated by Guardant’s representations to this Court. On September 21, 2018, Guardant submitted to the Court a Technical Tutorial purporting to identify the alleged problems solved by the “Patents-in-Suit”:



The inventors of Guardant’s patents were originally trained in electrical engineering at Stanford University before moving to the biological sciences. Leveraging their experience in signal communications, the inventors, who teamed up to found Guardant, reached an innovative solution to this problem. As the patents explain, Guardant’s inventors realized that the sequence of a polynucleotide can be thought of as an original message. This message must both be amplified, sent through a communications channel, then read and decoded. During each of these steps, noise can be introduced into the signal, distorting it. However, noise can be reduced.

The Technical Tutorial explains that, “The inventors of Guardant’s patents were originally trained in electrical engineering at Stanford University before moving to the biological sciences. Leveraging their experience in signal communications, *the inventors, who teamed up to found Guardant, reached an innovative solution to this problem.* As the patents explain, *Guardant’s inventors* realized that the sequence of a polynucleotide can be thought of as an original message.” Tutorial at 11. Guardant’s subsequent slides then identify the solution as tagging

be submitted to the USPTO the '754 Application Data Sheet, which states that "All Inventors Must Be Listed," and fraudulently identified Talasaz as the sole inventor. Consistent with this affirmative misrepresentation, only Talasaz submitted a declaration identifying himself as an inventor. Eltoukhy and Talasaz never identified Eltoukhy as an inventor to the USPTO at any time during the prosecution of the '754 Application. Instead, they suppressed facts and evidence regarding Eltoukhy's inventorship that should have been brought to the USPTO's attention. The '731 Patent issued on March 12, 2017, identifying Talasaz as the sole inventor.

42. On March 23, 2017, Guardant filed U.S. Patent Application No. 15/467,570 (the "'570 Application"), which eventually issued as the '743 Patent. On March 23, 2017, Guardant filed declarations from Eltoukhy and Talasaz in which they both swore under oath that they were inventors. However, on July 20, 2017, Eltoukhy and Talasaz caused to be submitted a request under 37 C.F.R. § 148 to "name only the actual inventors" and to "delete" Eltoukhy as an inventor. The request fraudulently stated that it was supported by a Corrected Application Data Sheet "including inventor information for all actual inventors." Consistent with this affirmative misrepresentation, the Application Data Sheet fraudulently identified Talasaz as the sole inventor by striking out Eltoukhy's name. Rather than identify Eltoukhy as a co-inventor, Eltoukhy and Talasaz suppressed facts and evidence regarding Eltoukhy's inventorship that should have been brought to the USPTO's attention. The '743 Patent issued on December 12, 2017, identifying Talasaz as the sole inventor. Thus, Eltoukhy and Talasaz originally recognized Eltoukhy as an inventor of the '743 Patent and then specifically removed him to further their fraudulent scheme.

43. On April 20, 2017, Guardant filed U.S. Patent Application No. 15/492,659 (the "'659 Application"), which eventually issued as the '822 Patent. Like the '754 Application, the Application Data Sheet fraudulently identified Talasaz as the sole inventor. Consistent with this

affirmative misrepresentation, only Talasaz submitted a declaration identifying himself as an inventor. Eltoukhy and Talasaz never disclosed Eltoukhy as an inventor to the USPTO at any time during the prosecution of the '659 Application. Instead, they suppressed facts and evidence regarding Eltoukhy's inventorship that should have been brought to the USPTO's attention. The patent issued on December 5, 2017 identifying Talasaz as the sole inventor.

3. The Identity of Eltoukhy As An Inventor Was Highly Material, and Eltoukhy and Talasaz Acted With A Specific Intent to Deceive the USPTO, Rendering the Patents-in-Suit Unenforceable

44. A patent is invalid if it does not name all the inventors. *See* 35 U.S.C. §§ 101, 115, 116. Title 35 U.S.C. § 115 provides that "An application for patent ... shall include, or be amended to include, the name of the inventor for any invention claimed in the application." Section 115 further states, "Except as otherwise provided in this section, each individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application."

45. The Manual of Patent Examining Procedure ("MPEP") thus instructs examiners to reject applications with improper inventorship. *See* MPEP § 2137.01 (explaining that "U.S. patent law" requires "naming of the actual inventors"). The MPEP explains that "if a determination is made that the inventive entity named in a U.S. application is not correct . . . a rejection should be made on this basis." *Id.* But for Eltoukhy and Talasaz's affirmative misrepresentations, suppressed evidence and withheld information, the PTO would not have allowed the claims of the '731, '822 and '743 Patents. The identity of the true inventors of Guardant's Patents-in-Suit was highly material to the issuance of the Patents-in-Suit.

46. Eltoukhy and Talasaz also acted with a specific intent to deceive the USPTO. At the time of the misconduct, Eltoukhy and Talasaz were aware that [REDACTED]

[REDACTED]

[REDACTED] Guardant's conduct was intended to have the anticompetitive effect of eliminating, or substantially hindering, competition in the liquid biopsy market and maintaining Guardant's monopoly power.

47. Eltoukhy's and Talasaz's deceptive intent and bad faith is also shown by, among other things, (1) [REDACTED]

[REDACTED]

[REDACTED]

48. At his deposition, Eltoukhy disputed few of the facts alleged above. Instead, he repeatedly testified that he could not remember what had occurred. Thus, Eltoukhy failed to dispute even the most troubling allegations, [REDACTED]

[REDACTED] Accordingly, the contemporaneous documents and testimony of other witnesses stand largely unrebutted and, individually and collectively, overwhelmingly support that

Eltoukhy and Talasaz acted with deceptive intent to defraud the USPTO in connection with the '731, '822 and '743 Patents.

49. Eltoukhy and Talasaz's conduct renders each of the Patents-in-Suit unenforceable. As detailed above, Eltoukhy and Talasaz engaged in affirmative misrepresentations, and suppressed information and evidence regarding Eltoukhy's inventorship. Eltoukhy and Talasaz's conduct amounts to fraud, affirmative acts of egregious misconduct, and omission of material information with a specific intent to deceive the USPTO. Indeed, a specific intent to deceive is the single most reasonable inference able to be drawn from the evidence.

50. Eltoukhy and Talasaz's broad pattern of inequitable conduct was also directly related to the '992 Patent, rendering the claims of that patent unenforceable as well. There is a significant relationship between and among the '731, '822, '743 and '992 Patents. The '992 Patent shares an almost identical specification to the '731, '822, and '743 patents, and relies on the earlier disclosed subject matter for written description support for its claims. By not naming Eltoukhy as an inventor on the '731, '822, and '743 Patents, Eltoukhy and Talasaz concealed that Eltoukhy also invented the fundamental ideas underlying the '992 Patent.

D. Guardant's Monopoly Power

1. The Relevant Antitrust Market

51. According to Guardant's allegations and testimony in this case, there is a relevant antitrust market or submarket for liquid biopsy services. Guardant's interrogatory responses and witnesses allege that Guardant competes in a liquid biopsy market that is distinct from the tissue biopsy market.

52. When asked by PGDx to identify "each market and/or market segment in which the technologies and/or the products that embody the Asserted Patents compete," Guardant

identified [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

53. Marc Jacobstein, Guardant's 30(b)(6) witness on the "markets . . . in which Guardant and PGDx compete," agreed that "there are distinct liquid and tissue markets": "One would be a liquid biopsy market. One would be a tissue biopsy market." 3/5/19 Tr. at 311-12.

54. Bill Getty, Guardant's VP of Oncology Marketing, agreed that "[t]here are distinct liquid and tissue markets" and "in terms of a competitive market in which [Guardant] actually compete[s], [he] view[s] tissue biopsy as being in a separate competitive market from liquid biopsy." 3/15/19 Tr. at 260.

55. According to Guardant's allegations and testimony, there is no other service that is a reasonably interchangeable substitute for a liquid biopsy. According to Guardant's documents and witnesses, [REDACTED]

[REDACTED] Lanman, Guardant's Chief Medical Officer, testified that liquid biopsies are clinically different from tissue biopsies because: (i) liquid biopsies result in less complications because only a blood sample is required; (ii) tissue biopsies may not be available at all because there may be insufficient tissue available; (iii) even where tissue is available, tissue biopsies may miss mutations because they analyze "just a needleful of material" that may not contain cancerous tissue; and (iv) because liquid biopsy is non-invasive, it allows for multiple tests that enable real time monitoring of treatment. 3/13/19 Tr. at 101-03.

56. Justin Odegaard, Guardant's VP of Clinical Development, colorfully testified that the difference between liquid biopsy and tissue biopsy is the difference between "apples" and "Zubaz parachute pants," which is "garish 1980's wear—funky sweat pants." 3/7/19 Tr. at 258-60. He explained that "everybody in the field talks about apples to apples and apples to oranges. And I think the point we wanted to emphasize here is that this is really distinct . . . They are, indeed, different things." 3/7/19 Tr. at 260.

57. Getty testified that "tissue biopsy and liquid biopsy . . . largely do not compete in the same marketplace" because they have "different modalities and different reasons why you may use them." 3/15/19 Tr. at 412. Getty further testified that "trying to now commingle those and say someone went with tissue over liquid is not really a thing If you choose liquid, you're choosing between two liquid products." 3/15/19 Tr. at 414.

58. Based on Guardant's allegations and testimony, there is no reasonably interchangeable substitute for the liquid biopsy services described herein and there is no cross-elasticity of demand between these services and other services. Based on Guardant's allegations and testimony, because of the performance of the services described herein, there are no other substitutes for the liquid biopsy services described herein. Other services, such as tissue biopsies, have distinct prices, distinct demand curves (with independent sensitivity to price changes), and distinct marketing approaches compared to liquid biopsy services described herein.

59. Thus, based on Guardant's allegations and testimony, buyers of liquid biopsies described herein would likely not switch to an alternative service in response to a small but significant non-transitory increase in price (a "SSNIP"). If one firm were to make all sales of all liquid biopsies described herein, it could profitably impose a SSNIP, charging non-cost justified

increases in price without losing so many sales as to make the practice unprofitable. This confirms that the services described herein constitute a distinct category of services for purposes of antitrust review, per the current version of the DOJ-FTC Horizontal Merger Guidelines (2010) at § 4.1.1 (“The Hypothetical Monopolist Test”).

60. The effective area of competition (or relevant geographic market) for the liquid biopsy market alleged herein is the United States.

2. Guardant’s Monopoly Power

61. Guardant’s witnesses have described the market for liquid biopsy as highly concentrated and comprised of a small number of market participants. Getty characterized the liquid biopsy market as a “smallish” market, with few competitors and “limited real competition.” 3/15/19 Tr. at 305-06, 318. Getty testified that [REDACTED]

[REDACTED]

62. Guardant’s documents and witnesses have [REDACTED]

[REDACTED] Getty testified that, “as it pertains to the comprehensive liquid biopsy market amongst oncologists, we believe it to be around 80 percent.” 3/15/19 Tr. at 291. Guardant’s internal documents also state, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

63. Guardant’s witnesses have alleged and testified that Guardant has the power to control prices for liquid biopsies. Getty testified that Guardant “set[s] the market rate for

comprehensive liquid biopsy” because it “has a dominant position in the market for comprehensive liquid biopsy amongst oncologists” and a “strong advantage over its competition” 3/15/19 Tr. at 289, 360. Getty testified that Guardant’s most significant “competitor” is not a competitor at all, but rather “apathy” of not wanting to perform testing. 3/15/19 Tr. at 202. The lack of competition affords Guardant the “luxury” of not having to increase its promotional investments to keep its share. 3/15/19 Tr. at 315. Getty testified that it may have to make promotional investments if the market becomes “more competitive.” 3/15/19 Tr. at 317. According to Getty, that “has not happened yet.” 3/15/19 Tr. at 317.

64. Jacobstein likewise testified Guardant has a “strong, if not commanding leadership position.” 3/5/19 Tr. at 281-82. Because of Guardant’s strength in the market, Jacobstein referred to Guardant as “the *800-pound gorilla*” in the “liquid biopsy market.” 3/5/19 Tr. at 294-300. Jacobstein testified that Guardant is the “clear leader” on many metrics, including “clinical, commercial volume.” 3/5/19 Tr. at 302-03. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

That is a telltale sign of an unhealthy market characterized by anticompetitive monopolization.

65. Guardant’s documents also allege that [REDACTED]

[REDACTED] For example, Guardant documents highlight [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3/5/19 Tr. at 309 [REDACTED] (“So these were some of the barriers that a competitor would have to overcome to enter the liquid biopsy market? A. Correct.”).

66. Thus, based on Guardant’s allegations and testimony, Guardant wields monopoly power in the liquid biopsy market. According to Guardant’s documents and witnesses, [REDACTED]

E. Guardant’s Anticompetitive Conduct

67. As detailed above, Guardant and its founders engaged in an orchestrated campaign of fraud on the USPTO to obtain and secure exclusive rights to the Patents-in-Suit. Guardant’s founders, Eltoukhy and Talasaz, fraudulently identified Talasaz as the sole inventor of the alleged inventions of the ’731, ’822, and ’743 Patents, when in fact Eltoukhy substantially contributed to these alleged inventions. [REDACTED]

[REDACTED] By so doing, Guardant unlawfully consolidated patent

rights in a single entity. Guardant did so in an attempt to ensure that no other entity could claim ownership and practice the patents or license others to do the same. Guardant's conduct was intended to have the anticompetitive effect of eliminating, or substantially hindering, competition in the liquid biopsy market.

68. Having fraudulently secured exclusive rights to the '731, '822, and '743 Patents from the USPTO, and ensured through its fraudulent scheme that it would keep exclusive rights to all of the Patents-in-Suit, Guardant then attempted to enforce them, in an anti-competitive manner, against PGDx and FMI, the two suppliers of liquid biopsies that Guardant claims are its two most significant competitors. Guardant did so to maintain and strengthen its monopoly power and tighten its stranglehold on the liquid biopsy market. By eliminating PGDx and FMI, Guardant intends to eliminate and foreclose competition and potential competition in the liquid biopsy market.

69. On information and belief, when Guardant filed its infringement claims, Guardant knew the Patents-in-Suit were invalid and unenforceable. Guardant's internal documents [REDACTED]

[REDACTED] Guardant's witnesses, including Guardant's 30(b)(6) witness in a recent litigation, also attributed the purported breakthroughs identified by the Patents-in-Suit as having been jointly developed by Eltoukhy and Talasaz. [REDACTED]

[REDACTED] Thus, Eltoukhy and Talasaz were well aware that they had fraudulently obtained the '731, '822, and

'743 Patents, and that their scheme was intended to avoid any ownership claim as to all of the Patents-in-Suit.

70. Based on the developments to date in this action, and on information and belief, Guardant only sought to enforce its invalid and unenforceable patents against PGDx and FMI to attempt to eliminate them from the liquid biopsy market. On information and belief, Guardant was hoping to use the present litigation to crush PGDx financially. Guardant's use of this litigation as an anticompetitive tool, rather than an attempt to obtain a determination on the merits, is evidenced by the manner in which Guardant has been litigating this action to date. For example, Guardant has forced PGDx to spend millions of dollars to defend itself, while refusing to examine PGDx's source code demonstrating the operation of PGDx's products or identify with any specificity how that source code purportedly practices Guardant's claims.

71. Guardant has alleged that it has an [REDACTED]

[REDACTED] Eltoukhy testified that (i) Guardant's goal in asserting the Patents-in-Suit is to foreclose PGDx and FMI from selling the accused products, (ii) Guardant is not seeking a royalty from PGDx and FMI, and (iii) Guardant is instead seeking an injunction against PGDx and FMI. Guardant's contentions and allegations thus support that Guardant is using its fraudulently obtained patents and this case to attempt to eliminate, or substantially hinder, competition to further its monopolistic goals.

72. [REDACTED]

[REDACTED] Guardant's internal documents reveal that [REDACTED]

[REDACTED]

[REDACTED] Getty testified that it is a “well understood” company goal for Guardant to maintain its alleged 80% market share. 3/15/19 Tr. at 369-70.

73. On information and belief, Guardant’s asserted claims are objectively baseless, because no reasonable litigant could conclude that Guardant’s claims were reasonably calculated to elicit a favorable outcome at least because of Guardant’s fraudulent conduct in obtaining the Patents-in-Suit, as described herein. On information and belief, Guardant did not have probable cause to assert its claims against PGDx at least because the Patents-in-Suit are invalid and unenforceable.

74. Based on developments to date in this action and on information and belief, Guardant’s claims were also subjectively baseless. Guardant’s claims against PGDx were merely an attempt to conceal its interference with PGDx’s customers and attempts to exclude PGDx from the market by attempting to force PGDx to either exit the market or spend millions of dollars to defend itself against Guardant’s baseless allegations. Based on developments to date in this action and on information and belief, Guardant’s claims were motivated by a desire to impose anticompetitive injury rather than a justifiable legal remedy. By eliminating PGDx and FMI, Guardant hopes to substantially eliminate competition, allowing Guardant to unlawfully expand and maintain its monopoly of the liquid biopsy market indefinitely.

75. Guardant lacks any legitimate business justification for the above-identified anticompetitive practices, each of which is illicit, and all of which Guardant has cumulatively used to monopolize and restrain trade in the relevant market. Guardant cannot claim it was justified in [REDACTED]

F. Guardant's Conduct Threatens to Harm Competition and Consumers

76. Guardant's conduct has and will cause substantial harm to competition and to consumers. Guardant's conduct threatens the price, quality, availability, and market-wide output of liquid biopsy services. Guardant's anticompetitive acquisition and maintenance of monopoly power and its anticompetitive conduct directly threaten demonstrable harm to competitive processes in the affected market.

77. Guardant's anticompetitive conduct, if left unchecked, will result in higher prices, fewer choices, and inferior services. If Guardant were to succeed in eliminating the two competitors it has identified as its most significant competitors, Guardant would be free to set its prices far above the level that would occur in the presence of true competition. [REDACTED]

[REDACTED] if Guardant were to exclude its most significant competitors in the liquid biopsy market. The exclusion of Guardant's most significant competitors would also result in fewer customer choices and inferior services.

78. Guardant's conduct also threatens continued innovation in the liquid biopsy space. If Guardant successfully excludes its most significant competitors, patients and healthcare

providers will be deprived of future innovations by these companies. Guardant's own incentive to innovate will also be decreased or eliminated. As a result, Guardant's conduct directly and substantially threatens competition, prices, market-wide output, and innovation.

79. Guardant's unlawful conduct has no pro-competitive benefit and no legitimate business purpose. Guardant's unlawful conduct has no effect on improving its efficiency or effectiveness at providing liquid biopsies and does not provide any benefit to consumers. Guardant's conduct has also not resulted in lower prices. To the contrary, as discussed above, Guardant's conduct has caused and threatens to cause higher prices.

G. PGDx's Antitrust Injury and Standing

1. PGDx's Antitrust Injury

80. PGDx has suffered losses as a direct consequence of the anticompetitive aspects of Guardant's conduct. Guardant's enforcement of the invalid and unenforceable Patents-in-Suit has produced significant injury to PGDx. Guardant has forced PGDx to expend substantial amounts of money, time, and human resources to defend this action. Such injuries are of the type the antitrust laws were intended to prevent and flow from that which makes Guardant's acts unlawful. Guardant is attempting to prevent PGDx from competing against Guardant in the relevant market. Guardant is attempting to force PGDx to either exit the market or spend substantial time and money defending against Guardant's baseless lawsuit. Guardant's anticompetitive conduct has also caused PGDx to lose customers, investors, and opportunities that would have otherwise been available.

81. Guardant's anticompetitive abuses have thus caused PGDx to suffer unreasonably large, ongoing monetary losses and opportunities as well as significant erosion of its goodwill and brand. All of PGDx's above-described losses are antitrust injuries – i.e., losses proximately

caused by the anticompetitive aspects and character of Guardant's conduct. The full extent of PGDx's losses will be demonstrated at a later stage of these proceedings.

2. PGDx's Antitrust Standing

82. PGDx has antitrust standing to bring the present claims for many reasons. As alleged above, PGDx has suffered antitrust injury. Guardant is attempting to prevent PGDx from competing against Guardant in the liquid biopsy market by enforcing fraudulently obtained patents. Owing to Guardant's above anticompetitive practices, PGDx has suffered direct, large, and ongoing losses.

83. Other relevant factors also show that PGDx has antitrust standing and should be permitted to bring this suit. There is a direct causal connection between Guardant's antitrust violations, the harm PGDx is suffering, and Guardant's intent to cause harm to competition. Guardant has targeted its anticompetitive conduct at PGDx because Guardant recognizes that, absent the anticompetitive conduct, PGDx has the potential to be an effective competitor.

84. As discussed above, PGDx's injuries are of the type for which the antitrust laws were intended to provide redress. PGDx's motives in this case also coincide with the public policies of antitrust law. PGDx seeks to prevent Guardant from engaging in anticompetitive acts that threaten to harm competition, PGDx, and other competitors or potential competitors. Precluding Guardant's anticompetitive behavior will open up the liquid biopsy market, allowing PGDx and other competitors or potential competitors to compete fairly against Guardant without the reality, threat, or potential threat of baseless litigation based on fraudulently procured patents. As a result, the goals of the antitrust laws will be achieved by encouraging free and open competition, which will increase quality and innovation while driving prices down.

85. PGDx is also the direct victim of Guardant's conduct and is uniquely situated to complain of the above-pled antitrust wrongs and to demonstrate their occurrence and anticompetitive effects. Based on the evidence and testimony that has come to light in this case, PGDx has unique insight into Guardant's practices and evidence to prove their occurrence and their injurious effects on competitive processes in the affected markets. PGDx has the evidence, understanding, direct knowledge, financial interest, and resources to state, develop, and present these antitrust claims.

86. Finally, there is no significant risk of duplicative recovery or complex apportionment. PGDx's losses directly flow from the anticompetitive conduct it now challenges. There is no risk of an improper allocation of these losses among various claimants, nor any risk that Guardant will be ordered to pay the same damages twice if it is ordered to compensate PGDx for its antitrust injuries. PGDx's losses are not speculative, remote, or tenuously connected to Guardant's antitrust misconduct. In addition, Guardant's anticompetitive misconduct has directly and significantly harmed PGDx in the manner pled above and in the very markets in which Guardant has committed its anticompetitive acts. PGDx therefore has antitrust standing to assert its present antitrust challenge against Guardant.

COUNT I

Declaratory Judgment - Non-Infringement of '731 Patent

87. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

88. An actual controversy exists between PGDx and Guardant regarding whether PGDx is infringing or has infringed the '731 Patent.

89. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '731 Patent.

90. PGDx is not infringing and has not infringed the '731 Patent.

91. Accordingly, PGDx seeks a declaratory judgment that it is not infringing and has not infringed the '731 Patent directly, indirectly, contributorily, or by inducement.

COUNT II

Declaratory Judgment – Invalidity of '731 Patent

92. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

93. An actual controversy exists between PGDx and Guardant regarding the validity of the '731 Patent.

94. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '731 Patent.

95. PGDx claims, upon information and belief, that the '731 Patent is invalid for failure to meet the Conditions for Patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 115, 116, and/or the judicial doctrine of double patenting.

96. Accordingly, PGDx seeks a declaratory judgment that the '731 Patent is invalid.

COUNT III

Declaratory Judgment – Non-Infringement of '822 Patent

97. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

98. An actual controversy exists between PGDx and Guardant regarding whether PGDx is infringing or has infringed the '822 Patent.

99. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '822 Patent.

100. PGDx is not infringing and has not infringed the '822 Patent.

101. Accordingly, PGDx seeks a declaratory judgment that it is not infringing and has not infringed the '822 Patent directly, indirectly, contributorily, or by inducement.

COUNT IV

Declaratory Judgment – Invalidity of '822 Patent

102. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

103. An actual controversy exists between PGDx and Guardant regarding the validity of the '822 Patent.

104. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '822 Patent.

105. PGDx claims, upon information and belief, that the '822 Patent is invalid for failure to meet the Conditions for Patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 115, 116, and/or the judicial doctrine of double patenting.

106. Accordingly, PGDx seeks a declaratory judgment that the '822 Patent is invalid.

COUNT V

Declaratory Judgment – Non-Infringement of '743 Patent

107. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

108. An actual controversy exists between PGDx and Guardant regarding whether PGDx is infringing or has infringed the '743 Patent.

109. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '743 Patent.

110. PGDx is not infringing and has not infringed the '743 Patent.

111. Accordingly, PGDx seeks a declaratory judgment that it is not infringing and has not infringed the '743 Patent directly, indirectly, contributorily, or by inducement.

COUNT VI

Declaratory Judgment – Invalidity of '743 Patent

112. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

113. An actual controversy exists between PGDx and Guardant regarding the validity of the '743 Patent.

114. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '743 Patent.

115. PGDx claims, upon information and belief, that the '743 Patent is invalid for failure to meet the Conditions for Patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 115, 116, and/or the judicial doctrine of double patenting.

116. Accordingly, PGDx seeks a declaratory judgment that the '743 Patent is invalid.

COUNT VII

Declaratory Judgment - Non-Infringement of '992 Patent

117. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

118. An actual controversy exists between PGDx and Guardant regarding whether PGDx is infringing or has infringed the '992 Patent.

119. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '992 Patent.

120. PGDx is not infringing and has not infringed the '992 Patent.

121. Accordingly, PGDx seeks a declaratory judgment that it is not infringing and has not infringed the '992 Patent directly, indirectly, contributorily, or by inducement.

COUNT VIII

Declaratory Judgment – Invalidity of '992 Patent

122. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

123. An actual controversy exists between PGDx and Guardant regarding the validity of the '992 Patent.

124. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '992 Patent.

125. PGDx claims, upon information and belief, that the '992 Patent is invalid for failure to meet the Conditions for Patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 115, 116, and/or the judicial doctrine of double patenting.

126. Accordingly, PGDx seeks a declaratory judgment that the '992 Patent is invalid.

COUNT IX

Declaratory Judgment of Unenforceability for Inequitable Conduct of the '731 Patent

127. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

128. An immediate, real, and justiciable controversy exists between PGDx and Guardant regarding the enforceability of the '731 Patent.

129. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '731 Patent.

130. PGDx claims, upon information and belief, that the '731 Patent is unenforceable due to inequitable conduct.

131. Accordingly, PGDx seeks a judgment declaring that the claims of the '731 Patent are unenforceable under the doctrine of inequitable conduct.

COUNT X

Declaratory Judgment of Unenforceability for Inequitable Conduct of the '822 Patent

132. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

133. An immediate, real, and justiciable controversy exists between PGDx and Guardant regarding the enforceability of the '822 Patent.

134. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '882 Patent.

135. PGDx claims, upon information and belief, that the '822 Patent is unenforceable due to inequitable conduct.

136. Accordingly, PGDx seeks a judgment declaring that the claims of the '822 Patent are unenforceable under the doctrine of inequitable conduct.

COUNT XI

Declaratory Judgment of Unenforceability for Inequitable Conduct of the '743 Patent

137. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

138. An immediate, real, and justiciable controversy exists between PGDx and Guardant regarding the enforceability of the '743 Patent.

139. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '743 Patent.

140. PGDx claims, upon information and belief, that the '743 Patent is unenforceable due to inequitable conduct.

141. Accordingly, PGDx seeks a judgment declaring that the claims of the '743 Patent are unenforceable under the doctrine of inequitable conduct.

COUNT XII

Declaratory Judgment of Unenforceability for Inequitable Conduct of the '992 Patent

142. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

143. An immediate, real, and justiciable controversy exists between PGDx and Guardant regarding the enforceability of the '992 Patent.

144. In its Complaint, Guardant claims that PGDx is infringing and has infringed the '992 Patent.

145. PGDx claims, upon information and belief, that the '922 Patent is unenforceable due to inequitable conduct.

146. Accordingly, PGDx seeks a judgment declaring that the claims of the '992 Patent are unenforceable under the doctrine of inequitable conduct.

COUNT XIII

Monopolization, 15 U.S.C. § 2

147. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

148. With respect to the allegations in this counterclaim, the relevant market is the market for liquid biopsy services and the relevant geographic market is the United States. Guardant contends and alleges that it dominates this market. Guardant's documents state that [REDACTED]

149. Guardant has willfully maintained and will further maintain its monopoly power in this market through exclusionary and anticompetitive means. During prosecution of the '731, '822, and '743 Patents, Eltoukhy and Talasaz, acting on behalf of Guardant, misrepresented and fraudulently withheld that Eltoukhy was an inventor. [REDACTED]

[REDACTED] They did so to consolidate rights to the Patents-in-Suit and bolster an anticompetitive scheme to exclude competition in the liquid biopsy market.

150. As a result, Guardant obtained the Patents-in-Suit by knowingly and willfully misrepresenting facts to the USPTO. Guardant then attempted to enforce the Patents-in-Suit knowing that they are invalid and unenforceable. Guardant's fraud on the USPTO and subsequent attempt to enforce invalid and unenforceable patents is in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Through this fraud, Guardant engaged in predatory or uncompetitive conduct with a specific intent to monopolize.

151. By engaging in this conduct, Guardant is abusing and has abused its monopoly power, and is attempting to impede competition in this market. Guardant is not competing on the merits and does not perform more efficient or superior services. Guardant's anticompetitive conduct instead threatens to harm competition, competitors, healthcare providers, and patients.

152. Guardant's unlawful conduct will directly and proximately cause injury or loss to interstate commerce and to consumers.

153. As a result of the Guardant's unlawful acts, PGDx has suffered and will continue to suffer antitrust injury in an amount to be proven at trial.

154. Guardant's conduct thus violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT XIV

Attempted Monopolization, 15 U.S.C. § 2

155. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

156. To the extent Guardant does not already have monopoly power, and in the alternative, there is a dangerous probability that Guardant will achieve monopoly power in the liquid biopsy market. Guardant's enforcement of its fraudulently obtained patents threatens to substantially eliminate competition in the liquid biopsy market and further establish Guardant as the dominant provider of liquid biopsy services.

157. Guardant has engaged in anticompetitive conduct with the specific intent to obtain monopoly power through exclusionary and anticompetitive means. During prosecution of the '731, '822, and '743 Patents, Eltoukhy and Talasaz, acting on behalf of Guardant, misrepresented and fraudulently withheld that Eltoukhy was an inventor. [REDACTED]

[REDACTED]

[REDACTED]

158. As a result, Guardant obtained the Patents-in-Suit by knowingly and willfully misrepresenting facts to the USPTO. Guardant then attempted to enforce the Patents-in-Suit knowing that they are invalid and unenforceable. Guardant's fraud on the USPTO and subsequent attempt to enforce invalid and unenforceable patents is in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Through this fraud, Guardant engaged in predatory or uncompetitive conduct with a specific intent to monopolize.

159. By engaging in this conduct, Guardant is abusing and has abused its monopoly power, and is attempting to impede competition in this market. Guardant is not competing on the merits and does not perform more efficient or superior services and products. Guardant's anticompetitive conduct instead threatens to harm competition, competitors, healthcare providers, and patients.

160. Guardant's unlawful conduct will directly and proximately cause injury or loss to interstate commerce and to consumers.

161. As a result of the Guardant's unlawful acts, PGDx has suffered and will continue to suffer antitrust injury in an amount to be proven at trial.

162. Guardant's conduct thus violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT XV

Declaratory Judgment – Attorneys' Fees

163. PGDx repeats, realleges, and incorporates by reference the foregoing paragraphs of the Counterclaims above.

164. An actual controversy exists between PGDx and Guardant regarding whether this is an exceptional case under 35 U.S.C. § 285.

165. Upon information and belief, this is an exceptional case under 35 U.S.C. § 285 entitling PGDx to its reasonably-incurred attorneys' fees incurred in connection with defending and prosecuting this action as a result of, *inter alia*, Guardant's assertion of the '731 Patent, the '822 Patent, the '743 Patent, and the '992 Patent against PGDx with the knowledge that PGDx does not infringe any valid or enforceable claim of the '731 Patent, the '822 Patent, the '743 Patent, and the '992 Patent and/or that the claims of the '731 Patent, the '822 Patent, the '743 Patent, and the '992 Patent are invalid or unenforceable.

166. Accordingly, PGDx seeks a declaratory judgment that this is an exceptional case under 35 U.S.C. § 285, and that PGDx is entitled to its reasonably-incurred attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, PGDx requests that this Court enter judgment in PGDx's favor as follows:

- A. Dismissing with prejudice Guardant's Second Amended Complaint;
- B. Declaring that PGDx has not infringed and is not infringing the '731 Patent, the '822 Patent, the '743 Patent, or the '992 Patent;
- C. Declaring that the '731 Patent, the '822 Patent, the '743 Patent, and the '992 Patent are invalid;
- D. Declaring that the claims of the '731 Patent, the '822 Patent, the '743 Patent, and the '992 Patent are unenforceable;

- E. Declaring that PGDx's defenses and counterclaims in this action present an exceptional case entitling it to reasonable attorneys' fees pursuant to 35 U.S.C. § 285, and awarding such fees to PGDx;
- F. Awarding PGDx its costs associated with the defense of this matter;
- G. Declaring that Guardant has violated Section 2 of the Sherman Act, 15 U.S.C. § 2;
- H. Awarding monetary damages to compensate PGDx for its injuries, an accounting of Guardant's unjust enrichment, a trebling of these damages, costs, and attorneys' fees;
- I. Granting injunctive relief prohibiting Guardant's anticompetitive and unlawful practices;
- J. Awarding prejudgment interest; and
- K. Awarding PGDx such other relief as this Honorable Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Defendant Personal Genome Diagnostics, Inc. demands a trial by jury on all issues so triable.

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