UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FOUNDATION MEDICINE, INC.,
Petitioner,

v.

GUARDANT HEALTH, INC.,
Patent Owner.

Case No. IPR2019-00636
U.S. Patent No. 9,902,992

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,902,992

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A. Ground 1: Claims 1-11, 13, 15-26 Are Unpatentable under 35 U.S.C. § 103 over Schmitt and Fan or Forshew 29

1. Motivation to Combine Schmitt with Fan or Forshew 29

2. Reasonable Expectation of Success 33

3. Claim 1 36

4. Claim 2: The method of claim 1, comprising providing less than 100 nanograms (ng) of the cfDNA molecules. 50

Claim 3: The method of claim 1, comprising providing less than 10 nanograms (ng) of the cfDNA molecules. 50

5. Claim 4: The method of claim 1, comprising providing between 100 and 100,000 human haploid genome equivalents of the cfDNA molecules, wherein the cfDNA molecules are tagged with between 2 and 1,000,000 unique identifiers. 51

Claim 5: The method of claim 1, comprising providing between 1,000 and 50,000 human haploid genome equivalents of the cfDNA molecules, wherein the cfDNA molecules are tagged with between 2 and 1,000 unique identifiers. 51

6. Claim 6: The method of claim 1, wherein each of the plurality of different barcode sequences is at least 5 nucleotides in length. 53

7. Claim 7: The method of claim 1, wherein the attaching comprises non-uniquely tagging the cfDNA molecules with at least 10 and at most 1,000 different barcode sequences. 53

8. Claim 8: The method of claim 1, wherein the attaching comprises uniquely tagging the cfDNA molecules. 54

9. Claim 9: The method of claim 1, wherein the attaching comprises performing blunt-end ligation or sticky end ligation. 55

10. Claim 10: The method of claim 1, wherein the attaching comprises non-uniquely tagging the cfDNA molecules such that no more than 5% of the tagged parent polynucleotides are uniquely tagged. 55

11. Claim 11: The method of claim 1, wherein at least 50% of the cfDNA molecules are tagged by the attaching. 56

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12. Claim 13: The method of claim 1, further comprising selectively enriching for polynucleotides mapping to one or more selected reference sequences prior to the sequencing, wherein the selectively enriching comprises (i) subjecting the cfDNA molecules to selective amplification against the one or more selected reference sequences, (ii) subjecting the tagged parent polynucleotides to selective amplification against the one or more selected reference sequences, (iii) subjecting the amplified progeny polynucleotides to selective sequence capture against the one or more selected reference sequences, or (iv) subjecting the cfDNA molecules to selective sequence capture against the one or more selected reference sequences.....57

13. Claim 15: The method of claim 1, wherein sequencing comprises massively parallel sequencing. 58

14. Claim 16: The method of claim 1, wherein the amplified tagged progeny polynucleotides are sequenced to produce an average of 5 to 10 sequence reads for each family. 58

15. Claim 17: The method of claim 1, wherein the base call for each family possesses an error rate below 0.0001%. 59

16. Claim 18: The method of claim 1, wherein each base of the tagged parent polynucleotides has at least 99% chance of being represented by at least one sequence read among the sequence reads mapped in e).....59

17. Claim 19: The method of claim 4, wherein grouping the sequence reads mapped in e) is further based on one or more of: sequence information at a beginning of the sequence derived from the cfDNA molecule, sequence information at an end of the sequence derived from the cfDNA molecule, and length of the sequence read. 61

18. Claim 20: The method of claim 4, wherein grouping the sequence reads mapped in e) is further based on a plurality of: sequence information at a beginning of the sequence derived from the cfDNA molecule, sequence information at an end of the sequence derived from the cfDNA molecule, and length of the sequence read. 62

19. Claim 21: The method of claim 1, wherein at least one single base substitution is detected.....63

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Claim 22: The method of claim 1, wherein the two or more members comprise a copy number variation (CNV). 63

20. Claim 23: The method of claim 1, wherein at least one indel is detected. 63

Claim 24: The method of claim 1, wherein at least one gene fusion is detected. 63

21. Claim 25: The method of claim 1, wherein at least one single base substitution and at least one copy number variation is detected. 65

22. Claim 26: The method of claim 1, further comprising detecting, at one or more genetic loci, one or more genetic aberrations selected from: a transversion, a translocation, an inversion, a deletion, aneuploidy, partial aneuploidy, polyploidy, chromosomal instability, chromosomal structure alterations, chromosome fusions, a gene truncation, a gene amplification, a gene duplication, a chromosomal lesion, a DNA lesion, abnormal changes in nucleic acid chemical modifications, abnormal changes in epigenetic patterns and abnormal changes in nucleic acid methylation. 66

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