PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Ins re Application of	)	Group Art Unit: 1637
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Bert VOGELSTEIN et al	)	Examiner: S. Woolwine
	)	
Serial No. 12/617,368	)	Confirmation No. 4461
	)	
Filed: November 12, 2009	)	Atty. Dkt. No. 001107.00794
	)	
For: DIGITAL AMPLIFICATION	)	

AMENDMENT

U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In response to the non-final office action mailed September 23, 2010, Applicants submit and request that the Patent Office enter the claim amendment and the terminal disclaimer.

In the event that any fees or credits are due, please charge or credit our deposit account no. 19-0733.

IIN THE CLAIMS:

Please substitute the following claim set for those currently of record.

1. (Original) A method for determining an allelic imbalance in a biological sample, comprising the steps of:

amplifying template molecules within a set comprising a plurality of assay samples to form a population of amplified molecules in each of the assay samples of the set, wherein the template molecules are obtained from the biological sample;

analyzing the amplified molecules in the assay samples of the set to determine a first number of assay samples which contain a first allelic form of a marker and a second number of assay samples which contain a second allelic form of the marker, wherein between 0.1 and 0.9 of the assay samples yield an amplification product;

comparing the first number to the second number to ascertain an allelic imbalance in the biological sample; and

identifying an allelic imbalance in the biological sample.

2. (Original) The method of claim 1 wherein the step of amplifying employs real-time polymerase chain reactions.

3. (Original) The method of claim 2 wherein the real-time polymerase chain reactions comprise a dual-labeled fluorogenic probe.

4. (Original) The method of claim 1 wherein between 0.1 and 0.9 of the assay samples yield an amplification product as determined by amplification of the first allelic form of the marker.

5. (Original) The method of claim 1 wherein between 0.1 and 0.9 of the assay samples yield an amplification product as determined by amplification of the second allelic form of the marker.

6. (Original) The method of claim 1 wherein the amplified molecules in each of the assay samples within the first and second numbers of assay samples are homogeneous such that the first number of assay samples do not contain the second allelic form of the marker and the second number of assay samples do not contain the first allelic form of the marker.

7. (Original) The method of claim 1 wherein the sample is from blood.

8. (Previously presented) A method for determining an allelic imbalance in a biological sample, comprising the steps of:

distributing nucleic acid template molecules from a biological sample to form a set comprising a plurality of assay samples;

amplifying the template molecules within the assay samples to form a population of amplified molecules in the assay samples of the set;

analyzing the amplified molecules in the assay samples of the set to determine a first number of assay samples which contain a first allelic form of a marker and a second number of assay samples which contain a second allelic form of the marker;

comparing the first number of assay samples to the second number of assay samples to ascertain an allelic imbalance between the first allelic form and the second allelic form in the biological sample.

9. (Original) The method of claim 8 wherein the sample is from blood.

10. (Previously presented) The method of claim 1 or 8 wherein between 0.1 and 0.6 of the assay samples yield an amplification product.

11. (Previously presented) The method of claim 1 or 8 wherein between 0.3 and 0.5 of the assay samples yield an amplification product.

12. (Previously presented) The method of claim 1 or 8 wherein the set comprises at least 500 assay samples.

13. (Previously presented) The method of claim 1 or 8 wherein the set comprises at least 1000 assay samples.

14. (New) The method of claim 8 wherein the step of amplifying employs real-time polymerase chain reactions.

15. (New) The method of claim 14 wherein the real-time polymerase chain reactions comprise a dual-labeled fluorogenic probe.

16. (New) The method of claim 8 wherein between 0.1 and 0.9 of the assay samples yield an amplification product as determined by amplification of the first allelic form of the marker.

17. (New) The method of claim 8 wherein between 0.1 and 0.9 of the assay samples yield an amplification product as determined by amplification of the second allelic form of the marker.

18. (New) The method of claim 8 wherein the amplified molecules in each of the assay samples within the first and second numbers of assay samples are homogeneous such that the first number of assay samples do not contain the second allelic form of the marker and the second number of assay samples do not contain the first allelic form of the marker.

Remarks

New dependent claims on claim 8, claims 14-18, are supported *inter alia* by original dependent claims on claim 1, claims 2-6.

Applicant notes the reconsideration of the issue of new matter and appreciates the conclusion that the subject matter of claim 1 was disclosed in the earliest priority application as well as in the particular application as originally filed.

Claims 1 and 6-13 stand rejected for non-statutory double patenting over claims 3, 7-11, 19, 24, and 31 of parent patent U.S. 6,440,706. Similarly, claims 2 and 3 stand rejected over the same set of issued claims combined with claims 12 and 13 of the '706 patent and combined with the Marras literature reference. Applicants submit a terminal disclaimer over the '706 which obviates these rejections.

If all issues are resolved, we request that the U.S. Patent and Trademark Office process this application for grant.

Respectfully submitted,

Date: October 6, 2010

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