Japanese Patent No. 6275145
Opposition no: 2018-700659 WSGR Ref: 42534-704.761

(Translation)

Decision

Opposition 2018-700659

505 Penobscot Drive, Redwood City, CA 94063, USA
Patent right holder
Guardant Health, Incorporated

SHUSAKU YAMAMOTO, Grand Front Osaka Tower C, 3-1 Ofuka-cho, Kita-ku, Osaka-shi, Osaka
Shusaku YAMAMOTO, Patent Attorney

SHUSAKU YAMAMOTO, Grand Front Osaka Tower C, 3-1 Ofuka-cho, Kita-ku, Osaka-shi, Osaka
Natsuki MORISHITA, Patent Attorney

SHUSAKU YAMAMOTO, Grand Front Osaka Tower C, 3-1 Ofuka-cho, Kita-ku, Osaka-shi, Osaka
Takatoshi IIDA, Patent Attorney

SHUSAKU YAMAMOTO, Grand Front Osaka Tower C, 3-1 Ofuka-cho, Kita-ku, Osaka-shi, Osaka
Daisuke ISHIKAWA, Patent Attorney

SHUSAKU YAMAMOTO, Grand Front Osaka Tower C, 3-1 Ofuka-cho, Kita-ku, Osaka-shi, Osaka
Kensaku YAMAMOTO, Attorney at law

10-2-202 Tsukuda-cho, Nishikyogoku, Sakyo-ku, Kyoto-shi, Kyoto
Opponent Sumiko NODA

The following decision has been rendered in connection with the Opposition filed against the inventions of Japanese

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Patent No. 6275145 entitled "SYSTEMS AND METHODS TO DETECT RARE MUTATIONS AND COPY NUMBER VARIATIONS".

Conclusion

The patent for claims 1-29 in Japanese Patent No. 6275145 shall be maintained.

Reasons

I Timeline of proceeding

The application for the inventions defined by claims 1-29 in Japanese Patent No. 6275145 is an application with an international filing date of September 4, 2013 (priority claims under the Paris convention: September 4, 2012, US; September 21, 2012, US; March 15, 2013, US; July 13, 2013, US). A patent was registered for the inventions on January 19, 2018.

Opposition was filed thereafter against the patent on August 7, 2018 by the Opponent, Sumiko NODA.

II Instant inventions

The inventions defined by claims 1-29 of Japanese Patent No. 6275145 are specified by the recitations of the respective claims 1-29 (hereinafter, referred to as "instant inventions 1", "instant invention 2", and the like, respectively). Claim 1 thereof is the following.

[Claim 1]
A method for detecting copy number variation comprising:

a. non-uniquely tagging extracellular polynucleotides or fragments thereof from a bodily sample from a subject, thereby producing a population of non-uniquely tagged extracellular polynucleotides;

b. sequencing said non-uniquely tagged extracellular polynucleotides, wherein each of the extracellular polynucleotide generates a plurality of sequencing reads;

c. filtering out reads that fail to meet a set threshold;

d. mapping the sequencing reads obtained from step (b), after reads are filtered out, to a reference sequence;

e. quantifying or enumerating mapped reads or unique sequencing reads in a plurality of predefined regions of the reference sequence; and

f. determining copy number variation in one or more of the plurality of predefined regions by:

i. normalizing a number of sequencing reads in each of the plurality of predefined regions to each other and/or a number of unique sequencing reads in the plurality of predefined regions to each other; and/or

ii. comparing a number of sequencing reads in each of the plurality of predefined regions and/or a number of unique sequencing reads in the plurality of predefined regions to normalized numbers obtained from a control sample.

III Summary of Reasons for Opposition

The summary of reasons for opposition that have been set forth by the Opponent and the methods of proof are the following.

1 Instant inventions should be revoked because instant inventions 1-10, 13, 14, 15, 20, 21, 23, and 29 should be rejected under Sec. **29(1)(iii)** of the Japanese Patent Law as being anticipated by the subject matter described in Exhibit Ko No. 1, and instant inventions 1-29 should be rejected under Sec. **29(2)** of the Japanese Patent Law as being obvious to those skilled in the art over the subject matter described in Exhibit Ko No. 1 and the subject matter described in Exhibit Ko Nos. 2-9.

2 Instant inventions 1-29 should be revoked because said inventions should be rejected under Sec. **29(2)** of the Japanese Patent Law as being obvious to those skilled in the art over the subject matter described in Exhibit Ko No. 5, as well as Exhibit Ko Nos. 3,4, and 7-9.

[Method of proof]

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Exhibit Ko No. 1:
Chiu, et al., "Non-invasive prenatal assessment of trisomy 21 by multiplexed maternal plasma DNA sequencing: large scale validity study", BMJ (2011) p. 1/9-9/9 and Web extra appendices (p. 1-8), <URL> https://doi.org/10.1136/bmj.c7401
Exhibit Ko No. 2:
Chiu, et al., "Noninvasive prenatal diagnosis of fetal chromosomal aneuploidy by massively parallel genomic sequencing of DNA in maternal plasma", Proc. Natl. Acad. Sci. USA (2008) vol. 105, no. 51, p. 20458-20463 and Supporting Information (p. 1/17-17/17)
Exhibit Ko No. 3:
"Multiplexed Sequencing with the Illumina Genome Analyzer System" (2008) p. 1-4 <URL> https://www.illumina.com/Documents/products/datasheets/datasheet_sequencing_multiplex.pdf
Exhibit Ko No. 4:
Kinde, et al., "Detection and quantification of rare mutations with massively parallel sequencing", Proc. Natl. Acad. Sci. USA (2011) vol. 108, no. 23, p. 9530-9535 and Supporting Information (p. 1/10-10/10)
Exhibit Ko No. 5:
US Patent No. 8195415
Exhibit Ko No. 6:
Wang, et al., "Digital karyotyping", Pro. Natl. Acad. Sci. USA (2002) vol. 99, no. 25, p. 16156-16161
Exhibit Ko No. 7:
CASAVA v1.8.2 User Guide (2011), <URL> http://gensoft.pasteur.fr/docs/casava/1.8.2/CASAVA_1_8_2_UG_15011196C.pdf
Exhibit Ko No. 8:
Shaw, et al., "Genomic analysis of circulating cell-free DNA infers breast cancer dormancy", Genome Res. (published online OCT 2011) vol. 22, p. 220-231
Exhibit Ko No. 9:

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Nord et al., "Accurate and exact CNV identification from targeted high-throughput sequence data," BMC Genomics (2011) p. 1/10-10/10, <URL> http://www.biomedcentral.com/1471-2164/12/184

IV Findings of facts

The descriptions in Exhibit Ko Nos. 1-9 are summarized as follows (The Appeal Bench prepared the translation from English to Japanese)

1 Exhibit Ko No. 1

(1) Descriptions of Exhibit Ko No. 1

Exhibit Ko No. 1, which is a document made available to the public prior to the priority dates, describes that: to rule out fetal trisomy 21 among high risk pregnancies, multiplexed maternal plasma DNA sequencing analysis was used to measure the proportions of DNA molecules that originated from chromosome 21, and a fetus was diagnosed as a trisomy 21 fetus when the z score for the chromosome 21 DNA molecules was > 3 (page 1, left column, lines 19-25; and page 1, right column, lines 1-3).

Exhibit Ko No. 1 also describes that maternal plasma DNA molecules were extracted and sequenced using the same protocol described in Reference 24 (Note by the Appeal Bench: corresponding to Exhibit Ko No. 2) other than the introduction of multiplexing (page 2, right column, lines 21-24). As the summary of the protocol, Exhibit Ko No. 1 further describes that: a unique synthetic DNA "barcode" of six base pairs, which served as a signature for a sample, with one index used per maternal plasma sample, was introduced onto one end of each plasma DNA molecule, and multiplexed sample mixtures consisting of multiple maternal plasma DNA preparations were co-sequenced (page 2, right column, lines 41-51); and the sequencing was performed on the Genome Analyzer II (Illumina) or Genome Analyzer IIx (Illumina), and after the sequencing, the actual DNA molecules that belonged to a specific sample were

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