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Paper No. 7
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMBRY GENETICS CORPORATION,
Petitioner

v.

THE JOHNS HOPKINS UNIVERSITY
Patent Owner

Case IPR2017-02095
Patent 7,915,015 B2

Before LORA M. GREEN, TINA E. HULSE, and RICHARD J. SMITH, *Administrative Patent Judges.*

SMITH, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Ambry Genetics Corporation ("Petitioner") filed a Petition ("Pet.") to institute an *inter partes* review of claims 1, 5, and 10 of U.S. Patent 7,915,015 B2 (the "'015 patent"). 35 U.S.C. § 311. The Johns Hopkins University ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314. To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of any challenged claim of the '015 patent. Therefore, we do not institute an *inter partes* review for any challenged claim of the '015 patent.

A. Related Proceedings

The '015 patent has been asserted in pending district court proceedings: *Esoterix Genetic Laboratories, LLC and The Johns Hopkins University v. Ambry Genetics Corporation*, United States District Court for the Middle District of North Carolina, Case No. 1:16-cv-1111-WO-JEP (the "Ambry Litigation"). Pet. 1–2; Paper 3, 2. The '015 patent was also asserted in litigation styled *Esoterix Genetic Laboratories, LLC and The Johns Hopkins University v. Myriad Genetics, Inc. and Myriad Genetics Laboratories, Inc.*, United States District Court for the Middle District of North Carolina, Case No. 1:16-cv-1112-WE-JEP, but that case has been dismissed. Pet. 2; Paper 3, 2. The '015 patent was also asserted in litigation styled *Esoterix Genetic Laboratories, LLC and The Johns Hopkins University v. Life*

Technologies Corp, et al., Civil Action No. 1:12-cv-01173-CCE-JEP (MDNC). Paper 3, 2–3.

Petitioner also filed petitions for *inter partes* review of certain claims of related U.S. Patent No. 6,440,706 (IPR2017-02086); U.S. Patent No. 7,824,889 (IPR2017-02093); and U.S. Patent No. 8,859,206 (IPR2017-02096). Pet. 2; Paper 3, 2.

B. The '015 Patent

The '015 patent relates to diagnostic genetic analyses. Ex. 1001, 1:20. With the understanding that somatic mutations are the primary cause of cancer, new opportunities for basic research into the pathogenesis of cancer have arisen. *Id.* at 1:27–32. For example, in some cases, detecting neoplastic cells in urine, stool, and sputum is possible at a stage when the primary tumors are still curable and the patients are asymptomatic. *Id.* at 1:35–40. Thus, it is important to be able to detect small populations of mutant cells among a large excess of normal cells. *Id.* at 1:33–35, 44–46. Accordingly, the specification states that "[i]t is an object of the present invention to provide methods for determining the presence of a selected genetic sequence in a population of genetic sequences." *Id.* at 2:3–5.

The disclosed method involves diluting a biological sample to a point where a practically usable number of the diluted samples contain a proportion of the selected genetic sequence (analyte) relative to total template molecules. *Id.* at 4:20–23. The diluted samples are separately amplified so that the amplified products have a proportion of the analyte sequence that is detectable by the detection means chosen. *Id.* at 4:7–10. With this method, single template molecules can be amplified so that the products are completely mutant or completely wild-type. *Id.* at 4:11–13.

The specification refers to this method as "digital amplification." *Id.* at

4:42–43. According to the specification, "[t]he ultimate utility of Digital Amplification lies in its ability to convert the intrinsically exponential nature of PCR to a linear one." *Id.* at 5:65–67. The specification further states that "[i]t should thereby prove useful for experiments requiring the investigation of individual alleles, rare variants/mutations, or quantitative analysis of PCR products." *Id.* at 5:67–6:2. For example, the specification identifies "allelic imbalance" as a potential application of digital amplification. *Id.* at 5:29–30; 43–64 (Table 1). According to the specification, "[a]llelic imbalances often result from a disease state." *Id.* at 7:8–9.

C. Illustrative Claim

Petitioner challenges claims 1, 5, and 10 of the '015 patent, of which claim 1 is an independent claim. Claim 1, as amended during *ex parte* reexamination, is reproduced below:

> 1. A method for determining an allelic imbalance in a biological sample, comprising the steps of:
>
> distributing isolated nucleic acid template molecules to form a set comprising a plurality of assay samples, wherein the nucleic acid template molecules are isolated from the biological sample;
>
> amplifying the isolated nucleic acid template molecules within the set to form a population of amplified molecules in individual 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, wherein between 0.1 and 0.9 of the assay samples yield an amplification product of at least one of the first and second allelic forms of the marker;

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.

Ex. 1001, 20.

Claim 5 depends from claim 1, and claim 10 depends from claims 1 or 8. Claim 8 is an independent claim but is not addressed by Petitioner. Accordingly, we treat Petitioner's reference to claim 10 in the Petition as solely based on its dependency on claim 1.

D. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. §§ 102(b) and/or 103 based on the following specific grounds. Pet. 4.

Reference[s]	**Basis**	**Claims challenged**
Chiang[1]	§ 102(b)	1, 5
Sykes[2]	§ 102(b)	1, 5, 10
Chiang and/or Sykes	§ 102(b)/§103	1, 5, 10

Petitioner also relies on the Declaration of Gregory A. Buck, Ph.D. Ex. 1007.

[1] Pie-Wen Chiang et al., *Use of a Fluorescent-PCR Reaction to Detect Genomic Sequence Copy Number and Transcriptional Abundance*, 6 GENOME RESEARCH 1013–26 (1996) ("Chiang"). Ex. 1031.
[2] P.J. Sykes et al., *Quantitation of Targets for PCR by Use of Limiting Dilution*, 13 BIOTECHNIQUES 444–49 (1992) ("Sykes"). Ex. 1011.

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