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Paper No. 18
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROCHE MOLECULAR SYSTEMS INC.,
Petitioner,

v.

ILLUMINA, INC.,
Patent Owner.

Case IPR2015-01091
Patent 7,955,794 B2

Before LORA M. GREEN, ZHENYU YANG, and TINA E. HULSE, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION
Denying Motion for Joinder
and Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108; 37 C.F.R. § 42.122(b)

I. INTRODUCTION

On April 24, 2015, Roche Molecular Systems, Inc. ("Roche," "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–22 of U.S. Patent No. 7,955,794 B2 (Ex. 1001, "the '794 patent"). Paper 3 ("Pet."). Petitioner filed a Motion for Joinder concurrently with the Petition. Paper 2 ("Mot. Joinder"). Illumina, Inc. ("Illumina," "Patent Owner") filed a Preliminary Response to the Petition (Paper 13, "Prelim. Resp."), as well as an Opposition to the Motion for Joinder (Paper 9, "Opp. Mot. Joinder"). Upon request from the panel, Petitioner filed a Reply to Patent Owner's Preliminary Response. Paper 15 ("Reply").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is 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).

The statute grants the Board discretion to deny a petition, even when the conditions for review may have been met. *See id.* (stating only that the Director may not institute review unless certain conditions are met). For the reasons that follow, in light of the totality of circumstances presented in this case, we deny the Petition. 35 U.S.C. §§ 314(a), 325(d); *see also* 35 U.S.C. § 316(b) (noting that the rules for *inter partes* review proceedings shall take into account the "regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings"), 37 C.F.R. § 42.108(b) ("At any time prior to institution of *inter partes* review, the Board may deny some or all of the grounds for unpatentability.").

A. Related Proceedings

Petitioner states that the '794 patent is the subject of the copending district court case, *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, Case No. 3:14-cv-01921 (N. D. Cal.), which has been consolidated with *Verinata Health, Inc. v. Ariosa Diagnostics*, Case No. 3:12-cv-05501-SI (N.D. Cal.). Pet. 2.

In addition, this IPR is related to IPR2014-01093, to which Petitioner is seeking joinder. Specifically, we instituted an *inter partes* review in IPR2014-01093 on January 8, 2015, on the ground that claims 1–22 are anticipated by Fan.[1] Ariosa Diagnostics, Inc. ("Ariosa") is the nominal Petitioner in IPR2014-01093, while Roche is the nominal Petitioner in the instant proceeding. Roche, however, was added as a real party-in-interest in IPR2014-01093 (IPR2014-01093, Paper 35), and Ariosa was named as a real party-in-interest in the instant proceeding (Paper 4).

B. The '794 Patent

The '794 patent issued on June 7, 2011, with Mun-Jui Richard Shen, Arnold Oliphant, Scott L. Butler, John E. Stuelpnagel, Mark S. Chee, Kenneth M. Kuhn, and Jian-Bing Fan as listed co-inventors. Ex. 1001. The '794 patent provides "a number of methods directed to the multiplexing amplification and/or genotyping reactions of target sequences to create amplicons that can subsequently be detected on an array." *Id.* at 1:54–57.

Specifically, the '794 patent discloses "a variety of compositions and methods directed to multiplexed analysis of nucleic acids." *Id.* at 5:32–34. The '794 patent states "[a]s used herein, the phrase 'multiplex' or grammatical equivalents refers to the detection, analysis or amplification of

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[1] Fan et al. ("Fan"), Pub. No. US 2002/0172946 A1, published Nov. 21, 2002 (IPR2014-01093, Ex. 1004).

more than one target sequence of interest." *Id.* at 5:61–64. As taught by the '794 patent, the methods generally include steps of complexity reduction, specificity, and amplification. *Id.* at 5:47–49. The nucleic acid to be detected, that is, the target sequence, may be DNA or RNA. *Id.* at 8:9–17.

C. Illustrative Claim

Petitioner challenges claims 1–22 of the '794 patent. Claim 1, the only independent claim, is illustrative, and is reproduced below:

> 1. A multiplex method for determining whether a sample contains at least 100 different target sequences, comprising:
>
> a. providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support;
>
> b. contacting said target sequences with a probe set comprising more than 100 different single-stranded probes, wherein each of said more than 100 different probes comprises:
>
> i) a first universal priming site, wherein each of said more than 100 different probes has identical universal priming sites, and
>
> ii) a target specific domain, such that different double stranded hybridization complexes are formed, each of the different hybridization complexes comprising one of said more than 100 different single-stranded probes and one of the different single-stranded target sequences from the sample;
>
> c. removing unhybridized probes;
>
> d) contacting said probes of the hybridization complexes with a first enzyme and forming different modified probes;
>
> e. contacting said modified probes with:
>
> i) at least a first primer that hybridizes to said universal priming site;

ii) NTPs; and

iii) an extension enzyme;

wherein said different modified probes are amplified and forming different amplicons;

f. immobilizing said different amplicons to a second solid support, and

g. detecting said different amplicons immobilized to said second solid support, thereby determining whether the sample contains at least 100 different target sequences.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–22 of the '794 patent on the following grounds:

Reference(s)	**Basis**	**Claim(s) challenged**
Shuber[2]	§ 102	1–3, 5–8, 14, 15, 17
Shuber	§ 103	1–3, 5–8
Straus[3]	§ 102	1–3, 5–9, 11, 13–15, 17, 21
Shuber and Fodor[4]	§ 103	4
Strauss and Fodor	§ 103	4
Shuber and Backman[5]	§ 103	9–11, 13–15, 17
Shuber and Straus	§ 103	9–11, 13–15, 17

[2] Shuber, US 5,834,181, issued Nov. 10, 1998 (Ex. 1003).
[3] Straus, Pub. No. US 2002/0086289 A1, published Jul. 4, 2002 (Ex. 1004).
[4] Fodor et al. ("Fodor"), US 6,197,506 B1, issued Mar. 6, 2001 (Ex. 1005).
[5] Backman et al. ("Backman"), US 5,792,607, issued Aug. 11, 1998 (Ex. 1006).

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