

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THERMO FISHER SCIENTIFIC, INC.,
Petitioner,

v.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,
Patent Owner.

Case IPR2018-01367
Patent 8,835,113 B2

Before ERICA A. FRANKLIN, MICHELLE N. ANKENBRAND, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Thermo Fisher Scientific, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 3–5, 7, 20, 22, and 25–27 of U.S. Patent No. 8,835,113 B2 (Ex. 1001, “the ’113 patent”). Paper 1 (“Pet.”). The Regents of the University of California (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. Upon considering the Petition and the Preliminary Response, along with the circumstances involved in this case, we determine that Petitioner has not shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. Accordingly, we deny the Petition and decline to institute an *inter partes* review.

A. *Related Proceedings*

Petitioner and Patent Owner identify an ongoing district court proceeding involving the ’113 patent: *The Regents of the University of California et al. v. Affymetrix, Inc. et al.*, No. 3:17-cv-01394 (CASD). Pet. 67; Paper 4, 2. The parties also note that Petitioner has concurrently filed a separate petition involving the ’113 patent (IPR2018-01368) and, shortly thereafter, filed two petitions involving a related patent, U.S. Patent No. 8,110,673 B2 (IPR2018-01369 and IPR2018-01370). Pet. 67; Paper 4, 1–2.

B. *The ’113 Patent*

The ’113 patent relates to methods for assaying a sample for an aggregant using an aggregation sensor. Ex. 1001, 1:32–34. “An aggregant to be assayed may be a target biomolecule (e.g., a polysaccharide, a

polynucleotide, a peptide, a protein, etc.).” *Id.* at 15:55–58. “The aggregation sensor comprises a component that can bind to an aggregant or class of aggregants.” *Id.* at 10:10–12. The Specification explains that “[c]onjugated polymers have proven useful as light gathering molecules in a variety of settings.” *Id.* at 1:49–50. In particular, “[w]ater-soluble conjugated polymers such as cationic conjugated polymers (CCPs) have been used in bioassays to improve detection sensitivity and provide new routes of selectivity in analyzing biomolecules.” *Id.* at 1:51–55. The molecular structure of those molecules “allows for a collective response and, therefore, optical amplification of fluorescent signals.” *Id.* at 2:33–37. Specifically, “[t]he large number of optically active units along the polymer chain increases the probability of light absorption, relative to small molecule counterparts.” *Id.* at 2:37–39. The presence of target DNA in a sample may be detected upon delivery of excitations to fluorophores, using facile fluorescence resonance energy transfer (FRET). *Id.* at 2:39–42.

The Specification explains that “[r]ecent studies indicate that energy transfer between segments in conjugated polymers may be substantially more important than along the backbone” and that external perturbations that decrease the elongation of the backbone or bring its segments closer together may be used to modify emissive properties of the polymer in solution. *Id.* at 2:46–49. Based on that information, the Specification states that the inventors recognized “a small number of fluorescent units within a polymer sequence could be activated by structural changes that compressed or aggregated the polymer chains to ultimately change the emission color” and then designed a cationic conjugated polymer structure in accordance with that principle. *Id.* at 2:50–55. According to the Specification,

“[e]lectrostatic complexation with negatively charged DNA can be used to reduce the average intersegment distance. When combined with a fluorophore labeled peptide nucleic acid (PNA) strand, the polymer can be used to design a three color DNA detection assay.” *Id.* at 2:55–60.

C. Illustrative Claim

Claim 1 of the ’113 patent, reproduced below, is the only independent claim, and is illustrative of the claimed subject matter.

1. A method of assaying a sample for an aggregant, the method comprising:
 - (a) combining the sample with an aggregation sensor comprising
 - (i) a polymer comprising a plurality of first optically active units forming a conjugated system, having a first absorption wavelength at which the first optically active units absorb light to form an excited state that can emit light of a first emission wavelength, and a plurality of solubilizing functionalities; and
 - (ii) one or more second optically active units that can receive energy from the excited state of the first optically active unit;
wherein said aggregation sensor comprises at least three first optically active units per second optically active unit and the second optically active unit is grafted to the conjugated system;
 - (b) contacting the sample with light of the first absorption wavelength; and
 - (c) detecting the optical properties of the aggregation sensor to assay the sample for the aggregant.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 3–5, 7, 20, 22, and 25–27 of the ’113 patent on the following grounds:

Claim(s)	Basis	References
1, 20, 22, 25, and 26	§ 103(a)	Hou ¹ and Ingnas ²
1, 3–5, 7, and 27	§ 103(a)	Hou, Bazan, ³ and the Handbook ⁴

Petitioner also relies upon the Declaration of Kirk S. Schanze, Ph.D. (Ex. 1002).⁵ Patent Owner relies upon the Declaration of Dwight Seferos, Ph.D. (Ex. 2008).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings).⁶ Under that standard, and absent any special

¹ Hou et al., *Novel red-emitting fluorene-based copolymers*, 12 J. MATER. CHEM. 2887-2892 (2002) (“Hou”) (Ex. 1007).

² Ingnas et al., WO 2003/096016 A1, published Nov. 20, 2003 (“Ingnas”) (Ex. 1006).

³ Bazan et al., WO 2004/001379 A2, published Dec. 31, 2003 (“Bazan”) (Ex. 1033).

⁴ Haugland, HANDBOOK OF FLUORESCENT PROBES AND RESEARCH PRODUCTS, 9th ed., Molecular Probes (2002) (“the Handbook”) (Ex. 1005).

⁵ Petitioner includes the letters “TFS” with its exhibit numbers. We do not adopt that practice in this decision.

⁶ The Office recently changed the claim construction standard to be employed in an *inter partes* review. See *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51340 (October 11, 2018). However,

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