UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ENVIROLOGIX INC.,

Petitioner

v.

IONIAN TECHNOLOGIES, INC.,

Patent Owner

————————

Case IPR2018-00405
Patent 9,562,263 B2

————————

Before ULRIKE W. JENKS, CHRISTOPHER G. PAULRAJ, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge.*

DECISION

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

I.   INTRODUCTION

EnviroLogix Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–8 and 10–35 of U.S. Patent No. 9,562,263 B2 (Ex. 1001, "the '263 patent"). Paper 1 ("Pet."). Ionian Technologies, Inc ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

We have authority 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). Upon consideration of the arguments and evidence presented in the Petition and the Preliminary Response, we are not persuaded that Petitioner has established a reasonable likelihood that it would prevail in its challenges to claims 1–8 and 10–35 of the '263 patent. Accordingly, we do not institute an *inter partes* review of claims 1–8 and 10–35.

II.   BACKGROUND

A.   *Related Proceedings*

Petitioner identifies three related patents: U.S. Patent No. 9,562,264 B2 ("the '264 patent"), U.S. Patent No. 9,617,586 B2 ("the '586 patent"), U.S. Patent No. 9,689,031 B2 ("the '031 patent"). Pet. 2 ("Petitioner reserves the right to petition for *inter partes* review of 9,562,263, 9,617,586 and 9,689,031"). The claims in the '264 patent are directed to a method of amplifying a target polynucleotide. We note that Petitioner has filed a request for *inter partes* review of the '264 patent. *See* IPR2018-00406. Concurrently herewith, we issue also a decision in that related proceeding.

B.   *The '263 Patent (Ex. 1001)*

The '263 patent issued from Application No. 14/067,620, filed October 30, 2013, which is a continuation of Application No. 11/778,018, filed July 14, 2007.

The '263 patent relates to amplification of nucleic acid targets using a nicking enzyme. A nicking enzyme amplification reaction (NEAR) requires the presence of (1) a nucleic acid target, (2) at least two template oligonucleotides, (3) a thermophilic nicking enzyme, (4) a thermophilic polymerase, and (5) buffer components all held at the reaction temperature. Ex. 1001, 18:32–36.

The '263 patent provides that when using "a double-stranded target, both templates can interact with the corresponding target strands simultaneously." *Id.* 18:47–48. "The double-strand formed from the extension of both templates creates a nicking enzyme binding site on either end of the duplex. This double-strand is termed the NEAR amplification duplex." *Id.* 19:16–19. The NEAR amplification method "do[es] not require the use of temperature cycling, as often is required in methods of amplification to dissociate the target sequence from the amplified nucleic acid." *Id.* 19:51–54. The '263 patent provides that even though temperature cycling is not required, the temperature should be high enough to minimize nonspecific binding. *Id.* 20:2–3. "The polymerase may be mixed with the target nucleic acid molecule before, after, or at the same time as, the nicking enzyme." *Id.* 19:54–58. "The reaction is run at a constant temperature, usually between 54° C. and 60° C. for the enzyme combination of Bst polymerase (large fragment) and Nt.Bst.NBl nicking enzyme." *Id.* 21:17–20. The product of the NEAR amplification can be visualized by gel

electrophoresis or mass spectroscopy. *Id.* 10–67. Alternatively, the product

can be detected in real-time using SYBR II fluorescence (*id.* 27: 6–15),

Fluorescence Resonance Energy Transfer (FRET) (*id.* at 27:18–32), or using

molecular beacons. *Id.* at 27:36–47.

    C.   Illustrative Claim

Claim 1, the sole independent claim of the '263 patent is illustrative

and reproduced below:

> 1.   A method of amplifying a target polynucleotide sequence, the method comprising:
>> (a) obtaining, from an animal, plant or food, a sample comprising a target nucleic acid, the target nucleic acid comprising the target polynucleotide sequence,
>> (b) without first subjecting the target nucleic acid to a thermal denaturation step associated with amplification of the target polynucleotide sequence, combining, in a single step, the obtained sample directly with an amplification reagent mixture or diluting the obtained sample and combining, in a single step, the diluted sample with an amplification reagent mixture, in either case, the amplification reagent mixture being free of bumper primers and comprising:
>> (i) a polymerase,
>> (ii) a nicking enzyme,
>> (iii) a first oligonucleotide comprising a 5' portion that comprises a nicking enzyme binding site that is non-complementary to the target polynucleotide sequence and a 3' portion that hybridizes to the target polynucleotide sequence, and
>> (iv) a second oligonucleotide comprising a 5' portion that comprises a nicking enzyme binding site that is non-complementary to the target polynucleotide sequence and a 3' portion that hybridizes to the target polynucleotide sequence,
>> (c) subjecting the reaction mixture formed by the step of combining to essentially isothermal conditions to amplify

the target polynucleotide sequence without the assistance of bumper primers, and

(d) detecting the amplified target polynucleotide sequence in real time within 10 minutes of subjecting the reaction mixture to essentially isothermal conditions.

Ex. 1001, 32:14–47 (formatting added).

D. Prior Art

Petitioner relies upon the following prior art references:

Ehses et al. ("Ehses")	*Optimization and design of oligonucleotide setup for strand displacement amplification*, 63 J. BIOCHEM. BIOPHYS. METHODS 170–186 (2005).	Ex. 1002
Ehses ("Ehses Dissertation")	*Isothermale in vitro Selektion und Amplifikation zur Untersuchung von Evolutionsvorgängen*, Dissertation (2005).	Ex. 1003
Ehses (Dissertation Translation")	*Isothermal In Vitro Selection and Amplification to Investigate Evolutionary Processes*.	Ex. 1004
Piepenburg et al. ("Piepenburg")	US 2005/0112631 Al, publ. May 26, 2005.	Ex. 1005
Kong et al. ("Kong")	WO 01/94544 A2, publ. Dec. 13, 2001.	Ex. 1006
Kato and Kuramitsu ("Kato")	*Characterization of thermostable RecA protein and analysis of its interaction with single-stranded DNA*, 259 FEBS Journal 592–601 (1999).	Ex. 1007

Petitioner also relies upon the Declaration of Dr. Jeremy Edwards. (Ex. 1008).

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