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.

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IPR2018-00405
Patent 9,562,263 B2

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

PAULRAJ, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Requests for Rehearing
37 C.F.R. § 42.71(d)

I. INTRODUCTION

EnviroLogix Inc., (hereafter "Petitioner") filed a Request for Rehearing of our Decision Denying Institution of *inter partes* review. Paper 14 ("Req. Reh'g"). To summarize, Petitioner filed a petition seeking *inter partes* review of U.S. Patent No. 9,562,263 B2 (Ex. 1001, "the '263 patent"). Paper 1 ("Pet."). We denied institution based upon our consideration of the challenges presented, including the anticipation ground relying upon Ehses[1]. *See* Paper 12 ("Decision").

In its Request for Rehearing, Petitioner contends that the Decision Denying Institution should be withdrawn, and *inter partes* review should be instituted because we misapprehended the teachings and disclosures of Ehses. Req. Reh'g 15. Specifically, Petitioner contends that the board misapprehended Ehses's teachings relevant to the claim terms (a) "omitting a thermal denaturation" step, and (b) "detecting the amplified product within 10 minutes." *Id.* at 1.

Having considered the arguments set forth in Petitioner's Request for Rehearing, we decline to institute *inter partes* review.

II. DISCUSSION

A party requesting rehearing has the burden to show a decision should be modified by specifically identifying all matters the party believes were misapprehended or overlooked, and the place where each matter was addressed previously in a motion, opposition, or a reply. 37 C.F.R. § 42.71(d). When rehearing a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may arise if a decision is

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[1] Ehses et al., *Optimization and design of oligonucleotide setup for strand displacement amplification*, 63 J. BIOCHEM. BIOPHYS. METHODS 170–186 (2005) (Ex. 1002).

based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000).

In its Request for Rehearing, Petitioner challenges our finding that "although Ehses might disclose a methodology that omits the initial thermal denaturation step, Petitioner has not shown that this method results in a detectable product." *See* Decision 11. Petitioner contends that "[t]he only claim requirement that is not expressly disclosed in Ehses is that product is detected by monitoring fluorescence intensity in real-time *during the first ten minutes* of the reaction," but the limitation is inherently disclosed "because Ehses monitors the formation of amplified product in real time, [and] the product is necessarily detected as it accumulates." Req. Reh'g 3, 8. With respect to such monitoring, Petitioner argues that "Ehses discloses the same type of real-time detection using an ICycler and 'an intercalating fluorescence dye TOPRO-1'" as the real-time detection described by the examples of the '263 patent. *Id.* at 8 (citing Ex. 1002, 178; citing Petition at 12 (citing Ex. 1001, 27:1–47)(emphasis removed).

We remain unpersuaded by this argument. As discussed in our Decision, anticipation by inherency requires that any missing material must be recognized by the POSITA as *necessarily* present. Decision 19 (citing *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999)). In the Petition, Petitioner contends that Ehses discloses amplification of a target in real time based on Ehses's teaching that "the increase in fluorescence intensity was monitored" and Dr. Edwards' opinion that "[d]yes that bind DNA, like TO-PRO-1, generate a fluorescent signal upon binding that is detected in" real time. Pet. 21 (citing Ehses 175; Ex. 1008 (Edwards Decl.) ¶ 82).

In order to meet the claim requirements, however, Petitioner must first show that Ehses performed real-time detection in an assay that also omits the initial denaturation step. *See* Decision 11; *see* Prelim. Resp. 11 ("the petition provides no comparison of the reaction conditions disclosed in Ehses to the reaction conditions recited in the claims"). But Ehses does *not* teach omitting the denaturation step as part of its Standard and Nicking protocols. *See* Ehses 175 (2.1.2 Standard SDA and 2.1.3 Nicking SDA). Rather, in a single sentence, Ehses mentions the omission of a denaturation step only in comparison to the experimental protocols in which a denaturation step is expressly included, but even then cautions that such an omission tends to result in undesirable side reactions. Ehses 177. Thus, contrary to Petitioner's arguments, we do not find that Ehses teaches real-time detection of target DNA within 10 minutes was necessarily performed using the TO-PRO-1 dye when "omitting the initial denaturation step." *Id.*

We further note that Ehses's Standard SDA protocol uses "either 1 μM TO-PRO-1 or 1:5 SYBR Gold" as the visualization dye. Ehses 175. But there is no evidence on this record that TO-PRO-1 and SYBR Gold can be used interchangeably in a real-time detection assay. The '263 patent, for example, does not use SYBR Gold or TO-PRO-1 in any of its real-time detection assays, but instead uses a different fluorescence dye—SYBR II—for monitoring product accumulation in real-time. *See* Ex. 1001, 8:64–9:9 *see* 27:8–9 ("The fluorescence increases as SYBR II intercalates into the amplified double-stranded products"). And despite Dr. Edwards' reference to "[d]yes that bind DNA, like TO-PRO-1" (Ex. 1008 ¶ 82), Petitioner has not argued or otherwise presented evidence showing that SYBR Gold would necessarily detect double stranded target product within 10 minutes—particularly in light of Ehses's teaching that omission of the

initial denaturation step tends to result in side reactions. *See* Ehses 177.[2] Accordingly, we are further unpersuaded by Petitioner's argument because Petitioner has not established that Ehses performed real-time detection under the claimed conditions using TO-PRO-1, or that the alternative, SYBR Gold, would necessarily detect double stranded product within 10 minutes when the nicking assay was run in the absence of a denaturation step.

Petitioner further contends that we misapprehended the kinetic profile of Ehses's real-time detection reaction. Req. Reh'g 10–11. We did not. We recognized in our Decision that Ehses teaches a "two step kinetic profile," wherein "using an intercalating fluorescence dye TOPRO-1 in real-time detection, after about 20 min the fluorescence intensity signal shows a steep increase." Decision, 12 (citing Ehses, 178). Based on that teaching, we concluded that "the Ehses reference itself indicates that using real-time detection based on fluorescence intensity will take longer than 10 minutes." *Id.* As noted above, Ehses does not teach that real time detection is necessarily performed when omitting the denaturation step. But even assuming that Ehses could be interpreted in a contrary manner, Petitioner did not present any evidence with its Petition showing either that the real time detection in Ehses would necessarily begin immediately (i.e., at or near "time zero") or that the target product would necessarily be detected within 10 minutes when the denaturation step is omitted.

In its Request for Rehearing, Petitioner relies upon Figure 3.4 of Ehses Dissertation as teaching that real-time detection with TO-PRO-1 begins near time

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[2] Although not established as prior art, the Ehses Dissertation indicates that TO-PRO-1 fluoresces in the presence of double stranded DNA, whereas SYBR Gold detects both double and single-stranded products. *See* Ex. 1004, 37.

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