UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EnviroLogix Inc.,
Petitioner

v.

Ionian Technologies, Inc.,
Patent Owner.

Case IPR2018-00405
Patent 9,562,263

MOTION FOR REQUEST FOR RECONSIDERATION

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I. INTRODUCTION

EnviroLogix Inc. ("Petitioner") requests reconsideration (rehearing) under § 42.71(d) of the institution decision issued July 30, 2018 (the "Decision") in the above-identified matter. The Board's Decision misapprehended Petitioner's argument and the corresponding disclosures in Petitioner's prior art relative to two claim limitations.

Specifically, the Board misapprehended the prior art's disclosures in its analysis of the (a) "omitting a thermal denaturation" step (the "omitting step") and (b) the "detecting the amplified product within 10 minutes after subjecting the reaction mixture to essentially isothermal conditions" step (the "detecting step"). (Decision at 10.)

The prior art expressly discloses omitting thermal denaturation. (Petition at 17 (citing Ex. 1002-Ehses at 177-¶3); Ex. 1008-Edwards at ¶¶71-72.) The Board agrees with Petitioner on this point. (*See* Decision at 11 ("Ehses teaches such a step may be omitted.")) However, the Board "agree[d] with the Patent Owner that there is insufficient evidence . . . to show that a target product would be detectable when the thermal denaturation step is omitted[.]" (*Id.*) As discussed in detail below, this finding appears to be based on a misapprehension of Ehses's disclosures regarding target product detection. (*Id.* at 10-11.) The Board misapprehends the evidence by focusing on disclosures identified in the Preliminary Patent Owner Response

("POPR"), which are not relevant to detecting a target product in real time within 10 minutes under isothermal conditions. Instead, the evidence discussed in the POPR relates to Ehses detecting a target product using "staining." (*See* Decision at 10-11.) This evidence is not relevant to detection in real time because staining does not detect a target product in real time, but is a form of end-point detection. In other words, staining detects product *after* the amplification reaction has concluded. (*See* Ex. 1002-Ehses at 176, lines 1-2 ("The reaction was stopped by addition of stop/loading dye . . .").) Once a reaction has been stopped, the target product is no longer being detected in real time.

Moreover, the Board misapprehended Petitioner's argument regarding the detecting step occurring under **isothermal conditions**. (Decision at 10.) The evidence cited by Patent Owner relating to staining is not relevant to detection that occurs under isothermal conditions because prior to staining the target product undergoes thermal denaturation. (*See* Ex. 1002-Ehses at 176, lines 2-3 ("…and products were denatured at 95ºC for 10 min. Analysis was performed as described above.").)

Likewise, and at Patent Owner's invitation to do so per arguments presented in the POPR, the Board misapprehended Petitioner's arguments regarding whether a target product would be detectable within 10 minutes. Petitioner's argument is based on inherency, and relates to detection of product as it occurs in real time during

isothermal incubation. (Petition at 22.) This type of detection is expressly disclosed in the prior art—all that is missing from the disclosure of Ehses is an express statement that the amplified product is, in fact, detected "within 10 minutes." Importantly, because Ehses monitors the formation of amplified product in real time, the product is necessarily detected as it accumulates.

The issue of whether the prior art inherently discloses the detecting step is at least a disputed issue of material fact. In the POPR, Patent Owner did not present any expert testimony to show that it is not inherently disclosed. The Petition and the supporting declaration of Dr. Edwards show otherwise. At this stage and for purposes of institution, such disputed issues of material fact must be resolved in Petitioner's favor under § 42.108. The Board overlooked this rule and credited Patent Owner's attorney argument about unrelated types of "detection."

Finally, the Board misapprehended the legal standard for analyzing anticipation by relying on the alleged "undesirability" of omitting an initial denaturation step from Ehses's protocol. Specifically, Patent Owner argued that Ehses teaches that omitting a denaturation step undesirably results in side reactions. However, obviousness concepts including "undesirability" and "teaching away" are not relevant to Petitioner's anticipation argument regarding Ehses.

For the reasons identified above and explained in detail below, Petitioner requests reconsideration under § 42.71(d).

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