UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC., Petitioner,

v.

HOLOGIC, INC., Patent Owner.

Case PGR2017-00002 Patent 9,247,989

PATENT OWNER'S BRIEF CONCERNING EX PARTE TRUCKAI

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Pursuant to the Board's December 4, 2017 Order (Paper No. 21), Patent Owner Hologic, Inc. ("Hologic") submits this brief to address the Board's October 18, 2017 decision in *Ex Parte Truckai* (Ex. 3001), which conclusively establishes that Minerva's attacks on the '989 patent are contrary to the disclosures of the specification itself.

I. The Board Found That The Specification At Issue Here Discloses Both Mechanical And Inflation-Based Expansion.

In *Ex Parte Truckai*, the Board heard the appeal of Petitioner Minerva Surgical, Inc. ("Minerva") from an Examiner's finding that a claim for an endometrial ablation method was anticipated. Ex. 3001, at 1-2 (citing US 2002/0022870 A1 (published Feb. 21, 2002) ("Truckai")). There, the sole independent claim comprised insertion of a probe with "an expandable-contractible frame that carries a compliant energy-delivery surface," and two expansion means: "actuating the frame to expand the energy-delivery surface in the uterine cavity," and further, "actuating an inflation source to further expand the energy-delivery surface in the uterine cavity." *Id.* at 2.

Examining the disclosures of Truckai, the Board made five detailed Findings of Fact ("FF") about its First Exemplary Embodiment and illustrative figures. Ex. 3001, at 3-6 (citing Truckai ¶¶11-22, 31, 56-89, 95 & Figs. 1-10 & 20). Relevant here, Truckai and the '989 patent share a common specification; all passages and figures discussed by the Board thus have *identical* counterparts in the '989 patent. *Compare id.* with Ex. 2001, at 2:36-3:20, 3:45-59, 4:58-9:24, 9:53-62 & Figs. 1-10 & 20.¹

As the Board noted, Truckai recites: "the electrode carrying means 12 may be provided to have *additional components inside it that add structural integrity* to the electrode carrying means when it is deployed within the body." Ex. 3001, FF5 (citing Truckai ¶85 (emphasis by Board)). This verbiage follows a description of actuating internal springs to expand the electrode carrying means. Id. (citing Truckai ¶¶81-83). "Thus," the Board found, "Truckai teaches that the balloons 52, shown as expanding the electrode carrying means in Figure 10, can be an additional component relative to the springs 15 and 19 to hold the electrode carrying means 12 in contact with the uterine tissue to be ablated." Id. Because Truckai discloses *both* "actuating the frame to expand the energy-delivery surface in the uterine cavity," and "actuating an inflation source to further expand the energy-delivery surface in the uterine cavity," it anticipates Minerva's sole independent claim. Id. at 7.

¹ The common specification is from provisional application No. 60/084,791, filed on May 8, 1998.

On appeal, Minerva raised the same argument that it advances here: that "the inflatable balloons 52 disclosed by Truckai cannot be used with these spring members 15 and 19, but can only be used as an alternative thereto." Ex. 3001, at 8. Rejecting this based on disclosures in the specification itself, the Board reasoned that "[t]he balloons 52 are disclosed by Truckai as a potential *addition* to the structure" already described, "which *includes* the springs 15 and 19." *Id.* at 9 (emphases added). The balloons are therefore "'additional components inside' the electrode carrying means 12, which serve to 'add structure integrity to the electrode carrying means." *Id.* (citing FF4, FF5).

II. The Board's Reasoning Applies Here.

The foregoing analysis is correct, and dispositive of Minerva's core contention that mechanical and inflation expansion are solely "alternative" or incompatible means based on the '989 specification. Ex. 1001, at 51-66. The Board rejected this as contrary to the plain text, where the specification expressly conveys that balloons are "a potential addition" to mechanical expansion. Ex. 3001, at 9. This exegesis of what the specification objectively teaches applies with equal force here, and the '989 specification's *identical* disclosures thus satisfy the written description requirement for the claimed invention utilizing both mechanical and inflation expansion. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (written description asks whether the specification objectively shows "possession" of the claimed invention). In Ex. 3001, the Board needed only to review the plain language of Truckai to find that such an invention was disclosed. It should do the same here.

The Board's findings in Ex. 3001 likewise impel a finding of enablement. "A prior art reference cannot anticipate a claimed invention if the allegedly anticipatory disclosures cited as prior art are not enabled." *In re Antor Media Corp.*, 689 F.3d 1282, 1287 (Fed. Cir. 2012) (citation omitted). To challenge anticipation, Minerva could have asserted—as it has here—that the operative language in Truckai is non-enabling, and offered evidence to rebut the presumption of enablement. *See id.* at 1288; 37 C.F.R. § 41.33(d). Minerva instead repeated its argument that mechanical and inflation expansion are alternate or incompatible approaches.

Here, too, Minerva cannot plausibly argue that the Board erred, or that a different result should obtain. Minerva may argue that the record in this proceeding contains expert testimony, but such extrinsic matter cannot undermine an unambiguous finding that the disclosures in the specification alone anticipate. And, Minerva declined in *Ex Parte Truckai* to present evidence to challenge the presumption of enablement, instead offering attorney argument that the Board rejected as contrary to the specification.

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