NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

HOLOGIC, INC.,
Appellant

v.

MINERVA SURGICAL, INC.,
Appellee

2018-1550

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-00868.

Decided: April 19, 2019

MATTHEW M. WOLF, Arnold & Porter Kaye Scholer LLP, Washington, DC, argued for appellant. Also represented by MARC A. COHN; JENNIFER SKLENAR, Los Angeles, CA; SEAN MICHAEL CALLAGY, San Francisco, CA.

MICHAEL T. ROSATO, Wilson Sonsini Goodrich & Rosati, PC, Seattle, WA, argued for appellee. Also represented by STEVEN W. PARMELEE; MATTHEW A. ARGENTI, Palo Alto, CA.

Before NEWMAN, REYNA, and HUGHES, *Circuit Judges.*

HUGHES, *Circuit Judge*.

This is a patent case involving a method to detect perforations during uterine ablation. Hologic, Inc., appeals a decision of the Patent Trial and Appeal Board finding claims of U.S. Patent No. 6,872,183 unpatentable as obvious. *See Minerva Surgical, Inc. v. Hologic, Inc.*, No. IPR2016-00868 (P.T.A.B. Oct. 5, 2017). Because we agree with the Board's construction of the term "monitoring for the presence of a perforation in the uterus using a pressure sensor," and because substantial evidence supports the factual determinations underpinning the Board's obviousness conclusion, we affirm.

I

A.

Hologic, Inc., owns the '183 patent, which is directed to a "method[] for detecting the presence of perforations in body cavities" during ablation. '183 patent col. 1 ll. 13–14. Ablation is a medical procedure which involves distending or inflating a body cavity with fluid and heating that fluid to a sufficiently high temperature to destroy the cells lining the cavity. It is often used to treat abnormal bleeding within the endometrial layer of the uterus. Introducing fluid into the uterus, however, creates several risks. For example, if the uterus is perforated, "steam or hot fluids generated during ablation, as well as portions of the medical device itself" can "escape the uterus and cause serious injury to nearby organs." J.A. 1583 ¶ 29. Electrical energy can also cross through perforations and "caus[e] electrical shock and thermal damage" to the body. J.A. 1583 ¶ 29.

The '183 patent addresses and minimizes these risks by proactively "detecting the presence of perforations in body cavities." '183 patent col. 1 ll. 13–14. It describes "a

system and method that pressurizes a body cavity and detects whether the body cavity can maintain a pressurized condition." *Id.* col. 1 ll. 14–17; *see also id.* col. 2 ll. 38–43. If the cavity cannot maintain a pressurized condition, "the user is alerted that there may be a perforation in the organ." *Id.* col. 2 ll. 43–44.

Independent claim 1 of the '183 patent is representative for purposes of this appeal and is reproduced below.

> **1.** A method of ablating a uterus, comprising the steps of:
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> inserting an ablation device into a uterus;
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> flowing an inflation medium into the uterus;
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> monitoring for the presence of a perforation in the uterus using a pressure sensor; and
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> treating the interior of the uterus using the ablation device.

Id. col. 8 ll. 10–15.

B.

Minerva Surgical, Inc., filed a petition for *inter partes* review of the '183 patent asserting that claims 1–15 are obvious over various combinations of prior art references. Minerva relied on a total of seven references, four of which are relevant to this appeal.

First, U.S. Patent No. 5,891,094 (Masterson) describes a method for thermally ablating the uterus. Masterson discloses using a pressure sensor to monitor intrauterine pressure and suggests optionally including a flow control sensor to alert a physician "to a possible leak somewhere within [the] system . . . or within the patient." J.A. 1073.

Second, U.S. Patent No. 3,871,374 (Bolduc) "is directed to an instrument and method for monitoring the integrity of the uterus and for dispensing a fluid . . . into both canals

of the Fallopian tubes of a female." J.A. 1128. The device in Bolduc only operates if it can apply a predetermined fluid pressure within the uterus because "[w]eak, diseased or ruptured uterus walls," e.g., walls with a perforation, will be unable to contain the device or maintain that fluid pressure. J.A. 1130.

Third, International PCT Application Publication No. 97/24074 (Isaacson) discloses an ablation device which uses pressure transducers to "monitor the pressure of the fluid" at different locations. J.A. 1090. If pressure readings vary, Isaacson teaches that a "uterine perforation" may exist. J.A. 1091.

Finally, U.S. Patent No. 5,503,626 (Goldrath) is directed to a system for monitoring the amount of fluid in the uterus during ablation. The system in Goldrath measures the differential between pressure readings at two locations. If the differential exceeds a preset value, the patient may be "absorbing too much fluid." J.A. 1190. Goldrath describes "terminat[ing]" the procedure under such circumstances. J.A. 1190.

C.

The Board instituted review on all asserted grounds. Each of the grounds relied on a combination of prior art references including either: (1) Masterson and Bolduc; or (2) Isaacson and Goldrath.

The Board determined that a person of ordinary skill in the art was someone "who had, through education or practical experience, the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering or a related field and at least an additional two to three years of work experience developing or implementing electrosurgical devices." J.A. 17. The Board rejected Hologic's argument that a skilled artisan would need experience specifically with uterine devices because the '183 patent "explicitly discloses that the invention is

applicable to body cavities generally and indicates that the problem with perforations is not unique to the ablation of the uterus." J.A. 16.

Turning to the merits, the Board found that a skilled artisan "would have been motivated to combine Masterson and Bolduc to improve the safety of the ablation device." J.A. 25. The Board rejected Hologic's contention that Masterson did not describe claim 1's step of "monitoring for the presence of a perforation in the uterus using a pressure sensor" and determined that Masterson and Bolduc, when combined with other information in the prior art, disclosed all the relevant limitations of the '183 patent. The Board therefore concluded that claims 1, 4, 6, 7, 9, 11–13, and 15 are obvious over Masterson and Bolduc; claim 5 is obvious over Masterson, Bolduc, and Himmelstein;[1] claims 8 and 10 are obvious over Masterson, Bolduc, and Benaron;[2] and claim 14 is obvious over Masterson, Bolduc, and Isaacson.

The Board similarly found that a skilled artisan would have been motivated to combine Isaacson and Goldrath to improve the safety and efficacy of the claimed ablation devices. The Board again denied Hologic's assertion that the prior art did not describe "monitoring for the presence of a perforation in the uterus using a pressure sensor." Because Isaacson and Goldrath, when combined with other information in the prior art, disclosed all the relevant limitations of the '183 patent, the Board concluded that claims

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[1] U.S. Patent No. 4,542,643 (Himmelstein) discloses that testing pressure over a preselected time period is conventional within the field.

[2] U.S. Patent No. 5,785,658 (Benaron) describes monitoring the state of a device during minimally invasive surgery and "produc[ing] an interlock control signal." J.A. 1160. It further notes that "the feedback/interlock feature of the analyzer can be overridden and/or disabled by the surgeon as a matter of choice." *Id.*

1–4, 6, 7, 9, and 11–15 are obvious over Isaacson and Goldrath; claim 5 is obvious over Isaacson, Goldrath, and Himmelstein; and claims 8 and 10 are obvious over Isaacson, Goldrath, and Benaron.

Hologic appeals the Board's construction of "monitoring for the presence of a perforation in the uterus using a pressure sensor" and its determinations as to level of skill in the art and motivation to combine. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II

Obviousness is a question of law based on underlying factual findings. *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1369 (Fed. Cir. 2017). Those factual findings include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) whether a skilled artisan would be motivated to combine the prior art. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012); *see also Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 449 (Fed. Cir. 2015). We review the Board's legal conclusions *de novo* and its factual findings for substantial evidence. *Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1324 (Fed. Cir. 2017). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)).

A.

We first address the Board's construction of the claimed step of "monitoring for the presence of a perforation in the uterus using a pressure sensor." *See* '183 patent col. 8 ll. 13–14, 42–43. Minerva asserts that the Board did not construe this step. It maintains that the relevant portion of Board's decision focused solely on the scope and content of the prior art. We disagree. Although the parties did not expressly dispute the meaning of "monitoring for

the presence of a perforation in the uterus using a pressure sensor" before the Board, Hologic impliedly argued "that the monitoring must be *only* for a decrease in intrauterine pressure that is caused by a perforation." J.A. 27 (emphasis in original). The Board considered and rejected this contention, noting instead that it "read the monitoring step as encompassing monitoring for decrease in intrauterine pressure that may be caused by a perforation but may alternatively be caused by malfunctions in the equipment." J.A. 27. We find that, by espousing this reading of the term, the Board construed the monitoring step to mean "monitoring for any change in pressure regardless of cause."[3]

We review the Board's claim construction, which here relied solely on intrinsic evidence, *de novo*. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The Board issued its decision on December 15, 2017. At that time, during *inter partes* review of an unexpired patent, the Board gave claims their "broadest

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[3] Minerva implicitly acknowledges that the Board performed some measure of claim construction. It contends that "[r]ather than reading out any particular aspect of the claims, the Board correctly observed that the monitoring step of the claims do[es] not require monitoring for a pressure anom[a]ly caused *only* by a perforation." Resp. Br. 43 (emphasis in original). Minerva includes this assertion in a section of its brief concluding that "[t]he Board's findings regarding the prior art disclosure demonstrate that it did not interpret the claims in a way that eliminated the requirement of monitoring for a perforation using a pressure sensor." Resp. Br. 46. While this conclusion purports to focus on the Board's factual findings, it also relates to the way the Board interpreted the monitoring step, i.e., how it construed the claim.

reasonable interpretation in light of the specification."[4] 37 C.F.R. § 42.100(b) (2017).

On appeal, Hologic again argues that the monitoring step requires monitoring only for changes in uterine pressure caused by a perforation. We reject this contention. The specification explains the pressure sensor "monitors pressure" and delivers signals to a microprocessor, which "determines if pressure in the body cavity . . . has failed to achieve a predetermined threshold (indicating a perforation in the body cavity) or if it has and maintained the threshold for a predetermined time period (indicating that the body cavity has no perforation)." *See* '183 patent col. 5 ll. 22–30. While the specification suggests that certain conditions may reveal the possibility of perforation, the patent does not limit the sensor's monitoring to these situations. Indeed, the specification explicitly notes that other issues, such as kinked tubing, may lead to a "false test result." *See id*. col. 7 ll. 44–46. We thus decline to limit the "monitoring" step as Hologic proposes. We instead construe the monitoring step to mean "monitoring for any change in pressure regardless of cause" because any change in pressure might signify the existence of a perforation.

Given our construction of "monitoring for the presence of a perforation in the uterus using a pressure sensor,"

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[4] The United States Patent and Trademark Office has since revised its claim construction standard. *See* 83 Fed. Reg. 51,340, 51,358 (Oct. 11, 2018) (codified at 37 C.F.R. § 42.100(b)). As of November 13, 2018, the Board construes a claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). Our review, however, is governed by the prior version of 37 C.F.R. § 42.100(b) because Minerva filed its petition prior to November 13, 2018.

substantial evidence supports the Board's determination that Masterson discloses this step. Hologic argues that Masterson is directed to maintaining a stable pressure in the uterus rather than tracking changes in pressure. Hologic is correct that Masterson emphasizes the importance of maintaining a constant pressure, but it ignores that Masterson also contemplates scenarios in which a constant pressure cannot be maintained. For example, Masterson describes attaching a "flow control sensor" to monitor the flow of liquid into the uterus. *See* J.A. 1073. It notes that "[b]y detecting a flow of liquid from fluid reservoir 176, the care giver may be alerted to a possible leak somewhere within system 160 or within the patient." *See* J.A. 1073. Pressure would not remain constant in the presence of a leak because, as Hologic admits, leaks cause pressure to decrease. Additionally, the system disclosed in Masterson can be configured to alert users about abnormal operating conditions "such as . . . over or under pressure." *See* J.A. 1073. If Masterson can alert users to these conditions, then it must be able to monitor for changes in pressure. And if it can monitor for changes in pressure, then it discloses the limitations of the monitoring step.

Substantial evidence also supports the Board's finding that Isaacson discloses the type of monitoring claimed by the '183 patent. Isaacson describes monitoring pressure in the uterus by calculating "the differential between the two transducers." J.A. 1090. It explains that these pressure readings impact fluid flow rate and that, "by monitoring the volume and flow rate of the fluid discharged from the uterus and comparing [it] with the monitored volume and flow rate of the . . . fluid charged to the uterus, the possibility of the uterine perforation can be detected." J.A. 1091. In other words, it discloses monitoring for changes in pressure and suggests that a perforation may cause any observed change. It thus teaches the monitoring claimed by the '183 patent.

B.

We next consider the finding that a skilled artisan need not have experience with uterine ablation devices. Hologic contends that a skilled artisan must have experience working with uterine ablation devices, not just any electrosurgical device, because the claims are directed to solving issues specifically associated with uterine ablation.

"Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (quoting *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983)).

Substantial evidence supports the Board's determination that a skilled artisan was someone who had "experience developing or implementing electrosurgical devices" generally rather than uterine devices specifically. *See* J.A. 17. While the claims are directed to uterine ablation, the patent specification speaks in terms of "body cavities," with the uterus comprising just one example of a body cavity. *See* '183 patent col. 1 ll. 12–17, 20–21, 22–25, 28–33, 49–57; *id.* col. 2 ll. 13–17, 31–34, 35–44, 45–58; *id.* col. 7 l. 63–col. 8 l. 8. The specification also notes that, although the description of the preferred embodiment "is with reference to a perforation detection system having a device usable to ablate tissue within a uterus, the present invention is applicable to perforation detection within other body cavities." *Id.* col. 7 ll. 63–66. The patent further states that "[t]hose having ordinary skill in the art will certainly understand from the embodiment disclosed herein that many modifications are possible without departing from the teachings hereof" and that "[a]ll such modifications are intended to be encompassed within the following claims." *Id.*

col. 8 ll. 4–8. The prior art, furthermore, treats inventions directed to uterine ablation as representative of inventions directed to other body cavities. For example, Masterson describes "methods and devices for thermally ablating *hollow body organs, such as the uterus*." J.A. 1065 (emphasis added). Given these disclosures, we cannot say that the record lacks sufficient "relevant evidence as a reasonable mind might accept as adequate to support" the Board's findings. *See Novartis*, 853 F.3d at 1324.

Hologic argues that we should reverse because the Board failed to expressly consider all the factors discussed in *Daiichi*. We have cautioned, however, that the *Daiichi* factors "are not exhaustive but are merely a guide." *See Daiichi*, 501 F.3d at 1256. The Board was not required to analyze level of skill in the art on a factor-by-factor basis. It is enough that it applied the principle of *Daiichi* and assessed level of skill in the art on a holistic basis.

C.

Finally, we address the finding that a skilled artisan would have been motivated to combine Masterson with Bolduc and Isaacson with Goldrath.[5] Hologic contends that there is no evidence that combining either set of references would improve safety.

The Board found that a skilled artisan would have been motivated to combine Masterson and Bolduc because incorporating Bolduc's pressure-based perforation monitoring into Masterson's ablation device would have improved the device's safety. Substantial evidence supports this determination. Masterson discloses monitoring for abnormal operating conditions and, if such conditions arise, automatically ceasing the operation "to provide increased safety to

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[5] In reaching this issue, we reject Hologic's contention that the Board did not adequately explain the bases for its determinations.

the patient." J.A. 1073. Bolduc describes monitoring for abnormal conditions in the uterus before performing medical procedures. As Minerva's expert, Dr. Pearce,[6] testified, a "skilled artisan would reasonably have incorporated pressure-based perforation monitoring" of Bolduc to the ablation device of Masterson "in order to maximize the usefulness of the pressure sensor in Masterson's system and method, and also improve the safety of the ablation device and treatment procedure." J.A. 773 ¶ 59. Hologic contends that a skilled artisan would not have thought to combine Masterson and Bolduc because their systems are incompatible. We agree with the Board, however, that any alleged incompatibility would not preclude a motivation to combine because "[t]he test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference." J.A. 29 (citing *In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012)).

Substantial evidence also supports the determination that a skilled artisan would have been motivated to combine Isaacson and Goldrath to improve safety. Both references discuss detecting perforations by measuring

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[6] Hologic argues that the Board erred in considering Dr. Pearce's testimony because he lacked enough experience with uterine ablation devices. Because we find no error in the Board's finding regarding level of skill in the art, we hold that it did not abuse its discretion in crediting the testimony of Dr. Pearce, who "has extensive knowledge related to the design of electrosurgical ablation devices and some knowledge of endometrial ablation devices." J.A. 51; *see Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (noting that "[w]e defer to the Board's findings concerning the credibility of expert witnesses").

pressure. Isaacson describes using multiple pressure sensors to monitor intrauterine pressure and explains that different pressure readings between locations may indicate the presence of a perforation. Goldrath discloses that a user can measure pressure to determine whether "the amount of fluid leaving the uterus is less than the amount entering," i.e., whether there is a leak. J.A. 1190, 1192. Both references also discuss preventing ablation if the system detects an issue with pressure. Isaacson, for instance, discloses using a safety circuit to prevent ablation if electrodes in the uterus are not submerged in fluid. Goldrath describes "terminat[ing]" treatment if there are any abnormal operating conditions, such as inadequate pressure. J.A. 1190. Given these similarities, we agree that a skilled artisan would have been motivated to apply the teachings of Goldrath to Isaacson's pressure sensor. As Dr. Pearce explained, "a skilled artisan would have recognized that Isaacson's endometrial ablation method would benefit from a safety mechanism that prevents treatment if the pressure test fails, such as disclosed by the combination of Isaacson and Goldrath." J.A. 812 ¶ 169.

Hologic asserts that a skilled artisan would not have combined these references because they do not disclose any issues with safety which might incentivize improvement. We disagree. The lack of any specific safety concerns does not preclude a motivation to make a device safer. As Hologic's expert, Dr. Martin, admitted, there are times when it may be beneficial to add redundant safety features to a medical device.

With respect to claim 7,[7] Hologic argues that a skilled artisan would not have added any pre-treatment steps to the inventions of Masterson or Isaacson because lengthening the procedure runs counter to conventional wisdom.

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[7] Claim 7 prevents treatment until after the monitoring step is complete.

Minerva's expert, Dr. Mirabile,[8] however, testified that "a physician performing endometrial ablation procedures in November 1999 would gladly have extended the duration of the procedure if the ultimate result was a safer treatment for the patient." J.A. 31. Indeed, Dr. Mirabile noted that a system already existed that lengthened the procedure to check for perforations prior to ablation. Thus, evidence shows that adding a pre-treatment step that would require lengthening the time of the procedure would not have dissuaded a skilled artisan from combining the relevant references.

III

We have considered the parties' remaining arguments and find them unpersuasive. We conclude that the Board correctly construed the step of "monitoring for the presence of a perforation in the uterus using a pressure sensor" and that substantial evidence supports the Board's determinations regarding level of skill in the art and motivation to combine. Therefore, we affirm the decision of the Patent Trial and Appeal Board that the challenged claims of the '183 patent are invalid as obvious.

AFFIRMED

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[8] Hologic argues that the Board erred in considering Dr. Mirabile's testimony because he had not reviewed the prior art references at issue in this case. The Board noted, however, that "Dr. Mirabile's testimony is not directed to the combination of the asserted prior art references, but to the conventional wisdom with regards to endometrial ablation at the relevant time period." J.A. 52. We find no abuse of discretion in the Board's determination that Dr. Mirabile had enough knowledge and skill to testify about this topic.