United States Court of Appeals for the Federal Circuit

ELEKTA LIMITED,
Appellant

v.

ZAP SURGICAL SYSTEMS, INC.,
Appellee

2021-1985

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2019-01659.

Decided: September 21, 2023

JENNIFER LIBRACH NALL, DLA Piper US LLP, Austin, TX, argued for appellant. Also represented by STANLEY JOSEPH PANIKOWSKI, III, San Diego, CA; AARON PATRICK BOWLING, Arnold & Porter Kaye Scholer LLP, Chicago, IL.

APRIL ELIZABETH ISAACSON, Kilpatrick Townsend & Stockton LLP, San Francisco, CA, argued for appellee. Also represented by ANDREW JAMES ISBESTER; MATTHEW MEYER, Menlo Park, CA.

Before REYNA, STOLL, and STARK, *Circuit Judges*.

REYNA, *Circuit Judge*.

Appellant Elekta Limited appeals from a Final Written Decision of the United States Patent Trial and Appeal Board that found certain claims of U.S. Patent No. 7,295,648 unpatentable as obvious. Elekta challenges the Board's findings related to motivation to combine and reasonable expectation of success. We affirm.

BACKGROUND

U.S. Patent No. 7,295,648

Elekta Limited ("Elekta") is the owner of U.S. Patent No. 7,295,648 (the "'648 patent"), titled "Method and apparatus for treatment by ionizing radiation." J.A. 2–3. The '648 patent discloses a device for treating a patient with ionizing radiation for certain types of radiosurgery and radiation therapy. '648 patent, 1:6–8. The invention uses a radiation source, e.g., a linear accelerator (referred to as a "linac"), mounted on a pair of concentric rings to deliver a beam of ionizing radiation to the targeted area on the patient. *See id*. at 4:4–13; *see also id*. at 4:33–34; *see also id* at 7:24–25. Figures 5 and 7 illustrate the claimed device features.

Id. at Figs. 5 & 7.

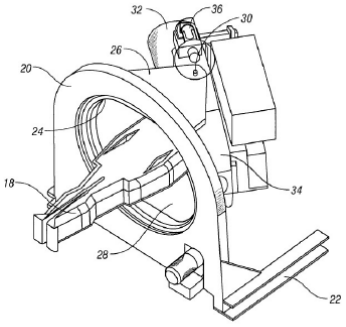

FIG. 5

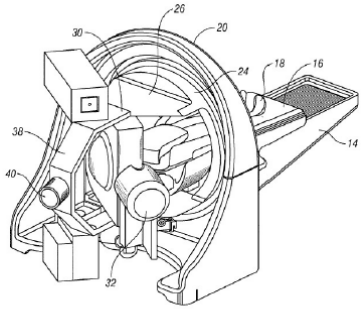

FIG. 7

Figure 5 shows the claimed apparatus' interior structure from the foot end with the patient table [18] and all exterior covers removed. *Id*. at 5:8–9; *id*. at 7:5–6. Figure

7 shows the claimed apparatus' interior structure from the head end. *See id*. at 5:10–12. A rotatable ring [24] is supported by a mounting ring [20]. *Id*. at 7:12–13. The rotatable ring [24] rotates around the patient [18]. *Id*. at 7:13–14. Extending out of the rotatable ring [24] are two mounting brackets [26, 28], which provide a pivotal mounting point [30]. *Id*. at 7:14–23. A linac [32] is mounted to the pivotal mounting point [30], and a motor [36] is used around the linac housing [34] to assist in rotating the linac [32] around the pivotal mounting point [30]. *Id*. at 7:24–27. The apparatus allows the linac to be manipulated such that it can move closer to and further from the patient and approach the patient at various angles. *Id*. at 7:31–34. This movement allows for the delivery of ionizing radiation to different target areas from different angles on the patient, as well as in differing intensities. *See id*. at 7:41–49.

The '648 patent contains apparatus and method claims. There is one independent, apparatus claim (Claim 1) and one independent, method claim (Claim 18). We do not find it necessary to reach Claim 18. The parties agree that Claim 1 is illustrative. Claim 1 recites:

> 1. A device for treating a patient with ionising radiation comprising:
>
> a ring-shaped support, on which is provided a mount,
>
> a radiation source attached to the mount;
>
> the support being rotateable about an axis coincident with the centre of the ring;
>
> the source being attached to the mount via a rotateable union having a [sic] an axis of rotation axis which is non-parallel to the support axis;
>
> wherein the rotation axis of the mount passes through the support axis of the support and the

> radiation source is collimated so as to produce a beam which passes through the co-incidence of the rotation and support axes.

Id. at 9:54–67.

On September 27, 2019, ZAP Surgical Systems, Inc. ("ZAP") filed before the United States Patent Trial and Appeal Board ("Board") a petition for *inter partes* review ("IPR") challenging claims 1–4, 7–13, 16–18, 20, and 22–23 of the '648 patent. On April 1, 2020, the Board instituted an IPR on all grounds asserted in the petition. The petition relied on several prior art references, but pertinent to this appeal are three references: U.S. Patent No. 4,649,560 ("Grady"); a publication, K.J. Ruchala et al., *Megavoltage CT image reconstruction during tomotherapy treatments*, PHYS. MED. BIOL. 45, 3545–3362 (2000) ("Ruchala"); and U.S. Patent No. 4,998,268 ("Winter").

Grady discloses an X-ray tube mounted on a sliding arm connected to a rotating support. Grady, Abstract. Figure 1 illustrates the X-ray stand, where inner rings [3, 4] rotate around the patient lying on the table [T]. *Id*. at 1:46–52. Figures 1 and 2 illustrate a rectangular sleeve [8] that extends from the rings, in which an arm [9] slides via motor drive. *Id*. at 1:53–56. The outer end of the arm [9] is connected to a carriage [10], which carries an X-ray tube that is rotated around a patient to take X-ray images. *See id*. at 1:56–66.

Grady Figures 1 and 2 are illustrated as follows:

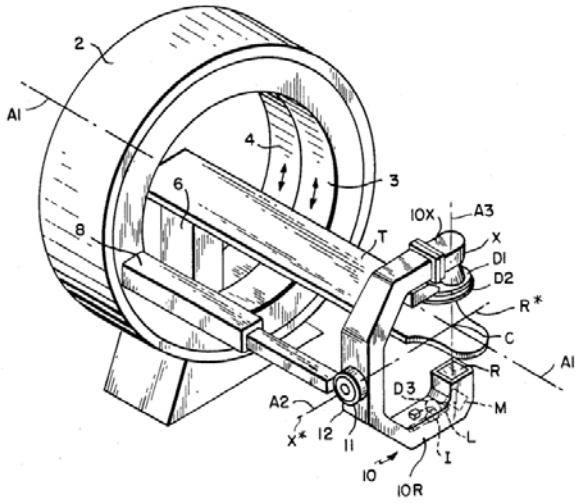

FIG. 1

Id. at Fig. 1.

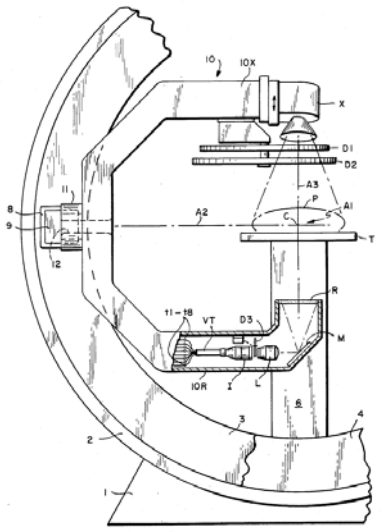

FIG.2

Id. at Fig. 2.

Ruchala discloses a linac-based tomotherapy treatment system, whereby, like a computerized tomography

("CT") scanner, "the patient remains still, but the linac and detector rotate about the patient" to deliver a treatment dose to the target tumor. J.A. 2147; *see also* J.A. 2144–61. Ruchala notes that the linac is fitted with a "multileaf collimator" to "allow for a highly conformal treatment that will deliver [a] dose to the tumour while sparing sensitive structures." J.A. 2144. The CT imaging capability, according to Ruchala, ensures "properly positioning the patient's body and interior organs" and "know[ledge] that the treatment was delivered as intended." *Id.*

Winter—relied on as background art in the petition—discloses the "combination [of] a diagnostic CT scanner using radiant energy for imaging," which is used "for therapeutically irradiating a target." Winter, Abstract; *see* J.A. 7. It touted the combination as "provid[ing] more accurate localization of the area to be irradiated than prior art use of the gamma knife as a standalone radiation therapy unit." Winter, 2:23–26. According to Winter, this is because the combination allows for "more accurate positioning of the patient due to the fact that a single device having diagnostic imaging capability is used for both imaging and therapy purposes." *Id.* at 2:41–45.

BOARD'S FINAL WRITTEN DECISION

On March 30, 2021, the Board issued its Final Written Decision, concluding that all the challenged claims were unpatentable as obvious. Specifically, the Board found that claims 1–4, 7–8, 11, 12, 17, 18, 20, and 23 were obvious over the combination of Grady and Ruchala (and independently obvious over the combination of U.S. Patent No. 5,207,223 ("Adler"), and Grady); and that claims 9, 10, 13, 16, and 22 were obvious over of the combination of Grady, Ruchala, and U.S. Patent No. 5,945,684 ("Lam") (and

independently obvious over the combination of Adler, Grady, and Lam). J.A. 70.[1]

The Board addressed Elekta's arguments that a skilled artisan would not have been motivated to combine, and would not have had a reasonable expectation of success in combining, the Grady device with the linac described in Ruchala. *See* J.A. 27–36. The Board also considered whether a skilled artisan would have been dissuaded from combining the devices because one device was an imaging device, rather than a radiation device, and because the linac's weight would render the Grady device inoperable, imprecise, and unsuitable for treatment. J.A. 34–35. The Board concluded that a skilled artisan would have been motivated to combine Grady and Ruchala. J.A. 36.

Elekta appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

STANDARD OF REVIEW

We review the Board's legal conclusions *de novo* and its factual findings for substantial evidence. *ACCO Brands Corp. v. Fellowes, Inc.*, 813 F.3d 1361, 1365 (Fed. Cir. 2016). Substantial evidence means "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000) (citation omitted).

Obviousness is a question of law with underlying factual issues relating to the "scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and any objective indicia of non-obviousness." *Randall Mfg. v. Rea*,

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[1] Elekta also moved during the proceeding to amend its claims. J.A. 2; J.A. 67–68; J.A. 71. The Board denied that motion. J.A. 71. Elekta does not challenge that denial on appeal.

733 F.3d 1355, 1362 (Fed. Cir. 2013) (first citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007); then citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966)). Whether a skilled artisan would have been motivated to combine references or would have had a reasonable expectation of success in combining references are questions of fact reviewed for substantial evidence. *Regents of Univ. of California v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018).

DISCUSSION

On appeal, Elekta makes three principal arguments: that the Board's findings on a motivation to combine are unsupported by substantial evidence, Appellant's Br. 26; that the Board failed to make any findings, explicit or implicit, on a reasonable expectation of success, *id.* at 4, 18; and that even had the Board made such findings, those findings are not supported by substantial evidence, *id.* at 2.

I

We first address Elekta's argument that a skilled artisan would not have been motivated to combine prior art references disclosing radiation imagery with the references disclosing radiation therapy. Appellant's Br. 26.

Obviousness requires, *inter alia*, a finding that a skilled artisan would have been motivated to combine the teachings of prior art in such a way that the combination discloses the claimed limitations. *See OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382 (Fed. Cir. 2019). The inquiry into the existence of a motivation to combine assumes that a skilled artisan is a person of ordinary creativity with common sense, common wisdom, and common knowledge. *See Fleming v. Cirrus Design Corp.*, 28 F.4th 1214, 1223 (Fed. Cir. 2022). Thus, an obviousness determination does not always require prior art to expressly state a motivation for every obvious combination. *See, e.g.,*

id. Nor does an obviousness showing "require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention." *Novartis Pharms. Corp. v. West-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051, 1059 (Fed. Cir. 2019) (citation omitted).

Elekta contends that "[n]o substantial evidence supports the Board's finding that there was a motivation to combine these references by replacing the X-ray imaging source in Grady with a linac therapeutic source as proposed in the Petition," because the linac "ionising radiation source [would] not offer any imaging improvement and also requires extreme precision due to its potentially lethal side effects." Appellant's Br. 29, 31. According to Elekta, the Grady device is for imaging and does not contemplate a heavy linac or account for the lack of precision that would result from the linac's additional weight. *Id*. at 30–31.

The Board acknowledged Elekta's argument that a skilled artisan would not have been motivated to combine Grady and Ruchala because the weight of the linac would render the device essentially inoperable and thereby fail to provide a viable solution for focusing therapeutic radiation on the target. *See* J.A. 31–33. But the Board found that heavy linacs were known in the art during the pertinent period and that their weight could be adequately handled by robotic arms. J.A. 35. The Board supported this conclusion by reviewing "the prosecution of the '648 patent, [which demonstrated that] patents directed to imaging devices were cited, and were not distinguished based on an argument that imaging devices were not relevant art." J.A. 32. In addition, the Board framed the pertinent field as one that "includes the engineering design of sturdy mechanical apparatus[es] capable of rotationally manipulating *heavy* devices in three dimensions oriented in a variety of approach angles with high geometrical accuracy, in the context of the radiation imaging and radiation therapy environment." J.A. 34 (emphasis added). The Board

credited ZAP's expert as having experience with such devices. *Id*. It also recognized the differences between radiation imaging devices and radiation therapy devices, and it found that a skilled artisan would not have been dissuaded from combining the references based on these differences. *See* J.A. 35.

The Board determined that "persons of ordinary skill in the applicable art would have readily understood the advantages of the three-dimensional manipulation capabilities of the Grady approach" and not been dissuaded by the "difficulty in accommodating heavy linacs" or the need for "precision" in making that combination. *Id*. On that basis, the Board determined that a skilled artisan would have been motivated to combine the references disclosing radiation imaging with references disclosing radiation therapy. J.A. 36.

We hold that the Board's finding that a skilled artisan would have been motivated to combine the Grady device with Ruchala's linac is supported by substantial evidence, including the prosecution history of the '648 patent, the teachings of the asserted prior art references, and the expert testimony of record. Specifically, as explained above, during prosecution, the patentee notably did not argue that prior art references directed to imaging devices were not relevant art. *See* J.A. 32 (citing J.A. 949–81). In addition, Ruchala teaches that combining imaging with the delivery of radiation is advantageous because it can improve the accuracy of radiation delivery and verify that the dose of radiation was received. *See, e.g.*, J.A. 2144, Abstract. Another prior art reference in the record before the Board, Winter, discloses that combining an imaging system with a radiation source is preferable because it allows for "more accurate positioning of the patient due to the fact that a single device having diagnostic imaging capability is used for both imaging and therapy purposes." Winter, 2:41–45. And ZAP's expert, Dr. McCarthy, opined that a person of ordinary skill in the art would have been motivated to

make the proposed combination because it would "eliminat[e] the need to move a patient from an imaging apparatus to a separate treatment apparatus" and would "reduce the patient's exposure to radiation." J.A. 1378–84 ¶ 74. Taken together, this evidence provides substantial support for the Board's finding that a person of ordinary skill in the art would have been motivated to make the proposed combination.

II

Elekta argues that the Board erred as a matter of law because it failed to articulate *any* findings on reasonable expectation of success. Appellant's Br. 18. We disagree.

To be clear, an obviousness determination requires finding that a person of ordinary skill in the art would have had a reasonable expectation of success. *Regents of Univ. of Cal.*, 903 F.3d at 1291. Reasonable expectation of success refers to the likelihood of success in combining references to meet the limitations of the claimed invention. *Intelligent Bio–Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016).

Unlike a motivation to combine determination, which requires an explicit analysis, *KSR*, 550 U.S. at 418, a finding of reasonable expectation of success can be implicit, *see Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 836 (Fed. Cir. 2015). We understand that requiring less than an explicit statement may appear to be in tension with our review of Board determinations under the Administrative Procedure Act ("APA"), which requires the Board to "explain[] its decisions with sufficient precision, including the underlying factfindings and [its] rationale." *Packard Press, Inc. v. Hewlett-Packard Co.*, 227 F.3d 1352, 1357 (Fed. Cir. 2000). But there is no such tension where the Board makes an implicit finding on reasonable expectation of success by considering and addressing other, intertwined arguments, including, as we hold today, a motivation to combine. *See Merck*, 808 F.3d at 836. In those circumstances, we can

"reasonably discern" an implicit finding by the Board on reasonable expectation of success. *In re NuVasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

We have previously held that an implicit finding on reasonable expectation of success under such circumstances is acceptable. *Merck*, 808 F.3d at 836–37. In *Merck*, the patent owner argued that the prior art teaches away from the proposed combinations. *Id.* at 834. The Board disagreed. *Id*. On appeal, the patent owner faulted the Board's final written decision for failing to make an express finding that a skilled artisan would have had a reasonable expectation of success in combining the references. *Id*. at 836. We held that "[b]y rejecting [the patent owner's] argument that the prior art taught away from combining [the references], the Board impliedly found a reasonable expectation of success." *Id.* Under these circumstances, we declined to overturn the Board's decision simply because it did not "state expressly" that a skilled artisan would have had a reasonable expectation of success. *Id*. at 836–37.

Here, as in *Merck*, we can reasonably discern that the Board considered and implicitly addressed reasonable expectation of success based on the arguments and evidence presented to the Board on motivation to combine. *See id*. For example, Elekta raised reasonable expectation of success arguments before the Board in asserting that ZAP's proposed combination would result in an inoperable device, result in an inferior quality product, and would teach away because the combination would not produce the result sought by the '648 patent owner due to the heavy weight of the linac. *See* J.A. 3385–87; *see also* J.A. 3170.

Elekta also argued that because the prior art combination would not "provide a viable solution for focusing a therapeutic radiation source on the target," it would not work for its intended purposes, and thus would "negat[e] any reasonable expectation of success." J.A. 914–15; J.A. 3885–87. And when asked during oral argument what

reasonable expectation of success arguments it made before the Board, Elekta reiterated its argument that "a POSITA would not have expected the structure to be a viable solution for focusing the therapeutic radiation source on the target, which was the stated goal of the invention." Oral Arg. 4:22–5:25. Elekta's briefing and expert declarations also focused on how the weight of the device, and the resulting lack of precision and control, evidenced a lack of expectation of success and motivation to combine. J.A. 3887; J.A. 3375.

These and other of Elekta's similar arguments also were made in connection with whether a skilled artisan would have been motivated to combine the prior art. In these circumstances, the Board made no error in addressing the issues of motivation to combine and reasonable expectation of success in the same blended manner that Elekta chose to present those very issues.

In finding that "persons of ordinary skill in the applicable art would have readily understood the advantages" of Grady and would not have been dissuaded by the "difficulty in accommodating heavy linacs" or concerns related to "precision" in targeting for radiation therapy in making that combination, the Board implicitly addressed Elekta's argument on reasonable expectation of success. *See* J.A. 35. On this basis, we hold that the Board made a sufficient, implicit finding that a skilled artisan would have had a reasonable expectation of success in combining the prior art references. *See Merck*, 808 F.3d at 836–37.

III

We next address Elekta's argument that, even if the Board made an implicit finding, "there is [no] substantial evidence that could support a finding that a skilled artisan would have reasonably expected to succeed" in combining the asserted references. Appellant's Br. 2, 4.

Evidence of a reasonable expectation of success, just like evidence of a motivation to combine, "may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved." *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 2000). The evidence need not lead to a single conclusion to support a finding of substantial evidence. *Velander v. Garner*, 348 F.3d 1359, 1378–79 (Fed. Cir. 2003).

In this case, and as explained above, the arguments and evidence of reasonable expectation of success are the same for motivation to combine. To be clear, a finding of a motivation to combine does not necessarily establish a finding of reasonable expectation of success. *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1344 (Fed. Cir. 2021). But in some cases, such as here, the evidence establishing a motivation to combine may establish a finding of reasonable expectation of success.

In view of the foregoing, we conclude that the Board's finding that a skilled artisan would have had a reasonable expectation of success in combining Grady and Ruchala is supported by substantial evidence.

IV

Elekta argues that "no substantial evidence in the record would support a finding that ZAP met its burden to show reasonable expectation of success by clear and convincing evidence." Appellant's Br. 21–22.

Elekta misstates the applicable burden of proof. *See id*. In an IPR, the petitioner bears the burden in the petition to demonstrate by a preponderance of the evidence that the challenged patent (or portions thereof) is unpatentable. *See* 35 U.S.C. § 316(e) ("In an *inter partes* review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."). Apart from its

erroneous statement of the law, Elekta further failed to develop an argument concerning ZAP's correct burden of proof. *See* Reply 11–13. We therefore deem this argument frivolous and waived. *See Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1341 (Fed. Cir. 2006).

CONCLUSION

We have considered Elekta's other arguments and find them unpersuasive. We hold that the Board's findings on a motivation to combine and its implicit finding on a reasonable expectation of success are supported by substantial evidence. We affirm.

AFFIRMED

COSTS

No costs.