

Fed. Circ. Elekta Holding May Make Patent Prosecution Harder

By **Sean Murray and Jeremiah Helm** (November 1, 2023, 3:13 PM EDT)

The U.S. Court of Appeals for the Federal Circuit recently issued a decision in *Elekta Limited v. ZAP Surgical Systems Inc.* that illustrates the breadth of evidence that may be used to prove obviousness.

On Sept. 21, the court **ruled** that evidence of the baseline knowledge in the field could both provide a motivation to combine prior art references and rebut the patent owner's argument that the prior art teaches away from the combination.

Notably, the court also held that the patent owner's failure to distinguish prior art during prosecution could be evidence that the prior art did not teach away from the proposed combination of references.

The Federal Circuit considered the issue in the context of an appeal from an order of the Patent Trial and Appeal Board in an inter partes review initiated by ZAP. The court ruled that substantial evidence supported the board's determination that certain claims of Elekta's patent were invalid for obviousness.

Elekta's patent discloses a device for treating a patient with ionizing radiation. The radiation source — a device known as a linac — is mounted on rings that surround the patient, so that the linac may be rotated around the patient.

The linac is mounted to the ring by means of a pivotable bracket, which allows the linac to be moved closer to or further from the patient and to be positioned at different angles relative to the patient. This arrangement allows the clinician to deliver radiation to the relevant part of the patient from virtually any angle and at different intensities.

ZAP filed a petition for inter partes review, which the board instituted. The independent apparatus claim in Elekta's patent required a radiation-treatment device with a rotatable radiation source.

In its final written decision, the board found all of the challenged claims to be obvious over the combination of (1) Grady, which disclosed a rotatable, radiation-based imaging device; and (2) Ruchala, which disclosed a nonrotatable, linac-based radiation therapy device.

Obviousness is a question of law based on underlying factual issues. To prove a patent claim is invalid for obviousness, the patent challenger must prove that a skilled artisan would have been motivated to combine prior art references and would have had a reasonable expectation of succeeding in doing so. Both issues are questions of fact that an appellate court reviews for substantial evidence.

On appeal to the Federal Circuit, Elekta argued that the board's finding of a motivation to combine Grady and Ruchala was not supported by substantial evidence. It also argued that the board made no finding that a skilled artisan would have had a reasonable expectation of success in making the combination, and that any such finding would have been unsupported



Sean Murray



Jeremiah Helm

by substantial evidence.

The Federal Circuit disagreed with Elekta on each point. The board had ruled that a skilled artisan would have been motivated to add a linac, like the one in Ruchela, to the Grady device so as to produce a radiation treatment device with a rotatable radiation source.

On appeal, Elekta's principal argument was based on the fact that linacs are very heavy. Elekta contended that the mounting structure in Grady could not have supported a heavy linac, and that consequently a person of ordinary skill in the art would not have been motivated to add a linac to the Grady device.

Thus, Elekta made the classic argument that the prior art teaches away from the proposed combination because it demonstrates the combination would be unworkable.

The Federal Circuit was unimpressed with Elekta's teaching-away argument and ruled that substantial evidence supported the board's finding of a motivation to combine. The court noted that "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."

Thus, a skilled artisan would not have been deterred by the weight of the linac because he or she would have known to add not just a linac to the Grady device, but also robotic arms to handle the linac's extra weight.

The Federal Circuit also emphasized that, during prosecution of the patent, Elekta did not argue that prior art imaging devices cited by the Patent Office were irrelevant. Elekta's silence was evidence that skilled artisans understood that imaging devices could be combined with linac-based radiation-therapy devices.

The court also credited the board's finding 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."

In addition, a third prior-art patent taught that combining an imaging system with a radiation source is desirable because it permits "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."

The board and the Federal Circuit deemed this further evidence that a skilled artisan would have wanted to add a linac to Grady's rotatable imaging device.

Finally, ZAP's expert opined that a skilled artisan would have been motivated to make the combination to obviate the need to move the patient between separate imaging and treatment devices and to reduce the patient's exposure to radiation. Taken together, this was substantial evidence supporting the board's finding of a motivation to combine.

The Federal Circuit quickly dispatched Elekta's argument on reasonable expectation of success. Elekta contended that a skilled artisan would not have had a reasonable expectation of success in combining Grady and Ruchela, because that person would have known the Grady device could not support the weight of a linac.

Elekta argued that the board failed to address the issue at all in its final written decision.

The Federal Circuit, however, ruled that the board had implicitly addressed the issue when it

found that a skilled artisan would have known to use robotic arms to support the linac. The court concluded that this implicit finding was supported by substantial evidence.

The Federal Circuit therefore affirmed the board's decision in its entirety.

The Federal Circuit's *Elekta* decision is striking in its reliance on the patent owner's failure, in prosecution, to make the specific argument that it later asserted in inter partes review. To be considered in an obviousness analysis, a prior art reference must be analogous, i.e., it must be in the same field or address the same problem as the challenged patent.[1]

In *Elekta*, the Federal Circuit essentially held that the failure to argue in prosecution that a cited reference is nonanalogous can sometimes be evidence, in a subsequent obviousness challenge, that a skilled artisan would have considered a proposed combination to be workable.

The board and the Federal Circuit appear to have reasoned that, by not arguing that imaging references were nonanalogous, *Elekta* acquiesced in the Patent Office examiner's express or implied determination that imaging references could be successfully combined with references disclosing a linac-based radiation-therapy device.

However, the Federal Circuit did not rely on the formal doctrine of acquiescence.

That doctrine precludes a patent owner from making certain arguments in litigation. But the Federal Circuit has held that the doctrine is not triggered by an applicant's mere silence in the face of a position taken by an examiner.

For example, in the 2005 *Salazar v. Procter & Gamble Co.* decision, the Federal Circuit ruled that "an applicant's silence regarding [an examiner's] statements does not preclude the applicant from taking a position contrary to the examiner's statements" in subsequent litigation.

And in the 2012 *Woods v. DeAngelo Marine Exhaust, Inc.* decision, the Federal Circuit held that amending a claim to overcome a rejection is not an admission that all limitations in the initial claim existed in the cited art.

Thus, *Elekta*'s mere silence in prosecution did not preclude it from taking any position in the inter partes review. Rather than rule that *Elekta* was precluded from making its teaching-away argument by the doctrine of acquiescence, the Federal Circuit held that *Elekta*'s failure to argue nonanalogousness in prosecution could be evidence that undermined *Elekta*'s teaching-away argument.

The court's ruling in *Elekta* could have a significant impact on how patent applications are prosecuted in the U.S.

Patent attorneys will now need to consider whether to argue that cited patents are nonanalogous, even if the attorney has a bulletproof argument that the proposed combination is missing a claim limitation, or that a skilled artisan would have had no reason to combine the references.

Those same attorneys may also wonder whether arguing that a reference is nonanalogous could be evidence on some other issue in a subsequent litigation, such as whether an accused product falls within the scope of the claim. After *Elekta*, the already difficult job of prosecuting patent applications may have become even more difficult.

Sean Murray and Jeremiah S. Helm are partners at Knobbe Martens.

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[1] See *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).